

**Canadian HIV
Fertility
Program**



**Women &
HIV
Research
Program**

National HIV Pregnancy Planning Guidelines

Development Team Meeting April 22-23, 2009

Westin Bayshore Hotel

Vancouver, British Columbia

Report

Women's College Hospital
Women's College Research Institute
2009

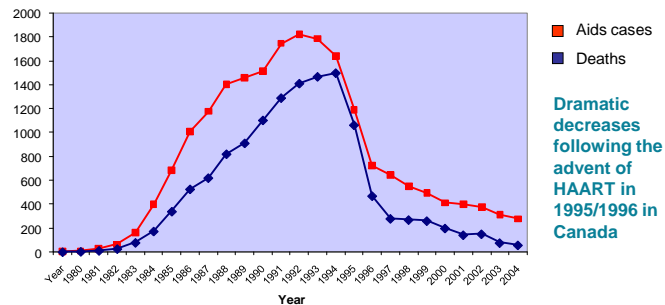
Authored by: Ms. Shari Margolese; Edited by Dr. Mona Loutfy

NATIONAL HIV PREGNANCY PLANNING GUIDELINES DEVELOPMENT

BACKGROUND:

During the past ten years, the natural history of human immunodeficiency virus (HIV) infection has significantly changed with the advent of combination antiretroviral therapy (cART). In the developed world, the mortality and morbidity caused by HIV have significantly decreased, resulting in a prolonged life expectancy and improved quality of life. The life expectancy of someone infected with HIV is currently unknown because successful treatment has only been widely prescribed since 1996. Although still younger than the age-matched general population, present projections estimate that a person will live at least 20 years from time of infection [1,2].

Decreasing mortality and morbidity



(HIV/AIDS in Canada, Surveillance Report to December 31, 2005, PHAC)

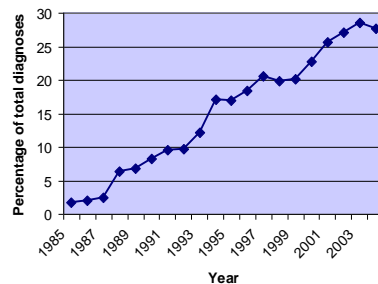


Globally, heterosexual contact is the most common mode of transmission of HIV and this trend has been steadily increasing in Canada. Partially because of this factor, women comprise nearly half of the prevalent cases of HIV worldwide. Globally, it is estimated that 33.2 million people

Increasing incidence and prevalence

Percent of positive tests in females in Canada

- In 1986, women comprised 2.1% of new diagnosed cases in Canada.
- In 1996, women comprised 18.6% of new cases diagnosed in Canada.
- In 2004, this number rose to 27.7%.



Report on HIV/AIDS - 2004
RS Remis et al.



are infected with HIV and/or have acquired immunodeficiency syndrome (AIDS). Of those, 15.5 million are women [3]. Most of these women living with HIV are of reproductive age (16-52 years) and may therefore be interested in pregnancy [3]. In Canada, by the end of 2002, there were an estimated 56,000 people with HIV/AIDS, 7,700 of whom were women [4, 5]. By the end of 2007, 64,800 positive HIV tests had been reported, where 10,514 of these were in women. Among them, at least 70% were of childbearing age [4, 5].

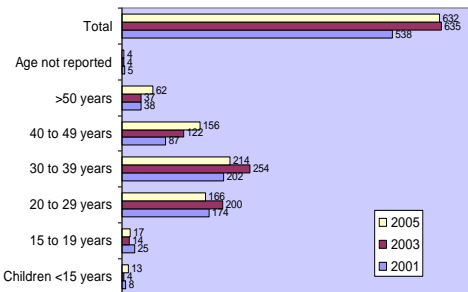
However, the interest in pregnancy exists not only among HIV-positive women that are of childbearing age, but also among HIV-positive men with HIV-negative and positive female partners, or HIV-positive men with same sex partners.

By December 2007, the proportion of those who tested HIV-positive in Canada and who indicated that heterosexual contact was their mode of acquisition was close to 30%, while 40% reported being men who have sex with men [5]. The proportion of heterosexual men living with HIV is rising, which leads to the increased importance for pregnancy planning for this population.

As a result of the increased life expectancy and improved quality of life of people living with HIV, the reduction in the rate of vertical transmission of HIV, and the fact that many HIV-positive people in Canada are of reproductive age, numerous HIV-positive individuals are considering having a family. This, in turn, leads to a consideration of issues relating to fertility and pregnancy planning. Historically, HIV-positive individuals and couples in which one or both partners were infected with HIV were discouraged from making plans to reproduce. Now, the medical community is more accepting of these individuals' or couples' wishes to have children. However, relatively little data exists regarding those wishing to start families, or the support, services and resources they require, especially in North America [6].

