Canadian HIV Pregnancy Planning Guidelines

These guidelines have been written and reviewed by the Canadian HIV Pregnancy Planning Guideline Development Team in partnership with the Society of Obstetricians and Gynaecologists of Canada, the Canadian Fertility and Andrology Society and the Canadian HIV/AIDS Trials Network. They were reproduced by the Infectious Diseases Committee and the Reproductive Endocrinology and Infertility Committee of the Society of Obstetricians and Gynaecologists of Canada and by the Canadian HIV Pregnancy Planning Guideline Development Team Core Working Group,* and endorsed by the Executive and Council of the SOGC.

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**Abstract**

**Objective:** Four main clinical issues need to be considered for HIV-positive individuals and couples with respect to pregnancy planning and counselling: (1) pre-conceptional health; (2) transmission from mother to infant, which has been significantly reduced by combined antiretroviral therapy; (3) transmission between partners during conception, which requires different prevention and treatment strategies depending on the status and needs of those involved; and (4) management of infertility issues. The objective of the Canadian HIV Pregnancy Planning Guidelines is to provide clinical information and recommendations for health care providers to assist HIV-positive individuals and couples with their fertility and pregnancy planning decisions. These guidelines are evidence- and community-based and flexible, and they take into account diverse and intersecting local/population needs and the social determinants of health.

**Outcomes:** Intended outcomes are (1) reduction of risk of vertical transmission and horizontal transmission of HIV, (2) improvement of maternal and infant health outcomes in the presence of HIV, (3) reduction of the stigma associated with pregnancy and HIV, and (4) increased access to pregnancy planning and fertility services.

**Evidence:** PubMed and Medline were searched for articles published in English or French to December 20, 2010, using the following terms: “HIV” and “pregnancy” or “pregnancy planning” or “fertility” or “reproduction” or “infertility” or “parenthood” or “insemination” or “artificial insemination” or “sperm washing” or “IVF” or “ICSI” or “IUI.” Other search terms included “HIV” and “horizontal transmission” or “sexual transmission” or “serodiscordant.” The following conference databases were also searched: Conference on Retroviruses and Opportunistic Infections, International AIDS Conference, International AIDS Society, Interscience Conference on Antimicrobial Agents and Chemotherapy, the Canadian Association of HIV/AIDS Research, and the Ontario HIV Treatment Network Research Conference. Finally, a hand search of key journals and conferences was performed, and references of retrieved articles were reviewed for additional citations. Subsequently, abstracts were categorized according to their primary topic (based on an outline of the guidelines) into table format with the following headings: author, title, study purpose, participants, results and general comments.

**Values:** The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care. Recommendations for practice were ranked according to the method described in that report (Table) and through use of the Appraisal of Guidelines Research and Evaluation instrument for the development of clinical guidelines.

**Sponsors:** The Society of Obstetricians and Gynaecologists of Canada, Women and HIV Research Program, Women’s College Research Institute, Women’s College Hospital, University of Toronto, Abbott Laboratories Canada, the Ontario HIV Treatment Network, the Canadian Institutes of Health Research, and the Canadian HIV Trials Network.

**Key Points and Recommendations**
HIV-positive people who are considering pregnancy should be counselled on the following issues so they can make an informed decision.

**Key Words:** HIV, pregnancy, insemination, fertility, transmission

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ENSURING A HEALTHY MOTHER, CHILD, AND FAMILY

Recommendations

1. Reproductive health counselling, including contraception and pregnancy planning, should be offered to all reproductive-aged HIV-positive individuals soon after HIV diagnosis and on an ongoing basis. (II-3A)

2. Men and women should be counselled on all relevant aspects of pregnancy planning, such as maintaining a healthy diet and lifestyle, the risk of genetic disease occurrence, and integrated prenatal screening, as outlined in current Canadian practice guidelines irrespective of their known HIV status. (III-A)

3. Women with no risk factors should start taking folic acid (in the form of vitamin supplements) 1 mg a day for 3 months before becoming pregnant and for at least the first 3 months of their pregnancy. (II-3A)

4. Women should be encouraged to give up smoking, drinking alcohol, and using recreational drugs, and should be referred for support if required. (III-A)

5. Both prospective parents should be tested for other sexually transmitted infections, even if they have conceived in the past and have no symptoms of infection. (III-A)

PSYCHOSOCIAL/MENTAL HEALTH ISSUES RELATED TO HIV PREGNANCY PLANNING AND FERTILITY

All individuals or couples planning pregnancy are potentially susceptible to psychosocial and mental health problems. An additional burden may be placed on the HIV-positive individual or couple because of stigma associated with the condition and the risks of HIV transmission.

Recommendations

6. Counselling should be performed by a knowledgeable health care professional or trained peer counsellor in a supportive, non-judgemental manner that takes into account sexual diversity and ethnocultural or religious beliefs and practices. (III-A)

7. Counselling should include a discussion of the potential risk for both horizontal (between partners) and vertical (from mother to child) transmission and how that might affect the mental health of one or both parents. (III-A)

8. HIV-positive people who intend to conceive should be made aware of the potential stigma and discrimination they may face from others who are less informed about how HIV is transmitted, horizontally and vertically. In addition, HIV-positive women who are not breastfeeding should be made aware that they may face disapproval from people who are not aware of their HIV status. (II-3A)

9. Further counselling may be suggested to help couples and individuals cope more effectively with fear, stigma, and other psychosocial issues, such as postpartum depression. (II-3A)

LEGAL AND ETHICAL ISSUES

Recommendations

10. All HIV-positive individuals should be counselled on the possible legal ramifications of non-disclosure of their HIV status to their sexual partner(s). (III-A)

11. HIV-positive women who are considering pregnancy should be counselled on the possibility of legal action if they do not permit antiretroviral therapy to be given to their baby after birth. (III-B)

12. Ethical considerations, including those related to the health status of HIV-positive individuals or couples, should be discussed during pre-conception counselling. (III-B)

ANTIRETROVIRAL AND OTHER DRUGS IN PREGNANCY PLANNING

Recommendations

13. Clinicians should review all medications that HIV-positive men and women may be using, including antidepressants, pain medications, over-the-counter medications, and hepatitis treatments, to ensure that they are safe during conception and pregnancy. (II-3A)

