



Canada's source for  
HIV and hepatitis C  
information

La source canadienne  
de renseignements sur  
le VIH et l'hépatite C

## Planning Pregnancies in 2014: Options and opportunities for care of people and couples affected by HIV

Presented by: Mona Loutfy, MD, FRCPC, MPH

Infectious Diseases Specialist & Clinical Researcher

Wednesday, October 8, 2014



Please make sure you access the audio  
portion:

**Toll-free access number:** 1-877-250-4348

**Access code:** 8859137

**The webinar will commence  
shortly.**

**All participants will be muted  
until the question period.**

# HIV-positive parenting in Canada

A webinar series co-organized by IHPREG and CATIE

**IHPREG** brings together Ontario's leaders on the issues associated with HIV during preconception, pregnancy, postpartum and in any circumstance following pregnancy.

**CATIE** is Canada's source for up-to-date, unbiased information about HIV and hepatitis C. We connect people living with HIV or hepatitis C, at-risk communities, healthcare providers and community organizations with the knowledge, resources and expertise to reduce transmission and improve quality of life.



IHPREG  
INTERDISCIPLINARY  
HIV PREGNANCY  
RESEARCH GROUP



# HIV-positive parenting in Canada

A webinar series co-organized by IHPREG and CATIE

Today's webinar is the first in a three-part series that will explore issues related to HIV, pregnancy and parenting in Canada. Stay tuned for:

- A Complicated Dilemma: HIV and infant feeding
- Life With Baby: What happens next?

We will share additional details with you shortly.

A French version of this webinar series will be presented in 2015.



IHPREG  
INTERDISCIPLINARY  
HIV PREGNANCY  
RESEARCH GROUP



# HIV-positive parenting in Canada

A webinar series co-organized by IHPREG and CATIE



**Dr. Loutfy** is a Clinician Scientist at Women's College Hospital and Associate Professor in the Department of Medicine at the University of Toronto. She is Director of the Women and HIV Research Program at Women's College Research Institute and practices at the Maple Leaf Medical Clinic in Toronto. Dr. Loutfy also dedicates her time to working with rural, remote and underserved women living with HIV in Saskatchewan.



IHPREG  
INTERDISCIPLINARY  
HIV PREGNANCY  
RESEARCH GROUP



**CATIE & IHPREG co-present:**

***Planning Pregnancies in 2014:  
Options and opportunities for care of  
people and couples affected by HIV***

Webex Webinar

Wednesday, October 8<sup>th</sup>, 2014 2-3 pm

Mona Loutfy, MD, FRCPC, MPH

Infectious Diseases Specialist & Clinical Researcher

Women's College Research Institute, Women's College Hospital & Maple  
Leaf Medical Clinic, Toronto, ON

# Disclosure

**No conflicts of interest to declare  
related to this work**

# Objectives

1. To review factors making fertility increasingly relevant in the context of HIV
2. To review issues related to fertility and HIV
  - Particularly related to horizontal transmission
3. To review the work of the Canadian HIV Fertility Program
  - Including the Canadian HIV Pregnancy Planning Guidelines
4. To answer any question on HIV and Pregnancy Planning

# Background

- Since there is,
  - Decreasing mortality related to HIV (life expectancy on average 50-60 years from diagnosis with ARVs for a young person\*)
  - Increasing prevalence of women who are HIV-positive (51% globally, 23% in Canada)
  - A majority of people living with HIV – are of reproductive age (> 80%)
  - Methods to reduce the chance of vertical transmission to < 1%

⇒ Persons living with HIV are going to be interested in **PREGNANCY PLANNING**

\* The Antiretroviral Therapy Cohort Collaboration, Life expectancy of individuals on combination antiretroviral therapy in high-income countries: a collaborative analysis of 14 cohort studies. *Lancet*. 2008; 372(9635):293 -9.



