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HIV Testing and Pregnancy

Medical and Legal Parameters of the Policy Debate

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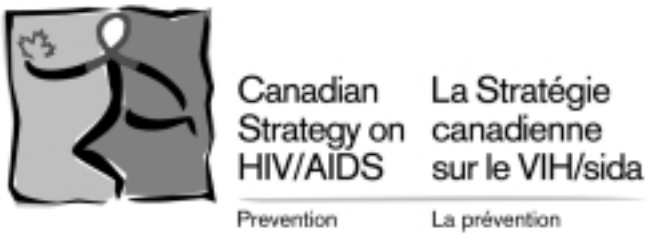

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Executive Summary

There are now a broad range of medical interventions and approaches available to reduce the risk of perinatal HIV transmission: behavioural counselling intended to prevent women of childbearing years from contracting HIV in the first place; avoidance of pregnancy by women who are HIV-positive; termination of pregnancy; antiretroviral prophylaxis; avoidance of invasive obstetrical procedures during pregnancy and birth; caesarian section delivery; and avoidance of breastfeeding. Beyond primary prevention efforts, the effectiveness of these interventions depends upon the identification of women who are HIV-positive at a point in their pregnancies when these interventions might prove helpful.

At present, the serostatus of many HIV-positive pregnant women in Canada goes undetected and, as a result, they are left without advice, care, and treatment that would assist them in making choices to best promote their own health and that of their foetuses during pregnancy.

These facts underscore the need for a medically and legally appropriate policy for the HIV testing of pregnant women in Canada.

The object of this paper is to analyze the following questions with a view to informing that policy development:

- Should HIV testing be offered to all pregnant women, or only to those at increased risk of HIV infection?
- Should HIV testing of pregnant women be voluntary, or should it be mandatory?
- Should physicians be required to secure the informed consent of pregnant women before proceeding with HIV testing, or can this requirement be abrogated?

- Should the HIV testing of pregnant women be characterized as "routine"? and
- What added supports are necessary to ensure the effectiveness of provincial and territorial policies for the HIV testing of pregnant women in Canada?

Directly at issue in this debate is the extent to which the rights of an HIV-positive pregnant woman may be overridden – if at all – to protect the health of the foetus she carries. Central to the analysis of the preceding questions, therefore, is the need to confront the potential for conflict between maternal and foetal interests presented by the HIV testing of pregnant women and to strike a balance between them in accordance with the current state of Canadian law.

The paper reviews the current state of the law in the following areas as a starting point for its analysis:

- What is the nature and extent of an individual's right to exercise informed consent to proposed medical interventions?
- What information must be disclosed to meet informed consent requirements for proposed medical interventions in the "ordinary" case?
- Who is responsible for making decisions about medical interventions that may affect the health or life of the foetus, and what information must physicians provide to inform that decision-making process?
- Is a woman's right to refuse a medical intervention abrogated by pregnancy?
- What are the constitutional limits upon governmental initiatives regarding the HIV testing of pregnant women?
- What are the general principles and approaches that would govern application of the *Canadian Charter of Rights and Freedoms*: (the "Charter") in those circumstances? and
- What are the general duties of governments in policy-making?

The paper's analysis yields the following recommendations:

1. Provinces and territories should require that physicians offer HIV testing to all pregnant women.

2. Provinces and territories should require that physicians offer HIV testing:

   (1) as early in pregnancy as possible; and
   (2) to women considering pregnancy.

3. Provinces and territories should require that HIV testing of pregnant women be voluntary.

4. Provinces and territories should require that physicians obtain the voluntary, specific and informed consent of pregnant women before proceeding with HIV testing. In particular, physicians must ensure that during pre-test counselling:

   (1) women are provided with sufficient information (which may include both written and oral information, and may involve health care providers other than physicians) to understand the purposes, risks, harms

and benefits of being tested or not tested, for them and for their foetuses;
(2) the information provided meets generally applicable standards for informed consent to HIV testing; and
(3) the information provided includes a fair and accurate summary of all interventions available to reduce the risk of perinatal HIV transmission, including, but not limited to, antiretroviral prophylaxis.

5. Provinces and territories should require that following receipt of HIV test results, physicians provide post-test counselling in accordance with generally applicable standards for HIV testing.

6. Provinces and territories should support the effectiveness of HIV testing policies for pregnant women with:

   (1) outreach to, and education of, physicians and other involved health care providers to:
      (i) increase awareness of the availability and effectiveness of medical interventions to minimize the risk of perinatal HIV transmission; and
      (ii) ensure adherence to the prescribed HIV testing policy;
   (2) appropriate compensation to physicians and other involved health-care providers to support adherence to the prescribed HIV testing policy, including, in particular, the delivery of comprehensive pre-test counselling to fulfil informed consent requirements;
   (3) outreach to, and education of, pregnant women to increase awareness of the availability of HIV testing and the availability and effectiveness of medical interventions to minimize the risk of perinatal HIV transmission;
   (4) access to appropriately specialized care and treatment to minimize the risk of perinatal HIV transmission for all pregnant women who test HIV-positive; and
   (5) evaluation of the policy's effectiveness at minimizing the number of perinatal HIV transmissions in Canada, and implementation of necessary changes.

7. Provinces and territories should avoid designating HIV testing of pregnant women as "routine."

8. Provinces and territories should require physicians to ensure that during pre-test counselling, women are advised that HIV testing is recommended for all pregnant women because:

   (1) it is important for all pregnant women to know their HIV status so that, if positive, they can have access to the full range of appropriate care and treatment to benefit their own health and that of their foetus; and
   (2) evidence indicates that women in Canada may be at risk of HIV infection without knowing it.

9. The licensing bodies for physicians should establish express standards of practice for the conduct of HIV testing for pregnant women and women

considering pregnancy, and take all steps necessary to implement, monitor and enforce compliance with these standards.

10. Provinces and territories that wish to support their HIV testing policies with amendments to their laboratory requisition forms:

    (1) should avoid "default" testing (ie, amendments that would permit testing to proceed in the absence of a patient's express refusal to consent to testing); and
    (2) should carefully investigate and assess the effect of all other proposed amendments upon physician practices, to ensure that they effectively block improper test orders (ie, those ordered in the absence of patients' voluntary, specific and informed consent).

11. Provinces and territories should support HIV testing policies for pregnant women with strong measures:

    (1) to protect the right of pregnant women to exercise informed consent to HIV testing;
    (2) to protect the right of pregnant women to confidentiality in relation to their HIV test results; and
    (3) to combat the stigmatization and discriminatory treatment of all persons diagnosed as HIV-positive.

12. The federal government should engage in the active regulation of all antiretroviral drugs used during pregnancy regardless whether their approved uses include reducing the risk of perinatal HIV transmission, as is mandated under the *Food and Drugs Act* (Canada) and Regulations. In particular it should:

    (1) take all necessary steps to continually assess the risks associated with the administration of those antiretroviral drugs used during pregnancy (for both women and the foetuses they carry), including the development and implementation of an active surveillance plan to monitor all adverse reactions;
    (2) further to (1), include mandatory reporting of all adverse reactions to antiretroviral drugs used during pregnancy, experienced over time by HIV-positive women and the foetuses they carry;
    (3) determine whether the appropriate management of identified risks associated with the use of antiretroviral drugs during pregnancy requires regulatory action and, if so, take all necessary steps to that end, including the communication of the nature and extent of all risks associated with the administration of antiretroviral drugs during pregnancy; and
    (4) in order to facilitate the actions described in (1) and (2) above, ensure effective communication links with physicians prescribing antiretroviral drugs, consumers, provincial/territorial health authorities, and regulatory authorities in other countries.

13. Federal, provincial and territorial governments should focus on effective and sustained primary prevention measures to reduce the number of HIV-positive women and men in Canada.

14. Provincial and territorial governments should consider requiring physicians to:

    (1) offer HIV testing to men considering fathering a child, on the basis of voluntary, specific and informed consent; and
    (2) counsel those men with HIV-positive test results to refer for counselling and HIV testing sexual partners who may be pregnant or considering pregnancy.

Introduction

Prior to 1994, those interventions known to reduce the risk of perinatal HIV transmission were limited: the prevention of HIV transmission to women of childbearing years, the deferral of pregnancy by women at increased risk of HIV infection and by HIV-positive women, the avoidance of breastfeeding by HIV-positive women, and the termination of pregnancies by HIV-positive women.

In 1994, the interim results of US Pediatric AIDS Clinical Trial Group Protocol 076 (PACTG 076) demonstrated that the administration of zidovudine (ZDV) to HIV-positive pregnant women and their infants could reduce the anticipated rate of perinatal HIV transmission by approximately two-thirds – from 25.5 percent to 8.3 percent. Subsequent experience confirming the interim results of PACTG 076, and achieving even lower rates of perinatal HIV transmission, has stimulated debate within the Canadian medical and public health communities as to how best to offer HIV testing to pregnant women so that those who might benefit from antiretroviral prophylaxis to reduce the risk of perinatal HIV transmission can be made aware of its availability, benefits, risks, and unknowns. The urgency of the need to take steps to respond to these developments is heightened by the steadily increasing prevalence of HIV infection among women of childbearing years in Canada, and the seriousness of the consequences associated with each HIV infection of an infant that might have been prevented – for the infant, for his or her family, and for society as a whole.

Directly at issue in this debate is the extent to which the rights of an HIV-positive pregnant woman may be overridden – if at all – to protect the health of the foetus she carries. Central to the analysis of the questions that follow, therefore, is the need to confront the potential for conflict between

maternal and foetal interests presented by the HIV testing of pregnant women and to strike a balance between them in accordance with the current state of Canadian law.

Should HIV testing be offered to all pregnant women, or only to those at increased risk of HIV infection? Should HIV testing of pregnant women be voluntary, or should it be mandatory? Should physicians be required to secure the informed consent of pregnant women before proceeding with HIV testing, or can this requirement be abrogated? Should the HIV testing of pregnant women be characterized as "routine"? What added supports are necessary to ensure the effectiveness of provincial and territorial policies for the HIV testing of pregnant women in Canada?

The object of this paper is to answer these questions based on an examination of the medical and legal parameters of the policy debate. Its conclusions take the form of recommendations that may assist in the development of policies regarding the HIV testing of pregnant women in Canada by the federal, provincial, and territorial governments.

Central to the analysis is the need to confront the potential for conflict between maternal and foetal interests and to strike a balance between them in accordance with the current state of Canadian law.

Medical Parameters of the Policy Debate

This Part examines the medical parameters of the debate regarding the HIV testing of pregnant women in Canada. How does perinatal HIV transmission take place (Mechanism of Perinatal HIV Transmission)? What is the current epidemiology of perinatal HIV transmission (Epidemiology of HIV Infection in Women and Children)? What interventions are available to reduce the risk of perinatal transmission (Interventions to Reduce the Risk of Perinatal HIV Transmission)? With respect to antiretroviral prophylaxis, in particular, what are its limitations, risks and unknowns (Limitations, Risks and Unknowns of Antiretroviral Prophylaxis)? And, finally, what alternative approaches should be considered for the HIV testing of women in Canada (Alternative Approaches to HIV Testing of Pregnant Women)?

Mechanism of Perinatal HIV Transmission

The possibility that the etiologic agent of AIDS could be transmitted perinatally was identified early in the AIDS epidemic, well before the agent itself was identified. On 17 December 1982, the *Morbidity and Mortality Weekly Report* (a publication of the US Centers for Disease Control) reported unexplained immunodeficiency and opportunistic infections in infants born to women who were either Haitian or intravenous drug users.[1] This report was included in the 22 January 1983 issue of the *Canadian Disease Weekly Report* (a publication of the Canadian Laboratory Centre for Disease Control) together with an editorial note, which concluded that:

[1] Centers for Disease Control (CDC). Unexplained Immunodeficieny and Opportunistic Infections in Infants – New York, New Jersey, California. 1982; 31(49); 665-667.

> Transmission of an "AIDS agent" from mother to child, either *in utero* or shortly after birth, could account for the early onset of immunodeficiency in these infants.[2]

These epidemiologic reports gave support to the theory that AIDS was caused by a bloodborne infectious agent, transmitted in the same ways as hepatitis B virus (HBV). By 1983, it was generally accepted within the medical and scientific communities that AIDS could be transmitted perinatally.[3]

It is now well established that perinatal HIV transmission can take place at any one of the following times through foetal or infant exposure to infected maternal body fluids:

- *Intrauterine*, meaning in the uterus before labour and delivery. Intrauterine HIV transmission is presently estimated to account for 25 to 30 percent of cases of perinatal transmission.[4] Transmission at this stage is thought to take place either through viral passage across the placenta or through the passage of maternal blood into foetal circulation as a result of placental tears causing the transfusion of infected blood into the amniotic sac.[5]
- *Intrapartum*, meaning at the time of labour and delivery. Recent research suggests that most perinatal HIV transmission takes place intrapartum, with estimates as high as 60 to 75 percent.[6] Mechanisms of intrapartum HIV transmission are presently understood to include "direct contact of the foetus with infectious maternal blood and genital secretions during passage through the birth canal or through ascending infection from the vagina or cervix."[7]
- *Postpartum*, meaning after delivery. Postpartum HIV transmission from mother to infant takes place through breastfeeding. Estimates put the risk of infection through breastfeeding at 10 to 20 percent in addition to the risks of intrauterine and intrapartum infection.[8] HIV transmission to infants through breastfeeding can take place regardless whether the mother contracted HIV before the birth or at some point after the baby was born.

In Canada, the rate of HIV transmission from an HIV-positive mother to her infant varies from 15 to 25 percent in the absence of intervention.[9]

The likelihood that HIV transmission from mother to infant will take place may be increased by the presence of one or more of the following co-factors: high maternal viral loads (although there is no identified threshold below which perinatal does not take place); maternal immune depletion (as identified by the presence of AIDS-defining conditions or reduced T-cell counts); the presence of other sexually transmitted diseases; maternal vitamin A deficiency; duration of membrane rupture; hemorrhage during labour; chorioamnionitis; and the conduct of invasive procedures during pregnancy and delivery.[10]

Despite therapeutic advances in the treatment of the symptoms and illnesses associated with HIV infection, in almost all cases the progression of HIV disease results in the gradual deterioration of the immune system and the onset of opportunistic infections that eventually prove fatal. In HIV-infected infants and children, disease progression is accelerated in comparison with adults. As summarized by Dr Catherine Peckham at the September 1997 Conference on Global Strategies for the Prevention of HIV Transmission from Mothers to

[2] Laboratory Centre for Disease Control (LCDC). Unexplained Immunodeficieny and Opportunistic Infections in Infants – United States. 1983; 9(4): 15-16.

[3] See, for example, GB Scott et al. Acquired Immunodeficiency in Infants. *New England Journal of Medicine* 1984; 310(2): 76-81.

[4] MF Rogers et al. Use of the polyamerase chain reaction for early detection of the proviral sequences of human immunodeficiency virus in infants born to seropositive mothers. New York Collaborative Study of Maternal HIV Transmission and Montefiore Medical Centre HIV Perinatal HIV Transmission Study Group. *New England Journal of Medicine* 1989; 320(25): 1649-1654; A Ehrnst et al. HIV in pregnant women and their offspring: Evidence for late transmission. *Lancet* 1991; 338: 203-207; and K Luzuriago et al. Early viremia and immune responses in vertical human immunodeficiency virus type 1 infection. *Journal of Infectious Disease* 1993; 167: 1008-1013.

[5] ML Newell et al. Prevention of Mother to Child Transmission of HIV-I Infection. *AIDS* 1997; 11 (Suppl A): 5165-5172.

[6] L Mofenson, C Wilfert. Pathogenesis and Interruption of Vertical Transmission. *Paediatric AIDS: The Challenge or HIV Infection in Infants, Children and Adolescents* (in press).

[7] ML Newell. Timing of Transmission. In: N Martin, FIMLS, AJ Ammann (eds). *Proceedings of the Conference on Global Strategies for the Prevention of HIV Transmission from Mothers to Infants*. 3-6 September 1997.

[8] Ibid at 14. See also: G John. Current Status of Breast-Feeding Studies on Preventing HIV Transmission. *Conference on Global Strategies*, supra, note 7 at 51-56.

[9] Reduction of HIV Transmission from Mother to Infant. *Canadian Communicable Disease Report* 1994; 20(12): 97-101 at 100. In the US, this rate is estimated to be 25.5 percent; in Europe it is approximately 16 percent: Recommendations of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus. *Morbidity and Mortality Weekly Report* 1994; 43(No RR-11) (5 August 1994); and C Peckham. Epidemiology and Risk Factors on HIV Transmission in Europe. *Conference on Global Strategies*, supra, note 7 at 7.

[10] Institute of Medicine, Committee on Perinatal Transmission of HIV. *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States*. MA Stoto et al, eds. Washington, DC: National Academy Press, October 1998, ch 4 at 2. All citations are as available on the Internet. Page references may not correspond to the printed version of the report.

Researchers have expressed concern that the number of avoidable perinatal HIV infections in Canada remains unacceptably high.

Infants: "By 6 years of age, 36 percent of infected children will have died or developed AIDS, 20 percent during the first year and 4.7 percent per year thereafter."[11]

Epidemiology of HIV Infection in Women and Children

The epidemiology of perinatal HIV transmission is necessarily linked to that of maternal HIV infection. In Canada, "[t]he estimated proportion of women among new HIV infections has increased steadily over time."[12] By the end of 1996, between 36,000 and 42,000 Canadians were estimated to be living with HIV; of these, 4000 to 5000 were women.[13] AIDS statistics tell a similar story. As reported by the Laboratory Centre for Disease Control in November 1997,

> [t]he total number of AIDS cases among adult women (delay adjusted) has increased from an average of less than 10 cases per year in the 1980s to nearly 170 cases per year in 1995-96. In addition, the proportion of AIDS cases among women has increased over time, particularly recently, from 6.2% of all AIDS cases before 1990, to 6.9% during 1990-1995, and 10.6% in 1996.

Of the total number of AIDS cases reported in Canada to 30 June 1997, 6.9 percent were among women. Of these, 73 percent were in women of childbearing age, 15 to 44 years.[14]

Women's major risk factors for HIV infection are injection drug use and heterosexual sexual activity. The proportion of women with AIDS infected through injection drug use has increased dramatically, from 6.5 percent before 1990 to 25 percent in 1996.[15]

A recent Canadian study that examined the epidemiology of perinatal HIV infection in Canada concluded that "[t]he identified number of children born to HIV positive women in Canada has steadily risen since 1985."[16] This increase is likely attributable to a combination of three factors: the increased prevalence of HIV infection in women of childbearing years, improvements in the identification of negative children born to HIV-positive mothers,[17] and a decline in the incidence of therapeutic abortion among HIV-positive women with the advent of antiretroviral prophylaxis.[18] With respect to maternal risk factors for HIV infection, the authors found that

> [t]he course of the epidemic varies geographically with IDU's driving the epidemic in British Columbia and sexual contact in Ontario. The population rate of children born to HIV+ mothers is highest in British Columbia. Women who are black or First Nation are over represented relative to their proportion in the population.[19]

Despite the fact that greater numbers of infants are being exposed to HIV perinatally, however, the overall rate of perinatal HIV transmission in Canada has decreased. While this decrease may reasonably be attributed to the fact that more HIV-positive women are undertaking antiretroviral prophylaxis to reduce the risk of perinatal HIV transmission,[20] researchers have expressed concern that the number of avoidable perinatal HIV infections in Canada remains unacceptably high.[21]

[11] Peckham, supra, note 9 at 5.

[12] LCDC. HIV and AIDS among Women in Canada. *HIV/AIDS Epi Update* (November 1997), at 1.

[13] Ibid.

[14] LCDC. Perinatally Acquired HIV Infection. *HIV/AIDS Epi Update* (November 1997), at 1.

[15] LCDC. HIV and AIDS among Women in Canada, supra, note 12 at 1.

[16] S King et al. The National Perinatal HIV Surveillance Program: Canada 1985-1996. #13221, *Conference Record*, 12th World AIDS Conference, Geneva, 28 June–3 July 1998.

[17] Ibid.

[18] C Hankins et al. Is Antiretroviral MCT Prophylaxis Provoking Increased Pregnancy Incidents in Women Living with HIV? #24199, *Conference Record*, supra, note 16.

[19] King, supra, note 16.

[20] Communication with Dr Susan M King, Associate Professor, Division of Infectious Diseases, Department of Paediatrics, University of Toronto, on 26 November 1997.

[21] See, for example, RS Remis. Preventing HIV Transmission from Mothers to Infants in Ontario 1994 to 1996: A Missed Opportunity. #23288, *Conference Record*, supra, note 16. N Lapointe et al. Antiretroviral Therapy in Pregnant Women in Canada: Access and Outcome 1995-96. Abstract no 203. 7th Annual Canadian Conference on HIV/AIDS Research, April-May 1998.

Interventions to Reduce the Risk of Perinatal HIV Transmission

Until 1985, interventions directed toward reducing the risk of perinatal transmission were limited to behavioural counselling intended to prevent women of childbearing years from becoming infected in the first place, and deferral of pregnancy by those women considered at increased risk of contracting AIDS infection until more was known about this new and threatening disease.

Following the identification of HIV as the etiologic agent of AIDS in 1984 and the subsequent development of a diagnostic test for HIV infection in 1985, the early emphasis on prevention through behavioural counselling continued. However, directive counselling encouraging women at risk of infection to defer pregnancy was replaced with an emphasis upon the counselling and voluntary HIV testing of both pregnant and non-pregnant women at increased risk of HIV infection, to allow those who were positive to make informed choices following non-directive counselling regarding the decision to become pregnant and, if already pregnant, the continuation of their pregnancies. HIV-positive pregnant women who chose to continue their pregnancies were counselled to avoid breastfeeding.[22]

In 1994, dissemination of the interim results of PACTG 076 and the corresponding recommendations of the US Public Health Service (the "PHS") introduced the possibility of intervention through antiretroviral drug therapy to significantly reduce the risk of perinatal HIV transmission.[23]

PACTG 076 was a randomized, multi-centre, double-blind, placebo-controlled clinical trial sponsored by the US National Institutes of Child Health and Human Development to investigate the effectiveness of ZDV to reduce the risk of perinatal HIV transmission. The pregnant women who participated in the study were HIV- infected, from 14 to 34 weeks gestation, had received no antiretroviral therapy during the current pregnancy, had no clinical indications for antepartum antiretroviral drug therapy, and had CD4 counts over 200 upon enrolment and did not breastfeed their infants. The regimen of ZDV administration studied was as follows:

- oral administration of 100 mg ZDV five times daily, initiated at 14-34 weeks gestation and continued throughout the pregnancy;
- during labour, intravenous administration of ZDV in a one-hour loading dose of two mg per kg of body weight, followed by a continuous infusion of one mg per kg of body weight per hour until delivery; and
- oral administration of ZDV to the newborn (ZDV syrup at two mg per kg of body weight per dose every six hours) for the first six weeks of life, beginning 8-12 hours after birth.

The interim results of the study revealed HIV transmission rates of 25.5 percent within the placebo group and 8.3 percent within the ZDV group, amounting to a reduction in the anticipated rate of perinatal HIV transmission of approximately two-thirds. The final results of the study, reported in 1996, were similar: HIV transmission rates of 22.6 percent within the placebo group and 7.6 percent within the ZDV group, achieving a reduction in the anticipated rate of perinatal HIV transmission of 66 percent.[24]

[22] CDC. Recommendations for assisting in the prevention of perinatal transmission of human T-lymphotropic virus types III/ lymphadenopathy-associated virus and acquired immunodeficiency syndrome. *Morbidity and Mortality Weekly Report* 1985; 34: 721-726.

[23] CDC. Recommendations of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus. *Morbidity and Mortality Weekly Report* 1994; 43(RR-11): 1-20.

[24] RS Sperling, DE Shapiro, RW Coombs et al. Maternal Viral Load, Zidovudine Treatment and the Risk of Transmission of Human Immunodeficiency Virus from Mother to Infant. *New England Journal of Medicine* 1996; 335: 1621.

The PHS responded to these interim results with recommendations that health care providers recommend the full PACTG 076 regimen to all HIV-infected pregnant women meeting the entry criteria for the study, as well as to women with similar clinical characteristics (the "1994 PHS Recommendations"). The PHS further recommended that specified components of the PACTG 076 regimen be discussed with, and in some cases recommended to, women presenting clinical characteristics more removed from the original entry criteria for the study. It advised, however, that the efficacy of the PACTG 076 regimen could not be considered to have been established for HIV-positive pregnant women with advanced disease, low CD4 lymphocyte counts or prior ZDV therapy, and that the long-term risks of ZDV used in this manner (for the mother or for the infant, irrespective of the mother's clinical characteristics) were not yet known.

Health Canada was initially reserved in its endorsement of the application of the PACTG 076 interim results to the Canadian context. The editorial comment that accompanied its reproduction of these results in a 1994 *Canada Communicable Disease Report* concluded:

> Based on this interim analysis of PACTG 076, ZDV therapy in HIV-positive women after their 1st trimester, during delivery, and to infants for 6 weeks thereafter has shown potential for a reduction in vertical transmission of HIV. In the United States, it has been recommended that women meeting the study entry criteria be treated with ZDV according to the protocol. At this time, individual clinicians and their HIV-positive female patients may wish to make treatment decisions on a case by case basis.[25]

Health Canada drew immediate attention to the question of HIV testing in response to PACTG 076:

> This study also has a public health dimension that goes beyond the clinical decision to offer treatment to pregnant HIV-positive women. There are approximately 400,000 live births each year in Canada. HIV seroprevalence studies among pregnant women across Canada suggest that this cohort might include approximately 140 to 150 HIV-positive pregnant women. Since HIV testing programs are the responsibility of provincial and territorial governments, the relevant authorities will have to analyze the most cost-effective approaches for offering testing to pregnant women who might be HIV-positive and wish to reduce the risk of HIV transmission to their infants.[26]

Indeed, as of 1992, the National Advisory Committee on AIDS to the federal Minister of Health (NAC-AIDS) had already altered its recommendation regarding HIV testing of pregnant women from targeted offers of testing to those women at increased risk of HIV transmission[27] to the provision of information about the risk of perinatal transmission and the availability of testing to all pregnant women in Canada.[28] In 1995, the PHS similarly altered its HIV testing recommendations for pregnant women from a targeted approach, in which HIV testing was offered to pregnant women at increased risk of HIV infection, to a universal approach calling for the counselling of all pregnant women to

[25] LCDC. Reduction of HIV Transmission from Mother to Infant, supra, note 9 at 100.

[26] Ibid.

[27] Human Immunodeficiency Virus Antibody Testing in Canada. *Canada Disease Weekly Report* 1989; 13(8): 37-47 at 39.

[28] National Advisory Committee on AIDS (NAC–AIDS). *HIV and Human Rights in Canada.* Ottawa: The Committee, 1992, at 19.

encourage them to be tested for HIV infection (the "1995 PHS Recommendations").[29] This shift in approach was attributed to both the advances in prevention and treatment of opportunistic infections in HIV-infected adults and children achieved since 1985 and the availability of ZDV therapy to reduce the risk of perinatal transmission.

The recommendations founded on the results of PACTG 076 were updated by the PHS in January 1998 (the "1998 PHS Recommendations").[30] These recommendations and the supporting commentary served three general purposes:

- they confirmed the effectiveness of the PACTG 076 regimen in women meeting the entry criteria for the study;[31]
- they confirmed the effectiveness of the PACTG 076 regimen in populations of HIV-infected women with advanced disease and receiving prior antiretroviral drug therapy (clinical characteristics differing from the PACTG 076 entry criteria);[32] and
- they integrated the PACTG 076 regimen together with the use of aggressive combination drug regimens ("highly active antiretroviral treatment" or HAART) that constitute the current standard of care in the treatment of HIV infection in non-pregnant adults in the US and Canada.

Commentary in support of the updated recommendations emphasized that there were no clinical trials to establish the effectiveness of antiretroviral drugs other than ZDV to reduce perinatal HIV transmission. Rather, the purpose of integrating HAART into the PACTG 076 regimen was to maintain an appropriate standard of care for HIV-infected pregnant women rather than abandon them to ZDV monotherapy, characterized as "suboptimal care."[33]

In Canada, preliminary 1997 data indicated that the pooled estimate of perinatal HIV transmission with antiretroviral prophylaxis was 3.5 percent as of August 1997.[34]

Most recently, at the 12th World AIDS Conference in Geneva, the following results were reported:

- further confirmation of the effectiveness of the PACTG 076 regimen;[35]
- the effectiveness of PACTG 076 integrated with HAART at reducing the rate of perinatal HIV transmission well below the 8.3 percent achieved in PACTG 076;[36]
- the effectiveness of elective caesarian section together with ZDV monotherapy or HAART at reducing the risk of perinatal HIV transmission to rates approaching zero.[37]

Study results reported in support of the last point above were especially dramatic. In the Gomez-Martin study, none of the 18 HIV-positive women who had received ZDV therapy and gave birth by caesarian section within one hour of ruptured membranes had HIV-positive newborns. Similarly, Samprini announced in the oral presentation of his results that none of the women who had received ZDV therapy and given birth by elective caesarian section delivery performed before the onset of labour had HIV-positive newborns.

Invasive obstetrical procedures (such as amniocentesis and chorionic villus sampling during pregnancy, and internal monitoring and scalp sampling during delivery) may increase the risk of perinatal HIV transmission and should therefore be avoided.[38]

[29] U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counselling and Voluntary Testing for Pregnant Women. *Morbidity and Mortality Weekly Report* 1995; 44 (RR-7): 1-15. Note: All references in this paper are to the electronically retrieved version, and may not correspond to the print version.

[30] U.S. Public Health Service Recommendations for Use of Antiretroviral Drugs During Pregnancy for Maternal Health and Reduction of Perinatal Transmission of Human Immunodeficiency Virus. *Morbidity and Mortality Weekly Report* 1998; 47(RR-2); 1-30. Note: All references in this paper are to the electronically retrieved version, and may not correspond to the print version.

[31] Ibid at 3.

[32] Ibid at 8-9. See also: L Mofenson. Intervention Strategies for Reducing Perinatal HIV Transmission. *Conference on Global Strategies*, supra, note 7 at 19.

[33] Ibid at 3 and 9.

[34] RS Remis. HIV Transmission from Mothers to Infants in the Province of Ontario, 1984-1996. (August 1997) at 8. This unpublished paper preceded the paper referenced in note 21 supra.

[35] See the following abstracts published in the *Conference Record*, supra, note 16: C Kind. Prevention of Vertical HIV Transmission: Limits of Success at the Population Level (#23283); S Paul et al. Evaluation of ZDV administration to pregnant women and their children born in 1993 through 1996 in New Jersey (#23287); ML Lindegren et al. Status of the perinatal prevention (#23306); and S Fiscus et al. Can zidovudine monotherapy continue to reduce perinatal HIV transmission? The North Carolina experience 1993-1997 (#33162).

[36] *Conference Record*, supra, note 16: K Beckerman et al. Control of Maternal HIV-1 disease during pregnancy (#12151); F Kramer et al. Combination therapy with nevirapine, zidovudine and a second nucleoside analog during pregnancy (#12152); J Lambert et al. Risk factors for perinatal HIV transmission in women/infants receiving zidovudine prophylaxis (#23265); D Money. An analysis of a cohort of 75 HIV infected pregnant women: Antiretroviral effects, obstetrical and neonatal outcomes (#32230). See also: C Rozioux. Implementation of Therapy to Reduce Transmission. *Conference on Global Strategies*, supra, note 7 at 23.

[37] See: The International Perinatal HIV Group. The Mode of Delivery and the Risk of Vertical Transmission of Human Immunodeficiency Virus Type 1 – A Meta-analysis of 15 Prospective Cohort Studies. To be published in the *New England Journal of Medicine*, 1 April 1999. See also: *Conference Record*, supra, note 16: L Mandelbrot et al. Decreased perinatal HIV-1 transmission following elective caesarian delivery with zidovudine treatment (#23272); A Deveikis. A 'bloodless caesarian section' and perinatal transmission of the human immunodeficiency

The efficacy of other strategies to reduce the risk of perinatal HIV transmission remain under study. These include: administration of HIV-hyperimmune globulin to infected pregnant women and their infants; efforts to boost maternal and infant immune responses through vaccination; virucidal cleansing of the birth canal before and during labour and delivery; modified and shortened antiretroviral regimens; and vitamin A supplementation.[39]

Beyond primary prevention efforts to reduce the incidence of HIV infection among women, the success of those interventions currently understood to reduce the risk of perinatal HIV transmission depends (assuming a seropositive mother) upon identification of women who are HIV-positive at a point in their pregnancies when the interventions can prove helpful. Canadian study results reported at the 12th World AIDS Conference in Geneva in 1998 concluded that many pregnant HIV-positive women go undetected and untreated in Canada.[40] These facts present the need for a medically and legally appropriate policy for the HIV testing of pregnant women in Canada.