14. All HIV-positive men and women who require combination antiretroviral therapy for their own health during the pre-conception period should be advised to continue their current regimens, but women should not take any drugs that are potentially teratogenic or considered toxic in pregnancy, substituting other drugs when necessary or possible. The most efficacious regimen that is safe in pregnancy should be selected. (II-3A)

15. HIV-positive women who do not require combination antiretroviral therapy for their own health need to consider starting treatment before becoming pregnant or no later than late in the first trimester of pregnancy. The most efficacious regimen that is safe in pregnancy should be selected. (II-3A)

16. HIV-positive men and women who require treatment should be encouraged to initiate combination antiretroviral therapy during the pre-conception period to reduce HIV plasma viral load, which can reduce the risk of HIV transmission to their HIV-negative partner or reduce the risk of superinfection of their HIV-positive partner. (II-3B)

17. All decisions about the use of combination antiretroviral therapy and other drugs during pregnancy should be made in consultation with experts such as HIV specialists and pharmacists. (III-A)

SCENARIO-BASED RECOMMENDATIONS FOR THE PREVENTION OF HORIZONTAL HIV TRANSMISSION

The recommended option may not always be the most practical or preferred option for the patient, given availability of services, cost, cultural beliefs, or personal risk evaluation. Physicians and other health care providers should provide non-judgemental support of the patient’s decision.

HIV-POSITIVE WOMAN AND HIV-NEGATIVE MAN

Recommendations

18. For serodiscordant couples in which the woman is HIV positive, it is preferable to attempt home insemination with the partner’s sperm during ovulation for 3 to 6 months before considering other methods. (III-A)

19. If home insemination is unsuccessful, couples should be referred to a gynaecologist for consultation and then to a fertility specialist for a complete fertility work-up and appropriate treatment when necessary, including counselling on all assisted reproductive technologies if pregnancy is not achieved in 6 to 12 months. (III-A)

ABBREVIATIONS

cART  combined antiretroviral therapy
ICS  intracytoplasmic sperm injection
IUI  intrauterine insemination
**HIV-POSITIVE SINGLE WOMAN OR HIV-POSITIVE WOMAN IN A SAME-SEX RELATIONSHIP**

**Recommendation**

20. Single HIV-positive women or HIV-positive women in a same-sex relationship should be referred to a fertility specialist and should consider the option of intrauterine insemination with HIV-negative donor sperm. This option is preferred over home insemination with donor sperm because the cost of sperm is high and intrauterine insemination performed in a fertility clinic has a higher success rate than home insemination. If sperm from a known donor is used for intrauterine insemination, regulations applicable to the donation of sperm must be followed. (III-A)

**HIV-POSITIVE MAN AND HIV-NEGATIVE WOMAN**

**Recommendations**

21. Serodiscordant couples in which the man is HIV positive should be referred to a fertility specialist and should consider the preferred option of sperm washing with intrauterine insemination. (II-2A)

22. If intrauterine insemination is unsuccessful, couples should consider in vitro fertilization or intracytoplasmic sperm injection with either sperm washing or the use of donor sperm. (II-3A)

23. HIV-positive men who do not require combination antiretroviral therapy for their own health should be encouraged to initiate combination antiretroviral therapy during the pre-conception period to reduce HIV plasma viral load, which can reduce the risk of HIV transmission to their HIV-negative partner. (II-3B)

**HIV-POSITIVE SINGLE MAN OR MALE SAME-SEX COUPLE**

**Recommendation**

24. HIV-positive single men or men in same-sex relationships who have an HIV-negative or HIV-positive surrogate should be referred to a fertility specialist. (III-A)

**HIV-POSITIVE MAN AND HIV-POSITIVE WOMAN**

It is common for seroconcordant couples to attempt natural conception, especially if both partners have fully suppressed viral loads. Seroconcordant couples may wish to consider intrauterine insemination with sperm washing to reduce the potential risk of super-infection or transmission of drug-resistant strains of HIV between partners.

**Recommendations**

25. Timed natural conception is recommended for seroconcordant couples who are taking combination antiretroviral therapy and who have fully suppressed HIV plasma viral loads. (II-3A)

26. Seroconcordant couples should be counselled on the risks and benefits of timed natural conception (including HIV superinfection and transmission of drug-resistant strains of HIV). (II-3A)

27. If timed natural conception is unsuccessful, couples should be referred to a gynaecologist for consultation and then to a fertility specialist for a complete fertility work-up and appropriate treatment when necessary, including counselling on all assisted reproductive technologies. (III-A)

**INFERTILITY INVESTIGATIONS AND TREATMENT**

Historically, fertility clinics in Canada have been reluctant to provide fertility investigation and treatment to HIV-positive people. Fertility experts concur that this has likely been due to a lack of information about HIV and its successful treatment coupled with a concern that serving HIV-positive people could deter HIV-negative individuals from accessing services. In 2010, the American Association of Reproductive Medicine released a statement in which it endorsed the provision of fertility services to all HIV-positive individuals.

**Recommendations**

28. HIV-positive people should be counselled about fertility problems that occur in the general population, including genetic disorders and advancing maternal age. (III-A)

29. Infertility investigations and treatment should be offered to HIV-positive people if required. (III-A)
30. All decisions about combination antiretroviral therapy during the pre-conception period and during pregnancy should consider the health of the HIV-positive person and reduction of the risk of horizontal and vertical transmission of HIV. Decisions about combination antiretroviral therapy should be made in consultation with an HIV specialist. (III-A)

HIV INFECTION CONTROL IN FERTILITY CLINICS

Recommendations

31. Fertility laboratories should follow Canadian Standards Association guidelines for infection control when handling HIV-positive materials. (III-A)

32. Potentially infectious materials should be stored in segregated containers and incubators to reduce the risk of HIV contamination. (III-A)

33. Bio-containment straws for specimen storage should be used to further reduce the risk of cross-contamination of samples. (III-A)

