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HIV and hepatitis C
information

La source canadienne
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le VIH et l'hépatite C

The HIV Prevention Pill: The State of PrEP Science and Implementation

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Overview

1. The Basics
2. A review of the science
3. An update on implementation
4. The future of PrEP
5. Questions



The Basics

HIV pre-exposure prophylaxis (PrEP)

- Ongoing use of antiretrovirals by **HIV-negative** individuals, starting before an exposure and continuing after
- A potential HIV prevention option during periods where a person is at “**high-risk**” of HIV infection
- PrEP involves:
 - The **daily use of a pill** containing tenofovir and emtricitibine (Truvada)
 - **Regular visits with a service provider** to test for HIV and STIs, monitor side-effects and toxicity, and provide risk-reduction and adherence support



The Science

How well does PrEP work?

| Study name | Year | Population | Type of PrEP | Overall reduction in HIV risk |
|---------------|------|---|----------------------|-------------------------------|
| iPrEX | 2011 | Gay men and other MSM and transgender women | Truvada | 44% |
| Partners PrEP | 2011 | Heterosexual serodiscordant couples | Truvada Tenofovir | 75% 67% |
| TDF2 | 2011 | Heterosexual men and women | Truvada | 62% |
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| FEM-PrEP | 2011 | Heterosexual women | Truvada | 0% |
| VOICE | 2013 | Heterosexual women | Truvada Tenofovir | 0% 0% |
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| FEM-PrEP | 2011 | Heterosexual women | Truvada | 0% |
| VOICE | 2013 | Heterosexual women | Truvada Tenofovir | 0% 0% |
| Bangkok Tenofovir Study | 2013 | People who use injection drugs | Tenofovir | 49% |

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How well does PrEP work?

| Study name | Type of PrEP | Overall reduction in HIV risk | Percentage with drug in their blood | |
|-------------------------|----------------------|-------------------------------|-------------------------------------|--|
| Partners PrEP | Truvada Tenofovir | 75% 67% | 82% | |
| TDF2 | Truvada | 62% | 80% | |
| Bangkok Tenofovir Study | Tenofovir | 49% | 67% | |
| iPrEX | Truvada | 44% | 51% | |
| FEM-PrEP | Truvada | 0% | <30% | |
| VOICE | Truvada Tenofovir | 0% 0% | <30% | |

How well does PrEP work?

| Study name | Type of PrEP | Overall reduction in HIV risk | Percentage with drug in their blood | Risk-reduction among consistent users |
|-------------------------|----------------------|-------------------------------|-------------------------------------|---------------------------------------|
| Partners PrEP | Truvada Tenofovir | 75% 67% | 82% | 86% 90% |
| TDF2 | Truvada | 62% | 80% | - |
| Bangkok Tenofovir Study | Tenofovir | 49% | 67% | 70% |
| iPrEX | Truvada | 44% | 51% | 92% |
| FEM-PrEP | Truvada | 0% | <30% | - |
| VOICE | Truvada Tenofovir | 0% 0% | <30% | - |

How safe is daily oral PrEP?

- PrEP **increased risk** of side effects including diarrhea, nausea, headache, fatigue and dizziness
- Some participants experienced **small decreases** in kidney health and bone mineral density
- Drug resistance was **generally rare**
- **No evidence** of risk compensation



State of Implementation

Moving PrEP into practice

- Guidelines
- Regulatory approval
- “Off-label” prescriptions
- Insurance coverage
- Demonstration projects and open label extensions (OLEs)

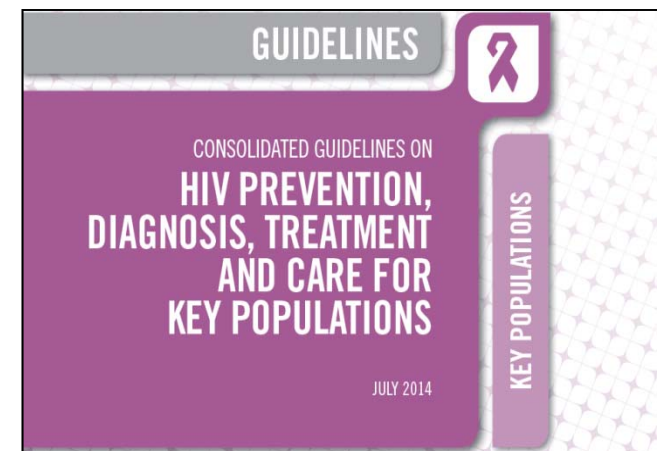
PrEP guidelines

- **CDC** - Clinical practice guidelines for healthcare providers
- **WHO** - HIV prevention programming guidelines
- No national guidelines in Canada
 - Quebec has developed provincial guidelines

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE



Regulatory Approval

- Truvada is approved for the **treatment of HIV** in most countries worldwide
- The Food and Drug Administration (FDA) in the United States is the only regulatory agency to approve Truvada for the **prevention of HIV**
- Truvada has **not been approved** for use as PrEP by Health Canada



“Off-label” prescriptions

- Prescription of an approved drug for an *unapproved* use
 - Common for some types of drugs
 - Legal in many countries, including Canada
- In general, a person in Canada can currently access PrEP if they can find;
 - a healthcare provider who is willing to prescribe Truvada “off-label”
 - a method of covering the cost (approx. \$800/month)
- Available, but not accessible?