Limitations, Risks and Unknowns of Antiretroviral Prophylaxis

Limitations of Antiretroviral Prophylaxis

Two primary limitations remain associated with antiretroviral prophylaxis integrating the PACTG 076 regimen with HAART to reduce perinatal HIV transmission: (1) HIV transmission is still observed; and (2) adherence to the therapeutic regime is essential but is physically, psychologically and financially demanding and can therefore prove difficult.[41] In relation to the latter point, the Institute of Medicine's Committee on Perinatal Transmission of HIV observed:

> The actual recommended ZDV regimen is complex insofar as it is fairly intensive, there is uncertainty regarding long term effects, administration involves coordination across providers and sites (e.g. obstetric and pediatric personnel, outpatient and inpatient services), and may be associated with side effects and complications that require monitoring.[42]

Risks and Unknowns of Antiretroviral Prophylaxis

Those antiretroviral drugs currently used in HAART include: ZDV, zalcitabine (ddC), didansine (ddI), stavudine (d4T), lamivudine (3TC), nevirapine, delavirdine, indinavir, ritonavir, saquinavir, and nelfinavir.[43] With respect to the risks associated with the use of these drugs during pregnancy, the 1998 PHS Recommendations emphasize that "[t]here are currently minimal data available on the pharmacokinetics and safety of antiretrovirals during pregnancy for antiretrovirals other than ZDV."[44] Even with respect to ZDV, the available data is incomplete.

All of these drugs present significant risks of serious adverse reactions outside the context of pregnancy. Many of them were approved for use on the basis of limited safety data in view of the life-threatening nature of HIV infection.[45]

virus (#23274); J Read. Mode of delivery and vertical transmission of HIV-1: A meta-analysis from fifteen prospective cohort studies (The International Perinatal HIV Group) (#23275 and #23603); R Lutz-Friedrick et al. Combining ZDV treatment and elective caesarian section reduces the vertical transmission of HIV-1 below 3% in the German perinatal cohorts (#23291); C Fortuny. Mother-to-Child transmission of HIV-1: Effect of preventative measures in full-term pregnancies (#23301); A Schaefer et al. Influence of caesarian section before parturition and antiretroviral prophylaxis on the materno-foetal transmission of HIV (#12466); O Gomez-Martin et al. Caesarian section (C/S) is effective in preventing perinatal HIV-1 infection in newborns delivered within one hour of ruptured membranes (#23305); A Semprini. An international randomised trial of mode of delivery in HIV infected women (#23599); and D Money et al. An analysis of a Cohort of 75 HIV infected pregnant women: Antiretroviral effects, obstetrical and neonatal outcomes (#32230).

[38] K Nolan. Human Immunodeficiency Virus Infection, Women and Pregnancy: Ethical Issues. *Obstetric and Gynecology Clinics of North America* 1990; 17(3): 651-668.

[39] 1995 PHS Recommendations, supra, note 29 at 7; and Mofenson, *Conference on Global Strategies*, supra, note 7 at 21-22.

[40] J Singer et al. Antiretroviral therapy in pregnant women in Canada: Access and outcome, 1995-1996 (#23315). *Conference Record*, supra, note 16. See also: Remis et al, supra, note 21; and Kind, supra, note 35.

[41] 1995 PHS Recommendations, supra, note 29 at 6.

[42] IOM Committee, supra, note 10, ch 6 at 29.

[43] Table 2. Preclinical and Clinical Data Relevant to Use of Antiretrovirals in Pregnancy. 1998 PHS Recommendations, supra, note 30.

[44] Ibid at 4.

[45] M Hooker et al. HIV adverse drug reaction (ADR) reporting scheme (#12385), *Conference Record*, supra, note 16.

Important areas of concern when they are used during pregnancy include the following:

- the changes in drug pharmacokinetics attributable to the many physiologic changes associated with pregnancy;
- the potential for teratogenicity, mutagenicity and carcinogenicity; and
- the pharmacokinetics and toxicity of transplacentally transferred drugs.[46]

In recognition of the seriousness of these concerns, both the 1994 PHS Recommendations and the 1998 PHS Recommendations suggest that the administration of antiretroviral prophylaxis be avoided during the first trimester of pregnancy to avoid exposure to antiretrovirals during foetal organogenesis.[47]

The US Food and Drug Administration (FDA) has classified ZDV, ddC, d4T, 3TC, nevirapine, delavirdine and indinavir as Pregnancy Category C, meaning that

> [s]afety in human pregnancy has not been determined, animal studies are either positive for fetal risk or have not been conducted, and the drug should not be used unless the potential benefit outweighs the potential risk to the fetus.[48]

The remaining antiretroviral drugs currently in use – ddI, ritonavir, saquinavir and nelfinavir – are classified by the FDA as Pregnancy Category B, meaning that

> [a]nimal reproduction studies fail to demonstrate a risk to the fetus, and adequate but well-controlled studies of pregnant women have not been conducted.[49]

Study results reported at the 12th World AIDS Conference in Geneva do give cause for concern

Risks and unknowns of ZDV use during pregnancy

The 1994 PHS Recommendations and the 1998 PHS Recommendations report that in PACTG 076, observed toxicity attributable to ZDV was minimal among the women enrolled in the study and that the only adverse effect observed among the infants was mild, transient anemia that resolved without treatment. The 1994 PHS Recommendations nonetheless cautioned that "although the ZDV regimen was not associated with serious short term adverse effects, such effects may be observed when this use of ZDV becomes more widespread."[50]

Indeed, study results reported at the 12th World AIDS Conference in Geneva do give cause for concern. Researchers examining the prevalence of major congenital malformations in 1315 live-born deliveries from 1993 through 1995 by HIV-positive women enrolled in New York State Medicaid reported:

> Within the study cohort, odds of major malformation were compared by presence of any maternal ZDV use and trimester of first use, with no maternal usage as the reference group. Odds ratios (ORs) were adjusted separately for maternal age, race, education, smoking, alcohol consumption, and illicit drug use as well as low birth weight and preterm delivery using Mantel-Haenszel methods.

[46] 1998 PHS Recommendations, supra, note 30 at 4.

[47] 1994 PHS Recommendations, supra, note 23 at 7; 1998 PHS Recommendations, supra, note 30 at 28.

[48] Supra, note 43.

[49] Ibid.

[50] 1994 PHS Recommendations, supra, note 23 at 4.

> ... 112 children in our cohort had a major malformation. After adjustment, the prevalence was 2.5 times that expected. ... Although we found no definitive statistical evidence supporting a link between maternal ZDV use and birth defects in this cohort, there is a clear need to assemble larger population-based cohorts of HIV positive parturients and their offspring, through both administrative data and registries, to explore further the associations seen here.[51]

The long-term adverse effects of ZDV therapy are unknown. Specific areas of concern based upon the results of animal studies, as highlighted in the various PHS Recommendations, are as follows:

- In rodent studies, prolonged, continuous high doses of ZDV administered to adult rodents have been associated with the development of noninvasive squamous epithelial vaginal tumours in 3 percent to 12 percent of females.[52]
- Two rodent studies evaluating the potential for transplacental carcinogenicity of ZDV have had differing results. In one ongoing study carried out by scientists at the National Cancer Institute, two very high daily doses of ZDV were administered during the last third of gestation in mice. The doses chosen for this study were near the maximum dose beyond which foetal toxicity would be observed and approximately 25 and 50 times greater than the daily dose given to humans, although the cumulative dose received by the pregnant mouse was similar to the cumulative dose received by the pregnant woman taking six months of ZDV. In the offspring of ZDV-exposed pregnant mice at the highest dose level followed for 12 months, a statistically significant increase in lung, liver, and female reproductive organ tumours was observed; the investigators also documented incorporation of ZDV into the DNA in a variety of newborn-mouse tissues, although this did not clearly correlate with the presence of tumours.[53]
- In one study, pregnant rats were administered toxic doses of ZDV during organogenesis (ie, equivalent to approximately 50 times the recommended daily clinical dose, based on relative body surface areas); developmental malformations and skeletal abnormalities were observed in 12 percent of fetuses.[54]

Also of concern is the potential for myopathy and cardiomyopathy in mother and infant,[55] and the development of ZDV-resistant virus that may inhibit the therapeutic effectiveness of ZDV (and, possibly, other nucleoside analogue reverse transcriptase inhibitors, in the event of cross-resistance) in the mother if and when needed for her own health.[56]

Risks and unknowns of other antiretroviral drugs during pregnancy

The use of 3TC and nevirapine during pregnancy have each received limited study. The results of this research indicate that, in the short term, both drugs were well tolerated by the women and no adverse effects were observed in the infants.[57] As with ZDV, however, such effects may be observed should their use during pregnancy become widespread. At the 6th Conference on Retroviruses and Opportunistic Infections, for example, French researchers announced that two infants of 200 mother–infant pairs that were administered

[51] CJ Newschaffer et al. Birth Defects and Zidovudine Use in HIV+ Women in New York State Medicaid. *Conference Record*, supra, note 16, #12376.

[52] 1998 PHS Recommendations, supra, note 30 at 5. See also 1994 PHS Recommendations, supra, note 23 at 5.

[53] 1998 PHS Recommendations, supra, note 30 at 5-6.

[54] 1994 PHS Recommendations, supra, note 23 at 6.

[55] Ibid at 5.

[56] Ibid at 6. An interim analysis of a three-year follow-up study of the women enrolled in PACTG 076 (PACTG 288) reports that: "Transient use of ZDV during pregnancy to prevent perinatal transmission in PACTG 076, which enrolled healthy women with CD4>200, was not associated with increased risk of clinical or immunologic disease progression." AD Bardeguez et al. Lack of Clinical or immunological disease progression with transient use of zidovudine (ZDV) to reduce perinatal HIV-1 transmission in PACTG 076 (#12233), *Conference Record*, supra, note 16.

[57] 1998 PHS Recommendations, supra, ote 30 at 5.

a combination of AZT and 3TC to reduce the risk of perinatal HIV transmission, had died exhibiting central nervous system disease and very similar mitochondrial abnormalities. These abnormalities were present at an increased rate over the norm (one in 100,000 infants) and were attributed by the researchers to the use of 3TC.[58] Moreover, the nevirapine study canvassed in the 1998 PHS Recommendations considered only single doses to the mothers (at the onset of labour) and infants (at 2-3 days old):

> Data on chronic dosing with nevirapine beginning at 38 weeks gestation is under study but not yet available; no data are available regarding the safety and pharmacokinetics of chronic dosing with nevirapine beginning earlier in pregnancy.[59]

With respect to the use of other antiretroviral drugs, the 1998 PHS Recommendations include the following information:

> It is important to recognize that transplacental carcinogenicity studies have not been performed for any of the other available antiretroviral drugs, and no long-term or transplacental animal carcinogenicity studies of combinations of antiretroviral drugs have been performed. …
>
> Delavirdine has not been studied in pregnant women. Delavirdine is positive on at least one *in vitro* screening test for carcinogenic potential. Long-term and transplacental animal carcinogenicity studies are not available for either of these drugs at the present time. Both [nevirapine and delavirdine] are associated with impaired fertility in rodents when administered at high doses, and delavirdine is teratogenic in rodents when very high doses are administered during pregnancy (ventricular septal defects were observed at doses associated with severe maternal toxicity). …
>
> Although Phase I studies of several protease inhibitors (indinavir, ritonavir and nelfinavir in combination with ZDV and 3TC) in pregnant infected women and their infants will soon start in the U.S., there are currently no data available regarding drug dosage, safety and tolerance of any of the protease inhibitors in pregnancy or in neonates. In mice, indinavir and ritonavir both have significant placental passage; however, in rabbits, indinavir shows little placental passage. Rodent data are not available on placental passage for saquinavir and nelfinavir, and transplacental passage of any of the protease inhibitors in humans is unknown.
>
> Administration of indinavir to pregnant rodents has revealed no evidence of teratogenicity. However, treatment-related increases in the incidence of supernumerary and cervical ribs were observed in offspring of pregnant rodents receiving indinavir at doses comparable to those administered to humans. In pregnant rats receiving high doses of ritonavir that were associated with maternal toxicity, some developmental toxicity was observed in the offspring, including decreased foetal weight, delayed skeletal ossification, wavy ribs,

[58] S Blanche et al. Zidovudine-Lamivudine for Prevention of Mother to Child Transmission. Abstract no 287. *Abstracts of the 6th Conference on Retroviruses and Opportunistic Infections*. Chicago, February 1999.

[59] 1998 PHS Recommendations, supra, note 30 at 5.

> enlarged fontanelles and cryptorchidism; however, in rabbits, only decreased foetal weight and viability was observed at maternally toxic doses. Rodent studies have not demonstrated embryo toxicity or teratogenicity with saquinavir or nelfinavir.
>
> Indinavir is associated with infrequent side effects in adults (hyperbilirubinemia and renal stones) that could be problematic for the newborn if transplacental passage occurs and the drug is administered near to delivery. Due to the immature hepatic metabolic enzymes in neonates, the drug would likely have a prolonged half-live and possibly exacerbate the physiologic hyperbilirubinemia observed in neonates. Additionally, due to immature neonatal renal function and the inability of the neonate to voluntarily ensure adequate hydration, high drug concentrations and/or delayed elimination in the neonate could result in a higher risk for drug crystallization and renal stone developments than observed in adults.[60]

In Canada, only ZDV has received approval by the Health Protection Branch of Health Canada pursuant to the *Food and Drugs Act* for use during pregnancy to reduce the risk of perinatal HIV transmission.

Recently reported results from Switzerland examining the safety of combination antiretrovirals in pregnant HIV-infected women,[61] retrospectively and prospectively, documented one or more adverse events in 21 of 37 women and in 17 of 30 infants. Adverse events in the women during pregnancy were reported to include: anemia, thrombocytopenia, hypermylasemia, elevation of LFTs, nephrolithiasis, hypertension, insulin-requiring diabetes, glucose intolerance and persistent nausea. Adverse events in the infants included: premature birth, anemia, hyperbilirubinemia, transient hepatitis, cryptorchidism, extrahepatic biliary atresia, cutaneous angioma, and intracerebral hemorrhage. The authors noted that only one infant had a major malformation, and that the intracerebral hemorrhages were not life-threatening.[62]

A British Columbia study undertaken to evaluate the effect of antiretroviral exposure and foetal and neonatal outcomes on 54 women also reported its results at the 12th World AIDS Conference in Geneva. Among the children born to the women in the cohort who used ZDV monotherapy or a variety of combination therapies the researchers observed no teratogenic effects and concluded that "the overall pregnancy and neonatal outcome was good." The researchers did report one intrauterine death at 33 weeks and oligohydramnios in 10.8 percent of the pregnancies exposed to antiretroviral drugs.[63]

Because it is difficult to extrapolate the results of animal studies to humans, the need for additional data and research regarding the safety – for HIV-positive women and their infants – of antiretroviral drugs used during pregnancy is clear.

Regulatory status of antiretroviral drugs used in HAART

In Canada, only ZDV has received approval by the Health Protection Branch (HPB) of Health Canada pursuant to the *Food and Drugs Act*[64] for use during pregnancy to reduce the risk of perinatal HIV transmission. The remaining drugs have been approved only for use by HIV-positive individuals to inhibit viral replication and disease progression. While "off-label" uses of those drugs by physicians are nonetheless permissible in Canada (for example, in an effort

[60] Ibid at 6-7.

[61] All women were taking two reverse transcriptase inhibitors, with or without a protease inhibitor.

[62] P Lorenzi et al. Safety of combined antiretroviral therapies with or without protease inhibitors in pregnant HIV-infected women and their offspring (#32453), 12th World AIDS Conference, Geneva, 1998, *Conference Supplement* at 27. Of 30 infants born as of the date of the abstract, only one was HIV-infected, and this was reported as possibly attributable to poor maternal adherence to the therapeutic regimen.

[63] Money et al, supra, note 37.

[64] *Food and Drugs Act*, RSC 1985, c F-27, as amended.

to enhance the effectiveness of ZDV in minimizing the risk of perinatal HIV transmission based upon reports in the relevant medical literature), it must be understood that such use takes place in the absence of any examination by HPB of their safety and efficacy.[65]

Surveillance of adverse reactions to antiretroviral drugs used in HAART

Given that many of the antiretroviral drugs currently available were approved for use on the basis of limited safety data in view of the life-threatening nature of HIV disease, there is a recognized need for rigorous post-market surveillance to monitor their safety and effectiveness.[66] For example, one recent study concludes that:

> The occurrence of unexpected major adverse events among newborns emphasizes the necessity to maintain updated registers concerning pregnancy, newborns and antiretroviral therapy. Observation time has not been sufficient to assess long-term side-effects of highly active antiretroviral therapy, lipodystrophy being the best example.[67]

With the release of the 1994 PHS Recommendations, an Antiretroviral Pregnancy Registry (the "US Registry") was created to collect observational data about the pregnancy outcomes of women receiving antiretroviral prophylaxis. The purpose of the US Registry was to provide surveillance for possible teratogenicity in infants. From a Canadian perspective, at least, it has failed to prove useful. Only limited information is sought by way of follow-up: a history of the mother's delivery and a description of the infant at the time of birth. Reporting to the US Registry is voluntary and, for those who do seek to report on a patient, difficult to achieve, with the result that the US Registry's capture rate to date has been poor. Finally, the usefulness of what little information the US Registry has collected is limited by the absence of any information on the population base of mother–infant pairs from which it is drawn.

The recently initiated Canadian HIV Health Line and Registry (the "Canadian Registry") has sought to overcome the problems encountered by the US Registry.[68] Rather than provide a single snapshot of the health of the infant at birth, the Canadian Registry includes a history of the mother's pregnancy that incorporates all factors relevant to foetal outcome, as well as descriptions of the infant (including malformations and developmental effects) at birth, six months of age, and every year thereafter to at least five years of age. Optimally, the Canadian Registry would follow these infants beyond the age of five years to 18 years and beyond. At present, however, the ability to do so is subject to the availability of funding. The present capture rate of the Canadian Registry is approximately 95 percent of all HIV-positive women who give birth in Canada, and efforts are underway to improve this rate to as close to 100 percent as possible. Finally, it is anticipated that the usefulness of the data gathered will be enhanced through access by the Canadian Registry to the background information on infant malformations and developmental problems in Canada gathered and analyzed by the Motherisk Program of the Hospital for Sick Children in Toronto. However, a significant limitation of the Canadian Registry is that it is essentially a research project and is therefore dependent upon the

[65] Pursuant to the relevant provisions of the *Food and Drugs Act* and regulations, notices of compliance issued to permit the distribution of new drugs are specific to those uses for which the manufacturers have produced evidence satisfactory to the HPB of their safety and efficacy. Manufacturers are prohibited under the Act and regulations from advertising the use of drugs for non-approved uses. Physicians are not, however, prohibited from using a drug for non-approved uses, a practice generally referred to as "off-label" use.

[66] Hooker et al, supra, note 45.

[67] P Lorenzi et al. Antiretroviral therapies in pregnancy: Maternal–foetal neonatal effects. *AIDS* 1998; 12(18): F241-247 at 247. The Geneva abstract of this study is referred to at note 62 above.

[68] The information set out in this paragraph was obtained during a personal communication between the author and Dr Susan King, Associate Professor of Pediatrics, Division of Infectious Diseases (Co-Director of the HIV/AIDS Program) of the Hospital for Sick Children in Toronto, Ontario, on 28 October 1998.

continued interest of the primary investigator and the availability of research funding rather than being integrated into the formal regulatory apparatus of the Health Protection Branch pursuant to the *Food and Drugs Act* and Regulations.

It is important to note, moreover, that neither the US Registry nor the Canadian Registry provide surveillance of the short- or long-term risks of antiretroviral drugs for the women who take them during pregnancy. Nor is there any other systematic means for collecting this information. The following interim results of a recent British study highlight the significance of this failure:

> Only 91 reports for anti-HIV drugs were received from the U.K. vis à vis Yellow Card Scheme between July 1996 and July 1997. The HIV ADR Reporting Scheme was launched in November 1997 and in the first 8 weeks 38 reports were received. Of these, two-thirds of reported reactions were serious and one case was fatal. Half of the reactions reported were not previously recognized suggesting that the Scheme is generating new drug safety signals. ... The initial response to the launch of the HIV ADR Reporting Scheme has been encouraging. If this is maintained, the Scheme will provide valuable information on adverse reactions with the potential to identify previously unreported reactions.[69]

In Canada, we have no equivalent to the UK's Yellow Card Scheme to solicit reporting to HPB by physicians of all adverse reactions attributable to the use of therapeutic drugs, including, in particular, antiretroviral drugs. Canada relies instead on spontaneous reports of adverse reactions to drugs, an approach that is estimated to yield reporting of only about one percent of all adverse reactions.[70] It is likely, therefore, that the baseline of such reports is even lower in Canada than it is in the UK, and the associated need for the systematic collection of this information that much greater in order to better appreciate the nature and extent of all short- and long-term risks to HIV-positive women caused by the use of antiretroviral drugs during pregnancy.[71] As noted by one author, moreover,

> if a long time elapses between ingestion of the drug and the adverse effect, as is the case with *in utero* exposure to the estrogen medication DES (diethylstilbesterol) and the development of vaginal cancer in a female child 20 years later, then the system [ie, of reliance upon spontaneous reporting] is likely to fail.[72]

These same weaknesses are apparent in the FDA's post-marketing surveillance of drugs:

> A major weakness of spontaneous anecdotal reporting is that it is difficult or impossible to estimate reliably how often adverse events might be occurring since, according to the FDA estimates, only about 1% of adverse events are ever reported. ...
>
> The monitoring system based on spontaneous reports is also incapable of detecting many important potential dangers of approved

[69] Hooker et al., supra, note 45.

[70] J Lexchin. How Safe Are Prescription Drugs? *Literary Review of Canada* (December 1998), at 22.

[71] By way of analogy, it is of interest to note that in the *Final Report of the Commission of Inquiry on the Blood System in Canada*, Commissioner Krever recommended that the HPB develop "an active program of post-market surveillance for blood components and blood products." The Honourable Mr Justice Horace Krever. *Commission of Inquiry on the Blood System in Canada: Final Report*, Vols. 1-3. Ottawa: Minister of Public Works and Government Services of Canada, 1997, vol 3, at 1069.

[72] Supra, note 70.

> drugs. For example, if a drug causes an event that might be expected as part of the natural history of the disease being treated, the spontaneous detection system fails. ... A spontaneous reporting system also cannot capture adverse events that manifest themselves as a disease with high prevalence or with a long delay between exposure and clinical manifestation. Cancer is the classic example. While spontaneous reporting makes a valuable contribution, it provides only a fraction of the information required to develop programs to protect the public from the health risks of marketed drugs.[73]

Canada cannot, in other words, rely upon the FDA for information regarding risks associated with the use of antiretroviral drugs during pregnancy that its own regulatory apparatus does not generate.

In summary, there is a paucity of data regarding the short- and long-term effects in women and their infants of antiretroviral prophylaxis to reduce perinatal HIV transmission. The demonstrated ability of this therapy to reduce the risk of perinatal HIV transmission and its devastating consequences is unquestionably significant. In developing an approach to the care and treatment of pregnant women to minimize the risk of perinatal HIV transmission, however, physicians and policymakers must equally bear in mind the potential seriousness of its known and unknown risks. The public health disasters of thalidomide and DES serve as powerful reminders of the possibility of harm presented by the use of therapeutic drugs during pregnancy.

In developing an approach to the care and treatment of pregnant women to minimize the risk of perinatal HIV transmission, physicians and policymakers must bear in mind the potential seriousness of its known and unknown risks.

Alternative Approaches to HIV Testing of Pregnant Women

Insofar as testing polices for HIV-positive pregnant women are concerned, four alternative approaches are often considered and contrasted.[74]

- *Voluntary HIV testing offered to pregnant women with identified risk factors*

  This approach calls for HIV testing to be offered to pregnant women who present with a history and/or signs and symptoms that place them at increased risk of HIV infection, as well as all pregnant women who ask to be tested irrespective of the presence or absence of identified risk factors for HIV infection.

  The test is performed only with the voluntary, specific and informed consent of each pregnant woman, including all standard components of pre- and post-test counselling.

- *Voluntary HIV testing offered to all pregnant women*

  This approach calls for HIV testing to be offered to all pregnant women irrespective of the presence or absence of identified risk factors for HIV infection.

  The test is performed only with the voluntary, specific and informed consent of each pregnant woman, including all standard components of pre-

[73] TJ Moore et al. Time to act on drug safety. *Journal of the American Medical Association* 1998; 279(19): 1571-1573 at 1572.

[74] In practice, the distinctions between these alternative approaches are not always clear. The Appendix provides a brief summary of the current practices regarding the HIV testing of pregnant women in all Canadian provinces and territories.

and post-test counselling. This approach is sometimes referred to as the "opt-in" approach.

- *Routine HIV testing of all pregnant women*

  This approach calls for HIV testing to be performed on all pregnant women by adding this test to the standard laboratory requisition form used to conduct prenatal assays.

  Routine testing does not, by definition, require that the test be performed without the voluntary, specific and informed consent of the pregnant woman tested, including all standard components of pre- and post-test counselling.

  Characterization of the test as "routine" may create a presumption on the part of the physician and/or the woman concerned that the test will be conducted and may diminish the importance attached (by one or both) to a full discussion of the risks and benefits of testing and to the full exercise of the woman's right to give or refuse her informed consent to HIV testing. Alternatively, the need for voluntary, specific and informed consent might be overlooked altogether. The woman's consent to be tested for HIV might be implied from her presentation to a physician seeking prenatal care and providing a blood sample for "routine blood work."

  A woman's specific refusal to be tested for HIV (sometimes referred to as "opting-out" of HIV testing) would be respected.

- *Mandatory HIV testing of all pregnant women*

  This approach calls for HIV testing to be performed on all pregnant women.

  The test is performed without the voluntary, specific and informed consent of the pregnant woman tested, and without all standard components of pre- and post-test counselling. Should a pregnant woman refuse to be tested for HIV, that choice would not be respected; the test would be performed against her will.

The following questions articulate the differences between the alternative approaches set out above. They constitute policy choices that must be made in designing a policy to govern the HIV testing of pregnant women in Canada.

- Should HIV testing be offered to all pregnant women, or only to those at increased risk of HIV infection?
- Should HIV testing of pregnant women be voluntary, or should it be mandatory?
- Should physicians be required to secure the informed consent of pregnant women before proceeding with HIV testing, or can this requirement be abrogated?
- Should the HIV testing of pregnant women be characterized as "routine"?
- What added supports are necessary to ensure the effectiveness of provincial and territorial policies for the HIV testing of pregnant women in Canada?

It is essential that any analysis of the relevant medical and scientific facts undertaken to make policy choices in response to these questions be informed by an appreciation of the current status of Canadian law.

Legal Parameters of the Policy Debate

Is a woman's right to refuse a proposed medical intervention abrogated by pregnancy?

This chapter examines the legal parameters of the debate regarding the HIV testing of pregnant women in Canada. What is the nature and extent of an individual's right to exercise informed consent to proposed medical interventions (The Right to Give or Refuse Consent to Proposed Medical Interventions)? What information must be disclosed to meet informed consent requirements for proposed medical interventions in the "ordinary"case (Informed Consent and HIV Testing in the "Ordinary" Case)? Who is responsible for making decisions about medical interventions that may affect the health or life of the foetus, and what information must physicians provide to inform that decision-making process (Decision-Making)? Is a woman's right to refuse a medical intervention abrogated by pregnancy (Is a Woman's Right to Refuse Abrogated by Pregnancy)? What are the constitutional limits on governmental initiatives regarding the HIV testing of pregnant women (Constitutional Limits on Legislative Initiatives for HIV Testing)? What are the general principles and approaches that would govern application of the *Canadian Charter of Rights and Freedoms* (the "Charter") in those circumstances (General Approach and Principles of a Charter Analysis)? And, finally, what are the general duties of governments in policymaking (The Duty of Governments in Policy-making)?

The Right to Give or Refuse Consent to Proposed Medical Interventions

The Duty to Seek Informed Consent

In Canada, the circumstances in which an individual may accept or decline a proposed medical intervention are governed by the legal doctrine of informed consent. Two landmark decisions of the Supreme Court of Canada, *Hopp* v *Lepp*[75] and *Reibl* v *Hughes,*[76] served to import the legal doctrine of informed consent into Canadian jurisprudence and articulate its general scope. As held by Chief Justice Laskin (as he then was) speaking for the Court in *Reibl*,

> [i]t is now undoubted that the relationship between surgeon and patient gives rise to a duty on the surgeon to make disclosure to the patient of what I would call all material risks attending the surgery which is recommended.[77]

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What was at issue in *Reibl* was the conduct of surgery to remove an occlusion in the plaintiff's left internal carotid artery. Since that case was decided, however, the doctrine of informed consent has been applied beyond the surgical context to a broad range of medical interventions. In particular, the Supreme Court of Canada has applied the doctrine to the conduct of diagnostic procedures.[78]

The underlying purpose of the legal doctrine of informed consent is to protect the autonomy of individuals. In *Malette* v *Shulman*, the Ontario Court of Appeal expanded upon this rationale as follows:

The right of a person to control his or her own body is a concept that has long been recognized at common law.

> The right of a person to control his or her own body is a concept that has long been recognized at common law. The tort of battery has traditionally protected the interest in bodily security from unwanted physical interference. Basically, any intentional nonconsensual touching which is harmful or offensive to a person's reasonable sense of dignity is actionable. Of course, a person may choose to waive this protection and consent to the intentional invasion of this interest, in which case an action for battery will not be maintainable. No special exceptions are made for medical care, other than in emergency situations, and the general rules governing actions for battery are applicable to the doctor–patient relationship. Thus, as a matter of common law, a medical intervention in which a doctor touches the body of a patient would constitute a battery if the patient did not consent to the intervention. Patients have the decisive role in the medical decision-making process. Their right of self-determination is recognized and protected by the law. As Justice Cardozo proclaimed in his classic statement, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." ...
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> The doctrine of informed consent has developed in the law as the primary means of protecting a patient's right to control his or her medical treatment. Under the doctrine, no medical procedure may

[75] *Hopp* v *Lepp*, [1980] 2 SCR 192.

[76] *Reibl* v *Hughes*, [1980] 2 SCR 880.

[77] Ibid at 884.

[78] *Ciarlariello* v *Schacter*, [1993] 2 SCR 119.

> be undertaken without the patient's consent obtained after the patient has been provided with sufficient information to evaluate the risks and benefits of the proposed treatment and other available options. The doctrine presupposes the patient's capacity to make a subjective treatment decision based on her understanding of the necessary medical facts provided by the doctor on her assessment of her own personal circumstances. A doctor who performs a medical procedure without having first furnished the patient with the information needed to obtain an informed consent will have infringed the patient's right to control the course of her medical care, and will be liable in battery even though the procedure was performed with a high degree of skill and actually benefited the patient.[79]

In *Malette* and, more recently, *Fleming* v *Reid*, the Ontario Court of Appeal firmly established that the right of a patient to give his or her informed consent to a proposed medical intervention encompasses, of necessity, the right to refuse it:[80]

> The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self-determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the doctor, who ultimately must decide if treatment – any treatment – is to be administered.[81]

The origins of the doctrine of informed consent lie in the common law, in the context of civil actions by patients seeking compensation from physicians and other health care providers on the grounds that they did not consent to the treatment received. In *Fleming*, however, the Ontario Court of Appeal elevated this right to constitutional status under the Charter.[82]

The Scope of Disclosure Required to Secure Informed Consent

The scope of the duty of disclosure established by the Supreme Court of Canada in *Hopp* and *Reibl* and followed by courts across Canada in subsequent cases requires a physician to discuss all "material risks" of the proposed intervention with a patient. Quoting the Court's earlier decision in *Hopp*, Chief Justice Laskin held in *Reibl* that a surgeon,

> generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the proposed operation.[83]

He further clarified the definition of "material risks" with the statement that,

> even if a risk is a mere possibility which ordinarily need not be disclosed, yet if its occurrence carries serious consequences, as for example, paralysis or even death, it should be regarded as a material risk requiring disclosure.[84]

[79] *Malette* v *Shulman* (1990), 37 OAC 281 (CA), at 285-86.