INTRODUCTION

Demand for HIV Pregnancy Planning and Fertility Services in Canada

The natural history of human immunodeficiency virus infection has changed significantly in the last decade with advances made in medical treatment, most specifically with the introduction of highly successful combination antiretroviral therapy.1 As a result, individuals living with HIV are now experiencing an improved quality of life and a prolonged life expectancy.1-3 In countries with greater resources, the mortality caused by HIV has significantly decreased and approaches general population norms. A recent study indicated that HIV-positive individuals within 7 years of their diagnosis have the same life expectancy as the general population.4 While the overall current life expectancy of someone infected with HIV is difficult to predict (as successful treatment has been widely prescribed only since 1996), present projections estimate that an individual living with HIV today will live at least 30 to 40 years from the time of infection.5

Another significant change in the field of HIV in the past 2 decades is that the rate of HIV infection in women has been steadily on the rise. By the end of 2007, it was estimated that approximately 65,000 Canadians were living with HIV and that 10,114 were women.6 This represents a 23% increase from 2002. Similarly, women now account for more than one quarter of new positive HIV test reports.7

The use of cART, possible Caesarean section (as indicated by current guidelines on pregnancy and HIV), and abstaining from breastfeeding have reduced the chance of vertical transmission of HIV to < 1%. These factors have likely led to the increasing number of pregnancies in HIV-positive women over the past decade.8 In Canada, all pregnancies to HIV-positive mothers are reported through a registry created by the Canadian Perinatal HIV Surveillance Program of the Public Health Agency of Canada. Their 2009 annual report indicates that 180 children were born to HIV-positive women in Canada that year. In the 4 preceding years, the number of children born to HIV-positive women was as follows: 238 (2008), 208 (2007), 194 (2006), and 189 (2005).9 Furthermore, pregnancy planning has been identified as a key area of importance to people with HIV in Canada.10 Nevertheless, the reproductive health concerns and services available and provided to people living with HIV have received minimal attention.

A gap exists between the desires and intentions of people living with HIV to have children and their need for support in doing so and the resources, relevant research, and support networks necessary for them to do so successfully and in a medically safe manner. Issues to consider in pregnancy planning when at least one partner has HIV are not just the prevention of vertical transmission but also the prevention of horizontal transmission and the management of potential infertility issues. In 2006, Ogilvie et al.7 conducted a research study to examine the fertility intentions of women living with HIV in British Columbia. Of the 182 women analyzed in the study, 25.8% expressed intentions to have children regardless of their clinical HIV status.7 Most recently, Loutfy et al.8 completed a cross-sectional study designed to assess fertility desires, intentions, and actions. This study surveyed 490 HIV-positive women of reproductive age (18 to 52) living in Ontario. Sixty-one percent were born outside Canada, 52% lived in Toronto, 47% were of African ethnicity, 74% were currently on cART, and the median age was 38. Sixty-nine percent wanted to give birth, and 57% intended to give birth in the future. This study found that the significant predictors of fertility intentions were younger age (age < 40), African ethnicity, living in Toronto, and a lower number of lifetime births (P = 0.02).8 In 2005, Oladapo et al. conducted a study determining the fertility desires and intentions of people living with HIV who were receiving care at a suburban specialist clinic in Sagamu, Nigeria.9 Of the 147 participants, 63.3% expressed a desire for child-bearing, even though 50.4% of them already had 2 or more children. Of those who wanted to have children, 71.5% of men and 93.8% of women intended to have 2 or more children in the near future.9 In 2009, Nattabi et al. conducted a systematic review of 29 studies of factors influencing fertility desires and intentions among people living with HIV and found that fertility desires were influenced by a variety of demographic, health, stigma-associated, cultural, and psychosocial factors.10
In all of the aforementioned studies, it was concluded that the desire and intention of HIV-positive individuals to have children were high and that clinical HIV status did not seem to be a predictor of fertility intentions. Specialized counselling, services, and support will be required to meet the needs of this group.

**Access to HIV Pregnancy Planning and Fertility Services in Canada**

Despite the fact that many HIV-positive individuals and couples wish to have children, there is a scarcity of HIV or fertility clinics in North America offering advice to HIV-positive individuals and couples on the management of HIV during pregnancy planning, timing of ovulation to allow fertilization, sperm washing (a procedure designed to remove viral particles from the sperm, reducing the chance of horizontal transmission), management of individuals or couples affected by infertility issues, and fertility treatments including intrauterine insemination and in vitro fertilization.

In Europe, HIV-positive couples have had access to reproductive assistance since the 1980s, and at least 5 European countries have national programs to assist people living with HIV in their pregnancy planning. As of 2003, less than 5% of fertility clinics in the United States offered reproductive care to HIV-serodiscordant couples. In Canada, services and treatment protocols differ depending on the clinic or centre, and therefore so do the costs. It is important to note that in most jurisdictions in Canada sperm washing, IUI, IVF, and ICSI are not covered by provincial medical services plans, so costs are charged directly to the patient.

A 2010 study by Yudin et al. showed that while over 70% of clinics surveyed were willing to see people living with HIV in consultation, substantially fewer had actually seen any people living with HIV within the previous 12 months. Services offered also varied by region, with clinics located in only 5 provinces offering fertility treatments to people living with HIV. Some important procedures were also less commonly available to people living with HIV. In particular, sperm washing was available in only 26% of clinics in 4 provinces, a service gap noted in the Newmeyer et al. study that described the barriers to services experienced by people living with HIV.

In addition to a deficiency in assisted reproductive services, there remains a scarcity of pregnancy planning, prenatal and postnatal care, and counselling programs for HIV-positive individuals and couples in Canada.

**Unintended Pregnancy**

As is the case in the general population, many pregnancies in people with HIV are unintended. An Ontario study of HIV-positive women of reproductive age found that 56% of their most recent pregnancies were unintended. One of the goals of these guidelines is to encourage health care providers to discuss pregnancy planning, including contraception, with their patients as early as possible after diagnosis to reduce the incidence of unintended pregnancy and to reduce the risk of both vertical and horizontal transmission of HIV.

**HIVAIDS AND HUMAN RIGHTS**

The World Health Organization states that “all couples and individuals have the right to decide freely and responsibly the number and spacing of their children and to have access to the information, education and means to do so.” This includes people living with HIV or AIDS. The human rights of those infected with and affected by HIV are frequently violated, and this can affect their intentions and desires with respect to having children. There is a need to integrate these guiding principles into all aspects of HIV pregnancy planning, fertility care, treatment and support for people living with HIV in Canada. Recommendations for care must be evidence-based, and their implementation must be flexible and ethnoculturally sensitive, and must also take into account diverse and intersecting local/population needs and the social determinants of health.