Majority of individuals infected are of child-bearing age

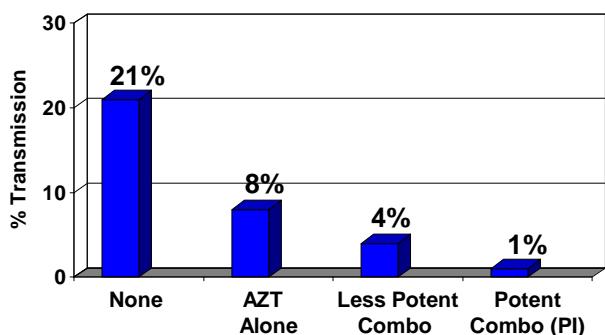
Number of positive HIV test reports among females in Canada, by age



- Reproductive age is defined as 20-44
- 82.8% of test reports are between 20 and 49 years

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Reduced rates of HIV MTCT



Women & Infants Transmission Study, 1990-1999
Cooper E et al. JAIDS 2002;29:484-94

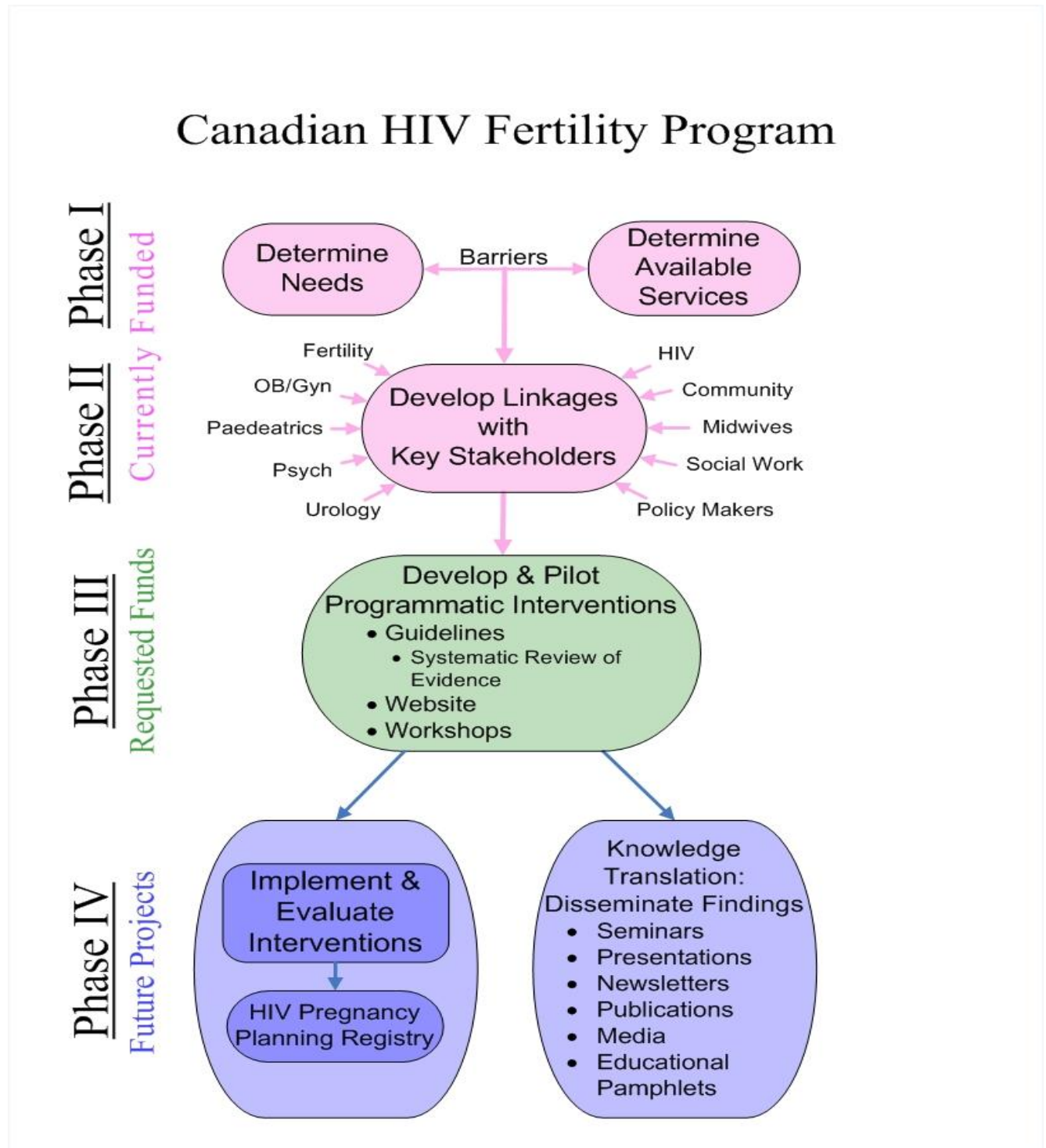
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Despite the fact that many HIV-positive individuals and couples wish to have children, there is a scarcity of HIV or fertility clinics in North America offering assisted reproductive services, such as advice on the management of HIV during pregnancy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

[7-15]. Europeans have been assisting HIV-positive couples to reproduce since the 1980s and at least five European countries have national programs helping people living with HIV with pregnancy planning [16-20]. In the United States (U.S.), as of 2003, still less than 5% of fertility clinics offered reproductive care to HIV-positive serodiscordant couples [6]. In Canada, Southern Ontario Fertility Technologies (SOFT) in London, Ontario was the first fertility clinic to offer services to HIV-positive individuals, such as sperm washing. A few years after SOFT established a precedent, the ISIS Regional Fertility Centre in Mississauga, Ontario and the Mount Sinai Reproductive Biology Unit in Toronto, Ontario began offering assistive reproductive techniques to HIV-positive individuals and couples [16, 21-25]. There are currently only four clinics in all of Canada that offer all artificial reproductive technology services to HIV-positive individuals and couples: the three previously mentioned and the University of Alberta Fertility Clinic.