[80] This point was directly in issue in *Malette*. The plaintiff had been rushed to hospital unconscious following an automobile accident in which she suffered serious injuries. The defendant physician ordered that she receive a blood transfusion that the trial judge concluded "may well have been responsible for saving her life." The plaintiff took issue with the defendant physician's conduct on the grounds that he should have respected her decision as a Jehovah's Witness not to be given a blood transfusion under any circumstances. The physician defended his conduct on the grounds that he was not satisfied that the card signed by the plaintiff evidenced an "informed refusal" on her part. The plaintiff won. See *Malette*, ibid at 283. The point was also directly in issue in *Fleming*, in which a psychiatric patient sought the right to avoid the compelled administration of antipsychotic drugs recommended by his treating physician pursuant to the scheme established by Ontario's *Mental Health Act*, RSO 1980, c 262: *Fleming* v *Reid*, (1991) 82 DLR (4th) 298 (CA).

[81] *Fleming*, supra, note 80 at 309-310.

[82] Ibid at 312-313. See also *Rodriguez* v *AG (BC)*, [1993] 3 SCR 519 at 587-588, per Sopinka J for the majority.

[83] *Reibl*, supra, note 76 at 884.

[84] Ibid at 884-885.

As rigorous as this general standard of disclosure may be, the standard is even more exacting for proposed medical interventions characterized as experimental. While there is no post-*Reibl* court decision that squarely addresses the standard of disclosure required when a proposed medical intervention is both therapeutic (ie, intended to benefit the health of the patient) and experimental (ie, its safety and efficacy remain unproven or the intervention has not been accepted as generally established medical practice[85]), the better view of the law is that physicians should observe a "perfect" level of disclosure.[86] In other words, the obligation to disclose is not limited to "material risks" as it is in the ordinary therapeutic context (subject, of course, to questions asked by the patient, which must be answered fully and frankly regardless whether the intervention may be characterized as experimental or not). Rather, patients are entitled to "a full and frank disclosure of all the facts, probabilities and opinions which a reasonable [person] might be expected to consider before giving his [or her] consent."[87] Of particular importance in such circumstances is the risk that the intervention might not succeed and the risk of associated adverse effects.

Physicians should observe a "perfect" level of disclosure.

Legislation in some provinces codifies the doctrine of informed consent to varying degrees. None of the legislative enactments to date derogate from the common law requirements established by the case law as set out above.[88]

Informed Consent and HIV Testing in the "Ordinary" Case

Authoritative guidelines for physicians in Canada, emanating from a range of professional organizations and licensing bodies, have clarified the standard of care expected of physicians when conducting HIV testing. Chief among these are the 1995 *Counselling Guidelines for HIV Testing* developed by an Expert Working Group of the Canadian Medical Association and published by the CMA ("CMA Guidelines").[89]

First and foremost, the CMA Guidelines state that "testing for HIV should always be voluntary and carried out only after the patient has given informed consent."[90] The CMA Guidelines further establish that application of the doctrine of informed consent in this context requires a physician to ensure that his or her patient "understand[s] the purposes, risks, harms and benefits of being tested, as well as those of not being tested" before performing an HIV test.[91] These requirements are often summarized in the phrase "voluntary, specific and informed consent."[92]

The CMA Guidelines provide detailed information regarding the steps to be taken by a physician to ensure that appropriate information is shared to enable the patient to achieve the requisite level of understanding. The essential steps are as follows:

- *The need for pre- and post-test counselling*

  HIV testing "must be preceded and followed by appropriate counselling by trained or experienced professionals."[93]

- *Essential components of pre-test counselling*

  These include:

[85] "Non-validated practice" is another term used by some legal commentators to describe medical interventions whose safety or efficacy remain unproven. See, for example, F Baylis et al. Ethical and Legal Issues Relating to Post-Exposure Prophylaxis (TEP) for Possible Non-Occupational Exposure to HIV. HIV Post-exposure Prophylaxis in the Non-Occupational Setting: Decision-Making in the Face of Uncertainty, 23-24 October 1998.

[86] EI Picard. *Legal Liability of Doctors and Hospitals in Canada*, 2d ed. Toronto: Carswell Legal Publications, 1984, at 115-121.

[87] *Halushka* v *University of Saskatchewan et al* (1965), 53 DLR (2d) 436 (Sask CA), at 444. More recently, see *Weiss* v *Solomon* (1989), 48 CCLT 280 (QSC), at 301-303. Although the court in *Halushka* was considering a research endeavour that presented no therapeutic benefit to the patient, Picard argues that the test articulated is nonetheless appropriate to the experimentation context: Picard, *The Legal Liability of Doctors and Hospitals in Canada*, supra, note 86 at 119.

[88] In Ontario, see the *Health Care Consent Act, 1996*, ss 10-11. In British Columbia, see the *Health Care (Consent) and Care Facility (Admission) Act*, RSBC 1996, c 181, ss 4-6 (not in force). In Prince Edward Island, see the *Consent to Treatment and Health Care Directives Act*, SPEI 1996, c 10, s 5 (not in force).

[89] These were developed by an Expert Working Group of the CMA based on the views of scientific experts and reports published as of March 1995 and reviewed prior to publication by representatives of a broad range of organizations with relevant experience, individual physicians and other health care professionals. See CMA Guidelines at 4.

[90] Ibid at 5.

[91] Ibid at 6.

[92] See, for example, NAC–AIDS, *HIV and Human Rights in Canada*, supra, note 28 at 19.

[93] CMA Guidelines, supra, note 89 at 4.

- assessment of the patient's risk of HIV infection;
- assessment of the window period;
- provision of information regarding HIV infection, risk-producing activities, and specific ways in which the patient can avoid or reduce risk;
- identification of testing options available in the region (specifically, anonymous testing, non-nominal testing, and nominal testing) and of the differences between these options;
- discussion of record-keeping with respect to the test results and of the availability of those records to other health care professionals;
- discussion of the implications of testing (the advantages and disadvantages) so that the patient has an opportunity to weigh them in the context of his or her particular circumstances; and
- determination of the timing of testing and the post-test visit, should the patient choose to proceed with the HIV test.

- *Essential components of post-test counselling*

  These include:

  - communication of the test result;
  - assessment of the patient's understanding of the test result;
  - assessment of the need for follow-up and care (including any need for a subsequent HIV test, and undertaking the necessary steps to provide that follow-up and care); and
  - discussion of the importance of risk-reducing behaviour irrespective of the test result.

Professional guidelines for physicians emanating from other professional organizations and licensing bodies in Canada are consistent with the contents of the CMA Guidelines set out above.[94]

The consequences of HIV testing for those men and women who test positive are serious – personally, socially and legally. In their personal lives, individuals who test HIV-positive must confront the fact of their infection and the meaning of that diagnosis for their present and future health. Socially, they must confront a range of difficult issues: the potential impact of their diagnosis upon those close to them, to whom and when they should disclose their HIV status (in some cases, at risk of physical violence), and the well-founded fear of stigma and discrimination associated with disclosure that still – in 1999 – can result in the loss of personal relationships, employment, shelter and medical care, and otherwise dramatically impact upon their quality of life.[95]

The consequences of HIV testing for those men and women who test positive are serious - personally, socially and legally.

The legal consequences that may flow from an HIV-positive diagnosis are equally far-reaching. Public health legislation enacted in all Canadian provinces and territories requires that all cases of AIDS be reported to public health officials; HIV positivity, in the absence of a diagnosis of AIDS, is reportable in many provinces and territories.[96]

This same legislation establishes, for each province and territory, a framework that governs the conduct of persons with designated infectious or communicable diseases (such as HIV disease and AIDS), insofar as that conduct may present a risk of transmission to another person or persons. The circumstances in which nominal reporting is required for persons with HIV

[94] See, for example, the guidelines and policy statements issued by the College of Family Physicians of Canada, the College of Physicians and Surgeons of Manitoba, the College of Physicians and Surgeons of British Columbia, and the College of Physicians and Surgeons of Ontario.

[95] For a full exploration of the discriminatory treatment to which people with HIV disease remain subject in Canada, see T de Bruyn. *HIV/AIDS and Discrimination: A Discussion Paper*. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1998.

[96] The specifics of current reporting obligations for HIV and AIDS in all provinces and territories are set out in detail at pp 231-233 of R Jürgens. *HIV Testing and Confidentiality: Final Report*. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1998.

and AIDS varies among jurisdictions, as do the circumstances in which public health officials may intervene to control the conduct of such persons and the steps public health officials may take to do so. There is no question, however, that the practical effect of a positive HIV test that may be linked to an individual is the potential for state-exercised surveillance and control of conduct by that person that presents a risk of HIV transmission to others.[97]

Although the specific content of provincial and territorial public health legislation varies between jurisdictions, all statutes that require the reporting of one's HIV status permit its disclosure under specified circumstances in the absence of consent on the part of the person tested. In particular, contact tracing efforts may result in the disclosure of a person's HIV status – even if it is undertaken on a non-nominal basis – and public health monitoring of risk-bearing conduct may in some cases result in the exercise of public health coercive powers, including the power to detain HIV-positive individuals for related care and treatment.

In the criminal context, the effect of the Supreme Court of Canada's decision in *R* v *Cuerrier* is to require those individuals who know they are HIV-positive to disclose their HIV status to sexual partners before engaging in conduct that poses "a significant risk of serious bodily harm."[98] The failure to do so may result in a criminal charge and conviction for aggravated assault contrary to section 268 of the *Criminal Code* (Canada).[99]

In *Crits* v *Sylvester*, the Supreme Court of Canada established that the standard against which a physician's conduct will be measured to assess whether he or she has been negligent is that of a reasonably prudent practitioner with a comparable level of skill and training.[100] Counselling guidelines and policy statements issued by professional associations and licensing bodies are an important source of evidence as to what constitutes an appropriate standard of practice for reasonably prudent physicians engaging in HIV testing and, accordingly, the appropriate standard of care for the purpose of assessing negligence in such circumstances. In the context of HIV testing and counselling, the CMA Guidelines would constitute an important source of guidance to Canadian courts. Although introductory wording to the Guidelines inexplicably asserts that "they are not intended to be construed or serve as a standard of medical care," there is little question that they are nonetheless viewed as such by practising physicians[101] and, as a result, would in all likelihood be treated as such by any court called upon to consider the matter. A summary of the CMA Guidelines as they relate to perinatal testing, published in the *Canadian Medical Association Journal*, supports such a view with the opening statement that

> [t]he CMA says physicians should *strongly recommend* that pregnant mothers be tested for HIV, reaffirming opposition outlined in its 1995 *Counselling Guidelines for HIV*.[102]

Finally, it is worth noting that the Supreme Court of Canada has held in cases following *Crits* that it is not bound in all circumstances to accept the standard of practice as established by reasonably competent physicians within a given medical discipline; in those cases in which the Court has departed from that standard it has imposed a higher rather than a lower standard of care.[103]

The decision of Justice Wilson of the Ontario Court (General Division) in *Canadian AIDS Society* v *Her Majesty the Queen in Right of the Province of*

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

[98] *R* v *Cuerrier*, [1998] 2 SCR 371 at 430-436. It is arguable that the reasoning adopted by the Supreme Court of Canada in *Cuerrier* will be held in subsequent cases to apply to conduct other than sexual conduct that may be said to pose "a significant risk of serious bodily harm."

[99] *Criminal Code*, RSC 1985, c C-46, as amended.

[100] *Crits* v *Sylvester* (1956), 1 DLR (2d) 502 at 508; aff'd [1956] SCR 991.

[101] Personal communication between L Stoltz and Dr Philip B Berger, Chief, Department of Family and Community Medicine, St Michael's Hospital, Toronto, Ontario, on 17 January 1999.

[102] Informed consent needed before HIV testing of mothers: CMA. *Canadian Medical Association Journal* 1997; 156(8): 1108.

[103] See, for example, *Reibl*, supra, note 76; and *Ter Neuzen* v *Korn*, [1995] 3 SCR 674.

There is little question that a physician who conducts an HIV test on a patient without meeting the basic elements of the doctrine of informed consent would be vulnerable to both a civil action for damages, as well as a prosecution for professional misconduct for a failure to meet adequate standards of practice.

Ontario et al is the only case to date in which a court has considered the application of the doctrine of informed consent to HIV testing. In that case, Justice Wilson concluded that the Canadian Red Cross Society had failed to obtain the informed consent of donors to HIV testing and the reporting of HIV-positive test results to public health officials. In reaching her conclusion, Justice Wilson expressly found that the donors' informed consent to HIV testing was required as a matter of law.[104]

Given the relevant jurisprudence, together with the seriousness of the consequences of HIV testing for persons so tested, there is little question that a physician who conducts an HIV test on a patient without meeting the basic elements of the doctrine of informed consent as prescribed in detail by the CMA Guidelines would be vulnerable to both a civil action for damages, as well as prosecution for professional misconduct by his or her licensing body for a failure to meet adequate standards of practice.

The question that must be asked next, therefore, is whether the right of a woman to give or refuse her informed consent to HIV testing is restricted or otherwise altered by the fact of her pregnancy? To answer this question one must examine the status of the foetus and the protection of foetal interests as provided for by the common law in Canada, and relevant statutory provisions.

Who is Responsible for Decision-Making on Behalf of a Foetus?

In Canada, a pregnant woman may lawfully terminate her pregnancy. This has been the case since 1988, when the Supreme Court of Canada struck down section 251 of the *Criminal Code* in *R* v *Morgentaler*, on the grounds that its requirement that all abortions be sanctioned by a therapeutic abortion committee was arbitrary and unreasonable and caused unnecessary delays, jeopardizing the health of women seeking abortions, in violation of section 7 of the Charter. In 1990, the federal government sought to re-criminalize abortion with Bill C-43: An Act Respecting Abortion. The Bill was defeated in the Senate. Since then, a few provinces have sought to restrict access to abortions through provincial legislative initiatives ultimately rejected by the Supreme Court of Canada as unconstitutional intrusions upon the federal government's legislative competence over criminal law.[105]

Although the question of foetal personhood was raised in argument before the Court in *Morgentaler*, the Court side-stepped that question in its reasons for judgment. The status of the foetus in Canadian law was, however, directly addressed in two subsequent decisions of the Supreme Court of Canada, *Tremblay* v *Daigle*[106] and *R* v *Sullivan*.[107]

In *Tremblay*, the Court ruled on the validity of an injunction obtained by the applicant, the biological father of the foetus carried by the respondent, to prevent the respondent from having an abortion. This appeal placed the foetal "personhood" question directly in issue because the respondent argued that the foetus was entitled to the right to life and the right to assistance extended by the Québec *Charter of Human Rights and Freedoms* to "every human being." As summarized by the Court, the respondent's contention was that

[104] *Canadian AIDS Society* v *Her Majesty the Queen in Right of the Province of Ontario*, at 28, 33 and 37 of the unreported judgment, which contains Justice Wilson's discussion of the legislation and the common law concept of informed consent, which was omitted in the case as reported in (1995), 25 OR (3d) 388 (Ont Ct Gen Div). In the context of the case before her, Justice Wilson was not required to determine whether the Red Cross was liable to those donors so tested without providing their informed consent. The case was not an action for damages for breach of the relevant standard of care. Rather, it was an application to have the court determine whether the Canadian Red Cross Society, having conducted the HIV tests without the donors' informed consent, was nonetheless required to comply with the reporting provisions of Ontario's *Health Protection and Promotion Act*. Justice Wilson's conclusions regarding the application of the *Canadian Charter of Rights and Freedoms* are discussed below.

[105] See, for example, *R* v *Morgentaler*, [1993] 3 SCR 463.

[106] *Tremblay* v *Daigle* (1989), 62 DLR (4th) 634 (SCC).

[107] *R* v *Sullivan* (1991), 63 CCC (3d) 97 (SCC).

> the word "human" is in reference to the "human race" of which the foetus is a part, and the word "being" signifies "existing," which the foetus certainly does. Thus ... a foetus is a human being.[108]

The Court rejected the argument in the following terms:

> This argument is not persuasive. A linguistic analysis cannot settle the difficult and controversial question of whether a foetus was intended by the National Assembly of Quebec to be a person under s.1 [of the Quebec Charter]. What is required are substantive legal reasons which support a conclusion that the term "human being" has such and such a meaning. If the answer were as simple as the respondent contends, the question would not be before our court nor would it be the subject of such intense debate in our society generally. ...
>
> In our view, the Quebec *Charter*, considered as a whole, does not display any clear intention on the part of its framers to consider the status of a foetus. This is most evident in the fact that the *Charter* lacks any definition of "human being" or "person." ... If the legislature had wished to grant foetuses the right to life, then it seems unlikely that it would have left the protection of this right to happenstance.[109]

The Supreme Court supported its decision with an analysis of both Québec jurisprudence interpreting the Civil Code and Anglo-Canadian law, and concluded that neither accord legal personality to the foetus.[110] Although the review of Anglo-Canadian law was unnecessary to determine the appeal, the Court strengthened the precedential value of its conclusions based upon that review by stating that it was "useful ... to avoid the repetition of the appellant's experience in the common law provinces."[111] *Tremblay*, therefore, stands as clear authority for the proposition that a statute cannot be read as affording substantive rights to the foetus in the absence of express language to that effect.

Tremblay is also significant for its unambiguous rejection of the appellant's assertion of "father's rights." The appellant argued that his contribution to the act of conception gave him an equal say, together with the respondent, over what happened to the foetus. The Court gave short shrift to this argument:

> There does not appear to be any jurisprudential basis for this argument. No court in Quebec or elsewhere has ever accepted the argument that a father's interest in a foetus which he helped create could support a right to veto a woman's decisions in respect of the foetus she is carrying. ... This lack of a legal basis is fatal to the argument about father's rights.[112]

The significance of this conclusion in the context of the matters under review in this paper is that it clearly posits the pregnant woman as the person responsible for making appropriate choices in respect of the foetus she carries.

R v *Sullivan*, decided by the Supreme Court of Canada shortly following *Tremblay*, involved two midwives charged under section 203 (now section 220) of the *Criminal Code* with criminal negligence causing death arising from the death of a foetus while still in the birth canal (Count No.1). The midwives

[108] *Tremblay*, supra, note 106 at 650.
[109] Ibid at 650-652.
[110] Ibid at 652-663.
[111] Ibid at 659-660.
[112] Ibid at 664.

were also charged with criminal negligence causing bodily harm under section 204 (now 221) of the *Criminal Code* in respect of injuries to the mother during the delivery (Count No.2). At trial, the midwives were convicted on Count No.1 in respect of death of the foetus and acquitted of Count No.2 in respect of bodily harm to the mother. The British Columbia Court of Appeal reversed the midwives' conviction on Count No.1 on the grounds that the foetus was not a person within the meaning of section 203 of the *Criminal Code*, but substituted a conviction on Count No.2 on the grounds that the foetus in the birth canal is, as a matter of law, part of the mother. The Supreme Court of Canada was called upon to review both of these conclusions.

The BC Court of Appeal's reasoning in relation to the first count anticipated that of the Supreme Court in *Tremblay*.[113] As summarized by the Supreme Court, the BC Court of Appeal

> first dealt with the issue of whether the child was a person within the meaning of s.203. After reviewing the law on this point in England, the United States and Canada, the court stated that, at common law, the line of demarcation for a foetus to become a person was the requirement that it be completely extruded from its mother's body and be born alive. The court noted that the [*Criminal Code*] reflected this position in defining when a child becomes a human being. It stated that Parliament drew no distinction between a person and a human being prior to 1953 and that when Parliament legislated with respect to criminal negligence in 1953, it did not intend to insert such a distinction into the *Code*. Accordingly, the child was not a person within the meaning of s.203 and Sullivan and Lemay could not be found guilty of criminal negligence causing death (to another person). The court noted, at p.79 that
>
> If Parliament considers it appropriate to protect a child during the birth process from criminally negligent acts by those attending and assisting at the birth, that is a matter upon which Parliament can legislate.[114]

The Supreme Court of Canada was unanimous in its approval of this reasoning, affirming its ruling in *Tremblay* that express statutory language is required to extend protections to a foetus, independent of its mother.[115]

On Count No.2, a majority of the Supreme Court reversed the BC Court of Appeal's substituted conviction on the grounds that the Court of Appeal lacked the necessary jurisdiction to disturb the acquittal granted by the trial judge. In reaching this conclusion, however, the Supreme Court majority did not reject the Court of Appeal's conclusion that the foetus in the birth canal is, as a matter of law, part of the mother. It simply observed that

> [i]t would not have been illogical to find that bodily harm was done to [the mother] through the death of the foetus which was inside of and connected to her body and, at the same time, to find that the foetus was a person who could be the victim of criminal negligence causing death.[116]

[113] The British Columbia Court of Appeal's decision in *Sullivan* was rendered before the decision of the Supreme Court of Canada in *Tremblay*.

[114] *Sullivan*, supra, note 107 at 103-104.

[115] Ibid at 106-107.

[116] Ibid at 109.

Considering this statement in view of the Supreme Court's conclusions in *Tremblay* and in *Sullivan* that the foetus is not a person, the better view as to the status of the foetus in Canadian law is that, absent express statutory provision to the contrary, the foetus must be treated as a part of the mother. This conceptualization of the status of the foetus supports a legal approach to consent to medical interventions that, consistent with the Court's response to the "father's rights" argument advanced in *Tremblay*, places responsibility for making appropriate choices in respect of the foetus with the pregnant woman and no one else.

Responsibility for making appropriate choices in respect to the foetus rests with the pregnant woman and no one else.

The Physician's Duty to Disclose Potential Harms to a Foetus

Consistent with the decisions of the Supreme Court of Canada reviewed above, Canadian jurisprudence interpreting and applying the doctrine of informed consent posits the pregnant woman as the decision-maker in respect of medical interventions that may impact upon the health of the foetus. If a proposed medical intervention presents the potential for harm to the developing foetus, then this information must be disclosed to the woman carrying that foetus, in accordance with the principles of the doctrine of informed consent.

In *Arndt* v *Smith*, the plaintiffs alleged negligence on the part of a physician for failing to warn a pregnant woman, Carole Arndt, of all material risks to her foetus presented by her illness with chicken pox while pregnant. Justice Hutchison concluded:

> I find that no duty is owed by Dr. Smith to Dennis Jackson, who was not a patient of Dr. Smith's, solely because he is Miranda's father. This logically flows from the Supreme Court of Canada's decision in [*Tremblay*] where the court held that a father has no interest in a foetus so as to enjoin a mother from aborting...
>
> I turn now to the duty Dr. Smith owed to Ms. Arndt as a patient within her care. Specifically, I must determine the extent of Dr. Smith's duty to fully inform Ms. Arndt of the potential risks her foetus faced as a result of Ms. Arndt contracting chicken pox.
>
> The issue of informed consent to medical intervention has received a good deal of judicial comment. A good place to start a discussion of informed consent is the decision of the Supreme Court of Canada in *Reibl* ...[117]

Justice Hutchison then proceeded to apply the doctrine of informed consent, in all its rigour, to the facts of the case, and concluded that Ms Arndt had made an uninformed consent regarding abortion in the absence of information that ought to have been provided to her by Dr Smith.

Is a Woman's Right to Refuse a Medical Intervention Abrogated by Pregnancy?

Does Canadian law deprive a pregnant woman of the right to refuse a proposed medical intervention by virtue of her pregnancy, if the intervention is of benefit or potential benefit to the foetus she carries?

[117] *Arndt* v *Smith* (1994), 21 CCLT (2d) 66 (BCSC), 75-77; aff'd (1997), 148 DLR (4th) 48 (SCC); rev'g (1995), 126 DLR (4th) 705 (BCCA). See also *Sigouin et al* v *Wong et al* (1990), 4 CCLT (2d) 129 (BCCA), rev'g (1988), 46 CCLT 159 (BCSC); leave to appeal ref'd at (1991), 8 CCLT (2d) 223 (SCC) and (1991), 10 CCLT (2d) 236 (BCSC).

Does Canadian law deprive a pregnant woman of the right to refuse a proposed medical intervention by virtue of her pregnancy, if the intervention is of benefit or potential benefit to the foetus she carried?

Judicial Uncertainty Prior to 1997

Before the 1997 decision of the Supreme Court of Canada in *Winnipeg Child and Family Services (Northwest Area)* v *DFG*,[118] the answer to this question was uncertain. Judicial interventions to direct the conduct of pregnant women were sought by state agencies in order to protect the health of the foetuses they carried in a variety of circumstances with a variety of results. For example:

- In a 1981 decision, *Re Children's Aid Society for the District of Kenora and J.L.*,[119] a Provincial Court judge in Ontario authorized the apprehension of an infant four days after her birth. The mother in this case was characterized as a severe alcoholic. She was intoxicated at delivery, and the infant had alcohol in the blood, exhibited alcohol withdrawal symptoms, and was being treated for foetal alcohol syndrome. Although the order was sought after the infant's birth, the judge concluded in support of the order that she was a "child in need of protection" within the meaning of Ontario's *Child and Family Services Act* even before her birth.
- In a 1987 decision, *CAS, Belleville and T(L)*,[120] an Ontario Family Court judge declared a foetus a "child in need of protection" within the meaning of Ontario's *Child and Family Services Act* and issued an order that the foetus was a ward of the Society for a period of three months. At the same time, the judge issued an order for the assessment by a physician of the mother carrying the foetus, pursuant to the provisions of the *Mental Health Act* (Ontario). The conduct that grounded both orders was the mother's refusal

  > to seek, maintain or accept any form of medical assistance which is clearly necessary for the delivery of the child, particularly where there is a fear that the child could be born in an unhealthy state or in a situation where the child's life is at risk. I am satisfied that [the mother's] attitude, whatever may be its cause, is not one which is conducive to the safe and healthy delivery of the child.[121]

- In a 1988 decision, *Re Baby R.*, the British Columbia Supreme Court reversed a lower-court decision apprehending a foetus as a child in need of protection to override the mother's refusal to undergo a caesarian section delivery deemed necessary by the physician on call in the interests of the foetus. The Court concluded,

  > after examining the *Child and Family Service Act* [of British Columbia] and the other relevant law, that the powers of the superintendent to apprehend are restricted to living children that have been delivered. Were it otherwise, then the state would be able to confine a mother to await her delivery of the child being apprehended. For the apprehension of the child to be effective there must be a measure of control over the body of the mother. Should it be lawful in this case to apprehend an unborn child hours before birth, then it would logically follow that an apprehension could take place a month or more before term. Such powers to interfere with the rights of women, if granted, must be done by specific legislation and anything less will not do.[122]

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

[119] *Re Children's Aid Society for the District of Kenora and JL* (1981), 134 DLR (3d) 249 (Ont Prov Ct).

[120] *CAS, Belleville and T(L)* (1987), 7 RFL 191 (Ont Prov Ct).

[121] Ibid at 193.

[122] *Re Baby R* (1988), 53 DLR (4th) 69 (BCSC) at 80.

- In a 1990 decision, *Re A (in utero)*,[123] a judge of Ontario's Unified Family Court refused to grant an order sought by the Children's Aid Society for supervision of a foetus that required the mother to submit to prenatal care and attend a hospital for the birth of the child. In the event that the mother refused to do so, the Society also sought an order for wardship of the foetus and an order requiring her "to be detained in a hospital until the birth of the child and to undergo all necessary medical procedures for the well-being of the unborn child."[124] The judge was satisfied that the Society's concerns about the well-being of the foetus were justified, and that the foetus might suffer irreparable harm unless the mother obtained proper prenatal care and proper medical care upon delivery. These concerns included the facts that the husband and wife had lied to Society workers about the mother's prenatal care and that the mother was suffering from toxemia with a risk of severe medical complications at birth.[125] The judge nonetheless refused to grant the order sought on the grounds that the foetus was not a "child" within the meaning of Ontario's *Child and Family Services Act*, 1984 (a conclusion supported by the Supreme Court of Canada's decision in *Tremblay*, to which the judge made express reference) and that the Court's *parens patriae* jurisdiction could not support such an intervention:

  > The essence of the *parens patriae* jurisdiction is that the court is empowered to take steps to protect the child or the foetus, *in the place of the parent*. But here the child is actually inside of the mother. It is, therefore, impossible in this case to take steps to protect the child without ultimately forcing the mother, under restraint if necessary, to undergo medical treatment and other processes, against her will. I believe that the *parens patriae* jurisdiction is just not broad enough to envisage the forcible confinement of a parent as a necessary incident of its exercise. …
  >
  > There is no doubt that the state has an interest in protecting those foetuses that mothers have decided to bring to full term, but the means and criteria for their protection had best be left to the legislature or Parliament and not to the discretion of the judiciary.[126] [Emphasis in original.]

Recommendations of the Royal Commission on New Reproductive Technologies

In 1989, the federal government appointed a Royal Commission on New Reproductive Technologies to

> inquire into and report upon current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied.[127]

The Commission conducted extensive research, together with a wide range of activities to consult with interested persons and organizations. Its work culminated in the publication on 15 November 1993 of its *Final Report*, together with 15 volumes of background studies and surveys.

[123] *Re A (in utero)* (1990), 75 OR (2d) 82 (UFCJ).

[124] Ibid at 83-84.

[125] Ibid at 84-87.

[126] Ibid at 91-92.

[127] Royal Commission on New Reproductive Technologies. *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol 1 at 2. Ottawa: Minister of Government Services Canada, 1993. With respect to the multidisciplinary nature of the Commission, the Commissioners included a pediatrician with expertise in medical genetics, a theologian, a lawyer, a member of the business community, and an anthropologist.

The Commission gave careful consideration to the use of legislation and court decisions to control the conduct of a pregnant woman believed to be endangering the health or life of her foetus by refusing medical treatment considered necessary for foetal health. There was a sense of immediacy about the Commission's work in relation to this issue. The jurisprudential landscape at that time included an increasing incidence of judicial interventions in pregnancy and birth in Canada (as canvassed in the decisions highlighted above), and an awareness of developments in the US that included both considerable legislative activity to facilitate use of the criminal law to control the conduct of pregnant women and even more active courts that sanctioned interventions in pregnancy and birth and suggested that children might sue their mothers for damages arising as a result of maternal conduct during pregnancy.[128] The Commission concluded that

Trying to use the law and the courts to protect foetal health can only be counterproductive.

> trying to use the law and the courts to protect foetal health can only be counterproductive. Such laws may, on the surface, have appeal, because we all support the goal of the well-being of the foetus, and enacting them may appear to be a logical extension of society's interest in the health of the foetus. But there is nothing in our experience to demonstrate that such laws work in practice. Indeed, there is strong evidence to the contrary, particularly because the instruments available to the courts – forcing action under penalty of fines or incarceration – are brutally blunt and patently unsuited to the goal of promoting anyone's health or well-being. Clearly, if protecting the foetus is the goal, other methods are needed.

The most effective way of caring for the foetus is through appropriate support and caring for the pregnant woman.

> A societal interest in pregnancy and birth – to maximize the chances for the birth of a healthy child – is a goal commissioners strongly endorse; it is an important and worthy goal. But our examination of the legal, ethical, and social implications of judicial intervention leads to the inescapable conclusion that judicial intervention is neither an acceptable nor an effective method of achieving that goal. Because the woman's consent and cooperation are needed to ensure a positive outcome for the foetus, it follows that the most effective way of caring for the foetus is through appropriate support and caring for the pregnant woman. The Commission therefore recommends that
>
> 273. Judicial intervention in pregnancy and birth not be permissible. Specifically, the Commission recommends that
>
> (a) medical treatment never be imposed upon a pregnant woman against her wishes;
> (b) the criminal law, or any other law, never be used to confine or imprison a pregnant woman in the interests of her foetus;
> (c) the conduct of a pregnant woman in relation to her foetus not be criminalized;
> (d) child welfare or other legislation never be used to control a woman's behaviour during pregnancy or birth; and
> (e) civil liability never be imposed upon a woman for harm done to her foetus during pregnancy.

[128] Ibid, vol 2 at 949-961.

> 274. Unwanted medical treatment and other interferences, or threatened interferences, with the physical autonomy of pregnant women be recognized explicitly under the *Criminal Code* as criminal assault.
>
> 275. All provinces/territories ensure that they have in place
>
> (a) information and education programmes directed to pregnant women so that they do not inadvertently place a foetus at risk;
> (b) outreach and culturally appropriate support services for pregnant women and young women in potentially vulnerable groups; and
> (c) counselling, rehabilitation, outreach, and support services designed specifically to meet the needs of pregnant women with drug/alcohol additions.[129]

Judicial Certainty Since 1997

The Supreme Court of Canada dealt with these issues decisively in the 1997 *Winnipeg Child and Family Services* case referred to at the beginning of this section. At the time of the court order by the Manitoba Court of Queen's Bench that gave rise to this appeal, DFG was five months' pregnant and addicted to glue-sniffing, which presented a risk of damage to the nervous system of her developing foetus. DFG had previously given birth to three other children, two of whom had been injured *in utero* due to her glue-sniffing addiction. The order under appeal directed that DFG be placed in the custody of the Director of Child and Family Services and detained at the Health Sciences Centre until the birth of her child, where she was to follow a course of medical treatment prescribed by the Director. As stated by Justice McLachlin, writing for a majority of the Supreme Court, the legal question to be answered in *Winnipeg Child and Family Services* was:

> [A]ssuming evidence that a mother is acting in a way which may harm her unborn child, does a judge, at the behest of the state, have the power to order the mother to be taken into custody for the purpose of rectifying her conduct?[130]

Within the scope of this question, Justice McLachlin further articulated the issues on the appeal as follows:

> (1) Does tort law, as it exists or may properly be extended by the Court, permit an order detaining a pregnant woman against her will in order to protect her unborn child from conduct that may harm the child?
>
> (2) Alternatively, does the power of a court to make orders for the protection of children (its *parens patriae* jurisdiction), as it exists or may properly be extended by the Court, permit an order detaining a pregnant woman against her will in order to protect her unborn child from conduct that may harm the child?[131]

The starting point for Justice McLachlin's analysis of both issues was the general proposition "that the law of Canada does not recognize the unborn child as

[129] Ibid at 964-965.