**SCOPE OF DOCUMENT**

This guideline does not address the management of HIV during pregnancy or HIV testing during pregnancy, because this information is available elsewhere. Similarly, as there are guidelines dealing with fertility and infertility issues in the general population, these issues are not addressed in this document. The postpartum period and infant feeding options for people with HIV are outside of the scope of this document.

**ENSURING A HEALTHY MOTHER, CHILD, AND FAMILY**

Although management of HIV in pregnancy planning entails many special considerations, it is important to remember that most general recommendations for pregnancy planning also apply to HIV-positive individuals and couples.

The Public Health Agency of Canada is an important source of information to ensure a healthy mother, child, and family. *Eating Well with Canada’s Food Guide* provides women with the information they need to eat well during pregnancy and includes specific advice for all women...
of child-bearing age. Detailed recommendations for pregnancy and breastfeeding are available for health professionals. The Public Health Agency of Canada has described alcohol use in pregnancy as “an important public health and social issue for Canadians,” recognizing the increasing societal awareness of the significant personal and social costs associated with fetal alcohol spectrum disorder. In addition to specific guidelines for alcohol use and nutrition during pregnancy, the agency has produced The Sensible Guide to a Healthy Pregnancy, which includes guidance on general nutrition, folic acid, alcohol, physical activity, smoking and oral health.

In addition, SOGC has published numerous guidelines addressing most of these topics.

**Recommendations**

1. Reproductive health counselling, including contraception and pregnancy planning, should be offered to all reproductive-aged HIV-positive individuals soon after HIV diagnosis and on an ongoing basis. (II-3A)
2. Men and women should be counselled on all relevant aspects of pregnancy planning, such as maintaining a healthy diet and lifestyle, the risk of genetic disease occurrence, and integrated prenatal screening, as outlined in current Canadian practice guidelines irrespective of their known HIV status. (III-A)
3. Women with no risk factors should start taking folic acid (in the form of vitamin supplements) 1 mg a day for 3 months before becoming pregnant and for at least the first 3 months of their pregnancy. (II-3A)
4. Women should be encouraged to give up smoking, drinking alcohol, and using recreational drugs, and should be referred for support if required. (III-A)
5. Both prospective parents should be tested for other sexually transmitted infections, even if they have conceived in the past and have no symptoms of infection. (III-A)

**PSYCHOSOCIAL/MENTAL HEALTH ISSUES RELATED TO HIV PREGNANCY PLANNING AND FERTILITY**

All individuals or couples planning pregnancy must consider the implications of psychosocial and mental health issues. An additional burden is placed on the HIV-positive individual or couple because of the stigma and discrimination associated with the condition and the risks of transmission. People living with HIV considering pregnancy may be concerned that they will experience stigma and discrimination simply for choosing to become parents and may worry that they will feel guilty about conceiving or breastfeeding, or that family members, friends, or community members may disapprove and withdraw support. As with legal and ethical issues, little information is available on this subject, and recommendations for psychosocial counselling have been based on expert consensus.

The transition to parenthood is often a time of great joy, but it is also life-altering and can result in considerable stress and anxiety. When one or both prospective parents have HIV, the stress can be greatly increased. Even in 2009, the stigma and marginalization associated with HIV continued to place a significant psychological burden on those who were affected. A 2007 study showed that health care professionals play a large role in the systemic discrimination against people living with HIV who wish to have children. Thus the environment in which HIV-positive parents live is one that can easily cause psychological distress.

Although the mental health needs of pregnant women have been studied, less is known about the specific mental health needs of HIV-positive pregnant women. A large 2004 American study examined minority women who were pregnant and HIV-positive in 4 regions of the United States. They found that depressive symptoms were severe and that social isolation, perceived stress, and ineffective coping strategies were among the factors associated with depression. On the other hand, the presence of a supportive partner was associated with fewer depressive symptoms. This type of research might enable the development of appropriate interventions that will decrease the risk of psychological morbidity for HIV-positive women during the pregnancy planning and antenatal periods.

An earlier, longitudinal study by Larrabee et al. in Texas followed 21 HIV-positive and 21 HIV-negative women from the antenatal period until 6 months postpartum using the Medical Outcome Survey–Short Form to assess overall quality of life. Overall, HIV-positive women reported increased health distress and a more difficult transition during the antenatal period than did HIV-negative control subjects. A similar difference was found at 6 months postpartum, but not during the perinatal period. Once again, seropositivity appears to be associated with poorer mental health during pregnancy.

There are few published studies about the mental health concerns of fathers, and even fewer about the mental health of HIV-positive fathers. However, it is known that a father’s behaviour during the early postnatal weeks can significantly affect the mental health status of new mothers, particularly with respect to postpartum depression, which has a prevalence rate of about 10%. As more and more people with HIV are living longer, healthier lives when they have access to medication, this will become an increasingly important area of research.
Recommendations

6. Counselling should be performed by a knowledgeable health care professional or trained peer counsellor in a supportive, non-judgemental manner that takes into account sexual diversity and ethnocultural or religious beliefs and practices. (III-A)

7. Counselling should include a discussion of the potential risk for both horizontal (between partners) and vertical (from mother to child) transmission and how that might affect the mental health of one or both parents. (III-A)

8. HIV-positive people who intend to conceive should be made aware of the potential stigma and discrimination they may face from others who are less informed about how HIV is transmitted, horizontally and vertically. In addition, HIV-positive women who are not breastfeeding should be made aware that they may face disapproval from people who are not aware of their HIV status. (II-3A)

9. Further counselling may be suggested to help couples and individuals cope more effectively with fear, stigma, and other psychosocial issues, such as postpartum depression. (II-3A)

LEGAL AND ETHICAL ISSUES

Legal, ethical, and policy issues related to pregnancy and HIV remain challenging, and guidelines are still evolving because of the absence of policies and the inconsistencies in case law pertaining to the criminalization of HIV non-disclosure in cases of otherwise consensual sex. This section of the guidelines is therefore based on expert consensus and on the premise that people living with HIV are entitled to reproductive freedom without discrimination.