# Cross-sectional study to assess fertility desires & intentions

**N = 490 Ontario HIV+ women of reproductive age**

| Outcome                             |                              |
|-------------------------------------|------------------------------|
| <b>Fertility desired (N = 475)</b>  | <b>69% (95% CIs, 64-73%)</b> |
| 0                                   | 31%                          |
| 1                                   | 32%                          |
| ≥ 2                                 | 37%                          |
| <b>Fertility intended (N = 465)</b> | <b>57% (95% CIs, 53-62%)</b> |
| 0                                   | 43%                          |
| 1                                   | 26%                          |
| ≥ 2                                 | 31%                          |
| <b>Fertility actions (N = 456)</b>  |                              |
| Approached partner                  | 32%                          |
| Approached doctor                   | 26%                          |
| Stopped BC to become pregnant       | 12%                          |

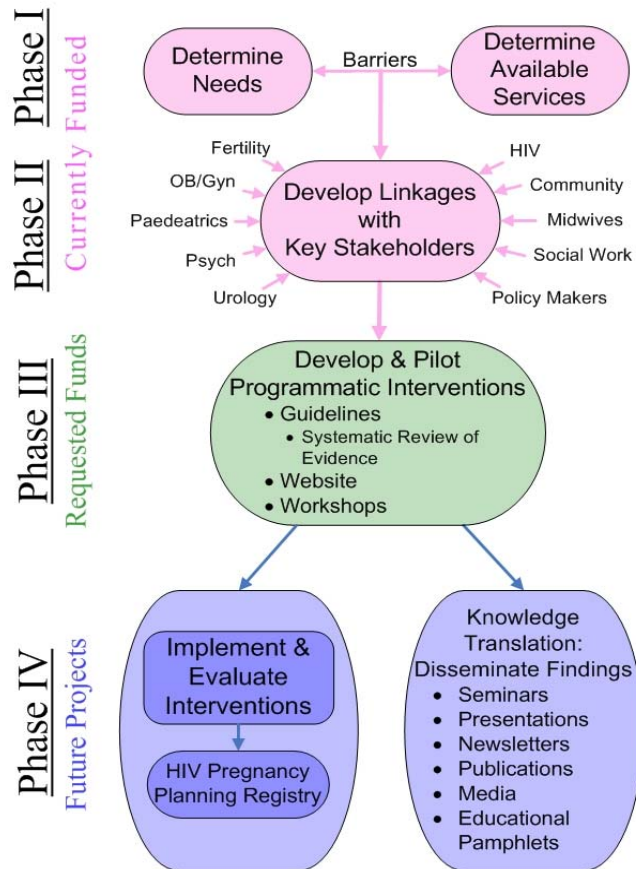
Loutfy et al. PloS ONE 2009

# 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

### Canadian HIV Fertility Program



# Canadian HIV Fertility Program Diagram

- **One of Program's Goal:** to have the discussion of pregnancy, reproduction, pre-conception planning as part of routine HIV care
  - **Between all HCP & HIV-positive patients**
- **Why:** many reasons
  - We want pregnancies of HIV-positive women to be planned in order to improve maternal & infant health, and reduce vertical and horizontal transmission
  - Allow for discussion of contraception, sexual health, harm & transmission reduction, criminalization

# Canadian HIV Fertility Program-CHFP

- CHFP planned activities
  - Link key national stakeholders (Fertility, HIV, OB/Gyn, Midwives, Community, Family Practice, Social Work, Health Promotion, Psychiatry, Policy Advisors, Government, Researchers, Pediatricians, Others)
  - Develop national guidelines on pregnancy planning and reproduction for HIV-positive Canadians
  - Develop knowledge translation and education tools
    1. Pamphlets
    2. Workshop
    3. Fact sheets
    4. Website