[130] *Winnipeg Child and Family Services*, supra, note 118 at 935.

[131] Ibid at 936-937.

a legal or juridical person."[132] A majority of the Supreme Court of Canada[133] concluded, in relation to both issues, that the existing state of the law could not support the relief sought by Winnipeg Child and Family Services (the "Agency"):

> Putting the matter in terms of tort, there [is] no right to sue, whether for an injunction or damages, until the child [is] born alive and viable. The law of tort as it presently stands might permit an action for injury to the foetus to be brought in the child's name after its birth. But there is no power in the courts to entertain such an action before the child's birth.[134]...
>
> [With respect to *parens patriae*, the] law as it stands is clear: the courts do not have *parens patriae* or wardship jurisdiction over unborn children. This is the law in the European Community, Great Britain and Canada. In Canada, all courts which have considered the issue, save for the trial judge in this case, appear to have rejected the proposition that the *parens patriae* jurisdiction of the court extends to unborn children.[135]

The law of Canada does not recognize the unborn child as a legal or juridical person.

The real question on both points, then, was whether the common law could properly be extended to support a judicial intervention to compel a pregnant woman to submit to a medical intervention of potential benefit to her foetus against her clearly expressed competent wishes. Again, a majority of the Supreme Court concluded that it could not. Justice McLachlin summarized their concerns in the following paragraph:

> The proposed changes ... involve moral choices and would create conflicts between fundamental interests and rights. They would have an immediate and drastic impact on the lives of women as well as of men who might find themselves incarcerated and treated against their will for conduct alleged to harm others. And, they possess complex ramifications impossible for this court to fully assess, giving rise to the danger that the proposed order might impede the goal of healthy infants more than it would support it. In short, these are not the sort of changes which common law courts can or should make. These are the sort of changes which should be left to the legislature.[136]

In the context of the policy choices under examination in this paper, it is worthwhile to canvass more specifically the matters that were of concern to the Court in reaching this decision.

- *The physical interdependence of mother and foetus*

  As stated by the Court, "for practical purposes, the unborn child and its mother-to-be are bonded in a union separable only by birth."[137] The liberty of the mother is thus "intimately and inescapably bound"[138] to the foetus. Enforcement by the state of a foetal interest or right that takes the form of a proposed medical intervention refused by the mother can therefore only be effected through the body of the mother, necessarily and profoundly compromising her rights to autonomy, self-determination and bodily integrity.

[132] Ibid at 937-939.

[133] Justice McLachlin wrote the reasons for judgment of the majority, which included Chief Justice Lamer and Justices La Forest, L'Heureux-Dubé, Gonthier, Cory and Iacobucci. Justice Major wrote dissenting reasons for judgment, with which Justice Sopinka agreed.

[134] Ibid at 939-940.

[135] Ibid at 955.

[136] Ibid at 941. In her reasons for judgment, Justice McLachlin directed this passage to the expansion of tort law. In a later passage, however, she gave similar reasons in relation to the extension of the Court's *parens patriae* jurisdiction (see ibid at 959-960).

[137] Ibid at 945.

[138] Ibid at 947.

As noted above, these are protected in Canadian law by the constitutionally protected right of individuals to exercise informed consent to proposed medical interventions, including the right to refuse potentially beneficial care and treatment.

- *The potential for maternal–foetal conflict*

  To grant the state the authority to impose its will upon a pregnant woman by restricting her rights to autonomy, self-determination and bodily integrity in the interests of foetal protection creates clear potential for conflict between the mother and the foetus she carries. This conflict will materialize whenever a pregnant woman seeks to conduct herself in a manner that is inconsistent with prevailing medical or societal norms as to what is appropriate to best protect the life and health of the foetus. Its consequences are myriad and far-reaching. Beyond the clear negative consequences for the pregnant woman, to the extent that she is forced to submit to a proposed medical intervention against her will, there are negative consequences for her relationship with her partner and her physicians as both take on the role of possible informants and enforcers of the will of the state rather than providers of support and care. There is also clear potential for the existence of this maternal–foetal conflict to work to the detriment of foetal health. As stated by Justice McLachlin:

  > First, it may tend to drive the problems underground. Pregnant women suffering from alcohol or substance abuse addictions may not seek prenatal care for fear that their problems would be detected and they would be confined involuntarily and/or ordered to undergo mandatory treatment. As a result, there is a real possibility that those women most in need of proper prenatal care may be the ones who will go without and a judicial intervention designed to improve the health of the foetus and the mother may actually put both at serious health risk. Second, changing the law of tort as advocated by the [A]gency might persuade women who would otherwise choose to continue their pregnancies to undergo an abortion. Women under the control of a substance addiction may be unable to face the prospect of being without their addicting substance and may find terminating a pregnancy a preferable alternative. In the end, orders made to protect a foetus' health could ultimately end in its destruction.[139]

A judicial intervention designed to improve the health of the foetus and the mother may actually put both at serious risk.

- *Vagueness and overbreadth*

  The Supreme Court rejected the Agency's submission that the potential intrusions upon the rights of pregnant women would be minimal because the duty of care could be narrowly defined to proscribe only activities that have no substantial value to a pregnant woman's well-being or right of self-determination and that have the potential to cause grave and irreparable harm to the child's life, health, and ability to function after birth.

  The Court's view was that this proposed formulation of the duty did not provide the "bright line" contended by the Agency. Implicit in Justice

[139] Ibid at 952.

In the end, orders made to protect a foetus' health could ultimately end in its destruction.

McLachlin's reasoning was the further concern that, having opened the door to state intrusion to remedy what might seem an obvious wrong, courts might well be persuaded to encroach further and further upon the freedom of pregnant women, second-guessing their lifestyle choices in the interests of foetal protection. Many behaviours – for example, alcohol consumption, cigarette smoking, and strenuous exercise – would not be easily classified on one side of the line or the other. Indeed, Justice McLachlin noted that the line itself would always be shifting as medical researchers struggle to determine what will cause "grave and irreparable" harm to a foetus: "[t]he difference between confinement and freedom, between damages and non-liability, may depend upon the grasp of the latest research and its implications."[140]

- *Selective enforcement*

  In a point related to the Court's concern about vagueness and overbreadth, Justice McLachlin noted, finally, that:

  > The pregnant women most likely to be affected by such a "knowledge" requirement [ie, the need to follow the latest research on threats to foetal health to avoid state intrusions designed to protect foetal health] would be those in lower socio-economic groups. Minority women, illiterate women and women of limited education will be the most likely to fall afoul of the law and the new duty it imposes and to suffer the consequences of injunctive relief and damage awards.[141]

The Supreme Court of Canada's decision in *Winnipeg Child and Family Services* confirms the inviolability at common law of a pregnant woman's right to exercise informed consent to a proposed medical intervention that may benefit the foetus she carries, and accept or decline that intervention free of state compulsion.

In summary, the Supreme Court of Canada's decision in *Winnipeg Child and Family Services* confirms the inviolability at common law of a pregnant woman's right to exercise informed consent to a proposed medical intervention that may benefit the foetus she carries, and accept or decline that intervention free of state compulsion. While the Court did acknowledge the legitimacy of the state's interest in protecting the health of a foetus in being carried to term and its ability to enact legislation to effect that purpose, emanating from the reasons for judgment of the majority is the strong suggestion (consistent with the findings, conclusions and recommendations of the Royal Commission on New Reproductive Technologies) that such legislation would not withstand constitutional challenge pursuant to the Charter.[142]

Constitutional Limits on Legislative Initiatives for HIV Testing

Legislation intended to authorize the state to compel a pregnant woman to submit, against her will, to a proposed medical intervention in the interests of her foetus would have to meet the following requirements:

- *Enactment by the appropriate level of government*

  The *Constitution Act, 1867* divides legislative competence by subject matter between the federal and provincial governments. Barring the development of circumstances that would require federal legislative action

[140] Ibid at 950.
[141] Ibid.
[142] Ibid at 960.

as a matter of "peace, order and the good government of Canada,"[143] the competence to enact such legislation lies with the provincial governments pursuant to sections 92(3) and (16) of the *Constitution Act, 1867* as either property and civil rights or matters of a local or private nature, respectively.[144]

- *Compliance with the Charter*

  While the *Constitution Act, 1867* serves to divide areas of legislative competence between the two levels of government, the effect of the Charter is to remove from both levels of government the ability to enact legislation that does not sufficiently respect individual rights and freedoms. In view of its conclusion that neither the common law of tort nor the Court's *parens patriae* jurisdiction could support the relief sought by the Agency, the majority's reasons for judgment in *Winnipeg Child and Family Services* did not specifically address the constitutionality of the order under appeal and the procedures that gave rise to it. As noted above, however, Justice McLachlin emphasized that legislation purporting to authorize the state to compel a pregnant woman to submit against her will to a proposed medical intervention such as HIV testing in the interests of her foetus would fall to be assessed against the provisions of the Charter.[145]

It is essential that governments engaging in policy development and other activities regarding the HIV testing of pregnant women comply with the relevant provisions of the Charter.

General Approach and Principles of a Charter Analysis

It is essential that governments engaging in policy development and other activities regarding the HIV testing of pregnant women comply with the relevant provisions of the Charter. To the extent that they do not, they act unlawfully and will be vulnerable to court challenges that seek to strike offending laws and policies, and seek compensation for associated injuries.

The Charter provisions of primary importance in reviewing the policy options for the HIV testing of pregnant women under consideration in this paper are set out below. These provisions are followed by a brief review of the general approach and principles that would likely govern the interpretation and application of these provisions by Canadian courts.

Section 32(1) of the Charter

> This Charter applies
> (a) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and the Northwest Territories; and
> (b) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province.

The object of this paper is to generate recommendations regarding the necessary elements of an appropriate policy for the HIV testing of pregnant women in Canada for consideration by the federal, provincial and territorial governments, for possible implementation by the governments, public health authorities, physicians, and other affected health care practitioners in private practice.

[143] The introductory words to s 91 of the *Constitution Act, 1867* grant legislative competence to the federal government over matters not exclusively assigned to the provinces for "the Peace, Order and good Government of Canada" (commonly referred to as the "POGG" power). Although health is one of those grey areas in which it is open to both levels of government to assert legislative competence, it is unlikely that the federal government could successfully enact legislation to authorize the compelled treatment of HIV-positive women using POGG, given the current jurisprudence interpreting when and how this power may be used. See, for example, *R* v *Crown Zellerbach Canada Ltd*, [1988] 1 SCR 401.

[144] *Schneider* v *The Queen*, [1982] 2 SCR 112 at 141-142.

[145] *Winnipeg Child and Family Services*, supra, note 118 at 960.

Federal, provincial and territorial ministries or departments of health are undeniably part of government and are therefore subject to the Charter. Moreover, longstanding Supreme Court jurisprudence interpreting the Charter has established that

> an activity will be subject to *Charter* review if, even although the act was not performed by "government," it was subject to such significant government control that it may effectively be considered an act of government for *Charter* purposes.[146]

As such, there is no doubt that the Charter applies to the formulation, dissemination and implementation of such policies.

Section 7 of the Charter

> Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

A complainant seeking to establish a violation of his or her section 7 rights under the Charter must prove two things: (1) that his or her right to one or more of life, liberty or security of the person has been breached;[147] and (2) that the breach is not in accordance with the principles of fundamental justice.[148]

Breach of life, liberty or security of the person?

Of significance to the issues canvassed in this paper are the rights of a pregnant woman to "liberty" and "security of the person."

In *Rodriguez* v *AG (BC)*, a majority of the Supreme Court of Canada defined the phrase "security of the person" to encompass the right of a person to be free of state-imposed intrusions upon both her physical and psychological integrity including, in particular, compelled medical interventions. As stated by Justice Sopinka, writing for the majority of the Court in that case:

> In my view, ... the judgements of this Court in *Morgentaler* can be seen to encompass a notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and freedom from state-imposed psychological and emotional stress. In *Reference re ss.193 and 195.1(1)(c) of the Criminal Code* (Man.), [1990] 1 SCR. 1123, Lamer J. (as he then was) also expressed this view, stating at p.1177 that "[s]ection 7 is also implicated when the state restricts individuals' security of the person by interfering with, or removing from them control over their physical or mental integrity." There is no question, then, that personal autonomy, at least with respect to the right to make choices concerning one's own body, control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person, at least to the extent of criminal prohibitions that interfere with these.[149]

More recently, in *Stillman*, a majority of the Supreme Court of Canada emphatically confirmed that the taking of bodily samples without consent violates an individual's right to security of the person:

[146] *Lavigne* v *Ontario Public Service Employees Union*, [1991] 2 SCR 211 at 240.

[147] The terms "life," "liberty," and "security of the person" are disjunctive. Each of the elements has been interpreted to hold meaning independent of the others; it is enough, therefore, for a complainant to establish that one of the three rights has been breached.

[148] *Reference re s 94(2) of the Motor Vehicle Act (BC)*, [1985] 2 SCR 485 at 501.

[149] *Rodriguez*, supra, note 82 at 588-589. The dissenting reasons for judgment of Justice McLachlin and of Justice Cory were in agreement on this point: see at 618 and 631 respectively. Chief Justice Lamer was the sole justice who did not express an opinion on this point in *Rodriguez*. See, however, Chief Justice Lamer's concurring reasons for judgment in *Reference re ss 193 and 195.1(1) of the Criminal Code (Manitoba)*, [1990] 1 SCR 1123 at 1176-1177.

> The taking of the dental impressions, hair samples and buccal swabs from the accused also contravened the appellant's s.7 *Charter* right to security of the person. The taking of the bodily samples was highly intrusive. It violated the sanctity of the body which is essential to the maintenance of human dignity. It was the ultimate invasion of the appellant's privacy. See *Pohoretsky*, *supra*. In *Dyment*, *supra*, at pp.431-32, La Forest J. emphasized that "the use of a person's body without his consent to obtain information about him, invades an area of personal privacy essential to the maintenance of his human dignity." Quite simply, the taking of the samples without authorization violated the appellant's right to security of the person and contravened the principles of fundamental justice.[150]

The taking of bodily samples without consent violates an individual's right to security of the person.

This conclusion has since been echoed in relation to medical interventions outside the criminal contexts considered in *Morgantaler*, *Rodriguez*, and *Stillman*. In *Fleming*, for example, the Ontario Court of Appeal unanimously held that provisions of Ontario's *Mental Health Act* purporting to authorize compelled medical treatment clearly engaged the applicants' right to security of the person:

> ... it is manifest that the impugned provisions of the Act operate so as to deprive the appellants of their right to "security of the person" as guaranteed by s.7 [of the Charter]. The common law right to bodily integrity and personal autonomy is so entrenched in the traditions of our law as to be ranked as fundamental and deserving of the highest order of protection. This right forms an essential part of an individual's security of the person and must be included in the liberty interests protected by s.7. Indeed, in my view, the common law right to determine what shall be done with one's own body and the constitutional right to security of the person, both of which are founded on the belief in the dignity and autonomy of each individual, can be treated as coextensive.[151]

Even more specific to the question of HIV testing, in *Canadian AIDS Society*, Justice Wilson of the Ontario Court (General Division) concluded that the conduct of HIV testing on blood donors and the reporting of HIV-positive test results to public health authorities as required by Ontario's *Health Protection and Promotion Act* without the consent of those to whom the results related amounted to a breach of their section 7 rights to security of the person.[152]

With respect to the liberty interest protected by section 7 of the Charter, well-established Supreme Court jurisprudence defines liberty to encompass the right of an individual not to be physically detained against his or her will.[153] In *R* v *Beare*, for example, the Supreme Court of Canada considered the constitutionality of statutory provisions that required a person to attend at a specific time and place to undergo fingerprinting, on pain of imprisonment for failure to comply. All parties before the Court acknowledged that the provision violated the right to liberty; at issue was whether the violation was in accordance with the principles of fundamental justice.

150 *R* v *Stillman*, [1997] 1 SCR 607 at para 51.

151 *Fleming*, supra, note 82 at 312.

152 *Canadian AIDS Society*, supra, note 104 at 52.

153 *R* v *Beare*, [1988] 2 SCR 387.

More broadly, Supreme Court jurisprudence suggests that the right to liberty recognized by section 7 may also encompass an individual's right to personal autonomy. In *B(R)* v *Children's Aid Society*, a case in which the parents of an infant asserted a constitutional right to refuse her a blood transfusion, Justice La Forest (with whom four of the nine Supreme Court Justices agreed on this point) concurred with the following statement of Justice Wilson in *Morgentaler*:

> ... an aspect of the respect for human dignity on which the *Charter* is founded is the right to make personal decisions without interference from the state. This right is a critical component of the right to liberty. Liberty, as was noted in *Singh*, is a phrase capable of a broad range of meaning. In my view, this right, properly construed, grants the individual a degree of autonomy on making decisions of fundamental personal importance.[154]

The foregoing passage from *Fleming* set out above suggests that the Ontario Court of Appeal is in agreement with such an approach. The Supreme Court, however, has yet to address the point decisively.

Breach in accordance with the principles of fundamental justice?

The Supreme Court of Canada has defined the principles of fundamental justice as follows:

> ... the principles of fundamental justice are to be found in the basic tenets and principles, not only of our judicial process, but also of the other components of our legal system.
>
> Whether any given principle may be said to be a principle of fundamental justice within the meaning of s.7 [of the Charter] will rest upon an analysis of the nature, sources, rationale and essential role of that principle within the judicial process and in our legal system, as it evolves.[155]

A law may violate the principles of fundamental justice either because its substance (ie, what it attempts to do) or its procedure (ie, how it attempts to do what it does) breaches a principle of fundamental justice.[156]

The principles of fundamental justice must be interpreted within the specific context in which section 7 is being asserted, including, in particular, those "principles and policies that have animated legislative and judicial practices in the field" both nationally and internationally.[157] As noted by Stratas, a legal commentator, this should include reference to international human rights instruments as "important expressions of the values and principles which underlie our legal system and which constitute principles of fundamental justice."[158]

[154] *B(R)* v *Children's Aid Society of Metropolitan Toronto*, [1995] 1 SCR 315 at 368-369.

[155] *Reference re s. 94(2) re Motor Vehicle Act (BC)*, supra, note 148 at 512-513.

[156] *Rodriguez*, supra, note 82 at 589-590.

[157] *Beare*, supra, note 153 at 402-403; *Kindler* v *Canada (Minister of Justice)*, [1991] 2 SCR 779.

[158] D Stratas. *The Charter of Rights in Litigation: Direction from the Supreme Court of Canada.* Aurora: Canada Law Book Inc., vol 1, 1997, at 17-29.

Canadian courts have held as follows with respect to those principles of fundamental justice relevant to the policy choices canvassed in this paper:

- *Breach of section 8 of the Charter*

  The Supreme Court of Canada has characterized section 8 of the Charter (together with sections 9 through 14) as a specific right that is encompassed within the generality of section 7:

  > Sections 8 to 14 [of the Charter] address specific deprivations of the "right" to life, liberty and security of the person in breach of the principles of fundamental justice, and as such, violations of s.7.[159]

  In other words, an impugned legislative provision or government action that breaches section 8 of the Charter necessarily constitutes a breach of section 7.

- *Arbitrariness*

  A deprivation of life, liberty or security must significantly enhance the interests of the state or it will be characterized as arbitrary and not in accordance with the principles of fundamental justice. As stated by Justice Sopinka, writing for a majority of the Supreme Court of Canada in *Rodriguez*:

  > Where the deprivation of the right does little or nothing to enhance the state's interest (whatever it may be), it seems to me that a breach of fundamental justice will be made out, as the individual's rights will have been deprived for no valid purpose.[160]

- *Overbreadth*

  The means selected by the state must not be too sweeping in relation to its objective. In *R* v *Heywood*, a majority of the Supreme Court of Canada held:

  > Overbreadth analysis looks at the means chosen by the state in relation to its purpose. In considering whether a legislative provision is over broad, a court must ask a question: are those means necessary to achieve the state objective? If the state, in pursuing a legitimate objective, uses means which are broader than necessary to accomplish that objective, the principles of fundamental justice will be violated because the individual's rights will have been limited for no reason. The effect of overbreadth is that in some applications the law is arbitrary and disproportionate.[161]

- *Procedural fairness*

  When purporting to infringe a person's right to life, liberty or security of the person, an appropriate measure of procedural protection (generally referred to as "procedural fairness") must be provided. The nature and extent of the procedural protections required will vary with the context, bearing in mind the competing interests of the individual and the state. It is important to note, however, when the substance of the requirement at issue is in breach

[159] *Reference re s.94(2) of the Motor Vehicle Act (BC)*, supra, note 148 at 512-513.

[160] *Rodriguez*, supra, note 82 at 594.

[161] *R* v *Heywood*, [1994] 3 SCR 761 at 792-793.

of section 7 for a substantive reason, no amount of procedural protection will cure that breach. In *Fleming*, for example, the Ontario Court of Appeal held:

> A legislative scheme that permits the competent wishes of a psychiatric patient to be overridden, and which allows a patient's right to personal autonomy and self-determination to be defeated, without holding a hearing as to why the substituted consent-giver's decision to refuse consent based on the patient's wishes should not be honoured, in my opinion, violates "the basic tenets of our legal system" and cannot be in accordance with the principles of fundamental justice: *Reference re: s.94(2) of the Motor Vehicle Act* (1985), 24 D.L.R. (4th) 536 at p.550, 23 C.C.C. (3d) 289, [1985] 2 SCR. 486.
>
> It is no answer to say that the patient has been afforded a full array of procedural protections with respect to the board's hearing when that hearing is not directed to the substitute consent-giver's decision, and the patient's competent wishes as expressed through the substitute consent-giver are irrelevant to the board's determination. In my opinion, it is plainly contrary to the principles of fundamental justice to force a patient take anti-psychotic drugs in his or her best interests without providing to the patient, or the patient's substitute, any opportunity to argue that it is not the patient's best interests but rather his or her competent wishes which should govern the course of the patient's psychiatric treatment.[162]

Everyone has the right to be secure against unreasonable search and seizure.

Section 8 of the Charter

> Everyone has the right to be secure against unreasonable search and seizure.

The Supreme Court of Canada has held that the purpose of section 8 of the Charter is to protect an individual's reasonable expectations of privacy against government encroachments: "the right of the individual to determine for himself when, how, and to what extent he will release personal information about himself."[163] The Court has further established that the section should be broadly interpreted to achieve that end.[164]

Section 8 of the Charter has been characterized by the Supreme Court of Canada as a specific right that is encompassed within the generality of section 7.[165] As noted above, a provision that breaches section 8 necessarily breaches section 7. Section 8 is the Charter provision most obviously of direct application to the matters under consideration in this paper.

As with section 7, the onus of burden of proof at this stage of a Charter analysis is upon the complainant. It is up to the person asserting that his or her right to be secure against unreasonable search and seizure has been violated to prove on a balance of probabilities that this is the case.

A Charter complainant seeking to establish a violation of section 8 must undertake a two-stage analysis, answering the following questions: has there been a "search" or "seizure"? and, if so, was it unreasonable?

162 *Fleming*, supra, note 80 at 317-318.

163 *R* v *Duarte*, [1990] 1 SCR 30 at 46.

164 *R* v *Dyment*, [1988] 2 SCR at 427, per La Forest J in separate concurring reasons (Dickson CJ concurring); and *R* v *Colarruso*, [1994] 1 SCR 20, per La Forest J for a majority of the Court.

165 *Reference re s 94(2) of the Motor Vehicle Act (BC)*, supra, note 148 at 502.

Has there been a "seizure"?

The essence of a "seizure" under section 8 of the Charter is "the taking of a thing from a person by a public authority without that person's consent."[166] The Supreme Court of Canada has held on more than one occasion that the taking of a blood sample in order to provide information to the state about the person from whom it is drawn, without the consent of that person, constitutes a seizure within the meaning of section 8 of the Charter.[167] This is so regardless whether the blood sample is drawn by a health care practitioner who is not a public authority if the sample (or the information it yields) subsequently passes directly or indirectly to a public authority.[168] Similarly, if blood drawn for one purpose is then subjected to further analysis for a different purpose, the second use constitutes a seizure within the meaning of section 8.[169]

Of particular relevance to the matters under consideration in this paper is Justice Wilson's conclusion in *Canadian AIDS Society* that the conduct of HIV testing and the reporting of HIV-positive test results by the Canadian Red Cross Society to a local medical officer of health pursuant to Ontario's *Health Protection and Promotion Act* without the donors' consent was a seizure within the meaning of section 8 of the Charter.[170]

Was the seizure unreasonable?

A seizure will be reasonable and in compliance with section 8 of the Charter if it is authorized by law, the law is reasonable, and the manner in which the search is carried out is reasonable. Each of these requirements must be considered in turn.

- *Authorized by law*

  This first requirement is straightforward. A seizure must be authorized by law, and any statutory requirements must be met in the execution of the seizure. If no statute expressly authorizes the seizure, then the seizure must be authorized by the common law or, alternatively, the circumstances must be found to present no reasonable expectation of privacy on the part of the complainant.[171]

- *The law is reasonable*

  The reasonableness of a statute purporting to authorize a seizure will depend upon the court's assessment of the following factors:

The nature of the privacy interest sought to be protected

A very high degree of privacy, and therefore a high degree of section 8 protection, attaches to bodily samples, including blood. Speaking for a majority of the Supreme Court of Canada in *R* v *Stillman*, Justice Cory observed that seizures that infringe "upon a person's bodily integrity ... may constitute the ultimate front to human dignity."[172] He noted, further:

> It has often been clearly and forcefully expressed that state interference with a person's bodily integrity is a breach of a person's privacy and an affront to human dignity. The invasive nature of body searches demands higher standards of justification. In *R.* v. *Pohoretsky*, [1987] SCR. 945 at p.949, Lamer J., as he then was,

[166] *Dyment,* supra, note 164 at 431.

[167] See, for example, *Dyment*, supra, note 164; *R* v *Collins*, [1987] 1 SCR 265; *Colarusso*, supra, note 164; and *Stillman*, supra, note 150.

[168] *Colarusso*, supra, note 164.

[169] Ibid.

[170] *Canadian AIDS Society*, supra, note 104 at 63.

[171] *Stillman*, supra, note 150 at paras 25-26.

[172] Ibid at para 39.

A very high degree of privacy, and therefore a high degree of section 8 protection, attaches to bodily samples, including blood.

> noted that, "a violation of the sanctity of a person's body is much more serious than that of his office or even of his home." In addition, La Forest J. observed in *R.* v. *Dyment*, [*supra*], at pp.431-32, "the use of a person's body without his consent to obtain information about him, invades an area of personal privacy essential to the maintenance of his human dignity." Finally, in *R.* v. *Simmons*, [1988] 2 SCR. 495, at p.517, Dickson C.J. stated:
>
> The third and most highly intrusive type of search is that sometimes referred to as the body cavity search, in which customs officers have recourse to medical doctors, to x-rays, to emetics, and to other highly invasive means.
>
> Searches of the third or bodily cavity type may raise entirely different constitutional issues for it is obvious that the greater the intrusion, the greater must be the justification and the greater the degree of constitutional protection.[173]

This characterization is not simply attributable to the physical aspects of the seizure, but to the need to protect the privacy of individuals, including, in particular, personal and informational privacy.[174]

Circumstances in which and the place the seizure is conducted

The Supreme Court of Canada has repeatedly identified hospitals as specific areas of concern in the protection of privacy, given the vulnerability of individuals seeking medical treatment.[175] A physician's office or other health care site would presumably warrant the same level of judicial concern. The reasons for this concern are twofold: first, concern that an accused person might be reluctant to get medical treatment for fear that he or she might incriminate himself of herself; and second, a broader concern that such activities might undermine the trust and confidence of the public in the administration of medical facilities.[176]

Purpose of the intrusion

This factor requires an assessment of the importance of the societal purpose served by the seizure to be weighed against the privacy interest for which protection is sought.[177]

Prior authorization

The term "prior authorization" refers to the exercise of judicial discretion by a person who can assess the conflicting interests in an entirely neutral or impartial manner (meaning that he or she cannot have investigatory or prosecutorial functions under the statutory scheme) to determine whether a search or seizure may be conducted and, if so, its proper scope. Section 8 jurisprudence to date establishes that searches and seizures conducted without prior authorization – "warrantless searches and seizures" – are presumed unreasonable, meaning that the onus of proof lies with the state to establish their reasonableness.

Prior authorization may be required to ground a constitutionally valid seizure in the regulatory or administrative context, where the degree of privacy reasonably expected by a person in the circumstances is high.[178] The exigency

[173] Ibid at para 42.

[174] See *Colarusso*, supra, note 164 at 60-61; and *Dyment*, supra, note 164 at 429-430.

[175] See *Colarusso*, supra, note 164 at 53; and *Dyment*, supra, note 164 at 432-434.

[176] Ibid at 433-434.

[177] *Colarusso*, supra, note 164.

[178] See, for example, *Baron* v *Canada*, [1993] 1 SCR 416 at 419.

of the circumstances is also relevant. The Supreme Court of Canada has ruled in more than one case that "what is ultimately important are not labels (though these are undoubtedly useful), but the values at stake in the particular context."[179]

The nature and type of authorization required (ie, the standard to be met and the evidence required to meet that standard) will depend upon the strength of the privacy and other interests at stake in the particular circumstances.[180] In *Hunter* v *Southam Inc*, Justice Dickson stated on behalf of a majority of the Supreme Court of Canada that the minimum standard for authorizing searches and seizures under section 8 of the Charter is that there be reasonable and probable grounds, established upon oath, to believe that an offence has been committed and that there is evidence to be found at the place of the search. He stated further that:

> [w]here the state's interest is not simply law enforcement as, for instance, where state security is involved, or where the individual's interest is not simply his expectation of privacy as, for instance, when the search threatens his bodily integrity, the relevant standard might be a different one.[181]

The manner in which the search is carried out is reasonable

With respect to this third requirement, the concern of the courts is that the seizure in issue be no broader and no more intrusive than it needs to be to achieve the stated societal purpose.[182]

Although the principles set out above have been articulated by the Supreme Court of Canada in the context of criminal cases (in particular those relating to bodily samples), Justice Wilson accepted and applied them in the civil context in relation to blood donations subjected to HIV testing without donor consent and the related reporting of those test results to public health authorities.[183]

Section 15(1) of the Charter

Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

One of the purposes of section 15(1) of the Charter was stated by Justice McIntyre of the Supreme Court of Canada in *Andrews* v *Law Society of BC* as follows:

> ... to ensure equality in the formulation and application of the law. The promotion of equality entails the promotion of a society in which all are secure in the knowledge that they are recognized at law as human beings equally deserving of concern, respect and consideration. It has a large remedial component.[184]

More recently, the Supreme Court has held that a second, related purpose of section 15(1) is to initiate "a desire to rectify and prevent discrimination against particular groups 'suffering social, political and legal disadvantage in our society.'"[185]

[179] *R* v *Wholesale Travel Group Inc*, [1991] 3 SCR 154 at 209.

[180] *R* v *McKinlay Transport Ltd*, [1990] 1 SCR 627 at 646-650.

[181] *Hunter* v *Southam Inc*, [1984] 2 SCR 145 at 168.

[182] See, for example, *Dyment*, supra, note 164.

[183] *Canadian Aids Society*, supra, note 104 at 62.

[184] *Andrews* v *Law Society of BC* (1989), 56 DLR (4th) 1 (SCC). All Supreme Court Justices agreed with the reasons for judgment of Justice McIntyre with respect to the purpose, interpretation and application of section 15, although there were dissenting opinions as to the result of the particular appeal under consideration.

[185] *Eldridge* v *British Columbia (Attorney General)*, [1997] 3 SCR 624 at 667.

The promotion of equality entails the promotion of a society in which all are secure in the knowledge that they are recognized at law as human beings equally deserving of concern, respect and consideration.