HIV-positive people who are planning pregnancy must access health services to assist them in dealing with medical and psychosocial issues, but this typically requires them to disclose their HIV status to partners and others. A 2004 report by the World Health Organization summarizing barriers to HIV serostatus disclosure by women in resource-poor countries indicates that the most common reasons for failure to disclose to partners included fear of accusations of infidelity, abandonment, discrimination, and violence.38

Fear of disclosing HIV status can also create difficulties in resource-rich countries. A recent case report suggested that cultural and family pressure contributed to the mother’s inability to adhere to antiretroviral therapy during pregnancy and breastfeeding with consequent vertical transmission.17 Canadian laws with respect to the criminal non-disclosure of HIV-positive status related to sexual activity continue to evolve on the basis of case law. In 1998 (R. v. Caerrier39) the Supreme Court of Canada ruled that people living with HIV could be found guilty of serious charges, such as aggravated assault, if they failed to disclose their HIV status to sexual partners when there was a significant risk of HIV transmission. According to the Canadian HIV/AIDS Legal Network, charges in these cases are becoming more serious: aggravated sexual assault, (which carries a maximum penalty of life imprisonment), and even murder.40

The Swiss have taken a different approach to criminalization of HIV transmission. In a public statement published in the Bulletin des Médecins Suisses,41 Dr Pietro Vernazza and colleagues argued that HIV-positive individuals on effective antiretroviral treatment cannot transmit HIV through sexual contact as long as the following criteria are met: the HIV-positive person is adhering to cART under the supervision of a medical doctor, his or her viral load has remained undetectable in the previous 6 months, and the person does not have another sexually transmitted infection. The report concludes that unprotected sex between an HIV-positive and an HIV-negative person does not constitute criminal negligence if the above-mentioned criteria have been met. This is in keeping with a UNAIDS policy brief42 stating that criminal charges against HIV-positive individuals who transmit the virus through sexual contact cannot be justified if the accused individual “took reasonable measures to reduce risk of transmission.” In this case, reasonable measures would include adherence to cART.

There is little information available on the effects of HIV criminalization laws on pregnancy planning, but legal cases do exist. In 2006, an HIV-positive woman in Hamilton, Ontario, was convicted of failing to provide the necessities of life for hiding her HIV-positive status from doctors, preventing them from administering antiretroviral therapy to her baby immediately after birth, which would have significantly reduced the child’s risk of becoming infected. The child tested HIV positive at 2 months of age, and the mother was sentenced to a conditional 6-month sentence to be served in the community.43

The imposition of criminal penalties for not disclosing HIV-positive status before having otherwise consensual sex will no doubt discourage HIV-positive people who are thinking about starting a family. Although it is not illegal in Canada for an HIV-positive man or woman to have children, criminalization of non-disclosure might deter disclosure of HIV status to health care providers and partners, and this could result in unplanned pregnancies and limit access to
prenatal care and conception counselling. Ideally, doctors and other health care providers should be involved from pre-conception when women are HIV-positive, so routine prevention measures can be planned in addition to cART to decrease transmission rates.

A 1996 paper published by Williams et al. reviewed the modest data available on reproductive decision-making in HIV-positive women and found that awareness of their HIV infection was not associated with pregnancy termination or subsequent pregnancy prevention. This confirms the fact that HIV-positive women are having and will continue to have children, so health professionals must be prepared to guide them in this process. There are ethical concerns associated with all pregnancies and with conception and assisted reproductive interventions, and these are addressed in SOGC guidelines. Ethical considerations common in HIV infection, such as the health of the prospective parents and their financial ability to care for a child, are reasonable and should be discussed with HIV-positive individuals and couples. Many health care providers cite “ethical” considerations when refusing to provide care. These are often “perceived” ethical considerations, such as concern that a child or partner will be infected with HIV, or they are based on stereotypes associated with a history of drug use. These perceptions generally arise from lack of information or failure to review and/or accept current scientific evidence on HIV transmission risk reduction. Refusal to provide HIV transmission risk-reduction services for people planning pregnancy is itself unethical and contrary to the human right to non-discrimination and the right to choose the number and spacing of children.

### Recommendations

10. All HIV-positive individuals should be counselled on the possible legal ramifications of non-disclosure of their HIV status to their sexual partner(s). (III-A)

11. HIV-positive women who are considering pregnancy should be counselled on the possibility of legal action if they do not permit antiretroviral therapy to be given to their baby after birth. (III-B)

12. Ethical considerations, including those related to the health status of HIV-positive individuals or couples, should be discussed during pre-conception counselling. (III-B)

### Combination Antiretroviral and Other Drugs in Pregnancy Planning

A substantial body of evidence has shown that potent cART not only prolongs the lives of people living with HIV but also significantly reduces the risk of both horizontal and vertical HIV transmission, thus leading to a greater number of people living with HIV having or planning to have children. These breakthroughs affect both men and women by reducing viral load to decrease the risk of horizontal HIV transmission and, for women, the risk of vertical transmission. It is well accepted that cART during pregnancy should take into consideration the health of both mother and child and that, with some exceptions, cART is generally safe in pregnancy. The selection of cART in pregnancy should consider drugs that are effective in and tolerable to the mother and that are of least toxicity to the fetus and newborn. Specifically, the mother should be treated not only to prevent vertical HIV transmission but also to ensure optimal therapy for herself. Both the Canadian consensus guidelines for the care of HIV-positive pregnant women, *Putting Recommendations into Practice*, and the United States Department of Health and Human Services guidelines recommend that women who are not already on cART for their own health before becoming pregnant can delay the initiation of therapy until after the first trimester. Delaying treatment until the second trimester is intended to reduce any theoretic teratogenic effects of cART, which may be greater in the first trimester. Fertility clinics generally require an HIV-positive woman to be on a successful cART regimen before she seeks fertility services, regardless of whether or not she requires cART for her own health. This is supported by recently presented conference abstract findings of the French cohort, which show that initiation of cART before conception or early in the first trimester led to the lowest vertical transmission rate of 0% to 0.6%.