CANADIAN HIV FERTILITY PROGRAM VISION

To champion a collaborative program that guides and assists people living with HIV in Canada with their fertility desires and pregnancy planning in a holistic, ethical, supportive and medically sound manner.



VANCOUVER IN-PERSON WORKSHOP REPORT

OBJECTIVE

Creating a National Network of individuals, organizations and resources is an important component of the NHPPG Project and the Canadian HIV Fertility Program. Our primary objective for this workshop was to link relevant national experts, for the first time, in order to draft national HIV pregnancy planning guidelines to support HIV-positive individuals living in Canada with their fertility and pregnancy planning needs.

MEETING SUMMARY

We partnered with the Canadian Association of HIV/AIDS Research (CAHR), who included our workshop as part of its formal pre-conference activities at the CAHR Conference held in Vancouver in April 2009. The workshop took place on April 22nd from 4 to 8 pm and on April 23rd from 8 am to 2 pm. For the in-person workshop, we brought together over 50 Canadian experts, including fertility and infectious disease experts, obstetricians, psychiatrists, policy experts, and community representatives who have interest and knowledge of the



fertility and pregnancy planning needs of HIV-positive individuals living in Canada. This workshop was essential to begin building consensus on these guidelines.

Two presentations by community experts took place with a special introduction by community leader Believe Dhliwayo. The first of these was by Marc and Julie Laprise of the Canadian Hemophilia Society about their experience of pregnancy planning as a serodiscordant couple, and the second was by activist Kecia Larkin about her experience of pregnancy planning as an HIV-positive Aboriginal woman. Drs. Matt Gysler and Scott Hamilton then presented on their experience as fertility experts providing full-service fertility and pregnancy planning options for individuals and couples living with HIV. Dr. Mona Loutfy and Ms. Shari Margolese led a discussion on the need that exists for full-service fertility and pregnancy options for Canadians living with HIV and presented an introduction to the NHPPG, as well as the consensus-building process to be used in the development of the NHPPG.

A large group discussion was held on the introductory section of the NHPPG. The Development Team reached consensus on the conceptual framework for the guidelines, the objectives of these guidelines, who these guidelines are for, issues not addressed within these guidelines, and the methods and grading to be used to complete the guidelines development. This was followed by four small group discussions to reach consensus on assigned sections with the use of the AGREE Instrument for development of clinical guidelines. Group 1 discussed important factors for all pregnancies, including ensuring the health of the mother, child and family, legal and ethical issues and psychosocial/mental health issues related to HIV pregnancy planning and fertility. Group 2 discussed ARVs and other drugs in pregnancy planning. Group 3 reviewed options for reducing risk of horizontal HIV transmission during conception. Group 4 discussed fertility issues in the context of HIV, including infection control in fertility clinics. Small groups presented their recommendations back to the larger NHPPG Development Team, and closing remarks were led by Ms. Shari Margolese and Dr. Mona Loutfy.

The workshop succeeded in laying the foundation for a National network of Canadian experts on the topic of HIV pregnancy planning and fertility, building consensus on the theoretical framework and objectives for the guidelines, the audience for the guidelines, the issues not to be addressed within the guidelines, and the methods for grading evidence and recommendations.

WORKSHOP PROCEEDINGS – DAY ONE

INTRODUCTION

Day one of the in-person workshop served as an opportunity for Development Team members to meet face-to-face for the first time, and familiarize the Team with the issues at hand. To facilitate this process, participants were asked to introduce themselves and their work related to HIV pregnancy planning and fertility. Presentations were given from the community and service provider perspectives as well as a project update from the co-principal investigators.

PROJECT UPDATE

Co-principle investigators, Dr. Mona Loutfy and Shari Margolese, welcomed the NHPPG Development Team to the workshop and gave a brief update of work completed in advance of the in-person meeting. This included:

- Creation of a core investigation team
- Development of a protocol
- Procurement of funding
- Identification of potential members of a NHPPG Development Team
- Invitation to participate in the Development Team
- Establishment of a Development Team of over 70 national experts from a variety of stakeholder groups
- Four national teleconferences to determine the scope of the literature review, to obtain feedback from the Development Team on progress to-date and an in-depth discussion regarding the framework under which the guidelines are to be developed
- Presentation to the Tri-partite Committee, in Ottawa, including the Society of Obstetricians and Gynaecologists of Canada (SOGC), the Canadian Fertility and Andrology Society (CFAS) and Assisted Human Reproduction Canada (AHRC)
- Meeting with ISIS Regional Fertility Clinic Staff
- Organization of an in-person meeting in Vancouver
- Liaising with the Canadian Association of HIV Researchers (CAHR) leading to a partnership for the in-person meeting
- Researching and preparing a draft of the NHPPG
- Submission and acceptance of an oral abstract presentation to the CAHR conference



COMMUNITY PRESENTATIONS



Believe Dhiwayo facilitated the community presentation portion of the workshop. Believe is professional man who has lived openly with HIV for more than 13 years. He is an HIV/AIDS community-based activist, a mentor, HIV/AIDS counselor, and a plumber by trade. Believe has worked with the Black Coalition for AIDS Prevention as an Immigration Settlement Adaptation Coordinator, and is a board member for HIV Legal Clinic of Ontario (HALCO). He continues to fight for the rights of PHAs and connects them to psychosocial services and

ensures there are adequate services for people living with HIV/AIDS and other disabilities in the Greater Toronto Area. Believe has initiated community based HIV/AIDS advocacy initiatives in Africa and the European communities, working intensively with community-based AIDS service organizations, UN agencies, civic organizations in Africa and Europe, and has mainstreamed HIV in non-HIV sectors. His passion is restoration of dignity and status of PWAs within the community, ensuring their rights are respected. He continues to inspire and empower others on how to live positively with HIV/AIDS despite the social stigma associated with it. He is married to a wonderful wife and has three children.