A complainant seeking to establish a violation of section 15(1) must prove: first, that he or she is not receiving equal treatment before or under the law or that the law has a differential impact on him/her in the protection or benefit accorded by law;[186] and second, that the impact of the law is discriminatory.[187]

Differential impact of law

With respect to the first stage of the analysis, the term "law" has been broadly defined in view of the large remedial object of section 15(1). In *McKinney* v *University of Guelph*, a majority of the Supreme Court of Canada held that a policy should be characterized as "law" for the purposes of section 15(1).[188] In reasons for judgment with which two other Justices agreed, Justice Wilson went further to state:

> I believe ... that on a purposive interpretation of s.15 the guarantee of equality before and under the law and equal protection and benefit of the law also constitutes a directive to the courts to see that discrimination engaged in by anyone to whom the *Charter* applies is redressed whether it takes the form of legislative activity, common law principles or simply conduct.[189]

The significance of this point is that a government policy, as well as conduct pursuant to (or perhaps even independent of) such a policy, may be subject to challenge on the grounds that it violates the equality rights extended by section 15(1) of the Charter.

Discrimination

With respect to the second stage of a section 15(1) analysis, the term "discrimination" was defined in *Andrews* as follows:

> a distinction, whether intentional or not but based on grounds relating to personal characteristics of the individual or group, which has the effect of imposing burdens, obligations or disadvantages on such individual or group not imposed upon others, or which withholds or limits access to opportunities, benefits, and advantages available to other members of society.[190]

Justice McIntyre emphasized that it is not enough for a complainant to point to a distinction in treatment on the basis of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability (the so-called "enumerated grounds") or an analogous ground; the distinction must involve prejudice or disadvantage.[191]

In *Brooks* v *Canada Safeway Ltd*, the Supreme Court of Canada held unanimously that:

> Discrimination on the basis of pregnancy is a form of sex discrimination [in violation of section 15(1) of the Charter] because of the basic biological fact that only women have the capacity to become pregnant. ...
>
> [Indeed,] distinctions based on pregnancy can be nothing other than distinctions based on sex or, at least, strongly "sex related."[192]

[186] In other words, each of the elements of section 15(1) is to be given effect: the right to equality before the law; the right to equality under the law; the right to equal protection under the law; and the right to equal benefit of the law.

[187] *Andrews*, supra, note 184 at 23-24. More recently, see *Eldridge*, supra, note 185 at 669-670.

[188] *McKinney* v *University of Guelph*, [1990] 3 SCR 229.

[189] Ibid at 383.

[190] *Andrews*, supra, note 184 at 18.

[191] Ibid at 22-23.

[192] *Brooks* v *Canada Safeway Ltd* (1989), 59 DLR (4th) 321 (SCC), at 338 and 339.

The combined effect of *Andrews* and *Brooks* is to provide that a government policy that causes prejudice or disadvantage to pregnant women will be vulnerable to challenge under section 15(1) of the Charter.

Discrimination on the basis of pregnancy is a form of sex discrimination.

Section 1 of the Charter

> The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Section 1 of the Charter comes into play only after a complainant has established that one or more of his or her Charter rights (ie, sections 7, 8 or 15(1)) have been violated. Up to the point of the section 1 analysis, the onus of proof rests with the complainant, who must prove that a Charter right has been violated. With the commencement of the section 1 analysis, however, the onus of proof shifts, and it is for the state to prove that the violation of the complainant's right or rights is justified.

The term "law" as used in the phrase "prescribed by law" in section 1 of the Charter has been interpreted by the Supreme Court of Canada to include a policy. As such, a policy may be relied upon by government in justification of an alleged Charter violation.[193]

The phrase "free and democratic society," as used in section 1,

> refers the court to the very purpose for which the Charter was originally entrenched in the Constitution: Canadian society is to be free and democratic. The Court must be guided by the values and principles essential to a free and democratic society which I believe embody, to name but a few, respect for the inherent dignity of the human person, commitment to social justice and equality, accommodation of a wide variety of beliefs, respect for cultural and group identity, and faith in social and political institutions which enhance the participation of individuals and groups in society.[194]

In assessing the government's justification of an impugned legislative provision or policy, courts will look to the legislation, policies and practices of other free and democratic societies.[195] They will also consider international treaties to which Canada is a signatory, and related documents.[196] When designing a policy to govern the HIV testing of pregnant women in Canada, therefore, relevant policies and guidelines emanating from international bodies such as the Joint United Nations Programme on HIV/AIDS (UNAIDS), from European countries and the United States, as well as from professional associations within and outside Canada, are an important source of guidance.

The Supreme Court of Canada has established the following test for determining whether an impugned legislative provision or government policy is justified under section 1 of the Charter:

(1) the objective, which the legislation or policy in issue is designed to advance, must be of sufficient importance to warrant overriding a constitutionally protected right or freedom;
(2) a three-fold proportionality test must be satisfied:

[193] *McKinney*, supra, note 188.

[194] *R* v *Oakes*, [1986] 1 SCR 103 at 136.

[195] *R* v *Ladouceur*, [1990] 1 SCR 1257.

[196] For example, see *Mills* v *The Queen*, [1986] 1 SCR 863; and *Kindler*, supra, note 157. Courts' use of such authorities is not limited to the section 1 analysis, but will also assist their assessment as to whether a given Charter right has been violated. These authorities are especially useful in determining the content of "principles of fundamental justice" for the purposes of section 7.

(a) the measure must be rationally connected to the achievement of the objective in question and not arbitrary, unfair or based on irrational considerations;
(b) the measure should impair as little as possible the right or freedom in question; and
(c) there must be a proportionality between the deleterious effects of the measure which is responsible for limiting the Charter right or freedom in question and the objective, and there must be a proportionality between the deleterious and salutary effects of the measure.[197]

Justice Bastarache, writing for a majority of the Supreme Court of Canada in *Thomson Newspaper Co* v *Canada (Attorney General)*, described the interrelationship between the branches of the three-fold proportionality test as follows:

> The focus of the first and second steps of the proportionality analysis is not the relationship between the measures and the *Charter* right in question, but rather the relationship between the ends of the legislation and the means employed. Although the minimal impairment stage of the proportionality test necessarily takes into account the extent to which a *Charter* value is infringed, the ultimate standard is whether the *Charter* right is impaired as little as possible *given the validity of the legislative purpose*. The third stage of the proportionality analysis provides an opportunity to assess, in light of the practical and contextual details which are elucidated in the first and second stages, whether the benefits which accrue from the limitation are proportional to its deleterious effects as measured by the values underlying the *Charter*.[198] [Emphasis in original.]

An important consideration for governments is the extent to which their actions or, conversely, decisions not to act, might leave them vulnerable to findings of negligence at some later time.

The Duty of Governments in Policy-making

How far does the duty of governments go? An important consideration for governments considering policy development and other activities relevant to the HIV testing of pregnant women is the extent to which their actions or, conversely, decisions not to act, might leave them vulnerable to findings of negligence at some later time. This section canvasses the common law duties of public authorities and the circumstances in which they might be found negligent.

Negligence on the Part of Public Authorities

The leading Supreme Court of Canada decisions defining the common law duties of public authorities and the circumstances in which they may be found negligent are *City of Kamloops* v *Neilsen*,[199] *Just* v *British Columbia*[200] and, most recently, *Lewis (Guardian ad litem of)* v *British Columbia*.[201] These decisions establish that the powers and duties of public authorities are definable in terms of public rather than private law. This is because courts must give due deference – "curial deference" – to the preeminent role of governments in deciding what resources should be directed to which ends. The circumstances in which liability for negligence will be imposed against a public authority are

[197] *Oakes*, supra, note 194 at 138-140; as modified by *Dagenais* v *Canadian Broadcasting Corp*, [1994] 3 SCR 835; applied in *Thomson Newspaper Co* v *Canada (Attorney General)*, [1998] 1 SCR 877.

[198] *Thomson Newspaper*, supra, note 197.

[199] *City of Kamloops* v *Neilsen*, [1984] 2 SCR 2.

[200] *Just* v *British Columbia*, [1989] 2 SCR 1228.

[201] *Lewis (Guardian ad litem of)* v *British Columbia*, [1997] 3 SCR 1145.

therefore more limited than those that would give rise to liability on the part of private actors.

In order for any negligence action to succeed in the imposition of liability against a defendant (public authority or not), a plaintiff must prove each of the following elements on a balance of probabilities:

- that the defendant owed the plaintiff a duty of care;
- that the defendant breached the standard of care owed to the plaintiff; and
- that the defendant's breach of the standard of care caused injury or damage to the plaintiff.

It is the legal principles governing the first and second of these elements that differ for public authorities as compared with private actors.

It is only in limited circumstances that a public authority will be held to owe a duty of care to individuals.

The duty of care

It is only in limited circumstances that a public authority will be held to owe a duty of care to individuals. The circumstances that must be considered are as follows:

- Are the parties in a relationship of sufficient proximity to warrant the imposition of a duty of care? In other words, was the relationship between the public authority and the plaintiff close enough that in the reasonable contemplation of the public authority, carelessness on its part might be likely to cause damage to the plaintiff?
- Is there an explicit statutory exemption removing the public authority from a duty of care?
- Is the public authority exempt from the imposition of a duty of care due to the nature of the decision that gave rise to the plaintiff's claim? That is, was the decision a pure policy decision in that it was motivated by social, political, economic or other like factors?

Policy decisions can be made without fear on the part of public authorities of civil liability so long as they are *bona fide* and not so irrational that they do not constitute reasonable exercises of ministerial discretion.

Where a statute confers powers but leaves the scale on which they are to be exercised to the discretion of a public authority, as do provincial and territorial public health statutes in relation to communicable diseases such as HIV infection or AIDS, it is open to the public authority to decide as a matter of policy whether the power should be exercised or not. The Supreme Court has expressly acknowledged that social, economic and political factors will frequently affect policy decisions, and that these are legitimate factors in governmental decision-making to be respected by courts. Policy decisions, in other words, can be made without fear on the part of public authorities of civil liability so long as they are *bona fide* and not so irrational that they do not constitute reasonable exercises of ministerial discretion. These requirements call for policy decisions to be made responsibly and for reasons that accord with the purpose of the statute in question. By contrast, as stated by Justice Wilson in *City of Kamloops*:

> an action for no reason or inaction for an improper reason cannot be a policy decision taken in the *bona fide* exercise of discretion. Where the question whether the requisite action should be taken has not even been considered by the public authority, or at least has not

> been considered in good faith, it seems clear that for that very reason the authority has not acted with reasonable care.[202]

Most provinces and territories have already issued policy statements in the form of recommendations or guidelines that address the HIV testing of pregnant women in an effort to reduce the risk of perinatal HIV transmission. As a practical matter, then, these provinces and territories have already made the policy decision to take action on this issue and it is therefore likely that a court would find that a duty of care does exist.

With respect to those jurisdictions in which no such recommendations or guidelines have been issued to date, a court would further consider whether their absence is attributable to a policy decision – ie, whether it was motivated by social, political, economic or other like factors. If so, it is less likely that a court would find the existence of a duty of care. However, two points are worth emphasizing:

Deciding by not deciding does not constitute a *bona fide* exercise of discretion by a public authority.

- first, the issue must have actually been addressed and a decision taken: deciding by not deciding does not constitute a *bona fide* exercise of discretion by a public authority;[203] and
- second, even if the matter is addressed and a decision taken on the basis of policy considerations, the court will nonetheless scrutinize the decision to ensure that it was taken for reasons that accord with the purpose of the public health statute in question.

The standard of care

Once a policy decision has been made to exercise a power, there is a duty at the operational level to use "due care" or "reasonable care" in giving effect to it. This is the ordinary negligence standard to which all defendants are subject (public authorities or not). At the operational level again, however, public authorities are extended deference by courts in respect of policy considerations that will attend the exercise of a given statutory power. Courts are prepared to recognize and support the legitimacy of social, economic, or political considerations as a determinative factor in this decision-making process, subject to the requirement that policy decisions be *bona fide* and not so irrational that they do not constitute a reasonable exercise of discretion. This approach is driven home by the following statement of Justice Wilson in *City of Kamloops*, in which she summarizes the reasons of Lambert JA in the British Columbia Court of Appeal decision that was the subject of the appeal, with which she clearly agrees:

> [Mr Justice Lambert concluded that] the city could have made a policy decision either to prosecute or to seek an injunction. If it had taken either of those steps, it could not be faulted. Moreover, if it had considered taking either of those steps and decided against them, it likewise could not be faulted. But not to consider taking them at all was not open to it. In other words, as I read [the reasons of Lambert JA], his view was that the city at the very least had to give serious consideration to taking the steps toward enforcement that were open to it. If it decided against taking them, say on economic grounds, then that would be a legitimate policy decision

[202] *City of Kamloops*, supra, note 199.

[203] This requirement is linked to the existence of a statutory power. Such powers exist in provincial and territorial and public health legislation. Although similar in purpose and effect, their specific content varies between jurisdictions.

> within the operational context and the court should not interfere with it. It would be a decision made, as Lord Wilberforce put it, within the limits of a discretion *bona fide* exercised.[204]

The Commission of Inquiry on the Blood System in Canada

Although the primary focus of the Commission of Inquiry on the Blood System in Canada was the safety of Canada's blood supply, Commissioner Krever interpreted his mandate to include consideration of the effectiveness of federal and provincial public health bodies in their responses to the AIDS epidemic from 1981 onward. Having conducted the first and only independent review of the effectiveness of these institutions in the context of HIV/AIDS, the Commissioner's findings as set out in his *Final Report* are worth bearing in mind in this discussion. Those findings that imply some criticism are of particular interest, as they suggest those areas to which a court might reasonably be expected to turn its attention if called upon to consider – at some later date – the adequacy of federal, provincial and territorial actions to minimize the risk of perinatal HIV transmission in Canada:[205]

- Ministers of health in each of the provinces and territories were the ultimate authorities on public health matters within their respective jurisdictions pursuant to public health statutes which, in general, afforded them broad powers to take those steps deemed necessary to protect human health and prevent the transmission of communicable diseases.[206]
- Public health programs in the provinces were administered by health units based on geographical divisions, each of which

  > had a medical officer of health, or a person with a similar title, who was a physician and who advised the local board of health, carried out certain duties related to public health, and evaluated the status of the community's health. The statutory duties with regard to communicable diseases varied from province to province, but medical officers of health were expected to investigate all occurrences of notifiable or reportable disease in the municipality or region for which they were responsible; to establish the cause, mode of transmission, and probable source of the disease; and to identify other persons who might be at risk. They were also expected to take whatever steps were reasonably possible to suppress the disease in those who might already have been infected, to protect those who have not been exposed, to break the chain of transmission to prevent the spread of the disease, and to remove the source of infection.[207]

- Public health officials and policymakers at all levels required ongoing access to the most recent information available (local, national and international in scope) about the nature and extent of AIDS to inform their activities.[208]
- The role of the HPB, through its Laboratory Centre for Disease Control, appropriately included the delivery of services to the provinces, such as: advice and information to provincial departments or ministries of health; assistance in the diagnosis of communicable disease to help them identify and

[204] *City of Kamloops*, supra, note 199.

[205] This section identifies what appear to be main points of relevance to the matters under consideration in this paper; it does not purport to be an exhaustive review of the *Final Report*. It is important to note, moreover, that none of the findings set out in the *Final Report* were presented as findings of negligence on the part of federal, provincial, or territorial governments. To make such findings was never part of the Commissioner's mandate. Rather, his mandate was to make findings in support of recommendations to improve the safety of Canada's blood supply: see *Canada (Attorney General)* v *Canada (Commission of Inquiry on the Blood System)*, [1997] 3 SCR 440.

[206] Krever Commission, supra, note 71, vol 1 at 152-154.

[207] Ibid at 154-155.

[208] Ibid, vol 2 at 548.

react to identified threats; participation in surveillance, including monitoring public health nationally and internationally.[209] The HPB failed to take timely and appropriate steps to fulfil this role.[210]

- The role of the HPB, through its Therapeutic Products Directorate (previously called the Drugs Directorate), appropriately included "regulating drugs [under the *Food and Drugs Act*], setting standards for the safety and efficacy of therapeutic drugs, and monitoring compliance with those standards,"[211] including, in particular, through the post-market surveillance of adverse drug reactions. The HPB failed to take timely and appropriate steps in the exercise of its regulatory authority over blood and blood products as "drugs" within the meaning of the *Food and Drugs Act* to ensure their safety.[212]
- The exchange of information at both the federal–provincial and the interprovincial levels was irregular and, in some cases, inadequate to permit the necessary collaboration to respond rapidly and effectively to the AIDS epidemic.[213]
- Provincial public health officials did not avail themselves fully of the opportunities they had "to inform the general public about the ways in which AIDS was transmitted, the groups most at risk of infection, and measures that would reduce the risk of contracting AIDS."[214]
- Provincial public health officials did not avail themselves fully of the opportunities they had to guide the conduct of physicians so as to ensure that patients were properly counselled about all necessary steps to prevent the further spread of AIDS by their patients.[215]

[209] Ibid, vol 1 at 149-150.

[210] See, for example, ibid at 364 and vol 2 at 610-611.

[211] Ibid, vol 1 at 115.

[212] Ibid at 146-147, 283-284 and 330-337 and vol 2 at 405-414, 478, and 520-523.

[213] Ibid, vol 1 at 151-152 and vol 2 at 552-557.

[214] Ibid, vol 2 at 564.

[215] Ibid at 589.

Considering the Policy Choices

This chapter analyzes the essential policy choices to be made in designing a strategy to govern the HIV testing of pregnant women in Canada, as articulated in the previous chapter.

The public health objective of the analysis and recommendations is to minimize the number of perinatal HIV transmissions in Canada. This objective is consonant with the underlying purpose of public health legislation in Canadian provinces and territories. As succinctly stated in section 2 of Ontario's *Health Protection and Promotion Act*, for example:

> The purpose of this Act is to provide for the organization and delivery of public health programs and services, the prevention of the spread of disease and the promotion and protection of the health of the people of Ontario.

The goal of HIV testing policies for pregnant women is not to achieve the highest possible uptake rates in isolation from this larger public health objective. Rather, the goal must be to enable as many women as possible in Canada to benefit from the broad range of medical interventions now available to minimize the risk that they will transmit HIV to their infants.

HIV testing policies that target pregnant women at increased risk of infection rather than all pregnant women have consistently failed to identify significant numbers of HIV-positive women.

To Whom Should HIV Testing Be Offered?

HIV testing policies that target pregnant women at increased risk of infection rather than all pregnant women have consistently failed to identify significant numbers of HIV-positive women. Indeed, medical literature accumulated over

the past decade suggests that as many as half of HIV-infected women may be missed when risk-based HIV counselling and testing strategies are used.[216] There appear to be two main reasons for the failure of risk-based approaches:

- *Women are unaware of, or reluctant to disclose, risk behaviours*

  Women are frequently not tested for HIV because they are unaware of their risk for HIV infection or because they are reluctant to disclose potentially stigmatizing behaviours. One researcher has concluded that, "no matter how well informed they are, people tend to underestimate their risk for HIV."[217] A review of various studies suggests that as many as 42 to 86 percent of HIV-positive women do not report risk factors for HIV infection.[218]

- *Physician intransigence to universal offers of HIV testing*

  While few physicians state that they support offering HIV testing only to pregnant women with identified risk factors, in practice they are much more likely to encourage testing for women with identified risk factors than those whom they believe to be without risk factors.[219] Indeed, studies of physician practices have found that even those women who believe themselves to be at risk and specifically request HIV testing may be refused if their treating physicians do not believe that their circumstances warrant testing.

From a medical perspective, the problem with a failure rate of this magnitude is the likelihood that a significant number of women who might otherwise avail themselves of one or more interventions to reduce the risk of perinatal HIV transmission are denied that opportunity. The vast majority of professional associations, governments and other interested bodies, in Canada and elsewhere, have responded to this information with HIV testing policies and guidelines directed toward all pregnant women.[220] Most recently, the US Institute of Medicine Committee on Perinatal Transmission of HIV (the "IOM Committee") recommended that testing be universal on the grounds that: it alleviates the problem of many HIV-positive women being missed when risk-based or prevalence-based strategies are used; it is cost-effective (when the costs of testing are compared with the costs of caring for children whose HIV infections are avoidable); and it is the most prudent manner in which to respond to geographic shifts in the epidemiology of HIV infection.[221]

Given the strength of the relevant medical evidence, as well as the weight of professional opinion as reflected in the policy statements, recommendations and guidelines referred to above, a Canadian province or territory that aimed its policy at pregnant women at increased risk of HIV infection would be vulnerable to a negligence action by any woman whose HIV status was not diagnosed because of the narrow scope of the policy and resulted in perinatal HIV transmission. The essence of the plaintiff's argument in such a case would be that the government's decision not to recommend HIV testing for all pregnant women fell below the required standard of due care and, in so doing, caused an incidence of perinatal HIV transmission that might have been avoided.[222] To minimize the risk of a finding of negligence in such circumstances, a government would have to be able to prove that: (1) it fully considered whether the policy should be directed to all pregnant women rather than only those at increased risk of HIV infection; and (2) it based its decision

[216] S Landerman et al. Serosurvey of Human Immunodeficiency Virus Infection Parturients – Implications for Human Immunodeficiency Virus Testing Programs of Pregnant Women. *Journal of the American Medical Association* 1987; 258(19): 2701-2703; MK Lindsay et al. Routine Antepartum Human Immunodeficiency Virus Infection Screening in Intercity Population. *Obstetrics and Gynecology* 1989; 74: 289-294; MK Lindsay. Routine Voluntary Antepartum HIV Antibody Counselling and Testing: A Sound Public Health Strategy. *Clinical Obstetrics and Gynecology* 1996; 39(2) 305-315; MB Barbacci et al. Human Immunodeficiency Virus Infection in Women Attending an Inner-City Prenatal Clinic: Ineffectiveness of Targeted Screening. *Sexually Transmitted Diseases* 1990: 122-126; LJ Fehrs et al. Targeted HIV Screening at a Los Angeles Prenatal/Family Planning Health Center. *American Journal of Public Health* 1991; 81: 619-622; J Hawken et al. Risk Factors for HIV Infection Overlooked in Routine Antenatal Care. *Journal of the Royal Society of Medicine* 1995; 88: 634-636; D Gibb et al. Evaluating Antenatal HIV Testing in London, UK. Abstract Th.C.4615, presented at the XI International Conference on AIDS, 7-12 July 1996; SA Fiscus et al. Perinatal HIV Infection and the Effect of Zidovudine Therapy on Transmission in Rural and Urban Communities. *Journal of the American Medical Association* 1996; 275(19): 1483); MB Barbacci et al. Routine Prenatal Screening for HIV Infection. *Lancet* 1991; 337: 709-711.

[217] EJ Sobo. Attitudes toward HIV Testing among Impoverished Inner-City African American Women. *Medical Anthropology* 1994; 16: 17-38.

[218] HL Minkoff et al. Routinely Offered Prenatal HIV Testing. *The New England Journal of Medicine* 1988 (13 October): 1018.

[219] KA Phillips et al. HIV Counselling and Testing of Pregnant Women and Women of Childbearing Age by Primary Care Providers: Self-Reported Beliefs and Practices. *Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology* 1997: 14(2); 174-178. These authors concluded that although 90 percent of all providers are very likely to encourage women of childbearing age with risk factors to be tested, only 34 percent are very likely to encourage pregnant women without risk factors to be tested, and only 9 percent are very likely to encourage women of childbearing age without risk factors to be tested. Despite its documented failure at identifying women who may be at risk, in other words, many physicians who recognize the limitations of this method and who in principle do not support it continue to assess and treat their patients on the basis of perceived risk.

[220] In Canada, for example, see NAC–AIDS, supra, note 28 at 19; CMA, *Counselling Guidelines for HIV Testing*, supra, note 89 at 17; College of Family Physicians of Canada. *A Comprehensive Guide for the Care of Persons*

to implement a risk-based policy upon rational, social, economic or political factors.

Recommendation

1. ***Provinces and territories should require that physicians offer HIV testing to all pregnant women.***

Ideally women should know their HIV status before becoming pregnant.

A related issue is the question of timing. Many current policies are silent with respect to when HIV testing should be offered to all pregnant women. Some, however, specify that the counselling should be initiated as early in pregnancy as possible, possibly even before conception by women considering pregnancy.[223] In an editorial comment on a recently reported study demonstrating the effectiveness of a "universal counselling, voluntary testing" approach in four US states, the US Centers for Disease Control (the "CDC") notes that, "although prenatal care is an important opportunity to offer testing to prevent perinatal transmission, ideally women should know their HIV status before becoming pregnant."[224] In those of its guidelines directed toward preventing perinatal HIV transmission, the CDC has consistently recommended that women be offered counselling and access to testing before they become pregnant.[225]

Bearing in mind that the goal of HIV testing policies for pregnant women is to enable as many women as possible to benefit from consideration of the range of medical interventions available to reduce the risk of perinatal HIV transmission, it is reasonable to conclude that due care on the part of a government enacting such a policy requires these further recommendations to be made. To do so would minimize the risk that an HIV-positive woman would find herself in circumstances that limit the options otherwise available to her. For example, a woman whose HIV infection is diagnosed in the second trimester of pregnancy has lost the ability to choose not to become pregnant in the first place, would be precluded from following the full PACTG 076 protocol (which requires initiation of ZDV therapy at 14 weeks gestation), and would face heightened risks associated with termination of the pregnancy in the event that was the intervention she ultimately chose. The circumstances in which such a woman engaged in the decision-making process would also be less than ideal: in relation to both antiretroviral prophylaxis and the termination of pregnancy, she would be under considerable pressure to make her decision quickly.

Again, to minimize the risk of a finding of negligence should a government decline to include these further recommendations in its policy, it would have to be able to prove that: (1) it fully considered the question whether these additional recommendations should be included in its policy; and (2) it grounded its decision not to include these recommendations upon rational, social, economic or political factors.

Recommendation

2. ***Provinces and territories should require that physicians offer HIV testing:***

   (1) as early in pregnancy as possible; and
   (2) to women considering pregnancy.

with HIV Disease (Module 2: Infants, Children & Youth). Mississauga: The College, 1995, at 5; and the Society of Obstetricians and Gynaecologists of Canada. HIV Testing in Pregnancy. Clinical Practice Guidelines/Policy Statement No. 62 (June 1997), at 2. In the US, see: the 1995 PHS Guidelines, supra, note 29, as well as the policies of the following organizations as summarized in chapter 6 of the IOM Committee's recent publication, supra, note 10: American College of Obstetricians and Gynecologists; American Academy of Pediatrics; National Medical Association; American Academy of Family Physicians; American Medical Association; American College of Nurse Midwives; Association of Women's Health, Obstetric and Neonatal Nurses; Association of Maternal and Child Health Programs; and the AIDS Policy Centre for Children, Youth and Families. Internationally, see: *UNAIDS Policy on HIV Testing and Counselling* (August 1997); and Conclusions and Technical Recommendations of the *Subregional Workshop: Prevention of the Vertical Transmission of HIV (Argentina, Bolivia, Brasil, Chile, Paraguay and Uruguay)* (29-31 July 1998), at 5.

221 IOM Committee, supra, note 10, ch 7 at 3.

222 See supra at 53.

223 Appendix, infra.

224 CDC. Success in Implementing Public Health Service Guidelines to Reduce Perinatal Transmission of HIV – Louisiana, Michigan, New Jersey and South Carolina, 1993, 1995 and 1996. *Morbidity and Mortality Weekly Report* 1998; 47(33): 688-691 at 690.

225 See, for example, CDC Recommendations, supra, note 22 at 725; and 1995 PHS Recommendations, supra, note 29 at 10.

A government-initiated policy of mandatory HIV testing for pregnant women in Canada would give rise to constitutional challenge on the basis of sections 7, 8 and 15(1) of the Charter.

Should HIV Testing be Voluntary or Mandatory?

A government-initiated policy of mandatory HIV testing for pregnant women in Canada would give rise to constitutional challenge on the basis of sections 7, 8 and 15(1) of the Charter. Of these potential avenues for challenge, the Charter's section 8 guarantee against unreasonable search and seizure is the most directly applicable and will be the focus of analysis in this section.

The analytic framework for section 8 of the Charter has been set out above. There is little question that the mandatory HIV testing of a pregnant woman would constitute a "seizure" within the meaning of section 8, as the term has been defined by Canadian courts. The real issue for exploration is whether the seizure would be considered unreasonable. Of the three possible factors for consideration, only the first two are relevant to this context: whether the seizure is authorized by law and, if so, whether the law is reasonable.[226] In summary, it is unlikely that such a seizure would be considered reasonable. It is also unlikely that this breach of section 8 of the Charter could be justified under section 1.

Is the Seizure Authorized by Law?

Not authorized by existing statutory provisions

As canvassed above, the effect of jurisprudence emanating from the Supreme Court of Canada, beginning with *Morgentaler* and culminating with *Winnipeg Child and Family Services*, is to require that legislation purporting to authorize the compelled medical treatment of a pregnant woman in the interests of foetal health must do so in clear, unambiguous language. No such legislation exists in any Canadian province or territory. While all these jurisdictions have enacted public health legislation that provides for the compelled treatment of persons with designated communicable diseases in specified circumstances in order to prevent further disease transmission, they do not expressly provide for such treatment in the interests of protecting foetal health.

Not authorized by common law

The Supreme Court of Canada clearly established in *Winnipeg Child and Family Services* that the common law, as it exists or may be properly extended, does not permit an order detaining a pregnant woman against her will for the purpose of a compelled medical intervention in the interests of protecting foetal health. This finding is consistent with Supreme Court of Canada jurisprudence interpreting section 8 of the Charter, which provides that "where there is no statutory authorization for the seizure of bodily samples, consent must be obtained for the seizure to be lawful."[227] As such, mandatory HIV testing of pregnant women cannot be considered to be authorized by common law in Canada.

Reasonable expectation of privacy

In the absence of statutory authorization or authorization by the common law, a seizure may be found to be authorized by law if the complainant had no reasonable expectation of privacy in the thing or things seized.[228] That would not be the case in a mandatory HIV testing scenario. There is no question, based on decisions of the Supreme Court of Canada such as *Stillman*, that a very high

[226] The third factor, whether the seizure is conducted in a reasonable manner, is only relevant when a seizure has been conducted on the basis of a valid law.

[227] *R* v *Borden*, [1994] 3 SCR 145; applied in *Stillman*, supra, note 150 at para 46.

[228] *Stillman*, supra, note 150 at para 26.

degree of privacy attaches to bodily samples including blood. With respect to HIV testing in particular, Justice Wilson held in *Canadian AIDS Society* that blood donors had a reasonable expectation of privacy in their blood donations subjected to HIV testing and related reporting to public health officials by the Canadian Red Cross Society without their consent.[229]

In summary, any province or territory seeking to introduce mandatory HIV testing for pregnant women would have to support such a policy with legislation expressly authorizing the compelled treatment of pregnant women in the interests of foetal health. In the absence of such legislation, it is likely that the policy would be held by a reviewing court to be in violation of at least section 8 of the Charter on the grounds that it was not authorized by law.

Any province or territory seeking to introduce mandatory HIV testing for pregnant women would have to support such a policy with legislation expressly authorizing the compelled treatment of pregnant women in the interests of foetal health.

Is the Law Reasonable?

Assuming that a province or territory proceeded to this stage, would a reviewing court conclude that legislation purporting to authorize the mandatory HIV testing of pregnant women is reasonable? As indicated above, the answer to this question will depend upon an assessment of the following three factors: the nature of the privacy interest sought to be protected, the circumstances in which and the place where the seizure is conducted, and the purpose of the intrusion.[230]

Nature of the privacy interest sought to be protected

Without repeating here the jurisprudence canvassed above, there is no question that a very high degree of privacy, and therefore of section 8 protection, would attach to the blood samples and HIV test results of pregnant women subject to mandatory HIV testing in Canada.

The privacy interests to be protected include, first and foremost, the right of pregnant women to autonomy, self-determination and bodily integrity given that HIV testing intended to benefit the foetus can only be effected through the body of the mother. As reviewed in detail above, these rights are protected at Canadian law by the legal doctrine of informed consent. The right to exercise one's informed consent to a proposed medical intervention has been elevated to the status of a constitutionally protected right in Canada.

In comparable circumstances to those under consideration in this paper, in *Canadian AIDS Society*, Justice Wilson drew attention to the informational aspects of the right of privacy in addition to the right to privacy in one's person and in one's property. She cited with approval a conclusion of Justice LaForest speaking for a majority of the Supreme Court of Canada in *Dyment* that "the use of a person's body without his consent to obtain information about him invades an area of personal privacy essential to the maintenance of human dignity."[231] Justice Wilson concluded that the principles articulated by the Supreme Court of Canada in *Dyment* and other criminal cases had application in the civil context before her, and held that blood donors had a reasonable expectation of privacy in their HIV-positive test results pursuant to section 8 of the Charter.[232]

[229] *Canadian AIDS Society*, supra, note 104 at 62.