There is seldom discussion about the benefit of starting cART during the pre-conception period for men and women who do not require cART for their own health. Treatment before conception is a horizontal risk-reduction issue—as reduction in viral plasma load often correlates to reduction of viral load in semen and vaginal fluid—and should be discussed with the patient in all scenarios to reduce risk to his or her HIV-negative partner or reduce the risk of superinfection to his or her HIV-positive partner.

There are currently several ongoing studies looking at the efficacy of HIV pre-exposure prophylaxis in preventing HIV transmission to a non-infected partner in a serodiscordant couple during conception. The United States Centers for Disease Control and Prevention published an interim guidance document for the use of pre-exposure prophylaxis in men who have sex with men. This document is primarily based on the results of the investigators for the Pre-Exposure Prophylaxis Initiative.
study, which has shown pre-exposure prophylaxis to be efficacious in this population. Currently, the Centers for Disease Control and Prevention cautions against the use of pre-exposure prophylaxis by women for HIV prevention, as the FEM-PrEP Project (a study of pre-exposure prophylaxis for HIV prevention among heterosexual women) was stopped early because it was highly unlikely to be able to demonstrate the effectiveness of Truvada (emtricitabine and tenofovir disoproxil fumarate) in preventing HIV infection in women.

There are many non-cART medications that people living with HIV may be using to treat concurrent conditions, including but not limited to hepatitis C and depression, and adverse events from cART. Clinicians should review all prescribed, over-the-counter, and complementary therapies, as well as street drugs used by HIV-positive individuals before conception. Most notably, treatment for hepatitis C is considered to be teratogenic when used by either male or female partners. Hepatitis C treatment should be stopped at least 6 months before couples attempt to conceive.

**Recommendations**

13. Clinicians should review all medications that HIV-positive men and women may be using, including antidepressants, pain medications, over-the-counter medications, and hepatitis treatment, to ensure that they are safe during conception and pregnancy. (II-3A)

14. All HIV-positive men and women who require combination antiretroviral therapy for their own health during the pre-conception period should be advised to continue their current regimens, but women should not take any drugs that are potentially teratogenic or considered toxic in pregnancy, substituting other drugs when necessary or possible. The most efficacious regimen that is safe in pregnancy should be selected. (II-3A)

15. HIV-positive women who do not require combination antiretroviral therapy for their own health need to consider starting treatment before becoming pregnant or no later than late in the first trimester of pregnancy. The most efficacious regimen that is safe in pregnancy should be selected. (II-3A)

16. HIV-positive men and women who require treatment should be encouraged to initiate combination antiretroviral therapy during the pre-conception period to reduce HIV plasma viral load, which can reduce the risk of HIV transmission to their HIV-negative partner or reduce the risk of superinfection of their HIV-positive partner. (II-3B)

17. All decisions about the use of combination antiretroviral therapy and other drugs during pregnancy should be made in consultation with experts such as HIV specialists and pharmacists. (III-A)

**OPTIONS FOR REDUCING RISK OF HORIZONTAL HIV TRANSMISSION DURING CONCEPTION**

HIV-positive couples and individuals who wish to conceive a child need to consider the risk of horizontal HIV transmission during conception. That risk depends on a number of variables, including the HIV serostatus of each partner (i.e., HIV-positive woman and HIV-negative man or HIV-positive man and HIV-negative woman) and the plasma viral load and level of drug-resistant virus of each prospective parent. Couples and individuals should be counselled thoroughly about all horizontal HIV transmission risk-reduction methods before conception so they can make an informed choice about which conception method is most appropriate to their particular situation. Furthermore, prospective parents should be informed about the rate of success, availability, and cost of each conception option.

**Timed Natural Conception**

Natural conception has only recently been seen as an option for people living with HIV. Although not for everyone, natural conception is suitable in some circumstances, and the nature of each individual case must be evaluated. Prospective parents must have a frank discussion about the risks of horizontal HIV transmission to make an informed decision about this option. The relative risk of horizontal HIV transmission involved in natural conception is dependent on the plasma viral load of the HIV-positive partner, the frequency of intercourse, the presence of concurrent sexually transmitted infections, and which partner is infected. People living with HIV who do not have access to or who cannot afford assisted conception services may be more likely to attempt natural conception. Additionally, people living with HIV who fear stigma will be associated with the use of assisted conception services may be more likely to consider natural conception. More research is needed to determine the factors considered when couples decide to conceive naturally. In the case of an HIV-positive man who is not taking cART, the risk of HIV transmission to his uninfected female partner is quoted as 0.1% to 0.3% per act of intercourse. This assumes that the couple is in a stable relationship and that they are not participating in any other form of high-risk activity. Without the intervention of cART, the risk of transmission from an HIV-positive woman to her uninfected male partner is reported to be 0.03% to 0.09%. In general, plasma viral load may be concordant with the viral load of genital secretions.
However, people living with HIV and their uninfected partners should be counselled that this is not always the case. cART further reduces the risk when long-term viral suppression is achieved. Normally, the viral load in semen is lower than that in blood; however, this is greatly influenced by the use of cART, known to have optimal penetration of the genital tract, as well as the absence of coexisting sexually transmitted infections and the absence of drug resistance. It is possible to achieve an undetectable viral load in genital secretions with the long-term use of cART; however, assays to detect genital fluid viral load are not readily available.

In early 2008, the Swiss Federal Commission for HIV/AIDS issued a controversial statement authored by Vernazza et al., known as the Swiss Statement, claiming that an HIV-infected person on antiretroviral therapy with completely suppressed viremia (effective ART) is not sexually infectious and cannot transmit HIV through sexual contact provided “the HIV-positive individual takes anti-retroviral therapy and cannot transmit HIV through sexual contact provided that ‘the HIV-positive individual has an undetectable viral load’.” Thus, although there remains a slight risk of transmission, some serodiscordant couples opt to proceed with timed unprotected intercourse—only during ovulation—to reduce the number of exposures to HIV by the uninfected partner and to increase the probability of conception. Women should be directed to health care providers and the websites of relevant health care agencies for information about timing ovulation. Ovulation timing kits are available over the counter at most pharmacies.