Marc and Julie LaPrise shared their experience as a serodiscordant couple who decided to have children. Marc, who is HIV positive, and Julie had very few resources available to them at the time. They researched their options to conceive on the internet. After gathering and weighing the information they had found, they decided to try natural conception when Julie was ovulating. They agreed that they would try this method for six months. They also made an appointment with Southern Ontario Fertility Technologies (SOFT) clinic in London, Ontario for a consultation. There were many considerations involved their decision to conceive naturally. Ethically, they knew there was a risk that Julie could become infected even though Marc's viral load had been undetectable for many years. There was also the issue of Marc's health. Marc was living with HIV and hemophilia. The couple had to consider Marc's current and future state of health when deciding to start a family. Financially, there were the costs of assisted fertility to consider. Marc and Julie also experienced emotional stress during the decision-making process. Julie became pregnant three months after they started trying to conceive and they did not attend the appointment at the fertility clinic. Julie did not become infected with either HIV or HCV.

Marc and Julie's families were excited to hear the news that they were expecting a child. There were many questions about how they avoided horizontal transmission and comments such as, "Julie must really love Marc". Ultimately they found they had the support of their families. Julie gave birth to Bennett Marc Graham LaPrise on August 25, 2005.





In 2006 Marc and Julie decided to have another child. Along with the considerations for the first child, Marc and Julie also considered that they were now responsible for another life, Bennett. This led them to consider assisted fertility as a safer option for conception. Marc and Julie consulted with Dr. Martin at the SOFT clinic in London.

At the time, SOFT was the only clinic known to Marc and Julie that would provide service to HIV-positive couples.

Marc and Julie decided to proceed with sperm washing and intrauterine insemination (IUI). The process involved monitoring Julie's blood on a daily basis. Dr. Martin informed them that blood ovulation monitoring and other services were also provided at ISIS Regional Fertility Centre in Mississauga. This was helpful for Marc and Julie because they live in Mississauga and the travel to London was both time consuming (about an hour and a half drive each way) and costly. It would have been impossible for them to travel to London daily for the blood draws. SOFT clinic called Marc and Julie to tell them that she was ovulating and that they needed to come to London for insemination. ISIS Regional Fertility Centre now provides full service to HIV-positive individuals; however, at the time, this service was not available. The first attempt at conception by IUI was unsuccessful and they went through the process for another cycle. Julie became pregnant after the second attempt and Alaina Kandi Ann LaPrise was born November 27, 2007. Again, Julie did not become infected with HIV. Marc and Julie volunteer their time to share their experience with other serodiscordant couples considering a family.

Kecia Larkin is a 38 year-old member of the Blackfoot and Northwest Coast indigenous people of Canada. Kecia was the first Aboriginal woman in Canada to publicly disclose her HIV status, after testing positive on September 11, 1989. Kecia's willingness to discuss HIV came out of a fear for other Aboriginal people travelling to and from the cities of Canada, and a cultural responsibility to the future generations of Aboriginal people. Kecia began travelling with Dr. Jay Wortman to British Columbian reserves in July, 1990, in a provincial response of prevention through awareness. Kecia shared her experience of being diagnosed HIV-positive when she was just 18 years old. At the time, she was a ward of the courts. There was little hope for survival with HIV in 1989 and she prepared herself to die. Compounding this experience were the historical experiences, policies and practices involving Aboriginal people which deeply affected the health of future generations, including her. Aware that the health of Aboriginal people has to come from within the people, not from outside, Kecia embarked on a journey to, in her words, "save the world". Kecia desired to have children but thought that it was impossible for her. In fact, in 1990, she was told that she should have her tubes tied. She did not heed that advice and did not visit that doctor again.



What worked

[Her]

- Oak Tree
 - Coordinated clinic/appointments for pregnant women's support group
 - Willing HIV friendly GP in Victoria
 - Talking to other women who had babies/were pregnant
 - Factual, scientific information via medical community

[Him]

- Northern Alberta HIV Clinic
 - Factual, scientific information from my doc
 - Access to treatment
 - HIV Friendly Ob/Gyn
 - Meeting Pediatric HIV Clinic beforehand
 - Peer support

Tree Clinic in Vancouver for care. On January 25th she gave birth to a baby girl. She was the first HIV-positive woman to deliver at Victoria General Hospital.

Kecia's second pregnancy in 2001 was also unplanned. Kecia met with the HIV clinic to discuss her options, which had improved since her first pregnancy. It was recommended that she take Combivir to prevent vertical transmission. Kecia suffered from Bone Marrow Anaemia and required blood transfusions. She had an unplanned caesarean section due to low amniotic fluid and the position of the baby. Kecia describes the administration of AZT to her baby by a nurse as traumatic. The baby was transferred to the intensive care unit within minutes after birth due to fluid and partial collapse of the lung. Kecia had a tubal ligation after the second pregnancy and switched to a medication combination for her own health which was more tolerable.