[230] Given the relative strength of the arguments set out below, it is unlikely that the legislation could be insulated from challenge by including a requirement for prior authorization before HIV testing could be compelled in a given set of circumstances. It is therefore unnecessary to address this issue.

[231] *Canadian AIDS Society*, supra, note 104 at 61.

[232] Ibid at 62.

Circumstances in which and the place where the seizure is conducted

As discussed above, health care facilities are specific areas of concern in the protection of privacy, given the vulnerability of individuals seeking medical treatment. There is no question of the relevance of the reasons for this concern as expressed by the Supreme Court of Canada in the case law relevant to this context. In particular, there is a significant risk (as discussed in greater detail below) that those most in need of prenatal care will be driven underground.

Purpose of the intrusion

The societal purpose underlying a mandatory HIV testing regime for pregnant women would be the desire to identify those women who are HIV-positive and might therefore benefit from information about the range of medical interventions available to reduce the risk of perinatal HIV transmission, with the ultimate objective of supporting women's informed treatment choices to minimize the risk of perinatal HIV transmission in Canada. A reviewing court considering the reasonableness of legislation purporting to authorize mandatory HIV testing of pregnant women would weigh this purpose against the privacy interests for which protection is sought, as these are summarized above.

Government-mandated HIV testing could heighten the existing mistrust of the public health system in communities disproportionately effected by HIV, driving some women away from care.

The following three additional points would likely be considered in this analysis, weighing against the reasonableness of such a law:

- *Adverse effects of mandatory testing*

  To grant the state authority to impose its will upon a pregnant woman by compromising her rights to autonomy, self-determination, and bodily integrity creates clear potential for conflict between the interests of the mother and her foetus that may, in the end, jeopardize foetal health. In *Winnipeg Child and Family Services*, Justice McLachlin warned that the threat of such coercive action by the state might tend to drive underground the very women with the problems that are the intended focus of medical intervention, with the result that those pregnant women most in need of proper prenatal care will be the ones that go without, at risk to their own health and that of the foetus they carry. This is an important concern, and one that is often emphasized in the context of HIV. The consequences of HIV testing for those whose results are positive are serious and far-reaching, particularly for those at greatest risk of HIV infection who may already be marginalized from societal institutions:

  > Government-mandated HIV testing could heighten the existing mistrust of the public health system in communities disproportionately effected by HIV, driving some women away from care. Most experts also agree that the threat of mandatory or involuntary HIV testing and/or treatment will drive some women already mistrustful of the health care system even further from care. The fear of improper disclosure of HIV-related information is already a powerful disincentive to HIV testing for many women at risk. Faced with the prospect of mandatory testing, many women may shun medical

> care because of justifiable fears of discrimination in health care, insurance, employment and housing; because of rejection by partners, family, or friends, or even because of domestic violence.[233]

A related point focuses upon the need for a strong, trusting relationship between health care providers and their patients to support them through the complex demands of the decision-making process and, if chosen, treatment. This point is also canvassed more fully below.[234] Briefly, however, HIV testing will not result in reduced perinatal HIV transmission in and of itself. Rather, the results of testing must be accompanied by one or more treatment decisions on the part of the mother. For those pregnant women who undertake antiretroviral prophylaxis in particular, adherence to the prescribed regimen is essential for maximum reduction of the risk of perinatal HIV transmission. Recently reported studies emphasize the importance of supportive health care providers to patients' ability to do so. To place those same health care providers in the role of enforcers of the will of the state in the protection of foetal interests, rather than providers of support and care with a view to maintaining maternal and foetal health, cannot help but undermine – if not destroy – the foundation of the physician–patient relationship. As stated by one author:

> It is critically important that the testing of women be done with their full permission and full understanding of the benefits and risks of the test. ... The treatment of HIV disease and the potential prevention of transmission requires the full cooperation of a knowledgeable and committed patient. Mandatory programs based on coercion will only lead to greater distrust and result in patients who are appropriately reluctant to favourably consider therapeutic options presented by well-meaning health care professionals.[235]

Finally, it is worth noting that a US study comparing the cost-effectiveness of HIV testing based on identified risk factors, mandatory counselling of all pregnant women with voluntary testing, and mandatory testing concluded that mandatory testing would be the most cost-effective *unless* a mandatory testing strategy brought about changes in the behaviour of the women to be tested such as avoidance of medical care. In that case, the researchers cautioned that the benefits predicted by their statistical model might be negated.[236]

- *Effectiveness of voluntary testing*

Review of the relevant medical literature reveals that HIV testing programs for pregnant women that combine universal counselling with voluntary testing have achieved high uptake rates, many in excess of 80 percent.[237] A general range in uptake from 73 to 99 percent has been reported in France, Scandinavia, and the US.[238] It seems clear that the attitude of health care providers counselling pregnant women in relation to HIV testing is an important factor in determining whether testing will be accepted (ie, test acceptance is higher when providers strongly recommend testing).[239] While it is beyond the scope of this paper to analyze those factors that impact upon the uptake rates as reflected in these studies, it is important to note as a

[233] TM McGovern. Mandatory HIV Testing and Treating of Child-Bearing Women: An Unnatural, Illegal and Unsound Approach. *Columbia Human Rights Law Review* 1997; 468(28): 475. See also EB Cooper. Mandatory HIV Testing of Pregnant/Delivering Women and Newborns: A Legal, Ethical and Pragmatic Assessment. Abstract We.D. 491, 11th World Conference on AIDS, Vancouver, 10 July 1996.

[234] Infra at 74-75.

[235] AR Fleischman. The Wrong Answer to the Wrong Question. *The AIDS Reader* 1994; 4(5): 172-174.

[236] JW Thompson et al. The Cost-Effectiveness of Screening Strategies to Prevent Vertical Transmission of Human Immunodeficiency Virus. Abstract #We.C.3590, 11th World AIDS Conference, Vancouver, 1996.

[237] MK Lindsay et al. Routine Antepartum Human Immunodeficiency Virus Infection Screening in an Inner-City Population. *Obstetrics and Gynecology* 1989; 74: 289-294; D Mercey et al. Voluntary Universal Antenatal HIV Testing. *British Journal of Obstetrics and Gynaecology* 1996; 103: 1129-1133; AO Dubois. The Case against Mandatory Newborn Screening for HIV Antibodies. *Journal of Community Health* 1995; 20(2): 143-159 at 150; MK Lindsay et al. Determinants of Acceptance of Routine Voluntary Human Immunodeficiency Virus Testing in an Inner-City Prenatal Population. *Obstetrics and Gynecology* 1991; 78(4): 678; C Levine and MH Allen. Social Interventions in the Care of Human Immunodeficiency Virus (HIV)-Infected Pregnant Women. *Seminars in Perinatology* 1995; 19(4): 323-329; G Larsson et al. Screening for HIV in Pregnant Women: A Study of Maternal Opinion. *AIDS Care* 1990: 2: 223-228; TV Ellerbrook et al. Heterosexually Transmitted Human Immunodeficiency Virus Infection among Pregnant Women in a Rural Florida Community. *New England Journal of Medicine* 1992; 327: 1704-1709; Barbacci et al, supra, note 216; EL Ross, JC Morrison. Screening for Human Immunodeficiency Virus Infection during Pregnancy. *Pediatric AIDS and HIV Infection* 1997; 8: 12-14; and W Cozen et al. Screening for Hepatitis B Virus in Los Angeles County Prenatal Clinics: A Demonstration Project. *Journal of Acquired Immunodeficiency Syndrome* 1993: 6: 95-98.

[238] DM Gibb. Factors affecting uptake of antenatal HIV testing in London: results of a multicentre study. *British Medical Journal* 1998; 316: 259-261 at 260, citing Fiscus et al, supra, note 213; D Rey et al. Interest and limits of mandatory HIV prenatal screening: the south-eastern experience. *British Journal of Obstetrics and Gynaecology* 1998 (in press); and S Lindgren et al. Screening for HIV-1 antibodies in pregnancy: results from the Swedish national programme. *British Medical Journal* 1993; 307: 1447-1451.

general proposition that steps can be taken to improve uptake rates in the context of a voluntary HIV testing program still further by strengthening physician support for the initiative.[240]

- *Vagueness and overbreadth*

In *Winnipeg Child and Family Services*, a majority of the Supreme Court of Canada refused to accept the Agency's submission that it could define the scope of intervention by the state to compel treatment in the interests of foetal health so as to minimize the potential for intrusions upon the rights of pregnant women. The Court's concern was that, having opened the door to state intrusion, courts (and, presumably, legislatures) might be persuaded to encroach further and further upon the freedom of pregnant women in the interests of foetal health.

This concern is relevant to the HIV testing of pregnant women. If one accepts the degree of intrusion necessary to authorize mandatory HIV testing in the interests of foetal health, what principled approach justifies a refusal to authorize the further intrusions that would be necessary to compel the treatment of pregnant women in the interests of reducing perinatal HIV transmission – for example, with antiretroviral prophylaxis or caesarian section? This is the "vagueness" aspect of the problem.

Discussion of treatment options should be non-coercive, and the final decision regarding the use of antiretroviral drugs is the responsibility of the woman.

With respect to "overbreadth," any claim that mandatory HIV testing is necessary for pregnant women would be undermined by the fact that there is no call in Canada for the mandatory treatment of pregnant women to minimize the risk of perinatal HIV transmission. Indeed, although it is beyond the scope of this paper to develop this argument in detail, it is highly unlikely that a mandatory treatment initiative would survive constitutional challenge pursuant to the Charter for many of the reasons canvassed here in relation to HIV testing. Of particular importance in this regard is the experimental nature of antiretroviral prophylaxis in view of its risks and unknowns (as canvassed in detail above). Again, from a legal perspective, characterization of this treatment as experimental calls for the exercise of informed consent on the basis of a heightened or "perfect" level of disclosure.

Similarly, in the US all recommendations issued by the US PHS to date have emphasized the need to respect the informed choices of pregnant women regarding treatment. The following passage drawn from the 1998 PHS Recommendations illustrates the PHS's concerns in this regard:

> Discussion of treatment options should be non-coercive, and the final decision regarding the use of antiretroviral drugs is the responsibility of the woman. Decisions regarding use and choice of antiretroviral drugs in non-pregnant individuals are becoming increasingly complicated, as the standard of care moves toward simultaneous use of multiple antiretroviral drugs to suppress viral replication below detectible limits. These decisions are further complicated in pregnancy, as the long-term consequences of *in utero* of antiretroviral drugs, alone or in combination, for the infant are

[239] See, for example, Dubois, supra, note 237; IOM Committee, supra, note 10, ch 6 at 18; and S Jones et al. Does uptake of antenatal HIV testing depend on the individual midwife? Cross sectional study. *British Medical Journal* 1998; 316: 272-273 at 273.

[240] This issue is the subject of separate study by Health Canada.

> unknown. A decision to not accept treatment with ZDV or other drugs should not result in punitive action or denial of care, nor should use of ZDV be denied to a woman who wishes to minimize the exposure of the foetus to other antiretroviral drugs and therefore chooses to receive only ZDV during pregnancy to reduce the risk of perinatal transmission after receiving appropriate counselling.[241]

The UNAIDS Policy on HIV Testing and Counselling similarly emphasizes that:

> Regardless of the presence of risk factors or the potential for effective intervention to prevent transmission, women should not be coerced into testing, or tested without consent. Instead they should be given all relevant information and allowed to make their own decisions about HIV testing, reproduction and infant feeding.[242]

HIV testing is only useful insofar as it advances the larger public health goal of enabling as many women as possible to consider whether they might benefit from one or more of the range of medical interventions available to minimize the risk of perinatal HIV transmission and, if so, to pursue treatment. It is not a necessary step toward further public health activity in the sense that a positive HIV test result will not lead to mandatory treatment. Moreover, it is at least theoretically possible for a pregnant woman to give full consideration to the available options and reject them without being tested. This fact detracts from the exigency of the circumstances in issue.

- *Weight of current professional opinion*

The vast majority of professional associations and other interested organizations, in Canada and elsewhere, call for voluntary rather than mandatory HIV testing of pregnant women.[243] As stated by McGovern, a legal commentator:

> Most medical and public health experts support voluntary HIV counselling and testing as the most effective strategy for bringing HIV-infected and -affected women and children into care. Experts such as the Federal Centres for Disease Control, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics have consistently opposed proposals for mandatory testing of pregnant and child-bearing women as unnecessary and potentially harmful to women and their relationships to health care providers. These medical and public health experts agree that routine counselling and the offer of voluntary testing during prenatal care have been demonstrated to be the most effective way of identifying HIV-infected women and engaging them in care.[244]

These views are consistent with the conclusions reached by Canada's Royal Commission on New Reproductive Technologies following its careful consideration of the use of legislation and court decisions to control the conduct of pregnant women believed to be endangering foetal health. As noted above, the Commission concluded that while a coercive response to such

[241] 1998 PHS Recommendations, supra, note 30 at 11. See also 1994 PHS Recommendations, supra, note 23 at 6-7; and 1995 PHS Recommendations, supra, note 29 at 11.

[242] *UNAIDS Policy on HIV Testing and Counselling*, supra, note 220 at 1.

[243] Ibid. See also IOM Committee, supra, note 10.

[244] McGovern, supra, note 233 at 473-474.

> circumstances might be superficially appealing, it is unacceptable from a legal, ethical, and social perspective and, indeed, could only prove counterproductive.

In *Canadian AIDS Society*, Justice Wilson was called upon to consider whether the HIV testing of blood donors without their consent and the reporting of positive test results to public health authorities amounted to an unreasonable seizure in violation of section 8 of the Charter. She considered the reasonableness of the law that required this reporting, Ontario's *Health Protection and Promotion Act*, by weighing the relative benefits and detriments in accordance with the standard applied by Justice La Forest of the Supreme Court of Canada in *Dyment*: was the seizure justified by compelling circumstances showing great necessity or urgency?[245] The benefits of compliance with the reporting regime were characterized as public health benefits: the conduct of follow-up by public health officials to ensure that the HIV-positive donors were aware of their HIV status and provided with related counselling, and the undertaking of efforts to identify and counsel any identifiable partners in risk-bearing activity who are exposed to HIV transmission. The detriments identified were the profound personal, emotional, and financial consequences associated with confronting an HIV-positive diagnosis. Applying the *Dyment* standard – "compelling circumstances showing great necessity or urgency" – Justice Wilson concluded that application of the reporting provisions in issue was reasonable and therefore did not constitute a section 8 violation.

Justice Wilson's reasons for judgment reveal that the fact that the public health purpose at issue could not have been achieved by less intrusive means was a critical factor in her analysis:

> ... a less intrusive measure than full reporting was suggested by Dr. Schabas prior to the institution of this application. It was rejected as not practical by the Red Cross. It was also rejected by the applicant [Canadian AIDS Society]. The parties at my request made submissions about alternatives less than full reporting. After carefully considering the situation, I conclude that without an agreement between the parties, there are no viable options short of full compliance with the reporting requirements of the [*Health Protection and Promotion Act*]. ... the provisions are reasonable, and infringe rights as little as possible.[246]

Clearly, this is not the case with respect to the HIV testing of pregnant women. As noted above, the relevant medical literature indicates that voluntary HIV testing programs have achieved high uptake rates and that these may be improved still further – without infringing the constitutional rights of pregnant women – with various adjustments to the design and implementation of those programs. Moreover, the detriments presented by the imposition of a mandatory HIV testing regime for pregnant women go far beyond those identified by Justice Wilson in *Canadian AIDS Society*. Indeed, they have the ability to seriously undermine the ostensible effectiveness (and, therefore, the public health purpose) of mandatory testing by driving those most at risk of HIV infection – and therefore of perinatal HIV transmission – away from prenatal care altogether.

[245] *Canadian AIDS Society*, supra, note 104 at 63-64.

[246] Ibid at 69.

On balance, given all the circumstances and arguments set out above, it seems most likely that a reviewing court would conclude that legislation purporting to authorize mandatory HIV testing of pregnant women is an unreasonable intrusion upon their reasonable expectations of privacy, and therefore in violation of the Charter's section 8 guarantee of freedom against unreasonable seizure.

Can the Breach of Section 8 of the Charter Be Saved by Section 1?

The analytic framework that would be adopted by a reviewing court at this stage is set out in the analysis of legal parameters above.

As a practical matter, it is unlikely that a section 8 violation in these circumstances would be saved by section 1 of the Charter,[247] in view of strong statements by the Supreme Court of Canada questioning whether the balancing of interests would prove any different, given the matters already canvassed in relation to section 8.[248]

Recommendation

3. Provinces and territories should require that HIV testing of pregnant women be voluntary.

Securing Informed Consent

As discussed above, the current standard of professional care in Canada requires that HIV testing be carried out only after the person to be tested has given his or her voluntary, specific and informed consent following pre-test counselling. The necessary content of pre-test counselling, as prescribed by relevant professional bodies, is set out above.[249]

At issue in this point in the analysis is whether the standard requirement for informed consent to HIV testing based upon comprehensive pre-test counselling should be abrogated for pregnant women. This question is of particular importance given the recent recommendation of the IOM Committee that the US adopt "a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care."[250] The IOM Committee's clearly stated intention in making this recommendation was to relieve physicians of the obligation of providing the comprehensive pre-test counselling necessary to ground a woman's informed consent to HIV testing:

> Providers have reported that, in the context of prenatal care, pre-test counselling following standard HIV protocols (CDC 1994) is too onerous and that, therefore, many of their patients remain untested. Eliminating the requirement for extensive pre-test counselling, while requiring the provision of the basic information to all patients, would likely increase the proportion of women tested for HIV. *The Committee therefore recommends that pre-test counselling consist primarily of notification that HIV testing is a regular part of prenatal care for everyone, and that women have a right to refuse it.*[251] [Emphasis added.]

[247] Supra at 59ff.

[248] See, for example, *Baron*, supra, note 178.

[249] Supra at 26ff.

[250] IOM Committee, supra, note 10, ch 7 at 1.

[251] Ibid.

Notification to pregnant women that they will be tested for HIV unless they specifically refuse is, in other words, substituted for the exchange of information necessary to secure the informed consent of pregnant women to HIV testing.

In Canada, such an approach could be challenged as unconstitutional on the basis of sections 7 and 15(1) of the Charter. Of these, section 7 is the more directly applicable and will be the subject of analysis here. It is likely that such an approach would be found unconstitutional by a reviewing court as a violation of section 7 of the Charter that could not be justified under section 1. The reasons for this conclusion are set out below, following the analytic framework for section 7 set out in the discussion of legal parameters above.[252]

Is There a Breach of Life, Liberty or Security of the Person?

The phrase "security of the person" has been interpreted by courts to encompass the common law right to make choices concerning one's own body, control over one's physical and psychological integrity, and basic human dignity. Again, as stated by the Ontario Court of Appeal in *Malette*, in a passage reproduced at greater length above:

> The doctrine of informed consent has developed in law as the primary means of protecting a patient's right to control his or her medical treatment. Under the doctrine, no medical procedure may be undertaken without the patient's consent obtained after the patient has been provided with sufficient information to evaluate the risks and benefits of the proposed treatment and other available options.[253]

In *Fleming*, another case reviewed above, the applicants challenged provisions in Ontario's *Mental Health Act* that allowed their treating physicians to secure orders for compelled medical treatment without regard for the patient's wishes as expressed while competent. The Court concluded that it was "manifest" that the impugned provisions operated to deprive the applicants of their right to security of the person as guaranteed by section 7 of the Charter.[254] Similarly, there is little question that a government policy that purported to compromise to any degree the right of a pregnant woman to receive the necessary components of pre-test counselling that would allow her to give or refuse informed consent to HIV testing would breach her right to security of the person as guaranteed by section 7 of the Charter.

Based upon the reasoning of a minority of the Supreme Court of Canada in *B(R)*, it is also arguable – although less certain – that such a policy would be appropriately characterized as a breach of the liberty interest guaranteed by section 7. Given the strength of the analysis in relation to "security of the person," however, there is no need to pursue this argument further.

Is the Breach in Accordance with the Principles of Fundamental Justice?

The next step in the analysis is to assess whether the breach of security of the person would be found to be in accordance with the principles of fundamental justice. Again, a breach that may be characterized as in accordance with the

[252] Supra at 41ff.

[253] *Malette*, supra, note 79 at 286.

[254] *Fleming*, supra, note 80 at 312.

principles of fundamental justice does not constitute a violation of section 7 of the Charter even though it may impinge upon security of the person; an infringement upon security of the person that is not in accordance with the principles of fundamental justice, however, does amount to a section 7 violation.

In these circumstances, assuming that the policy mirrored that of the IOM Committee, three factors would be considered to reach this determination: the context in which the policy is introduced, arbitrariness, and overbreadth.

Context

As noted above, the question whether a principle of fundamental justice has been violated must be considered within the specific context at issue, including, in particular, those principles and policies that have animated legislative and judicial practices in the field, both nationally and internationally.

Outside the specific context of HIV-related care and treatment, it is important to consider the primacy that is afforded the right of individuals to exercise informed consent to proposed medical interventions. This principle is now so integral to Canadians' collective concept of human dignity that most provinces and territories have enacted legislation to ensure its preservation to the fullest extent possible by the appointment of "substitute decision-makers" or "substitute consent-givers" required by law to exercise the right of informed consent on behalf of individuals unable to speak for themselves due to incompetency.

Moreover, when legislatures have not gone far enough to protect the right of individuals to exercise informed consent to proposed medical interventions, the courts have not hesitated to intervene. This was the case in *Fleming*, for example. The applicants in that case complained that while Ontario's *Mental Health Act* required substitute decision-makers to act in accordance with patients' wishes as expressed while competent, it empowered a review board to overrule the substitute decision-makers' decisions without regard for those wishes. The Ontario Court of Appeal had little difficulty concluding that the statutory regime was "plainly contrary to the principles of fundamental justice." As stated by Justice Robins, speaking for all members of the Court in that case:

> In my view, no objection can be taken to procedural requirements designed to determine more accurately the intended effect or scope of an incompetent patient's prior competent wishes or instructions. As the Act now stands, the substitute consent-giver's decision must be governed by wishes which may range from an isolated or casual statement of refusal to reliable and informed instructions based on the patient's knowledge of the effect of the drug on him or her. Furthermore, there may be questions as to the clarity or currency of the wishes, their applicability to the patient's present circumstances, and whether they have been revoked or revised by subsequent wishes or a subsequently accepted treatment program. The resolution of questions of this nature is patently a matter for legislative action. But, in my respectful view, it is incumbent on the legislature to bear in mind that, as a general proposition, psychiatric patients are entitled to make competent decisions and exercise their right to

> self-determination in accordance with their own standards and values and not necessarily in the manner others may believe to be in the patient's best interests.[255]

Informed consent is not considered a frill by Canadian courts, to be abandoned because it is perceived as too burdensome by physicians.

In short, informed consent is not considered a frill by Canadian courts, to be abandoned because it is perceived as too burdensome by physicians. It represents a fundamental shift in paradigm that has placed responsibility for decision-making in relation to proposed medical interventions with patients (who must ultimately live with the consequences of those decisions) rather than their physicians. It is axiomatic that a necessary condition for the exercise of that responsibility is possession of all of the information relevant to the proposed intervention, so that the patient is able to consider and weigh the consequences of alternative courses of action.

HIV testing during pregnancy raises special issues of privacy, reproductive choice, and social risk that are not applicable to other tests conducted as a standard component of prenatal care.

Within the specific context of HIV-related care and treatment, the weight of professional opinion as reflected in current policy statements, recommendations and guidelines in Canada, the US, and internationally requires that pregnant women be provided all standard components of pre-test counselling to allow for the exercise of informed consent before HIV testing is conducted.[256] The only significant distinction between the information to be provided to pregnant women compared with others is the additional information provided to pregnant women about the range of medical interventions available to minimize the risk of perinatal HIV transmission in the event of a positive result. This further information is necessary to explain the special importance of HIV testing in the context of pregnancy.

From an international perspective, the following elements of the recent Guidelines on HIV/AIDS and Human Rights established by UNAIDS highlight the importance of informed consent in the context of HIV testing, particularly in the context of pregnancy:

- Article 1.7 of the International Covenant on Civil and Political Rights, which establishes the right to privacy, "encompasses obligations to respect physical privacy, including the obligation to seek informed consent to HIV testing";[257]
- Article 9 of the International Covenant on Civil and Political Rights, which establishes the right to liberty and security of the person, encompasses "respect for the right to physical integrity [which, in turn], requires that testing be voluntary and based on informed consent";[258]
- Guideline 3, "Public Health Legislation," provides that "public health legislation should ensure that HIV testing of individuals should only be performed with the specific informed consent of that individual";[259] and
- Guideline 8, "Women, Children and Other Vulnerable Groups," provides that "states should ensure that all women and girls of child-bearing age have access to comprehensive information and counselling about the prevention of HIV transmission and the risk of vertical transmission of HIV, as well as access to the available resources to minimize that risk, or proceed with childbirth, if they so choose."[260]

Insofar as the consequences of HIV testing during pregnancy are concerned, it is important to emphasize that such testing raises special issues of privacy, reproductive choice, and social risk that are not applicable to other tests

[255] Ibid at 318-319.

[256] Supra, note 220.

[257] Guidelines on HIV/AIDS and Human Rights. Annex I to *Second International Consultation on HIV/AIDS and Human Rights (Geneva, 23-25 September 1996): Report of the Secretary General* (E/CN.4/1997/37 20 January 1997, at 20).

[258] Ibid at 23.

[259] Ibid at 32.

[260] Ibid at 43.

conducted as a standard component of prenatal care.[261] One study examined the social, economic, and psychological changes in women's lives after demonstrated HIV seropositivity. The study evaluated the differences in health care, discrimination, economic loss, risk behaviours, relationship changes, and psychological status in 20 HIV-positive and 20 HIV-negative mothers. According to the authors, for some HIV-positive women health care delivery became a site of public exposure and personal stress. Most asymptomatic HIV-positive women maintained a high level of secrecy about their status, both protecting and isolating them; although HIV-positive women who had disclosed their status reported greater satisfaction with social support from friends (100 percent) and family (80 percent), many women had not disclosed it to any friends (65 percent) or family (25 percent), indicating fear of abandonment. The HIV-positive women did not feel that the current level of knowledge about HIV infection within their communities was sufficient to protect their best interests, even among their closest personal contacts.[262] The authors concluded that:

> Even with access to this unusual comprehensive care program (BAPAC), ... mothers with HIV disease face considerable fear of discrimination, both at home and in their community, and at the doctor's office. These data also suggest that in our current social environment, women with HIV infection are forced to do the work of educating themselves, their families and sometimes their health care workers about living with and preventing HIV infection.[263]

Women with HIV infection are forced to do the work of educating themselves, their families and sometimes their health care workers about living with and preventing HIV infection.

The IOM Committee makes the claim that its central recommendation substituting bare patient notification for informed consent is "in concert with recent analyses and policy changes in other countries," with specific reference to "routine HIV testing" in Alberta and a "recent clinical trial in Scotland."[264] This statement is inaccurate insofar as it suggests that Alberta's recently introduced testing program dispenses with the requirement that pregnant women give their informed consent to HIV testing. As set out in greater detail in the Appendix, the Alberta policy establishes the same benchmarks for the pre-test counselling of pregnant women as do the CMA Guidelines reviewed above.

With respect to the "recent clinical trial in Scotland," the IOM Committee appears again to be misinformed. While this trial did test an approach described as "routine/opt-out" with one group of women, the group were provided with both detailed written information and related counselling regarding HIV testing. As described by the primary author of the study:

> This group were sent a leaflet which was a combination of the blood tests and HIV specific leaflets of the RCT [randomized control trial]. This was because we found that it was useful to have information about all the tests, but more information was given about HIV than in the original blood tests leaflet of the RCT because we found that comprehensive information was important for informed choice and did not dissuade women from testing. HIV testing was discussed with all the women in this group. The discussion protocol was shorter than the original comprehensive protocol and longer than the original minimal protocol. It highlighted the benefits of

[261] Working Group on HIV Testing of Pregnant Women and Newborns. HIV Infection, Pregnant Women and Newborns: A Policy Proposal for Information and Testing. *Journal of the American Medical Association* 1990; 264(18): 2416-2420.

[262] P Lester et al. The Consequences of a Positive Prenatal HIV Antibody Test for Women. *Journal of Acquired Immunodeficiency Syndrome and Human Retrovirology* 1995; 10: 341-349.

[263] Ibid.

[264] IOM Committee, supra, note 10, ch 7 at 2.

> testing, explained why testing had become routine, explained the testing procedure and made it clear that the woman could refuse the offer if she wished.[265]

The IOM Committee does not itself appear completely comfortable with its central recommendation, in that it qualifies the recommendation with the further statement that: "This recommendation is not intended to diminish more extensive counselling when providers feel it is warranted."[266] If what the Committee is attempting to convey with this statement is the suggestion that comprehensive counselling for HIV testing need only be provided to those women considered by physicians to be at high risk, then it must be understood that such an approach is completely at odds with the move from targeted to universal offers of HIV testing for pregnant women. As explored elsewhere in this paper, the entire rationale for this change in approach is that the identified presence of risk factors cannot be relied upon to identify all those women who are actually at increased risk of HIV infection. Alternatively, this qualification may reflect the Committee's discomfort with the legal vulnerability of its proposal that pregnant women be deprived of the right to give or refuse informed consent to HIV testing. Certainly, it is of interest to note that while the Committee's report sets out detailed and comprehensive arguments in support of its conclusions from a medical perspective, it provides no comparable legal analysis despite the fact that its membership is represented to have included at least one individual with public health expertise.[267] There seems little question that US jurisprudence offers grounds for challenge similar to those canvassed in this paper.[268]

It is important, finally, to consider the context from which the IOM Committee's recommendation emerges. In 1996, two years after the release of the PACTG 076 findings, the US Congress considered the issue of perinatal HIV transmission and enacted the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996.[269] These amendments required the US Secretary of Health and Human Services to determine, by October 1998, whether HIV testing of all newborns born in the US whose mothers have not undergone prenatal HIV testing has become routine practice. As summarized by McGovern:

> If the Health and Human Services (HHS) Secretary determines that mandatory testing has not become routine practice, each state will have eighteen months in which to demonstrate one of the following or *lose* its Ryan White CARE Act Funds: (1) a fifty percent reduction in the rate of new AIDS cases resulting from perinatal transmission (comparing most recent data to 1993 data); (2) HIV testing of at least ninety-five percent of the women who have received at least two pre-natal visits prior to thirty-four weeks gestation; (3) a program of mandatory testing of all newborns whose mothers have not undergone pre-natal testing. As these benchmarks are virtually impossible to meet, Congress has in effect invited states to impose mandatory testing measures or lose all their Ryan White funding.[270] [Emphasis in original.]

[265] Personal communication between L Stoltz and W Simpson, 5 January 1999. The study results were recently published. See: W Simpson et al. Uptake and acceptability of antenatal HIV testing: randomized control trial of different methods of offering the test. *British Medical Journal* 1998; 316: 262-267. A publication with follow-up results is forthcoming in the *British Medical Journal*.

[266] IOM Committee, supra, note 10. ch 7 at 2.

[267] Ibid, Preface, at 2.

[268] See, for example, McGovern, supra, note 233 at 484-495.

[269] PL 104-146.

[270] McGovern, supra, note 233 at 470-71.

The IOM Committee was given a congressional mandate relevant to this decision-making process to determine

> the extent to which State efforts have been effective in reducing the perinatal transmission of the human immunodeficiency virus, and an analysis of the existing barriers to the further reduction in such transmission.[271]

In its report, the IOM Committee repeatedly states its view that mandatory newborn testing has limited utility in preventing perinatal HIV transmission. Reading between the lines, therefore, it seems most likely that the IOM Committee's recommendation is motivated by a desire to reach the prescribed 95 percent benchmark for the HIV testing of pregnant women and thereby avert the consequences of the Ryan White amendments: a significant loss of funds for important HIV-related care and treatment[272] or, alternatively, the imposition of mandatory newborn testing. These concerns are irrelevant to the Canadian context.

Arbitrariness

The Supreme Court of Canada has established that a deprivation of life, liberty or security of the person must significantly enhance the interests of the state or it will be characterized as arbitrary and not in accordance with the principles of fundamental justice.

In Canada, as explained at the outset of this Part, the purpose of HIV testing policies must be considered in the context of the larger public health objective to minimize the number of perinatal HIV transmissions in Canada. The goal is therefore not simply to achieve the highest possible testing uptake rates, but to enable as many women as possible to benefit from consideration of, and access to, the full range of medical interventions available to minimize that risk. Practically speaking, this means that any detrimental effects associated with abrogating women's right to exercise informed consent to HIV testing that result in more perinatal HIV transmission rather than less are of constitutional significance. Four areas of concern must be considered in this regard.