# Results

## SOGC CLINICAL PRACTICE GUIDELINE

No. 278, June 2012

# 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 reviewed 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.

### PRINCIPAL AUTHORS

Mona R. Loutfy, MD, Toronto ON

Shari Margolese, Toronto ON

Deborah M. Money, MD, Vancouver BC

**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



# General Principles for Pregnancy Planning

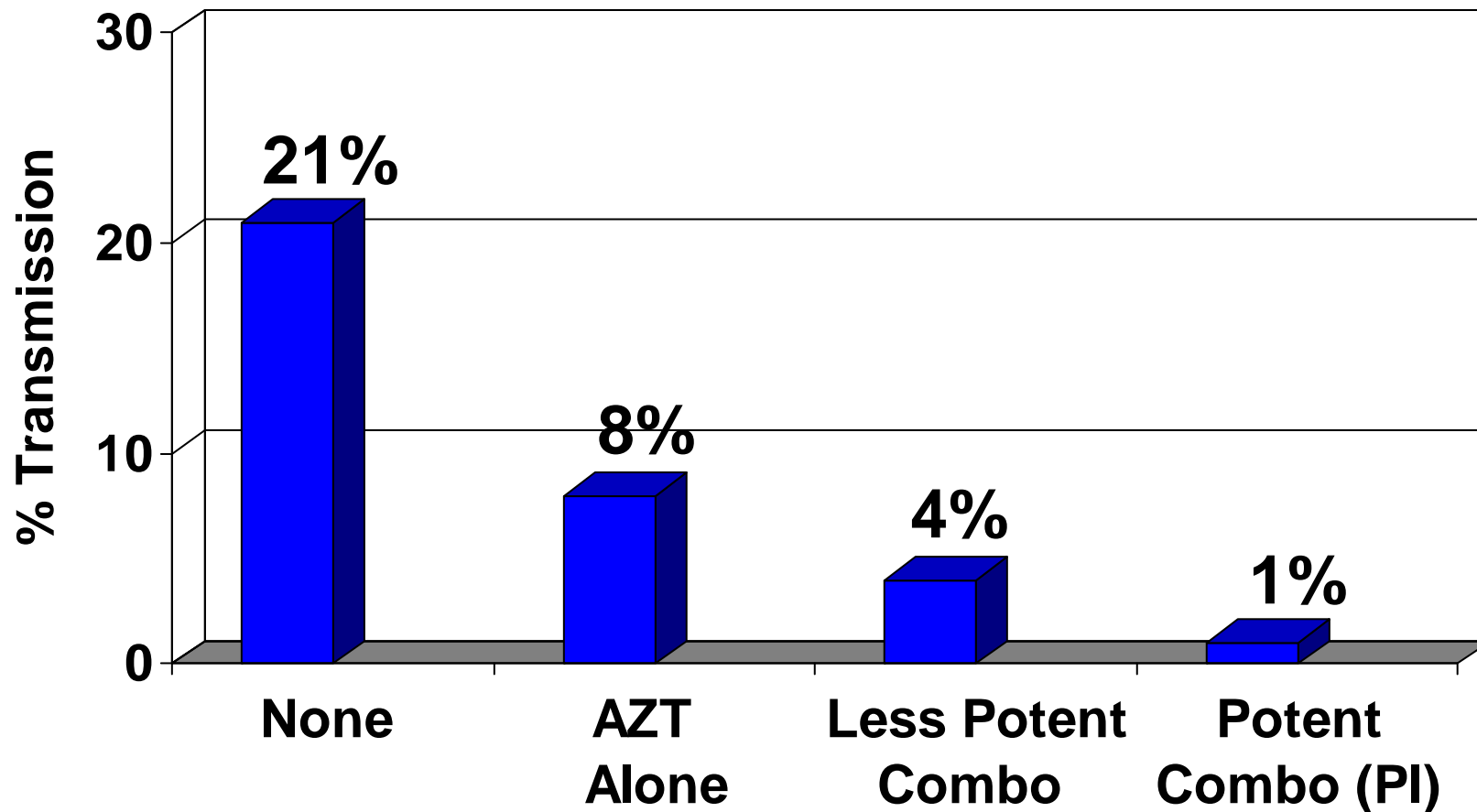
- Taking Folic Acid: 1 mg a day for 1-3 months before and during 1<sup>st</sup> trimester of pregnancy
- Not smoking and drinking
- Maintaining a balanced diet
- Terminating the use of recreational drugs