In closing Kecia shared her "words to live by" with the group:

- Learn how to navigate health care system
- Develop a questioning attitude
- Access advocacy/support
- Research everything
- Trust your own feelings
- Get copies of medical records/blood work
- Build your health care team
- Learn about your illness
- Talk to others who share your illness
- Don't be afraid to be skeptical
- Learn how to be a squeaky wheel and question privilege in health care. Not all is equal!

Kecia shared her experience of having two children while HIV-positive including which aspects of care worked and which did not. Kecia's first pregnancy in 1992-93 was unplanned. She thought that the morning sickness she was experiencing was actually AIDS-related sickness and she again prepared to die. When she realized she was pregnant she went to the Elders of her community for advice. At the time there was no treatment available to prevent vertical transmission of HIV. She decided to continue the pregnancy and went to the Oak

What didn't work

[Her]

- Stigma attached to exposing others to HIV
 - Community ignorance of reproductive issues-"You are going to bring a baby into the world for it to die" ...
 - Micro aggressions of nurses-"You aren't going to get pregnant again are you?", "How did you get HIV?"
 - Lack of support,policy/funding for women and children

[Him]

- Treatment Issues
 - Side effect management
 - AZT Administration Plan After Birth-Nurse was too eager
 - Slow follow up to low amniotic fluid
 - Lack of support/policy/funding still non-existent for women or children

SERVICE PROVIDER PRESENTATIONS



Mathias Gysler MD, FRCSC received his medical degree from the University of Western Ontario with fellowship training in Obstetrics and Gynecology at the University of Toronto in 1973. Following subspecialty training in Reproductive Endocrinology and Infertility at the University of Southern California (San Diego), he became a full-time staff member at the University of Toronto Obstetrics and Gynecology Department from 1980 to 1987. Dr. Gysler became actively involved in IVF in 1983 and upon leaving the University in 1987, he joined a community practice in Mississauga. He is the founding member and Medical Director of the ISIS Regional Fertility Centre. He has continued his active involvement in IVF with a number of Toronto clinics and maintains a gynaecology practice which is largely oriented toward infertility. Dr. Gysler is currently the Chief of

Staff at the Credit Valley Hospital in Mississauga, Ontario and is very involved with the development of legislature regarding infertility in Canada.

For the NHPPG workshop, Dr. Gysler gave a detailed and candid presentation to the group about the HIV Program at ISIS entitled “HIV/AIDS and Reproduction: HIV Discordant Couples Making Pregnancy Possible”. Dr. Gysler’s presentation included a discussion of the rationale for providing service to HIV-positive people, preparing the partners, staff and clinic for serving this population and managing the patients and their ongoing care.

The Rationale

In developing a rationale for treating HIV-positive patients, Dr. Gysler argued that the fundamental right for all people to have children (as described by the World Health Organization) must be weighed against both the risk of horizontal and vertical transmission. Dr. Gysler explained that since the risk of transmission has been dramatically reduced to close to 0, the right to have children supersedes the risk of infection. Furthermore, Dr. Gysler’s rationale included the fact that if ISIS looks after patients with Hepatitis B and C then there is no reason not to advise and treat patients carrying the HIV Virus.

Preparing the Partners

Dr. Gysler candidly described the discussion he began with his business partners in 2003. He admitted that they were skeptical at first, fearing that other patients may find out they were caring for HIV-positive patients and not use the facility. Dr. Gysler shared with his partners his rationale for treating people with HIV. They also discussed the official position of the American Society of Reproductive Medicine and other related associations, along with the risk of HIV transmission to patients and staff and the perceived risk of loss of clients.

Preparing the Clinic, Staff, Facility and Laboratory

In order for the practice to move forward to offer services it was imperative for the clinic partners and staff to adopt the vision and rationale that Dr. Gysler presented. Consistent with their vision, mission and values, it was decided that upon entering the ISIS clinic that HIV positive patients will:

- Find respect for their right to have children
- Be treated with respect and dignity
- Have the same access to treatments as anyone else
- Be as informed as possible about risks and benefits

Prior to opening the doors to HIV-positive patients, Dr. Gysler trained the administrative staff, clinical staff, ultrasound technicians, nurses, physicians, and laboratory staff on how to treat HIV-positive patients. ISIS developed clinical processes for specimen collection, labelling and processing along with instructions specific to HIV-positive patients. In the laboratory, incubators, media and storage facilities were prepared to accept potentially infectious materials.

Planning Clinical Activity

Dr. Gysler and his team established practice guidelines along with HIV treatment prerequisites in order to manage patients effectively. Guidelines were created for both male and female partners as described below.

Female Partner HIV-Positive:

- Consultation
- Basic infertility investigations
- Risk explanation
- Option of risk reduction
- Treatment outline to delivery
- IUI, cervical or vaginal insemination

Male Partner HIV-Positive:

- Consultation
- Infertility investigation same as other patients
- Strategies for risk reduction
- Optimal anti-retroviral therapy
- Sperm preparation for insemination
- Sperm preparation for IUI, IVF and/or ICSI treatments
- Intravaginal/cervical insemination, IVF/ ICSI

Outcome to Date

	seen	treated	No Treatment	IVF/ICSI	IUI/ intravaginal
Couples	36	17	19	7	10
Pregnant			0	4	3

9/12/2009 M Gysler

Impacting Factors

7/17 female consults age 41+y/o (41-46)

3/7 failed IVF

Age > 40

Poor ovarian reserve

Stage 4 Endometriosis

Poor continuation rate with IUI Treatments

Managing Ongoing Care

In order to manage the HIV pregnancy, Dr. Gysler refers patient for specialized pregnancy care and continues to follow them in his clinic as well. If the treatment is unsuccessful, the couple or individual is treated the same and offered the same options as any other infertile couple.