The medical evidence does not support the conclusion that removing the informed consent requirement in an HIV testing program for pregnant women will achieve higher uptake rates than a fully implemented voluntary testing program that respects informed consent requirements.

No clear evidence of higher uptake rates

The relevant medical evidence does not support the conclusion that removing the informed consent requirement in an HIV testing program for pregnant women will achieve higher uptake rates than a fully implemented voluntary testing program that respects informed consent requirements.

In support of its central recommendation to substitute patient notification for informed consent, the IOM Committee relies upon the results of the recently reported Scottish study discussed above. The Committee asserts that an uptake rate of 90 percent was achieved when the approach was switched "to opt-out (routine, with notification)." In fact, the uptake rate achieved in the study was 88 percent.[273] More important, this uptake rate was not achieved on the basis of "patient notification" rather than informed consent. As canvassed above, all women in the group described by the authors as "routine/opt-out" were provided detailed information regarding the risks and benefits of HIV testing, both in writing and in a counselling session with a midwife.

[271] Ibid.

[272] As summarized by the IOM Committee: "Nationally, more than $500,000,000 million (the 1998 appropriation for the Title II Program, which supports health care and support services, continuation of health insurance, pharmaceutical treatments, and other services through the States) is at stake in this decision. (HRSA, 1998a.)" See IOM Committee, supra, note 10, ch 1 at 1.

[273] Personal communication, supra, note 265.

As noted above, moreover, voluntary HIV testing programs for pregnant women that incorporate the comprehensive pre-test counselling necessary to allow women to give or refuse their informed consent to testing have achieved very high uptake rates. Again, a general range in uptake from 73 to 99 percent has been reported in France, Scandinavia, and the US.[274] Some of the study results in the US, as summarized by the IOM Committee itself, include the following:

- in the context of the CDC's Perinatal Guideline Evaluation Project, 87 percent to 100 percent of women surveyed across four sites were offered an HIV test and an average of 93 percent of these women had the test performed;[275]
- within the population of women who received prenatal care from Kaiser Permanente Medical Group in Southern California, the percentage of pregnant women tested for HIV increased from 55 percent in 1994 to 85 percent in 1997;[276]
- within the population of women giving birth in Texas in the first half of 1997, 86 percent were tested for HIV;[277]
- within the population of women who received prenatal care from the Kaiser Permanente Health Plan in Northern California, the percentage of women tested increased from 50 percent in 1994 to 80 percent in early 1998;[278]
- within the population of women receiving prenatal care at Grady Memorial Hospital in Atlanta, Georgia from July 1987 to June 1990, 95 percent consented to HIV testing;[279]
- within the population of women receiving prenatal care at Grady Memorial Hospital in Atlanta, Georgia from September 1989 to March 1990, 96 percent consented to HIV testing.[280]
- within the population of over 30,000 women registered for care at Grady Memorial Hospital in Atlanta, Georgia from 1991 to 1993, 95 percent of women accepted HIV testing.[281]

There is no suggestion in the relevant medical literature, by contrast, that providing the comprehensive information necessary to secure women's informed consent to HIV testing has an adverse impact upon the willingness of women to consent to testing.[282] Indeed, as discussed immediately below, it appears that the reverse is true.

Lack of information may reduce women's willingness to consent to HIV testing

Uptake rates for HIV testing within a specified population are a function of two variables: the percentage of women who are offered HIV testing and, of those, the percentage of women who accept testing. The IOM Committee's purpose in removing the informed consent requirement is to increase the percentage of women who are offered HIV testing during pregnancy. The Committee does not appear to have considered the possibility that the intervention calculated to have a positive impact on the first variable might have a negative impact on the second, leaving women less likely to accept HIV testing. There is a suggestion in the emerging medical literature, however, that this may prove to be the case. Most recently, as discussed above, the Scottish clinical trial highlighted by the

274 Supra, note 238.

275 IOM Committee, supra, note 10 at 22.

276 Ibid, ch 6 at 19.

277 Ibid.

278 Ibid, ch 6 at 25.

279 Ibid at 28.

280 Ibid.

281 Ibid, ch 6 at 26.

282 Simpson et al, supra, note 265 at 266.

IOM Committee (authored by Simpson et al) found that "comprehensive information [about HIV testing] was important for informed choice and did not dissuade women from testing" and that "women who perceived the benefits of testing were more likely to take the test."[283] Other studies have concluded that longer counselling sessions (presumably reflecting a greater exchange of information) increased the likelihood of test uptake. A recent study published in the same issue of the *British Medical Journal* as the Simpson study, for example, concluded that "HIV testing was twice as likely if pre-test discussions lasted longer than five minutes."[284] An earlier study similarly concluded that for every five-minute increase in the length of a counselling session, the odds of testing more than doubled.[285]

Comprehensive information about HIV testing was important for informed choice and did not dissuade women from testing.

Possible jeopardy to treatment relationship necessary to support medical intervention

This argument considers the potential impact of abrogating the requirement of informed consent to HIV testing upon the larger public health objective at issue in this paper: reducing the number of perinatal HIV transmissions in Canada by enabling as many women as possible to avail themselves of medical interventions. Of particular interest in this regard is a woman's decision to undergo antiretroviral prophylaxis to minimize the risk of perinatal HIV transmission.

A high proportion of HIV-positive pregnant women presently act to reduce the risk of disease transmission to their infants. A recently published British study concluded, for example:

> No mother who knew she had HIV infection breastfed. Uptake of antiretroviral therapy increased significantly over time, and the caesarian section rate was persistently high ... our findings complement those of an earlier study of uptake of interventions in the United Kingdom that showed a continued increase in uptake of interventions by mothers.[286]

The IOM Committee similarly concluded that "most women who are offered ZDV treatment initiate therapy" and assumed, for the purpose of comparing the effectiveness of alternative recommendations to reduce the rate of perinatal HIV transmission in the US, that "90% of women accept and comply with ZDV treatment when it is offered."[287] It is important to note, however, that the treatment uptake rates documented in studies relied upon by the Committee in support of this assumption reflect decisions by women who were tested for HIV in the context of programs that required their informed consent to testing. Would these decisions differ in the context of a testing regime in which women's right to give or refuse informed consent to HIV testing was abrogated? There is evidence to suggest that they would.

It is clear from the relevant medical literature that adherence to the complex treatment regime prescribed by PACTG 076 (with or without the addition of other antiretroviral drugs) is essential for maximum reduction of the risk of perinatal HIV transmission.[288] It is also clear that the maintenance of secure, trusting and supportive relationships between health care providers and their patients is integral to adherence to antiretroviral treatment regimes.[289]

The maintenance of secure, trusting and supportive relationships between health care providers and their patients is integral to adherence to antiretroviral treatment regimes.

[283] Ibid.

[284] Jones et al, supra, note 239 at 273.

[285] Cozen et al, supra, note 237.

[286] EGH Lyall et al. Review of Uptake of Interventions to Reduce Mother-to-Child Transmission of HIV by Women Aware of Their HIV Status. *British Medical Journal* 1998; 316: 268-270 at 269.

[287] IOM Committee, supra, note 10, ch 6 at 33 and 36.

[288] See, for example, Beckerman et al, supra, note 36; and T Frederick et al. Missed opportunities to reduce perinatal HIV transmission: maternal and neonatal zidovudine use in Los Angeles County. #23273, *Conference Record*, supra, note 16.

[289] See, for example: Frederick et al, ibid; L O'Connor. "Quality of care" – its effect on the experience and outcome of HIV positive women during pregnancy and childbirth. #42218; A Williams et al. Adherence to antiretroviral therapy among HIV positive women. #32374; M Gruffaz-Mauris. Furthering compliance with triple antiretroviral therapies: a common workshop between patients and a ward staff. #32340; GM Powell-Cope et al. Perceived health care providers support and HIV adherence. #32354; and J Quirk, J Wilks. Patient compliance on combination antiretroviral therapies. #32384 (all from the *Conference Record*, supra, note 16). H Loveday et al. Patient active coping, optimism and physician support are all vital to adherence to medication. #24378, in *Conference Supplement*, supra, note 62.

There is little question, finally, that women's experience of the circumstances in which they are tested for HIV has the potential to undermine their trust in the health care system. As noted by the IOM Committee, for example:

> The committee repeatedly heard reports about the emotional difficulty of receiving HIV positive test results, even under ideal circumstances. For some women, however, the shock is intensified by the circumstances under which they are informed of their status. In Birmingham, Alabama, specialty care providers reported that some private providers test women without their knowledge and then relate positive results over the phone. By the time these women make their way to the specialty clinic, they are already distrustful of the health care system.[290]

Any distinction between the Committee's example of HIV testing without consent and HIV testing on the basis of an inadequately informed consent is arguably without substance in this regard. There is a significant risk that confronting a woman with the far-reaching personal, social and legal consequences of a positive HIV test result without warning may irreparably damage her relationship with her health care providers and the health care system in general, compromising the chances that she will elect to undergo antiretroviral prophylaxis (or any other intervention) to minimize the risk of perinatal HIV transmission, or, if she does, adhere to the treatment regime.

Substituting patient notification for informed consent means that an important opportunity to provide HIV-negative women with the information they need to remain HIV-negative will be lost.

The IOM Committee appears to have given no consideration to this argument despite the importance of its assumption that substituting patient notification of HIV testing for informed consent to HIV testing would have no impact upon the percentage of women identified as HIV-positive in such a diagnostic regime who would ultimately initiate and adhere to medical interventions intended to reduce the risk of perinatal HIV transmission.

Loss of important prevention opportunity

Substituting patient notification for informed consent, as recommended by the IOM Committee, means that an important opportunity to provide HIV-negative women with the information they need to remain HIV-negative will be lost. A recently reported French study highlights the importance of this missed opportunity, concluding that:

> For many women, consultations for reproductive health and prenatal care are their only occasions of access to medical care. Our survey shows that two major opportunities to develop HIV prevention for sexually active women, which are the contraceptive advice and the communication of a prenatal HIV negative test result, are often missed by the French obstetrician-gynecologists.[291]

Even the IOM Committee does not dispute that the best way to reduce perinatal HIV transmission is by preventing HIV transmission to women of child-bearing years in the first place.[292] This missed opportunity is all the more important given the possibly increased risk of perinatal HIV transmission where maternal seroconversion occurs during pregnancy or breastfeeding (due to the high levels of circulating virus).

[290] IOM Committee, supra, note 10, ch 6 at 33-34.

[291] D Rey et al. Attitudes and Practices of French Obstetrician-Gynaecologists regarding HIV Prevention and Condom Promotion. #13568, Conference Record, supra, note 16.

[292] IOM Committee, supra, note 10, ch 7 at 12.

Overbreadth

The state will also violate the principles of fundamental justice if, in its pursuit of a legislative objective, it uses means that are broader than necessary.

As noted above, uptake rates for HIV testing among pregnant women are a function of two variables: the percentage of women who are offered HIV testing and, of those, the percentage of women who accept testing. The IOM Committee acknowledges that the factors most responsible for keeping HIV test uptake rates among pregnant women lower than what they might otherwise be are physician attitudes and practices rather than women's reluctance to be tested:

> Prenatal care providers are generally aware of the need for HIV testing, but there are still significant variations across the country in the application of recommended practices. Even in areas where the overwhelming majority of providers agree in principle that HIV testing should be offered to all pregnant women, only 50% to 75% actually offer the test to all women in their practices. Citing a lack of time, resources, legal requirements for pre-test counselling, and perceived risk, actual testing practices are often based on providers' assessments of maternal HIV risk, which are not very accurate. On the positive side, the available evidence suggests that when offered, 90% or more of women will accept an HIV test, and acceptance can be enhanced if providers strongly recommend the test and incorporate it into routine practice.[293]

The obvious response to the identified problems would appear to be recommendations that better encourage and support providers' ability to meet the standards established by the 1995 PHS Recommendations – for example, through provider education, adjustments to service delivery models, and appropriate compensation for the delivery of counselling. To do so would place the burden of the Committee's recommendations where they properly lie: with the health care providers that are the clearly identified source of the problem. Instead, however, the IOM Committee proposes that pregnant women forfeit their right to exercise informed consent in relation to HIV testing (in Canada, a constitutionally protected right) to remedy physicians' reluctance to actually meet a standard with which they agree in principle. In explaining its central recommendation, the Committee emphasizes that:

> routine testing will also reduce burdens on providers such as the need for costly extensive pre-test counselling and having discussions about personal risks that many providers think are embarrassing. A policy of routine testing might also help to reduce physicians' risk of liability to women and children when providers incorrectly guess that a woman is not at risk for HIV infection.[294]

Recently reported studies suggest that such efforts are critical.[295] A recently reported British Columbia study, for example, concluded that "[s]pecialized multidisciplinary antenatal care for HIV infected women seems to result in a significantly lower transmission rate of HIV [3.2% for those women who received specialized care versus 25% for those who did not]."[296] Presumably this

[293] Ibid, ch 6 at 37.

[294] Ibid, ch 7 at 3.

[295] See, for example, N McBennett. Developing a training initiative to support midwives in implementing policy on universal choice of HIV testing in pregnancy. #13566; and A Purchit et al. Current contraceptive practices and safer sex practices in a well-motivated cohort of HIV-infected women. #13567. In: *Conference Record*, supra, note 16.

[296] Money et al, supra, note 36.

finding stems, at least in part, from the fact that the physicians and other health care providers involved in the delivery of specialized care and treatment to HIV-positive pregnant women brought greater knowledge and better support to their patients in this difficult decision-making process.

It is likely that a reviewing court would conclude that an HIV testing policy for pregnant women that substitutes patient notification of HIV testing for informed consent to the test violates section 7 of the Charter.

While the IOM Committee does make a number of supporting recommendations directed toward improving the education and practices of health care providers in relation to HIV testing and associated care during pregnancy, it provides no evidence that aggressive pursuit of these measures could not successfully increase the number of providers who offer HIV testing to all the pregnant women in their practices. Indeed, the very high rates of HIV testing achieved in the context of voluntary counselling and testing programs conducted in accordance with the 1995 PHS Recommendations, which require the fully informed consent of women to HIV testing during pregnancy, stand as clear evidence to the contrary. In the absence of such evidence, the IOM Committee's central recommendation cannot be characterized as reasonably tailored to achieve its objective.

For all the reasons set out above, it is likely that a reviewing court would conclude that an HIV testing policy for pregnant women that substitutes patient notification of HIV testing for informed consent to the test violates section 7 of the Charter as a breach of security of the person not in accordance with the principles of fundamental justice.

The case of *Canadian AIDS Society*, discussed throughout this paper, merits further discussion at this point as the only case to date in Canada to directly address section 7 of the Charter in the context of HIV testing. As noted above, in her analysis of the application of section 7 of the Charter, Justice Wilson found that the conduct of HIV testing on blood donors and the reporting of HIV-positive test results to public health authorities as required by Ontario's *Health Protection and Promotion Act*, without the consent of those to whom the results related, amounted to a breach of their section 7 rights to security of the person.[297] She ultimately concluded, however, that this breach was in accordance with the principles of fundamental justice.

The bases upon which Justice Wilson reached this conclusion may be readily distinguished from those at issue in this context. First and foremost, Justice Wilson failed to consider that the reporting provisions of the HPPA ordinarily come into play following the conduct of an HIV test that has been undertaken with a patient's informed consent, obtained on the basis of a discussion that is required by the College of Physicians and Surgeons of Ontario (as well as the CMA Guidelines) to include reference to public health reporting requirements of this nature.[298] This omission represents a significant flaw in Justice Wilson's decision, given her earlier conclusion that the donors had not given their informed consent to the HIV testing of their donations. Second, there is an important difference between the public health impact of the activities at issue in *Canadian AIDS Society* and that at issue in this context. As noted above in relation to section 8, Justice Wilson placed great emphasis on the fact that there were "no viable options short of full compliance with the reporting requirements of the HPPA" to achieve the state's public health purpose.[299] That is patently not the case here. As canvassed in detail above, there is strong evidence to support the argument that voluntary HIV testing programs for pregnant women that incorporate the comprehensive pre-test

[297] *Canadian AIDS Society*, supra, note 104 at 52.

[298] College of Physicians and Surgeons of Ontario. Changes in HIV Testing in Ontario. *College Notices* 1992; 24(January): 2; and CMA Guidelines, supra, note 89 at 10.

[299] *Canadian AIDS Society*, supra, note 104 at 69.

counselling necessary to allow women to give or refuse their informed consent to testing have achieved uptake rates capable of achieving the public health purpose in issue.

Can the Breach of Section 7 of the Charter be Saved by Section 1?

What must be considered next is whether an HIV testing policy that substituted patient notification for informed consent could be justified under section 1 of the Charter. Again, the analytic framework that would be adopted by a reviewing court at this stage is set out in detail above.[300] In applying those principles to these circumstances, there are three points worth highlighting:

- *It is rare that a provision that violates the principles of fundamental justice will be justified under section 1 of the Charter*

  The Supreme Court of Canada has expressed doubt as to whether a violation of section 7 of the Charter could ever be justified under section 1 except, perhaps, in the context of exceptional conditions such as war, natural disasters, or epidemics.[301] This is because a court's analysis in relation to the principles of fundamental justice bears a resemblance to the analysis under section1. This similarity is evident here. The concerns canvassed above in relation to arbitrariness and overbreadth under section 7 are the same concerns that would be relevant to the three-fold proportionality test under section 1.

- *Cost-effectiveness is unlikely to justify abrogating women's right to exercise informed consent*

  One of the main arguments advanced by the IOM Committee in support of substituting patient notification of HIV testing for informed consent is the need to "reduce burdens on providers such as the need for costly extensive pre-test counselling."[302]

  While the Supreme Court of Canada has accepted in principle that an impugned government action may be justified under section 1 of the Charter by concerns about cost-effectiveness, there are few cases in which that argument has succeeded.[303] Professor Hogg, a legal commentator, observes that:

  > Professor Weinrib must be correct when she says that: "It is inherent in the nature of constitutional rights that they must receive a higher priority in the distribution of available government funds than policies or programs that do not enjoy that status." She concludes that: "A different preference for allocation of resources cannot justify encroachment on a right." The difficulty is to determine the point at which considerations of cost become so weighty that they would justify the limiting of a *Charter* right.[304]

  In the context of arguments about the cost-effectiveness of abrogating women's right to exercise informed consent to HIV testing, it is reasonable to expect that the significance of any alleged cost savings would fall to be assessed against the larger backdrop of the cost-effectiveness of a

A different preference for allocation of resources cannot justify encroachment on a right.

300 Supra at 50ff.

301 *Reference re s 94(2) of the Motor Vehicle Act (BC)*, supra, note 148 at 518 per Lamer J for the majority. More recently, see *Heywood*, supra, note 158. Indeed, the minority view has been expressed in the jurisprudence by Justice Wilson (as she then was) that, by definition, an infringement of section 7 not in accordance with the principles of fundamental justice could never be justified under section 1. See, for example, *Singh* v *Minister of Employment and Immigration*, [1985] 1 SCR 177, per Wilson J.

302 IOM Committee, supra, note 10, ch 7 at 3.

303 The argument failed, for example, in *Singh*, supra, note 301; and *Reference re s 94(2) of the Motor Vehicle Act (BC)*, supra, note 148. It succeeded in *R* v *Lee*, [1989] 2 SCR 1384; and *R* v *Chaulk*, [1990] 3 SCR 1303.

304 PW Hogg. *Constitutional Law of Canada*. Loose-Leaf edition, vol 2. Toronto: Thomson Canada Limited, 1992, at 35-26. The cite to the article quoted by Professor Hogg is: L Weinrib. The Supreme Court of Canada and Section 1 of the *Charter*. (1988), 10 Supreme Court LR 469 at 486.

successful program of HIV testing to minimize the number of perinatal HIV transmissions in Canada. Any increased cost associated with providing the comprehensive counselling required to respect women's right to exercise informed consent to HIV testing (for example, to preclude arguments by physicians that they are not adequately compensated for providing this important element of care and treatment) may well prove insignificant in comparison with the savings associated with the total number of perinatal HIV transmissions that have been avoided.

- *The burden of proof lies with the government*

  It is important to emphasize in relation to section 1 of the Charter that the burden of proof lies with the government seeking to justify its action, and that it must be prepared to adduce a sound evidentiary basis for its conclusions.

These arguments support a first-line approach to the HIV testing of pregnant women in Canada that respects the right of women to exercise voluntary, specific and informed consent to medical interventions, as this right has been defined by Canadian law. Governments should instead focus their efforts upon those non-intrusive means available to reduce the risk of perinatal HIV transmission. Any subsequent move to a policy that infringed upon that right would have to be carefully justified by government, with reliable evidence as to the relative ineffectiveness of these alternative, less intrusive means.

Given the long-term risks and unknowns associated with antiretroviral prophylaxis for pregnant women and their foetuses, it is at least possible that at some future date a government will find itself subject to a negligence action by an individual for whom those risks materialized, resulting in serious injury.

One final point warrants discussion in relation to the question of informed consent. It emanates from principles of negligence law rather than the Charter, and concerns the scope of information provided in relation to those interventions available to minimize the risk of perinatal HIV transmission.

There is a tendency in many of the current policies and guidelines regarding the HIV testing of pregnant women to focus upon the results of PACTG 076 and the subsequent success of antiretroviral prophylaxis as *the* reason to undergo HIV testing. While this focus is perhaps understandable in view of the dramatic results of that study and subsequent experience, it is not consonant with the requirements of the doctrine of informed consent as established by Canadian law. As discussed at length above, the doctrine of informed consent requires that patients be provided with "sufficient information to evaluate the risks and benefits of the proposed treatment and other available options."[305] In the context of HIV testing for pregnant women, this standard requires that women receive both the necessary information to meet generally applicable standards for informed consent to HIV testing (as argued above) as well as balanced information to explain the special importance of HIV during pregnancy in view of *all* interventions available to reduce the risk of perinatal HIV transmission, including, but not limited to, antiretroviral prophylaxis.

The legal importance to governments of ensuring that this standard is met is best understood with reference to a hypothetical. Given the long-term risks and unknowns associated with antiretroviral prophylaxis for pregnant women and their foetuses, it is at least possible that at some future date a government will find itself subject to a negligence action by an individual for whom those risks materialized, resulting in serious injury. Faced with such an action, a government whose HIV testing policy for pregnant women was skewed so as to

[305] *Malette*, supra, note 79 at 286.

persuade pregnant women to reach a pre-determined result – ie, acceptance of HIV testing and, if positive, antiretroviral prophylaxis – would find itself legally vulnerable. Rather, it is a balanced approach that is required. This is particularly so in view of the experimental nature of antiretroviral prophylaxis in that, as noted, only ZDV has received regulatory approval in Canada for use during pregnancy to reduce the risk of perinatal HIV transmission, and the effectiveness of even ZDV in women who do not meet the PACTG 076 entry criteria remains under study.

Recommendation

4. ***Provinces and territories should require that physicians obtain the voluntary, specific and informed consent of pregnant women before proceeding with HIV testing. In particular, physicians must ensure that during pre-test counselling:***

    (1) women are provided with sufficient information (which may include both written and oral information, and may involve health care providers other than physicians) to understand the purposes, risks, harms and benefits of being tested or not tested, for them and for their foetuses;
    (2) the information provided meets generally applicable standards for informed consent to HIV testing; and
    (3) the information provided includes a fair and accurate summary of all interventions available to reduce the risk of perinatal HIV transmission, including, but not limited to, antiretroviral prophylaxis.

Due care on the part of governments similarly requires that women receive all standard components of post-test counselling.

Having accepted that there is no legally justifiable basis upon which to deprive women of the standard components of pre-test counselling, due care on the part of governments similarly requires that women receive all standard components of post-test counselling. It is equally arguable that a failure to meet that standard might be characterized as sex discrimination in violation of section 15(1) of the Charter.

Recommendations

5. ***Provinces and territories should require that following receipt of HIV test results, physicians provide post-test counselling in accordance with generally applicable standards for HIV testing.***

6. ***Provinces and territories should support the effectiveness of HIV testing policies for pregnant women with:***

    (1) outreach to, and education of, physicians and other involved health care providers to:
        (i) increase awareness of the availability and effectiveness of medical interventions to minimize the risk of perinatal HIV transmission; and
        (ii) ensure adherence to the prescribed HIV testing policy;
    (2) appropriate compensation to physicians and other involved health care providers to support adherence to the prescribed HIV testing policy, including, in particular, the delivery of comprehensive pre-test counselling to fulfil informed consent requirements;

(3) outreach to, and education of, pregnant women to increase awareness of the availability of HIV testing and the availability and effectiveness of medical interventions to minimize the risk of perinatal HIV transmission;

(4) access to appropriately specialized care and treatment to minimize the risk of perinatal HIV transmission for all pregnant women who test HIV-positive; and

(5) evaluation of the policy's effectiveness at minimizing the number of perinatal HIV transmissions in Canada, and implementation of necessary changes.

Should the HIV Testing of Pregnant Women Be Characterized As "Routine"?

The object of this section is to identify the different reasons for characterizing HIV testing of pregnant women as "routine," to clarify and distinguish between the implications of doing so, and to make recommendations for its future use that are consistent with the current state of Canadian law as canvassed elsewhere in the paper.

Reasons for "Routine" Testing

One reason underlying characterization of HIV testing during pregnancy as "routine" is to communicate, to physicians and to patients, the prevailing view within the medical community that the presence of HIV infection should be diagnosed as early as possible in pregnancy to enable physicians to deliver appropriate care and treatment to their HIV-positive patients. An important part of this care and treatment is providing HIV-positive pregnant women with access to the full range of medical interventions available to minimize the risk of perinatal HIV transmission (including, but not limited to, antiretroviral prophylaxis). Equally important – although often overshadowed by the issue of perinatal HIV transmission – is the opportunity to provide appropriate access to HIV-related care and treatment to preserve and promote the health of the mother. Early diagnosis of HIV infection and appropriate access to related care and treatment is integral to the delivery of an appropriate standard of medical care to HIV-positive women (and men) irrespective of pregnancy. In the context of pregnancy, moreover, there are special concerns for maternal health that must be addressed. For example, infections such as chorioamnionitis may evolve more rapidly in HIV-positive pregnant women, requiring early and active medical management.[306]

With respect to physicians, the suggestion is that use of the term "routine" is an effective way to dislodge apparent reluctance in practice, or even intransigence, to offering HIV testing to all pregnant women despite the existence of policy statements, recommendations and guidelines issued by professional associations, governments, and other interested bodies. As concluded by the IOM Committee, for example:

> In several states, the overwhelming majority of providers agreed in principle with offering HIV testing to all patients, but in practice 50% to 75% actually did so (eg, Wisconsin, Colorado, Minnesota, North Carolina, and Connecticut) (Herczfeld, 1995; Nyquist,

[306] CFPC. *A Comprehensive Guide*, supra, note 220 at 24.

> undated abstract; Wisconsin AIDS/HIV Program, 1997; Mills et al., 1998; Walter et al., 1998). Instead, actual testing practice was based upon providers' assessment of maternal risk or the providers' perception of maternal risk.[307]

In Canada, the practices of physicians may be confused by policies that are somewhat in conflict. While the CMA Guidelines require that HIV testing be offered to all pregnant women, drawing no distinction between them on the basis of risk factors, for example, the Canadian College of Family Physicians advises that HIV testing should be *offered* to all pregnant women but *recommended* to women using injection drugs and women who have recently arrived in Canada from countries where HIV is pervasive.[308]

There is a subtle but important difference associated with saying that HIV testing should be routine for all pregnant women, as opposed to saying that it should be universally offered. Use of the word "routine" shifts the emphasis from merely offering the test to recommending that it be done as an important element of appropriate prenatal care for all women.[309] Put another way, given a policy, recommendation or guideline that HIV testing be offered to all women, a physician might extend the offer but not express the professional judgment to his or her patient that testing is appropriate. Use of the term "routine," on the other hand, effectively removes from that physician the scope for any professional judgment as to whether a woman's risk factors are such that HIV testing is unnecessary. Given the conclusions of many recent studies that patients' acceptance of testing is higher when providers recommend it or strongly recommend it,[310] the potential for increased test uptake with "routine" testing is clear.

With respect to patients, proponents of routine testing argue that it assists patients in overcoming significant barriers to accepting the test. Minkoff and Willoughby, for example, assert that:

> It is specifically worth noting that a woman is asked to consent to testing after being counselled about modes of transmission in essence being told that only unsafe sex or needle use would put her at risk. Thus, a patient who might be interested in taking the test but not sharing her risk-taking background might feel compelled to eschew the test to ensure her privacy. ... signing a consent form that would allow for the test would simultaneously provide *de facto* confession of unsafe sex.
>
> When an informed right of refusal approach is used instead of written informed consent, a psychological burden is shifted from those who would choose to test to those who would refuse in essence, requiring a special effort to say no. The confessional nature of testing (implicitly acknowledging risk behaviour through the act of signing consent) would be removed. Although some patients would choose to opt out of testing even if they had to assert their rights to do so, the percentage of individuals tested would undoubtedly increase dramatically.[311]

There is a subtle but important difference associated with saying that HIV testing should be routine for all pregnant women, as opposed to saying that it should be universally offered.

[307] IOM Committee, supra, note 10, ch 6 at 17.

[308] CMA Guidelines, supra, note 89 at 17; and CFPC, supra, note 220 at 5.

[309] IOM Committee, supra, note 10, ch 2 at 3.

[310] Ibid, ch 6 at 18, 21, and 22.

[311] H Minkoff, A Willoughby. Pediatric HIV Disease, Zidovudine in Pregnancy, and Unblinding Heelstick Surveys. *Journal of the American Medical Association* 1995; 274(14): 1165-1168 at 1166.

Characterization of a test as "routine" does not relieve physicians of their obligation to secure the voluntary, specific and informed consent of women to the diagnostic intervention.

As with physicians, moreover, characterizing HIV testing as "routine" may better communicate to patients the importance of HIV testing to appropriate prenatal care for all women than do current policies.

Implications of "Routine" Testing

Part of the difficulty in analyzing the impact of characterizing HIV testing as "routine" is that the term appears to have no fixed meaning. In this paper, the term has been defined to mean adding the HIV test to the standard laboratory requisition form used to conduct those prenatal tests generally undertaken as part of prenatal care.

From a legal perspective, characterization of a test as "routine" does not relieve physicians of their obligation to secure the voluntary, specific and informed consent of women to the diagnostic intervention (obligations that have been canvassed in detail above). This fact is not well understood by physicians, however. Indeed, anecdotally, it appears that the reverse is true: many physicians mistakenly believe that they need not secure the informed consent of pregnant women to those tests listed on the standard laboratory requisition form used in prenatal care because they are so-called "routine" tests. As a practical matter, it is likely that this mistaken belief has never been the subject of open controversy (in litigation or otherwise) because the personal, social and legal consequences associated with being confronted with a positive test result in response to the current standard prenatal tests are generally insignificant in comparison with those presented by an HIV-positive test result. With respect to syphilis, for example, safe and easily implemented treatment will cure a pregnant woman and prevent perinatal transmission nearly 100 percent of the time.[312] As explored in detail elsewhere in this paper, however, the personal, social and legal consequences associated with receiving an HIV-positive test result (especially during pregnancy) are myriad and far-reaching.

A significant problem with an HIV testing policy for pregnant women that characterizes the test as "routine" is the increased likelihood that women will be tested for HIV without their informed consent.

Even without characterizing HIV testing as "routine," there is significant cause for concern that women receive inadequate information to exercise their right to informed consent to HIV testing. For example:

- a recent study of physicians in Western Australia revealed that 74 percent of the physicians questioned did not believe that patient consent was always necessary before ordering HIV tests;[313]
- a US study found that only 17 percent of health care providers state that they use any HIV counselling and testing guidelines, that 75 percent of health care providers spend less than five minutes in pre-test counselling, and that 11 percent of health care providers assume that consent is implied by the patient visit;[314] and
- in British Columbia and Québec, women have reported being tested for HIV without the benefit of counselling and without providing their informed consent to the test.[315]

A significant problem with an HIV testing policy for pregnant women that characterizes the test as "routine," therefore, is the increased likelihood that women will be tested for HIV without their informed consent – in effect, mandatorily. Such a policy would be vulnerable to legal challenge for the reasons set out above. It therefore seems reasonable to avoid use of the term "routine" to describe the HIV testing of pregnant women in Canada.

312 KI Acuff, RR Faden. A history of prenatal and newborn screening programs: Lessons for the Future. In: *AIDS, Women and the Next Generation* (RR Faden et al, eds). New York: Oxford University Press, 1991, at 59-93.

313 RS Magnusson. Testing for HIV without specific consent: A short review. *Australian and New Zealand Journal of Public Health* 1996; 20(1): 57-60.