# Antiretroviral drugs and fertility

- **Preference is to have HIV+ person on appr. drugs**
  - Any ARVs except Efavirenz, D4T, ddI, ddC in women
  - i.e. 3 ARVs – 2 NRTIs (e.g. Combivir, Truvada, Kivexa) + boosted PI or NNRTI or Integrase inhibitor
  - For >3-6 months with viral load <40 copies/mL
  - Future mother and father should not have received HCV treatment for 6 months before conception
- **Exceptions:**
  - Women - long-term or slow progressor who doesn't need ARVs for her own health (i.e. CD4 > 500 cells/uL), can wait until 12 weeks gestation

# Reduce rates of HIV VT



**Women & Infants Transmission Study, 1990-1999**

***Cooper E et al. JAIDS 2002;29:484-94***



# HIV Pregnancy Guidelines

## Guidelines Updated – 2014:

- Centers for Disease Control and Prevention. U.S. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States.
  - Including use of ARVs & C/S and not breastfeeding
  - Up to date guidelines: <http://aidsinfo.nih.gov/guidelines/>

## Prevention of Horizontal Transmission

- **Different clinical scenarios:**
  1. HIV+ woman with HIV- man (serodiscordant) or who is single or in same sex relationship
  2. HIV+ man and HIV- woman (serodiscordant)
  3. HIV+ man and woman (seroconcordant)
  4. HIV+ man who is single or in same sex relationship or couple seeking egg donation or surrogate mother
- Different clinical scenarios have different risk of and require different strategies to prevent horizontal transmission

# For all scenarios

- Review all different options for insemination/conception attempt & continuum of risk including:
  - Unprotected intercourse (on ART, full viral suppression)
  - Unprotected intercourse with timed ovulation (on ART, full viral suppression)
  - Home insemination (i.e. turkey baster method)
  - Intrauterine insemination (IUI) (in fertility clinic)
  - Sperm washing followed by IUI
  - Other: IVF, ICSI, gestational carrier, adoption

## 1) HIV+ woman and HIV- man

- Review all different options for insemination & continuum of risk including:
  - Unprotected intercourse (on ART, full viral suppression)
  - Unprotected intercourse with timed ovulation (on ART, full viral suppression)
  - **Home insemination**
  - **Intrauterine insemination (in fertility clinic)**
  - Other: IVF, ICSI, gestational carrier, adoption

**Bold:** typically recommended by HCP due to lowest chance of horizontal transmission;  
All options after full understanding of risk

## 2) HIV+ man and HIV- woman

- Review all different options for insemination & continuum of risk including:
  - Unprotected intercourse (on ART, full viral suppression)
  - Unprotected intercourse with timed ovulation (on ART, full viral suppression)
  - **Sperm washing with IUI (in fertility clinic)**
  - Other: IVF, ICSI, sperm donor, adoption

**Bold:** typically recommended by HCP due to lowest chance of horizontal transmission;  
All options after full understanding of risk

## 2) HIV+ man and HIV- woman: Sperm Washing and IUI

- In 2007, Bujan *et al.* conducted a study involving 1036 serodiscordant couples (HIV+ male, -female) wishing to procreate
- **Results:**
  - **No transmission of HIV to female partner** observed after 3272 cycles with complete follow-up information
  - Pregnancy resulted in 580 / 3315 cycles where outcome was known
  - Clinical pregnancy rate = 17.5% (per cycle)

## 2) HIV+ man and HIV- woman

- Review all different options for insemination & continuum of risk including:
  - Unprotected intercourse (on ART, full viral suppression)
  - **Unprotected intercourse with timed ovulation (on ART, full viral suppression)**
  - **Sperm washing with IUI (in fertility clinic)**
  - Other: IVF, ICSI, sperm donor, adoption