G. Scot Hamilton, MSc, PhD earned his PhD in Physiology at the University of Western Ontario. For the past 12 years he has directed embryology laboratories for the ISIS Regional Fertility Centre in Mississauga and Heartland Gynecology and Fertility Clinic in Winnipeg, Manitoba. He is a Lecturer for the Physiology Department at the University of Western Ontario, a Surveyor for Accreditation Canada and participates on a number of advisory committees which review standards for assisted reproductive technology (ART) laboratories

Dr. Hamilton presented a detailed laboratory perspective on ART handling of HIV-positive patients including both personnel issues and procedural considerations.

Generally, uninformed staff members fear interaction with individuals carrying infectious diseases due to ignorance about the diseases; however, laboratory personnel, particularly blood lab technologists, are less susceptible to these fears because it is an essential part of their job. In order to desensitize personnel at ISIS it was necessary to provide advanced information regarding infectious status and handling of infectious materials. Dr. Hamilton clearly defined the standard procedures used to minimize the risk of HIV infection between partners and pointed out some of the issues to consider when choosing ART.

Potentially Infectious Male

The standard procedure (at ISIS and many ART labs) for processing semen for Intrauterine Insemination (IUI) or Freezing is density gradient centrifugation. This approach removes cells which would contain the virus.

Dr. Hamilton described the continuum of risk of ART: for example, IUI is safer than unprotected intercourse; in-vitro fertilization (IVF) is safer still; intro-cytoplasmic sperm injection (ICSI) is a single sperm per egg. Each step involves less exposure to semen/sperm.

Potentially Infectious Female

- IUI or Vaginal insemination of processed semen
- IVF egg retrieval does involve slight exposure to blood products

Scheduling and Surface Cleaning

Scheduling and surface cleaning are important; however, scheduling all potentially infectious patients at the same time adds relatively little in terms of added reduction in infectious transmission. Rather, the main benefit involves the provision of some additional time for staff to accommodate potential special needs (usually instructions only) of patients and additional time for surface cleaning.

Long Term Storage of potentially infectious material including Incubators and Liquid N2 Dewars

Dr. Hamilton suggested the following for storage of potentially infectious materials:

- Separate incubator (largely for appearance but allows ability to perform additional cleaning)
- Cryostorage (frozen gametes/embryos)
- Separate Dewars (Thermos-like units)
- Bio-containment straws (high-security CBS; are suitable for all patients)

WORKSHOP PROCEEDINGS – DAY TWO

The second day of the workshop began with a large-group-consensus-building discussion in the morning, followed by afternoon breakout sessions to examine specific sections of the guidelines. The large group reached consensus on the following topics:

- Framework
- Objectives of these guidelines
- Who are these guidelines for?
- Issues not addressed within these guidelines
- Methods and grading

Framework

During the teleconferences leading up to this in-person meeting, the development team decided to develop a conceptual framework for the NHPPG. Interested Development Team members met via teleconference to discuss a conceptual framework and theoretical approach for the NHPPG. Key points from the discussion included:

- Need for guidelines to be evidence based
- Need for the guideline process to be participatory and community-based
- Human rights/justice-based approach
- Consideration of the social determinants of health
- Consensus that HIV-positive people have the right to conceive

A draft conceptual framework was developed and reviewed by the larger group during the in person meeting in order to reach consensus. The group approved the following conceptual framework statement:

The development of these guidelines is a multidisciplinary partnership between community members, HIV specialists, fertility experts, obstetricians, midwives, social scientists, and policy advisors. Consistent with a community-based or participatory action approach, guideline development has included members of the affected community in all aspects of the project from inception to publication, including community participation as co-principal investigator and development team members. The Guidelines Development Team includes individuals and organizational representatives of each of the groups mentioned above as well as stakeholders from across diverse demographic groups and from across Canada for national representation.

Conceptually, these guidelines have been developed on the World Health Organization (WHO) premise 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” (WHO), including people living with HIV. By using a human-rights-based approach the Development Team recognizes that the human rights of those infected and affected by HIV are frequently violated and often impact on their intentions and desires to have children. Additionally the Development Team recognizes the need to cultivate strong leadership amongst all stakeholders and to integrate these mutually-agreed-upon guiding principles into all aspects of HIV pregnancy planning, fertility care, treatment, and support for all people living with HIV in Canada. Recommendations and their implementation must be evidence-based, accountable, and flexible, and take into account diverse and intersecting local/population needs based on the social determinants of health.

Objectives of these guidelines

The Development Team reached consensus on the primary objective of the NHPPG:

The objective of the National HIV Pregnancy Planning guidelines is to assist individuals living in Canada with their fertility and pregnancy planning needs through the provision of information and recommendations which are evidence-based, accountable, and flexible and take into account diverse and intersecting local/population needs based on the social determinants of health.

Who are these guidelines for?