**Home Insemination**

Home insemination is a particularly popular option for conception for HIV-positive women with HIV-negative partners and for same-sex female couples and single HIV-positive women with access to donor sperm. The procedure involves collecting sperm from a partner or donor in a sterile container or a condom. The sperm is drawn into a needle-less syringe and then inserted into the vagina as close to the cervix as possible. Optimal results are achieved when insemination is done during ovulation. This is a particularly attractive method, as it is very low cost and does not require the assistance of a fertility specialist. If home insemination is unsuccessful after 3 to 6 months, HIV-positive women should be advised to seek the assistance of a fertility specialist.

**Sperm Washing**

Sperm washing is a well-established, effective, and safe risk-reduction fertility option for serodiscordant couples in which the man is HIV-positive and the woman is HIV-negative and for seroconcordant couples when superinfection is a concern. Semen is centrifuged to separate live sperm (which do not carry HIV) from seminal plasma and non-germinal cells (which may carry HIV) and then inseminated into the female partner at the time of ovulation. This practice is well supported by the literature, which is extensive. In technical terms, sperm washing involves centrifuging ejaculated semen in a 40% to 80% colloidal silica density gradient to separate progressively motile HIV-free sperm from non-sperm components and seminal plasma, which remain in the supernatant. The sperm pellet at the bottom is re-suspended in a fresh medium and centrifuged twice before the preparation of a final swim-up. There is no consensus among researchers about the need to test washed sperm for detectable HIV RNA before the sample is used. A nucleic-acid-based sequence amplification (NASBA; Biomerieux, Basingstoke, UK) or similar commercial assay can be used; however, these assays are not commercially available in Canada. The number of washes is limited because repeated centrifuging leads to loss of sperm quality and quantity. A double-tube technique has been proposed to increase yield and reduce the need for post-wash HIV testing. Unfortunately, this technique has not been adopted by the majority of centres offering sperm washing, because it is not currently available commercially. According to studies published to date, there have been no reported cases of infection of the female partner when sperm washing is carried out following the reported published protocols in more than 3000 cycles of sperm washing combined with intrauterine insemination, in vitro fertilization and intracytoplasmic sperm injection. The results of a multicentre retrospective analysis of 1036 serodiscordant couples from 8 European centres offering sperm washing reported 2840 IUI cycles, 107 IVF cycles, 394 ICSI cycles, and 49 frozen embryo transfers. At least 6 months post-treatment there was careful HIV follow-up of the HIV-negative women. All tests recorded on the women were negative (7.1% lost to follow-up), giving a calculated probability of contamination equal to zero (95% CI 0 to 0.09). Clinical pregnancy rates recorded with all forms of treatment were comparable to those found in cycles carried out in HIV-negative couples.

**IUI, IVF, and ICSI**

IUI, IVF, and ICSI are fertility techniques that can reduce the risk of HIV transmission to the uninfected partner. IUI is most commonly used and is combined with sperm washing if the male partner is HIV positive. This process involves placing prepared sperm directly into the uterus.
during ovulation. For couples who wish to further reduce the risk of horizontal HIV transmission or for those who have infertility issues, sperm washing can be combined with ovulation induction, IVF, or ICSI.

IVF refers to the procedure whereby oocytes are exposed to spermatozoa outside the uterus, and a fertilized embryo is returned to the uterus for the gestation period.

Some studies have shown that because ICSI involves fertilization with only one sperm, the risk of possible HIV transmission in serodiscordant couples should be lower than with traditional assisted reproductive technology methods. This is because in traditional IUI women receive millions of spermatozoa, and in classic IVF the oocytes are exposed to thousands of spermatozoa.

Both IVF and ICSI are very expensive, costing up to $15,000 per cycle, making these procedures inaccessible to many people living with HIV.

A 2003 meta-analysis assessing the efficacy of assisted reproductive technologies in serodiscordant couples found they were less successful in the group in which the female partner was infected, with an overall pregnancy rate per assisted reproductive technology attempt of 6.7%. No pregnancies resulted from the IUI attempts, while 2 pregnancies resulted from the IVF and ICSI attempts.

A 2007 study examining the safety and effectiveness of assisted reproduction (IUI, IVF, and ICSI) using sperm washing for HIV-1 serodiscordant couples in which the male partner was infected showed pregnancy resulting in 580 of 3315 cycles. Throughout the period of treatment, all couples were required to use condoms during intercourse. IUI was the most frequently used procedure, representing 84% of procedure use. Out of the 580 pregnancies, there were 112 miscarriages, 8 extra-uterine pregnancies, 2 pregnancy terminations and 1 intrauterine death. Overall, no transmission of HIV to the female partner was observed with complete follow-up information in 967 out of 1036 cases.

Sperm Donation, Egg Donation, and Surrogacy

Sperm donation, egg donation, and surrogacy are discussed in depth in a joint policy statement on ethical issues in assisted reproduction prepared by the Society of Obstetricians and Gynaecologists of Canada and the Canadian Fertility and Andrology Society. However, these policies do not directly address the issues of people living with HIV. Sperm donation is available to the uninfected partners of HIV-positive men and to HIV-positive women. Surrogacy is not currently an option in Canada for HIV-positive single men or HIV-positive men in a same-sex couple. Sperm donation by HIV-positive men is restricted by Canadian law; however, it may be possible through the Donor Semen Special Access Program when the recipient is known to the donor. Further information is available from Assisted Human Reproduction Canada and fertility specialists. HIV-positive individuals and couples who require sperm donation, egg donation, or a surrogate are likely to require legal advice and contracts.

Adoption

Adoption is a legal and social process. It involves the transferring of rights over a child from birth parents to adoptive parents. In Canada, adoption is regulated provincially, so requirements vary depending upon geographical location. They may also differ depending upon whether the adoption is undertaken privately or through the public system, or is international. No current data are available on the success rate of adoption in Canada if one or both prospective parents are HIV positive. In the United States, Lambda Legal has successfully assisted same-sex couples and people living with HIV to adopt children.

SCENARIO-BASED RECOMMENDATIONS FOR THE PREVENTION OF HORIZONTAL HIV TRANSMISSION

The scenario-based recommendations are intended to guide health care providers during the pre-conception counselling process. All options, including risks and benefits, should be presented to prospective parents to facilitate informed decision making. Although the recommendations are based on expert opinion of the safest and most practical option for most individuals and couples, they may not always be the most practical or preferred option for some patients, depending on availability of services, cost, cultural beliefs, and personal preference. In these cases, physicians and other health care providers should provide non-judgemental support of the decision of the patient(s) involved.