PrEP uptake in Canada

- Survey of 160 staff at Canadian ASOs in 2012
 - 11% knew of a person who had used PrEP
 - 64% felt their organization did not have enough current knowledge about PrEP
- Survey of 86 Canadian healthcare providers in 2012-2013
 - 45% willing to prescribe PrEP; 13% had prescribed
- Survey of 426 Toronto MSM testing for HIV in 2013
 - None had used PrEP
 - 27% aware of PrEP; 51% willing to use

PrEP uptake in Canada



| Number of 'Neg + PrEP' profiles on BBRT in Canada | | | |
|---|-----------|-----------|-----------|
| | Aug 2014 | Sept 2014 | Oct 2014 |
| Montreal | 10 | 20 | 33 |
| Toronto | 13 | 13 | 20 |
| Vancouver | 8 | 5 | 10 |
| Calgary | 1 | 3 | 3 |
| Winnipeg | 1 | 1 | 2 |
| Ottawa | 1 | 1 | 1 |
| Hamilton | 1 | 1 | 1 |
| Halifax | 1 | 1 | 1 |
| London | 0 | 0 | 1 |
| Kingston | 1 | 0 | 0 |
| TOTAL | 37 | 45 | 72 |

Source: PrEP pops up on cruising sites – Marc-André LeBlanc (PositiveLite.com, originally published in French on The Warning's website)
<http://www.positivelite.com/component/zoo/item/prep-pops-up-on-cruising-sites>



FEB 13 **LEN TOOLEY ON PREP — PART ONE**

WEDNESDAY, 13 FEBRUARY 2013

AUTHOR // [John McCullagh](#) - Publisher

CATEGORIES // [As Prevention](#) , [Activism](#) , [Gay Men](#) , [Mental Health](#) , [Features and Interviews](#) , [Sexual Health](#) , [Health](#) , [Treatment](#) , [Population Specific](#) , [Sex and Sexuality](#) , [John McCullagh](#)

LEN TOOLEY IS AN HIV-NEGATIVE GAY GUY ON PRE-EXPOSURE PROPHYLAXIS WHO WORKS IN TORONTO AS A GAY MEN'S HEALTH PROMOTER, HIV EDUCATOR, TESTER AND COUNSELLOR. IN THE FIRST OF THREE INTERVIEWS ABOUT BEING ON PREP, HE DISCUSSES HIS DECISION TO GO ON IT.

2013 HIV INFLUENCERS HONORS



My PrEP experience

Home

What is PrEP?

Truvada Track - monitoring insurance and Medicaid coverage of Truvada for PrEP

2011 "My PrEP Experience" Posts

8+1 15

Thursday, April 18, 2013

PrEP – Is this just a phase I'm going through? [Part 1 of 3]

by Marc-André LeBlanc
Gatineau, Canada

This is the first installment of a three-part series. [Click here for Part 2.](#) [Click here for Part 3.](#)



On April 5, 2013 I took my first dose of Truvada as pre-exposure prophylaxis (PrEP).

So many questions were swirling in my head at that point, and had been for weeks and months. As I was about to swallow my first pill, I gazed outside the window and wondered...

- How did I end up in this situation where I feel like I need

Share
your
PrEP
story^{at}



My PrEP
experience

Your Experience is a Gift

If you have used or are using PrEP, we invite you to share your PrEP experience via audio, video, or in writing.

Why did you make the decision to use

Implementation questions

- How to identify 'optimal' PrEP candidates?
- How many people, and who, want to use PrEP?
- How is PrEP used in a 'real world' setting?
- What are the best ways to support adherence and risk-reduction?
- What impact does using PrEP have on overall health and well-being?
- What is the best setting for PrEP delivery?

Demo projects and OLEs

- Over 20 demonstration projects and OLEs currently ongoing/planned world wide
 - Over 15,000 participants
 - Range of different settings, contexts, and populations
 - Toronto-based demonstration project enrolling 50 MSM
- Evidence is beginning to emerge from these studies