The Development Team reached consensus on the audience for the NHPPG:

These guidelines are intended for use by HIV-positive individuals who are considering planning a pregnancy and the healthcare providers with whom they consult, including but not limited to physicians, fertility clinic staff, nurses, councilors (including those who are involved in post-test counseling), midwives, and community based organizations. Additionally, these guidelines are addressed to policy makers as a reference when defining policies such as reimbursement, and other regulations which affect access to pregnancy planning and fertility treatment, including access to information, care, treatment, and support for people living with HIV in Canada.

While discussing the audience for the NHPPG the Development Team stressed several points including:

- The importance of including pregnancy planning and fertility information in post-test guidelines including during immigration
- Importance of translating the guidelines into French
- The need to engage the Canadian Fertility and Andrology Society (CFAS), the Society of Obstetricians and Gynecologists of Canada (SOGC), Assisted Human Reproduction Canada (AHRC), the Association of Medical Microbiology and Infectious Disease (AMMI), and possibly the Canadian Medical Association (CMA), to endorse guidelines. *(Since the in-person meeting CFAS, SOGC and AMMI have agreed to work with the Development Team to endorse these guidelines.)

Issues not addressed within these guidelines

The Development Team agreed that it will be important to indicate what issues will not be addressed in the NHPPG. Consensus was reached that the following issues will not be included in the final guidelines and that readers would be directed to existing guidelines where applicable:

- management of HIV during pregnancy
- guidelines for testing for HIV during pregnancy
- post-partum period
- feeding options including breastfeeding
- fertility and infertility issues relevant to the general population

Methods and Grading

Dr. Loutfy reviewed the methods and grading to be used to develop the NHPPG. After a brief discussion the Development Team agreed to use the AGREE instrument, as it is what is used by the SOGC and other guideline-producing entities. Evidence collected during this process will be graded according to the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care. Additionally, the group agreed that it would be important to add a paragraph to the guidelines explaining that scientific evidence is not available for all aspects of the guidelines and that expert opinion and consensus would be used to grade such evidence.

Breakout sessions

The objectives of the breakout sessions were to discuss, revise and achieve consensus on the draft of the National HIV Pregnancy Planning Guidelines (NHPPG) by providing a forum in which to:

- Discuss the perspectives of a diverse group of stakeholders
- Determine whether the NHPPG represents the views of the stakeholders
- Discuss the recommendations presented in the NHPPG and make appropriate revisions
- Discuss the quality of the evidence presented in the NHPPG and assess its adequacy
- Determine if the NHPPG adheres to the adopted theoretical framework and revise if necessary
- Identify areas for further development within the NHPPG

To facilitate discussion and ensure broad participation, the NHPPG Development Team was to be divided into four small breakout groups of 7-10 people each. Each group was led by a community lead, academic or clinical lead and a Women's College Research Institute team member. Each group focused on one of the following aspects of the NHPPG:

- Legal / Ethical / Policy
- Psychosocial
- Scenarios / All pregnancies including ARVs and other Drugs
- Fertility Investigations, Treatments and Infection Control

Group 1 – Legal / Ethical / Policy

Group 1 discussed the importance of reaffirming the fundamental human right to have a healthy pregnancy free from discrimination. The group also noted that legal, ethical and policy issues remain challenging in terms of guideline development because of the limited available data and a wide range of interpretations of said data. In this case the group recommended that HIV-positive Canadians planning pregnancy should be counseled on the following points in order to make an informed decision about pregnancy planning:

- Access to services: costs, travel time, knowledge
- Healthcare coverage of services: assisted reproductive technologies; reversal of tubal ligation
- Criminalization: disclosure; partner exposure; transmission to infant
- Discrimination: in fertility clinics; Children's Aid Society; adoption agencies
- Confidentiality and Privacy

Group 2 -- Psychosocial Issues

Group 2 discussed that the NHPPG should be accessible to all individuals regardless of gender, sexual orientation or cultural group. Further, group 2 agreed that psychosocial issues could be compartmentalized into three distinct areas: social welfare, counseling and mental health.

- Social welfare: housing, financial concerns, guardianship of children, and other social determinants of health
- Counseling: pre-partum planning, breastfeeding, expectations of entire pre-intra- and post-partum processes, breastfeeding
- Mental Health: emphasis on the importance of mental health education and care, screening for depression in the pre-partum period as in general pre-conception counseling

Group 2 also had a lengthy discussion about discrimination and identified it as an intersecting problem from preconception to breastfeeding which includes self-guilt, guilt from community, peer guilt. Such discrimination manifests itself in potential loss of support. Recommendations to address these issues include providing additional resources to care providers (possibly in the form of a checklist or flow chart for quick reference) and information on how to refer people to other specialists.

Group 3 – Scenarios / All pregnancies including ARVs and other Drugs

This group had a large number of issues to consider during their discussions, including:

- Ensuring a healthy mother, child and family
- ARVs and other drugs in pregnancy planning
- Options for reducing risk of HIV transmission during conception

There was general consensus among members of this group that where available readers should be referred to other guidelines that exist. For example, there is some controversy about recommendations for the amount of folic acid which should be used by women in the preconception period. There was also general consensus the recommendations should not be too long and that there are certain issues that were gray areas in which no recommendations or guidelines could be made. The group members also agreed that gray areas be discussed and acknowledged in the guidelines rather than omitted. Further, the group reached consensus that preconception counseling was very important and that all of these areas, including those which are considered gray, be discussed with individuals or couples planning pregnancy.