**Bold:** typically recommended by HCP due to lowest chance of horizontal transmission;  
All options after full understanding of risk

# HPTN 052 Study

## Randomized Control Trial

- Compare early versus delayed ( $CD4 < 250$ ) ART for HIV-1 positive patients having 350-550  $CD4$  per  $mm^3$  and in stable sexual relationship with uninfected partner –outcome:
  - Transmission to uninfected partner (linked)
- 893 couples in Early Therapy Arm; 882 couples in Delayed Therapy Arm
- 28 HIV-transmissions were linked: 27 in Delayed Arm; 1 in Early Arm (occurred at 3 months post-ARVs) (0.1 per 100 person-years) [HR 0.04 (CI 0.01-0.27);  $p < 0.001$ ] = 96% reduction of HIV transmission with ART



# PreP (i.e. Pre-exposure Prophylaxis) for HIV+ man and HIV- woman

- **PreP to prevent horizontal transmission in serodiscordant couples in which the man is HIV+ and the woman is HIV-**
  - **No recommendation in CHPPG**
  - **American Statement:**
    - “PrEP use may be one of several options to help protect the HIV-negative partner in discordant couples during attempts to conceive” (CDC, 2012)
- **One clinical study on topic: Vernazza *et al.* AIDS 2011, 25:2005–2008**
  - 46 couples use PrEP with unprotected timed intercourse
  - None of the female partners had acquired HIV

# An economic evaluation of conception strategies for heterosexual serodiscordant couples with HIV-positive male partners

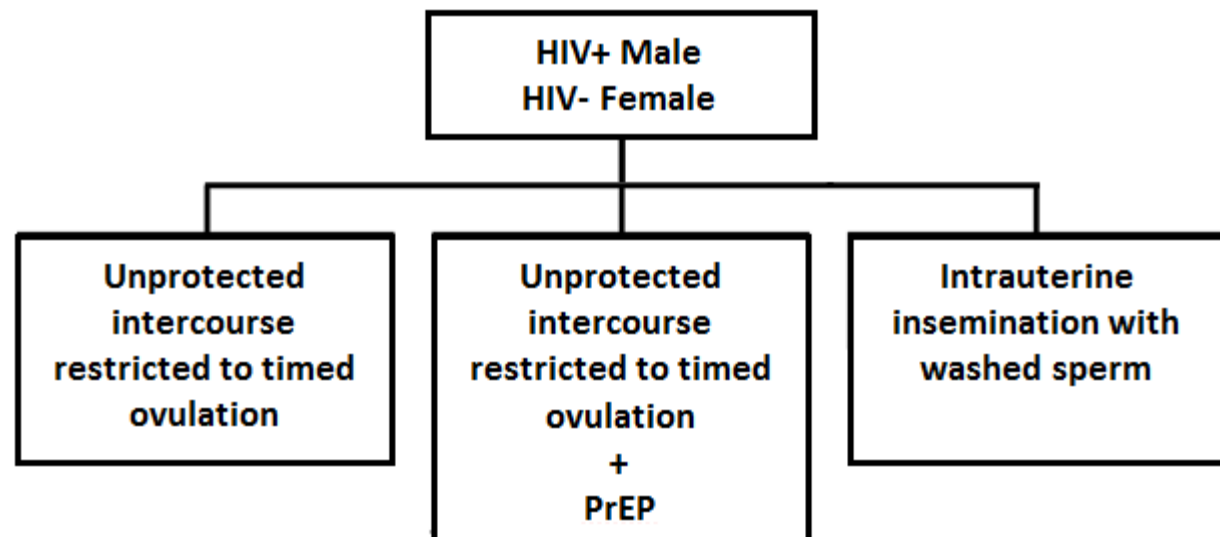
**Objective: determine which of 1) unprotected intercourse with timed ovulation (UITO), 2) UITO with PrEP (U-P) or 3) Sperm washing with IUI is most cost effective**