| Ongoing and Planned PrEP Trials and Demonstration Projects, as of November 2014 | | | | | | |
|---|---|-----------------------|---------------|---|--|--|
| Trials/Project | Sponsor/Under | Type/Category | Location | Population | Study Objectives | Status |
| PRELUDE Study | Kirby Institute, AIDS Council of New South Wales (ACON) and Positive Life New South Wales | Demonstration Project | Australia | Men and women of high and ongoing risk of HIV | To look into how clinics can provide PrEP. It will study whether people find it easy and agreeable to take PrEP every day, why they take it, what it's like to take it, and whether it changes how they have sex. It'll study how easy it is for doctors to use it with their patients, and what resources are necessary to make PrEP available. | Ongoing, started September 2014. |
| VicPrEP Demonstration Project | Monash University and Alfred Health of the Victorian AIDS Council/Gay Men's Health, funded by the Victorian Government | Demonstration Project | Australia | Gay men, IDUs, HIV-negative partners in serodiscordant heterosexual couples and people who have received non-occupational post-exposure prophylaxis (N-PEP) on more than two occasions in the previous 12 months. | To determine the effectiveness of PrEP in the local setting and the factors contributing to its success. Truvada will be administered 100 participants for up to 12 months. The other 100 participants will elect not to use Truvada, but agree to provide relevant information through regular on-line surveys. | Ongoing, started mid-July 2014. Expected completion July 2018. |
| Sliters Antiretroviral therapy Programme for Prevention of HIV –an Integrated Response (SAPPHire) | Centre for Sexual Health and HIV/AIDS Research, Zimbabwe, University College London, London School of Hygiene and Tropical Medicine, RTI, DFID, UNFPA | Open Label | Zimbabwe | Female sex workers | Seeks to enhance HIV treatment and prevention among 28,000, highway-based sex workers by increasing uptake and frequency of testing, demonstrate acceptability and feasibility of delivering PrEP, maximize retention in care, promote timely initiation of ART for those eligible, and maximize adherence to both ART and PrEP. | Ongoing, started July 2014. Expected completion October 2015. |
| Partners Demonstration Project | Led by a team of scientists from Kenya, Uganda and the US, funded by NIMH/NH, USAID and BMGF | Demonstration Project | Kenya, Uganda | Serodiscordant couples | Evaluates HIV prevention preferences among approximately 1,000 HIV serodiscordant couples, adherence to PrEP and ART and interface of reproductive health priorities and ART-based prevention. Will implement PrEP as 'bridge' to ART, providing PrEP to HIV-negative partner when HIV-positive partner is not yet on ART due to eligibility based on country guidelines or personal decision. | Ongoing, fully enrolled. Expected completion 2016. |
| PrEP(Brazil) | University of Sao Paulo, Centro de Referencia e Treinamento DST AIDS, Oswaldo Cruz Foundation | Demonstration Project | Brazil | MSM, transgender women | Plans to enroll 400 MSM and transgender women to assess the acceptability, feasibility and safety of daily, oral TDF/FTC as PrEP over 12 months. | Ongoing, expected completion date of January 2016. |

Are you concerned about getting HIV?

Toronto MSM PrEP 5 study (CTN 279)

We're looking for men who have sex with men, 18 and older, at high-risk for HIV acquisition to participate in a trial on the use of Truvada® to reduce their risk.

Pre-exposure prophylaxis or PrEP is a new strategy for preventing HIV that involves taking a prescription HIV medication every day. Researchers are looking for a limited number of HIV-negative, high risk men who have sex with men from the Toronto area for a one-year PrEP study. The study involves taking PrEP daily and regular clinic visits for doctor checkups, blood work and questionnaires. Participants will be compensated for their time.

For CTN 279 Contact: toronto@prp5study.com

For PrEP5 Study: www.prp5study.com

iPrEX OLE



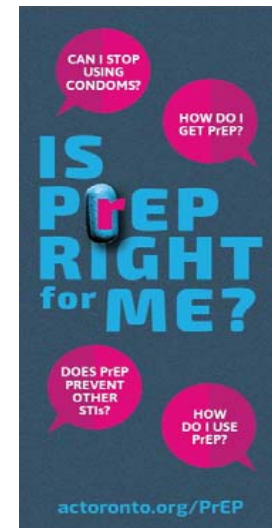
- Uptake was high
- Adherence was generally low
 - Drug levels equivalent to taking four to seven pills a week were only present at 33% of study visits
- Risk behaviour did not increase
 - Based on self-reported sexual risk behaviours and rate of syphilis infections
- PrEP reduced the rate of HIV infection by 49%
 - No HIV infections among those with drug levels equivalent to taking 4-7 pills a week



Moving Forward

Integrating PrEP into our work

- Improve awareness and knowledge of PrEP
- Support PrEP-related decisions
- Facilitate access to PrEP
- Support adherence and risk-reduction
- Push for demonstration projects, guidelines and regulatory approval



PrEP uptake in the United States



- Regulatory approval and local/national guidelines
- Awareness campaigns and PrEP resources
- Widespread financial coverage
- National PrEP telephone line for clinicians (PrEPline)
- Community 'navigators' (San Francisco)
- PrEP providers list (Seattle)

The future of PrEP?

- Intermittent use of Truvada pills
- Use of oral pills containing other antiretrovirals
- Rectal and vaginal gels
- Long-lasting injectables and intravaginal rings



Questions?

- To unmute your line for the question and answer period, press #6
- To mute your line, press *6
- Email questions to **jwilton@catie.ca**

Thank You!

Please evaluate this webinar!