Ensuring a healthy mother, child and family

Group 3 agreed that, generally, HIV-positive people planning pregnancy should be counseled following standard pre-conception counseling guidelines, in addition to information specific to HIV infection (e.g. women should start taking folic acid 1-5 mg/day 1-3 months prior to conception and for the first 2-3 months of pregnancy). As mentioned above, existing guidelines should be referred to when available.

ARVs and other drugs in pregnancy planning

Group 3 agreed that decisions made about the use of ARVs and other drugs during pregnancy should be done in consultation with experts such as infectious disease specialists and pharmacists. One of the key issues to be determined is when to start treatment for HIV infection in the context of pregnancy planning. This group recommends the following strategies:

HIV+ men and women who require ARVs for their health

For these men and women it was agreed to recommend ARVs during pre-conception period as required with women avoiding or switching from any drugs which are teratogenic.

Women who do not require ARVs for her health

For this group of women it is suggested that they be provided two options with a preferred option being recommended:

- Start ARVs in preconception period
- Start ARVs after first trimester (recommended)

Men who do not require ARVs for their health

There is seldom discussion about the benefit of starting ARV treatment during the pre-conception period for men who do not require ARV's for their health.

Group 3 felt that treatment before conception was a risk reduction issue as reduction in viral plasma load often correlates to reduction of viral load in semen.

Options for Reducing Risk of HIV transmission during conception

During their discussion of options for reducing risk of HIV transmission during conception Group 3 considered the following options:

- Timed natural conception with and without ART
- Home insemination
- Special methods of sperm washing
- Intra-uterine insemination (IUI), in-vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI)
- Sperm donation
- Surrogacy
- Adoption

Group 3 agreed that scenario-based recommendations dependant on the parent's sero-status should be used, and that all options be discussed in all scenarios so that individuals or couples could make informed choices about which option best suited their needs. As with recommendations for ARV therapy, a preferred option should be indicated where possible to further inform patients' decisions.

Scenarios and preferred options as agreed upon by group 3:

HIV-positive woman and HIV-negative man

- Preferred option: home insemination of IUI

HIV-positive single woman or HIV-positive woman in a same sex relationship

- Preferred option: home insemination or IUI with known or unknown sperm donor

HIV -positive man and HIV -negative woman

- Preferred option: sperm washing with IUI

HIV-positive single man or male same sex couple

- Preferred option: sperm washing with IUI with a known or arranged surrogate. Additionally, the group stressed the importance of addressing sperm donor legislation from 1996.

HIV-positive man and woman

- Preferred option: sperm washing with IUI

Group 4 - Fertility Investigations, Treatments and Infection Control

Group 4 undertook the task to discuss fertility investigations, treatments and infection control in the context of HIV. Group members agreed that HIV- positive people should be counseled about fertility issues that occur in the general population, including such issues as age which is a major factor when considering fertility issues. Additionally, the group agreed that infertility treatment should be offered to HIV-positive people if required. This group concurred with Group 3 that ARV recommendations should be made for risk reduction and should be made in consultation with an infectious diseases specialist.

When discussion infection control in fertility clinics Group 3 participants agreed that the most important factor is the use of universal precautions in all settings, not only in the presence of HIV. This is already common practice in fertility clinics.

Additionally, sperm and embryos can be safely stored in bio-containment straws in nitrogen (liquid or vapor). As Dr. Hamilton mentioned in his presentation, storing potentially infectious materials in segregated containers is often more for appearance of added security than a security requirement.

Other points discussed in this section included accreditation for fertility clinics. Fertility specialists in the group pointed out that accreditation is not standardized in fertility services. Community representatives suggested that when patients look for fertility centres they should know that there is accreditation and know what basic questions to ask to know if fertility centres are accredited or not.

Next steps

The next steps towards completion of the NHPPG include:

- Finalize literature review with assistance from Development Team Experts, specifically under the topic headings Legal and Ethical issues for pregnancy planning and fertility.
- Complete National Guidelines revisions based on recommendations from Vancouver in-person meeting and subsequent meetings.
- Finalize next draft of the National Guidelines.
- Organize a meeting of the Development Team in partnership with the CTN during their bi-annual meeting in October in Montreal to finalize the draft Guidelines.
- Organize one teleconference before the Montreal meeting.
- Organize one teleconference after the Montreal meeting.
- Continue to liaise with the SOGC to determine the appropriate process to finalize the Guidelines for publication.
- Continue to liaise AMMI Canada to co-endorse the guidelines with the SOGC.
- Apply for a CIHR, CBR or KT grant to continue to the implementation, monitoring and evaluation stages of the NHPPG initiative.
- Attend the CFAS conference in Montreal in November and present oral abstract.
- Distribute final Guidelines.
- Develop plan for the evaluation and uptake of the Guidelines.

Conclusion

The NHPPG in-person Development Team Meeting was highly successful in bringing together a wide variety of relevant Canadian stakeholders for the first time. National guidelines on pregnancy planning for HIV-positive individuals are now well underway through linking these key national stakeholders from diverse areas of expertise. These guidelines will be important to clinicians, policy makers and government agencies to understand how to support PHAs, fertility clinics and other service provider settings, allowing an increase in safer planned pregnancies for HIV-positive individuals.

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