314 Phillips et al, supra, note 219.

315 Personal communications between L Shap and M Summers of the Centre for Positive Women in Vancouver (6 August 1997) and L Shap and Daniella R Boulay of the Centre for AIDS Services in Montreal (9 December 1997).

Use of the term "routine" in relation to counselling for HIV testing – for example, as in the commonly used phrase "routine counselling/voluntary testing" – does not present the problems canvassed above.

Alternatives to Characterizing HIV Testing as "Routine"

Improving women's access to HIV testing during pregnancy is a worthy objective. Appropriately offered, HIV testing increases the range of choices available to pregnant women, or women considering pregnancy, to protect their own health and that of the foetus they may carry. It is important, therefore, to carefully consider any benefits associated with "routine" testing to determine whether these might somehow be preserved in the absence of the designation itself. There are two issues to explore in this regard:

- communicating the standard of care to physicians and patients; and
- facilitating physicians' adherence to the relevant standard of care.

Communicating the standard of care

Assuming that the underlying rationale for characterizing prenatal HIV testing as "routine" is to communicate the importance of HIV testing for all women during pregnancy, then a reasonable alternative is to make this recommendation to the patient explicit. The recommendation would be made as part of the informed consent process, together with an explanation of the reasons for the recommendation including, in particular, the facts that:

- it is important for all pregnant women to know their HIV status so that, if positive, they may have access to the full range of appropriate care and treatment to benefit their own health and that of their foetus; and
- evidence indicates that women in Canada may be at risk for HIV infection without knowing it.

Such an approach provides women with the necessary information to overcome the "confessional nature" of testing described above and to better inform their basis for decision-making in relation to this important test. It is also more consistent with the current legal paradigm for medical decision-making, as established by Canadian courts, which places responsibility for decision-making with the fully and appropriately informed patient. By contrast, seeking to influence women's acceptance of testing merely by characterizing the test as "routine" may be challenged as paternalistic and subtly coercive in that the underlying message is: "All women take this test, so you should too; there is no need to ask why."

Seeking to influence women's acceptance of testing merely by characterizing the test as "routine" may be challenged as paternalistic and subtly coercive.

This shift from a non-directive to a directive approach to HIV testing for pregnant women may fairly be viewed as a step toward "normalization." Normalization may be defined as

> [t]reating HIV/AIDS more like other infectious diseases for which early diagnosis is essential for appropriate therapeutic and preventive measures, within the requirements of informed consent and respect for confidentiality.[316]

In the context of concerns about perinatal HIV transmission, two British authors support "normalization," but only so far as is necessary to free health care

[316] DeCock and Johnson. From Exceptionalism to Normalisation: A Reappraisal of Attitudes and Practice Around HIV Testing. *British Medical Journal* 1998; 316: 290-293 at 290.

Diminishing the stigma associated with being tested for HIV must not be confused with decreasing the stigma associated with testing HIV-positive.

providers to overcome the reticence (based upon concerns about involuntary testing, stigmatization, and discrimination) to advocate HIV testing for pregnant women.[317] They emphasize that even normalization to this limited degree ought not to be undertaken without strong measures to protect the rights of individuals to informed consent and confidentiality in the context of HIV testing, and to combat the stigmatization and discrimination that are the source of most adverse reactions to HIV testing.[318] In January 1998, US AIDS activists, public health officials, and others are reported to have reached a similar conclusion, emphasizing that AIDS exceptionalism may only be curtailed in the context of efforts to reduce the need for a special approach in the first place, ie, by addressing issues of stigma and social risk.[319] Diminishing the stigma associated with being tested for HIV, in other words, must not be confused with decreasing the stigma associated with testing HIV-positive.

Facilitating physicians' adherence to the relevant standard of care

The institution of educational programs, targeting both physicians and patients, is necessary to achieve an effective program of voluntary and informed HIV testing of pregnant women.

With respect to physicians, the main benefit associated with characterizing HIV testing as routine is improving compliance with a policy requiring that HIV testing be offered to all pregnant women rather than only those presenting with identified risk factors.

Faced with a similar problem in the context of the Commission of Inquiry on the Blood System in Canada, Commissioner Krever recommended that the licensing bodies of the medical profession require in their standards of practice that treating physicians obtain the informed consent of patients to the administration of blood and blood products. Such a recommendation has two important effects. First, it clearly articulates the appropriate standard of practice for physicians. Second, it provides a legal mechanism through which patients may hold physicians accountable for a failure to meet that standard, through the complaints adjudication and discipline processes of the licensing bodies.

Clarification of the legal standard is unlikely to prove sufficient, however. As concluded by a recent Manitoba study, the institution of educational programs, targeting both physicians and patients, is necessary to achieve an effective program of voluntary and informed HIV testing of pregnant women.[320]

Two recent studies considering the efficacy of alternative strategies to improve physicians' testing practices (albeit not HIV-specific) have concluded that the dissemination of guidelines to physicians is a relatively weak intervention to achieve this objective in and of itself.[321] This finding raises the further question whether it would be appropriate to amend the standard laboratory requisition form for prenatal testing to include a tick box for HIV testing so as to improve physician compliance with a government-initiated policy that all pregnant women (or women considering pregnancy) be offered HIV testing on the basis of voluntary, specific and informed consent.

Favouring such an approach, both the studies referred to above emphasized the potential effectiveness of strategies to improve physician testing practices that employ more than one intervention, including, in particular, the combination of testing guidelines and laboratory requisition form changes:

317 Ibid at 291.

318 Ibid at 292.

319 IOM Committee, supra, note 10, ch 2 at 8-9.

320 J Embree et al. HIV-1 Testing in Pregnancy: The Manitoba Experience. Abstract no 449P. 7th Annual Canadian Conference on HIV/AIDS Research, 1998.

321 C van Walraven et al. Effect of Population-Based Interventions on Laboratory Utilization. *Journal of the American Medical Association* 1998; 280(23): 2028-2033 at 2032; and DH Solomon et al. Techniques to Improve Physicians' Use of Diagnostic Tests: A New Conceptual Framework. *Journal of the American Medical Association* 1998; 280(23): 2020-2027 at 2025-2026.

> Exercises to develop consensus among providers or other educational meetings were common but relatively weak interventions. Such interventions can be viewed as targeting attitudes or knowledge (predisposing factors). Often a consensus conference led to the development of guidelines for appropriate testing, which were then disseminated as the intervention. Mozes et al. found distribution of guidelines ineffective, but when combined with a change in the laboratory ordering form requiring justification of the test to be performed, ordering volume was reduced. Other selected studies also documented that combining a consensus conference with an audit was effective. Traditional education, aimed at predisposing attitudes or factors, was a weak intervention, but necessary and effective when coupled with strategies to reinforce attitudes or enable the desired behaviour.[322]

The potential effectiveness of changes to laboratory requisition forms, however, is the very reason they must be introduced with care:

> Environmental or administrative interventions can be incredibly effective at little expense; however, they must be chosen carefully. ...
>
> Finally, enabling factors that facilitate the preferred diagnostic behaviour through blocking improper test orders or defaulting to the intended practice are most potent.[323]

Some jurisdictions have amended their prenatal laboratory requisition forms so as to create a presumption of consent to HIV testing on the part of pregnant women in the absence of an express refusal.

Some jurisdictions have amended their prenatal laboratory requisition forms so as to create a presumption of consent to HIV testing on the part of pregnant women in the absence of an express refusal, evidenced by a ticked box with a prompt asking whether HIV testing has been refused. Using this laboratory requisition form, a pregnant woman who did not expressly refuse HIV testing (or whose refusal was not properly documented) would be tested by default, regardless of whether she gave her informed consent to the test. There are two important problems presented by such an approach. First, it may be criticized as indirectly coercive because it fails to provide women with a genuine option to refuse testing. It has been said that the psychology of this approach is such that few patients will sign a document insisting that a standard diagnostic tool be withheld. Second, it facilitates rather than blocks the conduct of an HIV test improperly ordered without informed consent (ie, unauthorized by the patient), increasing the chances that pregnant women will be tested on this basis. Such an approach would therefore be vulnerable to legal challenge for the reasons set out above.

One alternative approach would be to amend the standard prenatal laboratory requisition form to include HIV testing, but supplement the amendment to include specific prompts requiring physician justification for the test in accordance with the appropriate standard (ie, the presence of voluntary, specific and informed consent, as defined elsewhere in this paper). There is some evidence in the relevant medical literature that requirements for physician justification of orders for laboratory testing can prove effective. One study, for example, concluded

[322] Solomon et al, ibid at 2025-2026.

[323] Ibid at 2026.

> that when the responsibility is making a "what for" decision in ordering common laboratory tests is imposed, a modification of clinician behaviour is observed. A significant reduction in common laboratory testing is apparent even in the least restricted mode, suggesting that documentating [sic] the rationale for a given test generates restraints.[324]

At the same time, it is important to note that the subsequent Ontario study referred to above suggested that this was among a group of studies "limited by small numbers of patients and physicians" and therefore yielding findings of uncertain validity and generalizability.[325]

Yet another alternative approach would be to develop a separate laboratory requisition form specific to HIV testing during pregnancy, perhaps as a companion requisition form to the current standard form for all other prenatal tests.

Should a province or territory wish to consider amending its standard prenatal requisition form to somehow incorporate HIV testing using either of the alternatives identified above, it would be prudent to carefully evaluate the effectiveness of the proposed change or changes with a view to assessing whether the associated risks (ie, of facilitating unauthorized HIV testing conducted without informed consent, presenting serious and far-reaching consequences for those women whose results are positive) outweigh the benefits, with the vulnerability to legal challenge that this would imply for the reasons set out above.

Provinces and territories should not designate HIV testing of pregnant women as "routine."

Recommendations

7. ***Provinces and territories should avoid designating HIV testing of pregnant women as "routine."***

8. ***Provinces and territories should require physicians to ensure that during pre-test counselling, women are advised that HIV testing is recommended for all pregnant women because:***

   (1) it is important for all pregnant women to know their HIV status so that, if positive, they can have access to the full range of appropriate care and treatment to benefit their own health and that of their foetus; and

   (2) evidence indicates that women in Canada may be at risk of HIV infection without knowing it.

9. ***The licensing bodies for physicians should establish express standards of practice for the conduct of HIV testing for pregnant women and women considering pregnancy, and take all steps necessary to implement, monitor and enforce compliance with these standards.***

10. ***Provinces and territories that wish to support their HIV testing policies with amendments to their laboratory requisition forms:***

    (1) should avoid "default" testing (ie, amendments that would permit testing to proceed in the absence of a patient's express refusal to consent to testing); and

    (2) should carefully investigate and assess the effect of all other proposed amendments upon physician practices, to ensure that they

[324] M Novich et al. The laboratory test justified: An effective means to reduce routine laboratory testing. *American Journal of Clinical Pathology* 1985; 84: 756-759 at 758-759.

[325] van Walraven et al, supra, note 318 at 2028.

effectively block improper test orders (ie, those ordered in the absence of patients' voluntary, specific and informed consent).

11. ***Provinces and territories should support HIV testing policies for pregnant women with strong measures:***

    (1) to protect the right of pregnant women to exercise informed consent to HIV testing;
    (2) to protect the right of pregnant women to confidentiality in relation to their HIV test results; and
    (3) to combat the stigmatization and discriminatory treatment of all persons diagnosed as HIV-positive.

What Added Supports Are Necessary?

The *Food and Drugs Act* and Regulations

An important source of support for the effectiveness of provincial and territorial policies for the HIV testing of pregnant women in Canada (as well as the treatment of HIV-positive pregnant women with antiretroviral prophylaxis) is the federal government through the exercise of its regulatory responsibilities under the *Food and Drugs Act* over antiretroviral drugs used during pregnancy. As noted above, current approaches to antiretroviral prophylaxis during pregnancy is not limited to ZDV (which has received approval for use during pregnancy to reduce the risk of perinatal HIV transmission), but includes many drugs that have not been approved for such use. In relation to all these drugs, there is a paucity of data regarding the short- and long-term effects in women and their foetuses.

There are three important areas to explore in this context:

(1) federal regulatory authority over the "off-label" use of antiretroviral drugs during pregnancy;
(2) federal responsibility for post-marketing surveillance of all antiretroviral drugs used during pregnancy; and
(3) federal responsibility to communicate information regarding the risks associated with the use of antiretroviral drugs during pregnancy.

Federal responsibility for "off-label" use

The mandate of the federal Minister of Health and his delegates, pursuant to the *Food and Drugs Act* and regulations is "to protect the public against health hazards in the sale and use of ... drugs ...."[326] This mandate includes the very specific objective of ensuring the "judicious use" of drugs – ie, "identify[ing] and control[ling] dangers to the health of Canadians from drugs or their unwise use ...."[327] The Act defines the term "drug" broadly, to include:

> any substance or mixture of substances manufactured, sold or represented for use in ... the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals, ...[328]

[326] Foreword, Department Consolidation of the *Food and Drugs Act* and the Food and Drug Regulations. Ottawa: Minister of Supply and Services Canada, 1981, at (iv).

[327] CL Turriff, J Berger, RE Overstreet. Program Roles and Responsibilities, Resources, Systems and Procedures (Technical Report No. 9). *Program Evaluation Study of the Drug Safety, Quality and Efficacy Program, Health and Welfare Canada.* Ottawa: Program Audit and Review Directorate, Health and Welfare Canada, 25 May 1989, at 1-2.

[328] *Food and Drugs Act*, supra, note 64 at s 2.

Prohibitions established by the *Food and Drugs Act* prevent a manufacturer from labeling, packaging, treating, processing, selling, or advertising a drug so as to encourage or invite a use for which it has not received a notice of compliance.[329] By contrast, the federal government's authority and responsibilities under the Act are not confined to approved uses of drugs that have received notices of compliance, but extend to all known uses of all "drugs" as defined by the Act. The breadth of this authority is necessary for the federal government to police compliance with prohibitions. In other words, just because many of the antiretroviral drugs taken during pregnancy are not specifically approved for use during pregnancy to minimize the risk of perinatal transmission does not mean that the federal government is relieved of its responsibilities under the *Food and Drugs Act* and regulations if it is aware that these drugs are used in this context (as, indeed, it must be in view of widely reported uses in the relevant medical literature).

A court would conclude that a duty of care exists on the part of the federal government in relation to all antiretroviral drugs that have received notices of compliance.

Considering the legal principles governing negligence on the part of public authorities, as canvassed above, it is reasonable to expect that a court would conclude that a duty of care exists on the part of the federal government in relation to all antiretroviral drugs that have received notices of compliance. The effect of such a finding would be to impose upon the Minister of Health (and his delegates, including, in particular, the HPB) a duty at the operational level to use reasonable care in the exercise of his authority under the *Food and Drugs Act* and regulations to ensure the safety and efficacy of these drugs when used by Canadians.

As noted above, Commissioner Krever was highly critical of the HPB's failure in the 1980s and 1990s to take timely and appropriate steps in the exercise of its regulatory authority over blood and blood products as "drugs" (within the meaning of the *Food and Drugs Act*) to minimize the associated risk of HIV transmission. In this context, therefore, it seems reasonable to emphasize the need for the federal government (through the Minister of Health and, specifically, the HPB) to fully interpret and fulfil its mandate under the Act and regulations in relation to all antiretroviral drugs used during pregnancy.

Federal responsibility for post-marketing surveillance

In order to exercise its regulatory mandate under the *Food and Drugs Act* and regulations in relation to antiretroviral drugs used during pregnancy, it is essential that the federal government continually assess the risks associated with (or otherwise relevant to) their use during pregnancy and "determine whether the appropriate management of these risks includes a regulatory component."[330] It can only do so on the basis of current and accurate information.

As concluded by Commissioner Krever in his *Final Report*, this information should be garnered from the following sources:

- verification and validation of the results of tests and studies submitted by manufacturers;
- constant review of the scientific and medical literature; and
- constant monitoring of adverse reactions.[331]

With respect to the monitoring of adverse reactions associated with the use of antiretroviral drugs, it is clear (based upon the discussion in the chapter on

[329] Ibid at s 9.

[330] Krever Commission, supra, note 71, vol 3 at 1065.

[331] Ibid.

Medical Parameters of the Policy Debate above) that the federal government cannot take a passive approach, relying upon spontaneous reporting to generate all the information it requires. Rather, it must develop an active surveillance plan to look for sensitive indicators of possible problems.[332] It seems clear, moreover, that such a plan (which might include provincial and territorial participatiion) should not be limited to mother–infant pairs who have undergone antiretroviral prophylaxis, but should encompass all HIV-positive individuals to whom these drugs are administered. The information generated may reasonably be expected to improve the care and treatment available to both groups of patients.

Finally, as recommended by Commissioner Krever in his *Final Report*, an essential aspect of active post-marketing surveillance includes establishing communication links with groups of persons who use particular products, provincial/territorial and national public health authorities, and regulatory authorities in other countries.[333]

An essential aspect of active post-marketing surveillance includes establishing communication links with groups of persons who use particular products, provincial/territorial and national public health authorities, and regulatory authorities in other countries.

Federal government's responsibility to communicate information regarding risks

In response to the information garnered on an ongoing basis regarding risks associated with the use of antiretroviral drugs during pregnancy, the HPB "must determine whether the appropriate management of the risk includes a regulatory component"[334] and, if so, take such action. One area of regulatory action of particular importance is the communication of new information about associated risks to physicians prescribing the drugs and to their patients.

In many cases, therapeutic drugs cannot be rendered completely safe; their use will always present the risk of associated adverse effects. The ongoing communication of accurate information about the nature and extent of such risks is therefore essential because it provides the background against which physicians and their patients may enter into an informed dialogue and decision-making process with respect to the relative risks and benefits in a given situation.

The federal government may ensure the timely and comprehensive communication of risks associated with the use of antiretroviral drugs through a number of vehicles that may be used concurrently or, alternatively, depending upon the circumstances. These include: the labeling of drugs to provide "adequate directions for use," defined by HPB guidelines to include "such cautions and warnings as may be necessary for the proper and recommended use of the drug";[335] the dissemination of "Information Letters" to physicians, consumers, and other relevant bodies and individuals; participation in the development and dissemination of treatment guidelines, and the commissioning of expert guidance on hazards related to drugs in use.[336] The overall objective of such communications is to prevent the public from health hazards attributable to the use of therapeutic drugs.

Recommendation

12. The federal government should engage in the active regulation of all antiretroviral drugs used during pregnancy regardless whether their approved uses include reducing the risk of perinatal HIV transmission, as

[332] Lexchin, supra, note 70 at 22; Moore et al, supra, note 73 at 1572; and ibid at 1069.

[333] Ibid.

[334] Ibid at 1066.

[335] HPB, *Drugs Directorate Guidelines: Labelling of Drugs for Human Use*. Ottawa: Health and Welfare Canada, 1989, at 17-18. Past practices of the HPB demonstrate that product labeling is not restricted to approved uses. See, for example, the 1998 Product Monograph for labeling of Imitrex (a drug approved for the treatment of migraines) in relation to the treatment of cluster headaches, a non-approved use under the *Food and Drugs Act* and regulations: PRECAUTIONS: Cluster Headache: There is insufficient information on the efficacy and safety of sumatriptan in the treatment of cluster headache, which is present in an older, predominantly male population. The need for prolonged use and the demand for repeated medication in this condition renders the dosing information in applicable for cluster headache. *Compendium of Pharmaceuticals and Specialties*. Thirty-third edition. Ottawa: Canadian Pharmacists Association, 1998, at 754.

[336] For example, in 1991 the HPB's Drugs Directorate commissioned a Canadian HIV expert clinician-researcher to author a monograph for the guidance of Canadian physicians administering HIV therapy. The monograph was called "Anti-Retroviral Treatment: Side Effect Management," National Health and Welfare DD-91-4. One drug discussed in the monograph was Didanosine (ddI), which was not approved for use in Canada at that time but was in use through a special pre-market compassionate use protocol. The hazards were nonetheless substantial, and newly evolving side effects warranted special attention and communication to physicians. Personal communication between L Stoltz and Dr Michèle Brill-Edwards, former Assistant Director – Medical Bureau of Human Prescription Drugs, HPB, 28 January 1999.

is mandated under the* Food and Drugs Act *(Canada) and Regulations. In particular it should:

(1) take all necessary steps to continually assess the risks associated with the administration of those antiretroviral drugs used during pregnancy (for both women and the foetuses they carry), including the development and implementation of an active surveillance plan to monitor all adverse reactions;

(2) further to (1), include mandatory reporting of all adverse reactions to antiretroviral drugs used during pregnancy, experienced over time by HIV-positive women and the foetuses they carry;

(3) determine whether the appropriate management of identified risks associated with the use of antiretroviral drugs during pregnancy requires regulatory action and, if so, take all necessary steps to that end, including the communication of the nature and extent of all risks associated with the administration of antiretroviral drugs during pregnancy; and

(4) in order to facilitate the actions described in (1) and (2) above, ensure effective communication links with physicians prescribing antiretroviral drugs, consumers, provincial/territorial health authorities, and regulatory authorities in other countries.

The most effective and least intrusive way to reduce the incidence of perinatal HIV transmission in Canada is to implement sustained measures to prevent HIV transmission to women in the first place.

Continued Importance of Primary Prevention

The most effective and least intrusive way to reduce the incidence of perinatal HIV transmission in Canada is to implement sustained measures to prevent HIV transmission to women in the first place. To that end, it would be reasonable to complement the recommendations set out above with reference to the need to counsel men about the need for HIV testing themselves in view of the risk of sexual and perinatal HIV transmission. Those men who are HIV-positive should be further counselled to refer for counselling and testing sexual partners who may be pregnant or considering pregnancy.[337]

Recommendations

13. Federal, provincial and territorial governments should focus on effective and sustained primary prevention measures to reduce the number of HIV-positive women and men in Canada.

14. Provincial and territorial governments should consider requiring physicians to:

(1) offer HIV testing to men considering fathering a child, in a pregnancy on the basis of voluntary, specific and informed consent; and

(2) counsel those men with HIV-positive test results to refer for counselling and HIV testing sexual partners who may be pregnant or considering pregnancy.

[337] See, for example, supra, note 22. See also CN Hudson, L Sherr. Antenatal Testing in Europe. *The Lancet* 1997; 350(13 December 1997).

Appendix

Current Approaches to the HIV Testing of Pregnant Women by Canadian Provinces and Territories

Newfoundland

Beginning in 1992, Newfoundland recommended that all pregnant women have an HIV test and that physicians discuss the option of HIV testing with their patients during their prenatal visits. As of 1 April 1997, the Newfoundland Public Health Laboratory implemented a policy of treating the HIV test as routine, meaning that when physicians order "routine prenatal screening" (or use words to that effect), an HIV test is carried out in addition to tests for syphilis, rubella, and hepatitis B. The relevant communication to physicians emphasized that:

> As is the case for all tests and procedures, physicians should ensure their patients know what tests are being done and that they have consented. As well, physicians should be aware of tests ordered on their behalf by a regional nurse. Even if the nurse orders the tests, the responsibility still falls on the physician to ensure the patient is aware of what tests are being done.[1]

The new policy requires physicians to specifically state on the requisition if a patient does not consent to any of the tests normally included in

[1] *NLMA Communiqué*, January/February 1997, at 8.

routine testing, such as HIV testing. Alternatively, physicians may requisition specific tests individually rather than use the term "routine prenatal screening."

It is clear, in other words, that characterization of the HIV test as routine does not abrogate a physician's obligation to secure informed consent of his or her patient to the test. The communication endorses the CMA Guidelines as a guide for physicians with respect to prenatal testing procedures, mother-to-child transmission, and pre-test counselling.

Prince Edward Island

In Prince Edward Island, there is no formal policy for testing of pregnant women, but it is recommended that any woman who presents with risk factors for HIV be tested for HIV. Pregnant women who present with risk factors are counselled as to the positive and negative effects of HIV testing, offered the option of being tested, and asked to provide informed consent.[2] Recently, a recommendation was put forward by the Community Medical Health Committee that PEI adopt a different method of screening pregnant women for HIV. The form that the screening would take (ie, mandatory, routine, or voluntary) was not addressed.

Nova Scotia

The May 1994 "Guidelines for Antenatal Screening and Testing" established by the Reproductive Care Program of Nova Scotia recommended that HIV testing of pregnant women be carried out "as clinical judgment dictates" and that HIV testing of pregnant women requires informed consent and appropriate pre- and post-test counselling in accordance with the CMA Guidelines.[3] The guidelines were premised on the assumption that pre- and post-test counselling, in conjunction with education programs, would facilitate self-identification of those women at risk of HIV infection.

These guidelines are presently under revision to include a new recommendation that HIV testing be offered to all pregnant women and that "women who decline testing in the first trimester or who are known to engage in activities that put them at risk for contracting HIV should be offered testing again in conjunction with other blood work generally done at 24-28 weeks gestation."[4] There is no suggestion that the existing recommendation regarding informed consent and the need to adhere to the CMA Guidelines will be altered.

New Brunswick

New Brunswick has no formal policy for the HIV testing of pregnant women. Whether a woman is tested and how the testing is conducted will vary from region to region.

Outside the reproductive health clinic setting, testing of pregnant women is done by physicians on a discretionary basis. Pre- and post-testing counselling may be provided, and it is believed that some

[2] Communication with Dr Sweet on 1 August 1997.

[3] Reproductive Care Program of Nova Scotia. *Guidelines for Antenatal Laboratory Screening and Testing*, May 1994.

[4] *RCP Newsletter*, Spring 1998.

physicians may be testing women for HIV as part of the routine prenatal tests without their informed consent.

Based on a seroprevalence study conducted by the University of New Brunswick Faculty of Nursing that showed a seroprevalence of 4.1 per 10,000 pregnant women, it has been suggested that doctors offer HIV testing to all pregnant women. As of 1 August 1997, no HIV-positive pregnant woman had been treated prophylactically.[5]

Québec

In May 1997, Québec introduced the "HIV infection and pregnancy – Intervention programme" to govern HIV testing to reduce perinatal HIV transmission. The program requires HIV testing to be offered to all pregnant women and all women intending to conceive. The informational brochure for physicians emphasizes that:

> The programme's goal is to have all pregnant women and those who are intending to conceive receive relevant information on the HIV testing and zidovudine treatment (ZDV or AZT). They will then be given the opportunity to undergo HIV testing. **This information offer is universal.** Testing itself is **voluntary** and is carried out with the woman's consent.[6] [Emphasis in original.]

The brochure further emphasizes that counselling regarding HIV testing should begin as soon as possible in a pregnancy to ensure that an HIV-positive woman has available to her the entire range of choices regarding continuation of the pregnancy (including, specifically, the possibility of its termination).

The Intervention Programme provides physicians with comprehensive guidelines to assist in the counselling process. These are similar in content to the CMA Guidelines.

The program initiated the use of a "specific anti-HIV test prescription" form to requisition the test. This form is given to the pregnant woman so that she can decide for herself if she wishes to under HIV testing (having had an opportunity to consider the matter after leaving the physician's office). Use of this form also enables priority handling of the test by the laboratory so that results are received more quickly. Even if this specific form is not used, the program specifies that a separate HIV-specific requisition form be used "so that the woman can decide for herself whether or not to be tested [for HIV] without jeopardizing the prenatal blood screening."[7]

Ontario

Ontario has shifted its policy from a recommendation that "HIV testing *should be discussed* with all pregnant women and all women considering pregnancy" (established by the Chief Medical Officer of Health in 1995) to a policy that "HIV testing *must be offered* to all pregnant

[5] Communication with Dr Grace Getty, UNB Faculty of Nursing, on 1 August 1997.

[6] Ministère de la Santé et des Services sociaux. *HIV infection and pregnancy – Intervention programme*. Québec: Government of Québec, 1997, at 7.

[7] Ibid at 14.

women and all women considering pregnancy." The Ontario Ministry of Health is in the final stages of developing the materials that will accompany public announcement of this change, which is expected shortly.

The new policy will expressly require that the informed consent of each woman be sought and obtained prior to testing, and that pre- and post-test counselling be provided as part of that process. Ontario is developing its own guidelines to set out minimum standards for the conduct of that counselling.

The HIV test will be added to the current laboratory requisition for prenatal screening (together with HBV, rubella, and syphilis). The requisition requires physicians to check the box or boxes associated with the test results sought. With respect to the HIV test, the requisition will include two prompts: the first will require confirmation that counselling has been provided; the second will require confirmation that the woman has given her informed consent to the test. The Central Public Health Laboratory, which performs all HIV tests in Ontario, will not proceed with the HIV test unless both boxes have been checked in the affirmative. The requisition further highlights that HIV testing may be ordered separately using the ordinary serology requisition (ie, for a non-nominal HIV test) or at any anonymous HIV test site.[8]

Manitoba

Since March 1994, Manitoba Health and the College of Physicians and Surgeons of Manitoba have recommended that HIV testing be offered to all pregnant women regardless of risk factors identified. The policy states that the decision to be tested should be voluntary, based on informed consent, and include adequate pre- and post-test counselling. Guidance with respect to the conduct of the pre- and post-test counselling is provided by Manitoba Health's own HIV Counselling Guidelines, which are similar in content to the CMA Guidelines.[9] In December 1997, the Manitoba Advisory Committee on Infectious Diseases confirmed its July 1997 recommendation that this policy should be continued, and recommended further that the Manitoba Prenatal Record be revised to allow recording of the HIV test being offered and accepted or refused.[10]

Saskatchewan

Saskatchewan has not established its own policy to govern the HIV testing of pregnant women. The College of Physicians and Surgeons of Saskatchewan advises, however, that it provide all physicians with copies of the guidelines established by the Canadian Medical Association and the Canadian College of Family Physicians with respect to HIV testing and pre- and post-test counselling. Physicians are expected to comply with these guidelines.

[8] Communication with Ms Janice Tripp, AIDS Bureau, Ministry of Health, 2 October 1998.

[9] College of Physicians and Surgeons of Manitoba. *Guideline: Maternal and Neonatal HIV Testing and Management*, January 1995.

[10] Manitoba Advisory Committee on Infectious Diseases (MACID). *HIV Testing in Pregnancy: A Report of the HIV Prenatal Policy Working Committee to MACID*, December 1997.

Alberta

Effective 1 September 1998, Alberta moved from a policy of HIV testing of pregnant women on the basis of risk assessment to a policy of routinely offering HIV testing to all pregnant women as part of "routine, good prenatal care." Physicians must obtain the informed consent of all women tested, and this process includes comprehensive pre- and post-test counselling consistent with the CMA Guidelines. The HIV test has been added to the standard perinatal order form (together with ABO/Rh, RBC Antibody Screen, and HBV). The form includes a specific box with a prompt to determine whether the woman declined HIV testing. Unless there is a mark in this box, the HIV test is done.[11]

British Columbia

In 1994, the British Columbia Ministry of Health issued a recommendation stating:

> ... it is imperative that all pregnant women be strongly advised to have an HIV test. HIV testing should be done in accordance with the principles of informed consent and with adequate pre and post test counselling.[12]

Elsewhere in the statement, the policy is described as one of "routine testing." An HIV Counselling Checklist is appended to the policy statement, setting out essentially the same requirements for pre- and post-test counselling as established by the CMA Guidelines.

British Columbia employs a requisition form specifically designed for the purpose of HIV testing rather than incorporating HIV testing into a collection of standard prenatal assays. In addition, the British Columbia Reproduction Program distributes prenatal care record forms used to chart prenatal care by all family physicians and obstetricians that include two prompts: "Has HIV testing been discussed?" and "Has HIV testing been done?"[13]

Yukon

Since 1990, Yukon has strongly recommended that counselling and voluntary testing be offered to all pregnant women. In 1994, a notice stating that all prenatal women should be tested voluntarily was sent by the Chief Medical Officer of Health to all physicians. Much of the counselling is carried out by the community health nurses and, unlike most provinces, it is recommended that partners be screened as well.[14]

Northwest Territories

Since November 1996, the Northwest Territories has recommended that all pregnant women commencing the second trimester "be particularly considered for testing."[15] The guideline further provides that the process of HIV testing (for pregnant women, as for others) include:

> discussing the proposed test with the individual and obtaining his/her informed consent (often referred to as pre-test counselling);

[11] "Dear Colleague" letter dated 6 August 1998 from Dr JR Waters, Provincial Health Officer, Disease Control and Prevention, Alberta Health. This letter introduces the program to health care providers and provides supporting educational material for physicians and their patients.

[12] *British Columbia Centre for Disease Control Bulletin #1*. HIV Transmission in Pregnancy.

[13] Ibid.

[14] Communication with Pat Mandal on 8 September 1997.

[15] Northwest Territories Health and Social Services. *HIV Infection and AIDS Information for Health Professionals*, November 1996.

... conducting post-test counselling for those with both positive and negative results; and carrying out appropriate follow-up.