## **Base Case Analysis**

### ▶ Hypothetical cohort

- HIV-negative female partner is 30 years old and fertile
- HIV-positive male partner is fertile, cART for  $\geq 6$  months with viral load  $\leq 50$  copies/ml

### ▶ The decision

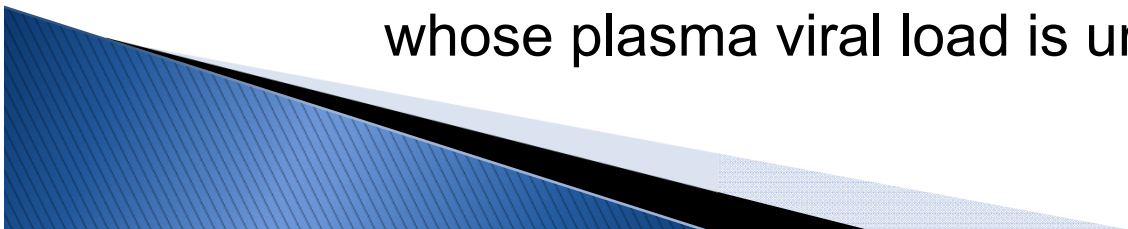


# Results

**Table 1. Base Case Analysis**

|        | Costs, \$CND | QALYs | Incremental<br>Costs, \$CND | Incremental<br>QALYs | \$ per QALY<br>gained |
|--------|--------------|-------|-----------------------------|----------------------|-----------------------|
| UIRTO  | 1,319.00     | 15.56 | -                           | -                    | Undominated           |
| U-PrEP | 1,757.00     | 15.41 | 438.00                      | -0.15                | Dominated             |
| IUIWS  | 16,229.00    | 15.24 | 14,910.00                   | -0.32                | Dominated             |

- ▶ **Recommendations for policy-makers**
  - Neither pre-exposure prophylaxis or washed sperm represent a better value for money relative to timed intercourse for fertile HIV-negative women residing in Ontario who wish to conceive with an HIV-positive man whose plasma viral load is undetectable



# New data ... hot THIS YEAR – CROI 2014

## ● PARTNERS STUDY

- Enrolled 1110 serodiscordant couples, 40% same-sex gay male
- Inclusion criteria: sex without condoms some of the time, no PreP or PEP, HIV+ partner on ART + VL < 200/mL
- Now has 2 years of follow up; aimed to finish in 2017
- 767 couples took part in 2-year analysis; a total of 894 couple-years of follow-up (240M+F-, 245F+M-, 282 MSM)
- **Results:**
  - MAIN NEWS: no transmissions within couples from a partner with an undetectable viral load (estimated 16,400 of sexual encounters in gay men and 14,000 in heterosexual couples)
  - Note: no transmissions does not mean ZERO RISK
  - They looked at the 95% CIs – upper risk 0.05% per act for receptive anal intercourse

### 3) Both partners are HIV+

#### ■ Superinfection:

- a condition in which a person with established HIV infection acquires a 2<sup>nd</sup> strain of the virus

#### ● Review all different options for insemination & continuum of risk including:

- Unprotected intercourse
- **Unprotected intercourse with timed ovulation**
- Sperm washing with IUI (in fertility clinic)
- Other: IVF, ICSI, sperm donor, adoption

**Bold:** typically recommended by HCP due to lowest chance of horizontal transmission;  
All options after full understanding of risk