HIV-Positive Woman and HIV-Negative Man

HIV serodiscordant couples in which the woman is HIV positive and the man is HIV negative should be counselled on the risks and benefits of timed natural conception, home insemination, IUI, IVF, ICSI, the option of a gestational carrier or true surrogate, and adoption.

Recommendations

18. For serodiscordant couples in which the woman is HIV positive, it is preferable to attempt home insemination with the partner’s sperm during ovulation for 3 to 6 months before considering other methods. (III-A)
19. If home insemination is unsuccessful, couples should be referred to a gynaecologist for consultation and then to a fertility specialist for a complete fertility work-up and appropriate treatment when necessary, including counselling on all assisted reproductive technologies if pregnancy is not achieved in 6 to 12 months. (III-A)

HIV-Positive Single Woman or HIV-Positive Woman in a Same-Sex Relationship
HIV-positive single women or HIV-positive women in a same-sex relationship should be counselled on the risks and benefits of home insemination with donor sperm (known donor or purchased sperm), IUI with donor sperm, IVF with donor sperm, ICSI with donor sperm, and the option of a gestational carrier or true surrogate with donor sperm, and adoption.

Recommendation
20. Single HIV-positive women or HIV-positive women in a same-sex relationship should be referred to a fertility specialist and should consider the option of intrauterine insemination with HIV-negative donor sperm. This option is preferred over home insemination with donor sperm because the cost of sperm is high and intrauterine insemination performed in a fertility clinic has a higher success rate than home insemination. If sperm from a known donor is used for intrauterine insemination, regulations applicable to the donation of sperm must be followed. (III-A)

HIV-Positive Single Man or Male Same-Sex Couple
Recommendation
24. HIV-positive single men or men in same-sex relationships who have an HIV-negative or HIV-positive surrogate should be referred to a fertility specialist. (III-A)

HIV-Positive Man and HIV-Negative Woman
HIV serodiscordant couples in which the male partner is HIV positive should be counselled on the risks and benefits of timed natural conception, home insemination, IUI with sperm washing or donor sperm, IVF with sperm washing or donor sperm, ICSI with sperm washing or donor sperm, and adoption.

Recommendations
21. Serodiscordant couples in which the man is HIV positive should be referred to a fertility specialist and should consider the preferred option of sperm washing with intrauterine insemination. (II-2A)
22. If intrauterine insemination is unsuccessful, couples should consider in vitro fertilization or intracytoplasmic sperm injection with either sperm washing or the use of donor sperm. (II-3A)

HIV-Positive Man and HIV-Positive Woman
Heterosexual couples in which both partners are HIV positive should be counselled on the risks and benefits of timed natural conception, IUI with sperm washing, IVF with sperm washing, ICSI with sperm washing, and adoption.

Recommendations
25. Timed natural conception is recommended for seroconcordant couples who are taking combination antiretroviral therapy and who have fully suppressed HIV plasma viral loads. (II-3A)
26. Seroconcordant couples should be counselled on the risks and benefits of timed natural conception (including HIV superinfection and transmission of drug-resistant strains of HIV). (II-3A)
27. If timed natural conception is unsuccessful, couples should be referred to a gynaecologist for consultation and then to a fertility specialist for a complete fertility work-up and appropriate treatment when necessary, including counselling on all assisted reproductive technologies. (III-A)

FERTILITY ISSUES IN THE CONTEXT OF HIV AND HIV INFECTION CONTROL IN FERTILITY CLINICS
Infertility Investigations and Treatment
Historically, fertility clinics in Canada have been reluctant to provide fertility investigation and treatment to people living with HIV. Fertility experts concur that this has likely been due to lack of information about HIV and concern that serving people living with HIV could deter HIV-negative individuals from accessing services. However, it is common practice in many fertility clinics across Canada to offer investigation, treatment, and storage of potentially infected specimens to people with other infectious diseases.
such as hepatitis B and C, and similar practices can be applied to the handling of HIV-infected materials.

As all fertility clinics should be operating using Canadian Standards Association procedures for universal precautions and infection control, there are no scientific grounds on which to refuse services to people living with HIV.

### Recommendations

**28.** HIV-positive people should be counselled about fertility problems that occur in the general population, including genetic disorders and advancing maternal age. (III-A)

**29.** Infertility investigations and treatment should be offered to HIV-positive people if required. (III-A)

**30.** All decisions about combination antiretroviral therapy during the pre-conception period and during pregnancy should consider the health of the HIV-positive person and reduction of the risk of horizontal and vertical transmission of HIV. Decisions about combination antiretroviral therapy should be made in consultation with an HIV specialist. (III-A)

### HIV Infection Control in Fertility Clinics

Fertility laboratories routinely treat all samples as potentially infectious, in accordance with the Canadian Standards Association guidelines, for the protection of both health care workers and patients. Storage of potentially infectious materials in segregated containers and incubators may slightly decrease the risk of HIV contamination.

### Recommendations

**31.** Fertility laboratories should follow Canadian Standards Association guidelines for infection control when handling HIV-positive materials. (III-A)

**32.** Potentially infectious materials should be stored in segregated containers and incubators to reduce the risk of HIV contamination. (III-A)

**33.** Bio-containment straws for specimen storage should be used to further reduce the risk of cross-contamination of samples. (III-A)

### APPLICABILITY

There are potential barriers to applying the recommendations outlined in these guidelines. Fertility services are not available to HIV-positive individuals and couples in all provinces. Additionally, many of the fertility services recommended in these guidelines are expensive and not covered by most provincial or private health insurance coverage and are therefore inaccessible to many people living with HIV.

### SUMMARY

The implementation of these guidelines will assist HIV-positive individuals and couples with their fertility and pregnancy planning needs through the provision of clinical information and recommendations. It will also reduce the risk of transmission of HIV between partners and transmission from mother to child and will increase the rate of pregnancy planning in the HIV-positive population by providing safer options for conception, reducing the stigma associated with pregnancy and HIV, and improving access to pregnancy planning and fertility services.

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JUNE JOGC JUIN 2012 ● 589
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