# Results: Guideline Highlights

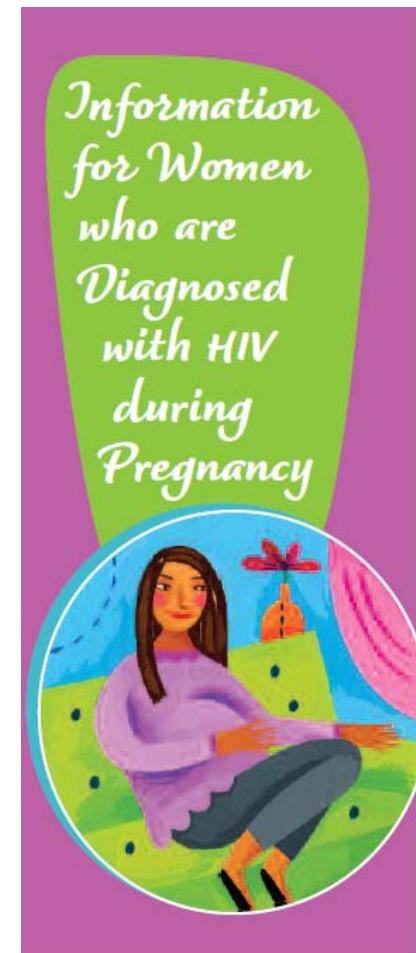
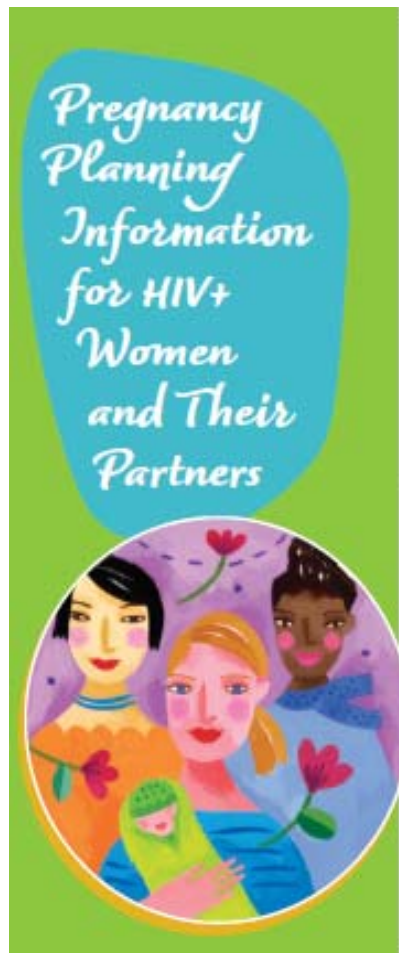
- **Infertility investigations and treatment**
  - HIV-positive people should be counseled about fertility issues that occur in the general population
  - Infertility investigations and treatment should be offered to HIV-positive people if required.





# Pamphlets

Available in French & English at [www.catie.ca](http://www.catie.ca)



# **“This is an Issue of Reproductive Rights”**

**“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.”**

World Health Organization, UN Population Fund, Joint United Nations Programme on HIV/AIDS (UNAIDS), and International Planned Parenthood Federation. Sexual and reproductive health and HIV/AIDS: A framework for priority linkages, 2005.  
Available at [http://www.who.int/reproductive-health/stis/docs/framework\\_priority\\_linkages.pdf](http://www.who.int/reproductive-health/stis/docs/framework_priority_linkages.pdf) .



# Acknowledgements

## Thank You!

### Our Team

Women and HIV Research Program Staff

Canadian HIV Fertility Program Investigators, Staff & Students  
CHPPG Development Team



# HIV-positive parenting in Canada

A webinar series co-organized by IHPREG and CATIE

**Gladys** has been working as a Peer Research Associate on a number of projects for over 5 years. She is currently employed as a PRA with CHIWOS in Toronto. Gladys' work has allowed her to collaborate closely with HIV positive women and their healthcare providers. She is very proud of the work she did on *The HIV Mothering Study*, which looked at the experiences of HIV positive women in their first year of motherhood. Her work has mostly revolved around women's health and well-being. Gladys is a mother of 2 and she lives in Toronto.



IHPREG  
INTERDISCIPLINARY  
HIV PREGNANCY  
RESEARCH GROUP



# Thank you!



Next webinar in our series **HIV-positive parenting in Canada:**

A Complicated Dilemma:  
HIV and infant feeding

Please evaluate this webinar!