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

James Wilton  
Coordinator, Biomedical Science of HIV Prevention  
CATIE

# Overview

1. The Basics
2. A review of the science
3. An update on implementation
4. 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?



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TDF2	2011	Heterosexual men and women	Truvada	62%



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TDF2	2011	Heterosexual men and women	Truvada	62%
FEM-PrEP	2011	Heterosexual women	Truvada	0%
VOICE	2013	Heterosexual women	Truvada Tenofovir	0% 0%

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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%	90% 86%
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 and liver health and bone mineral density
- Drug resistance was **generally rare**
- **No evidence** of risk compensation

# State of Implementation

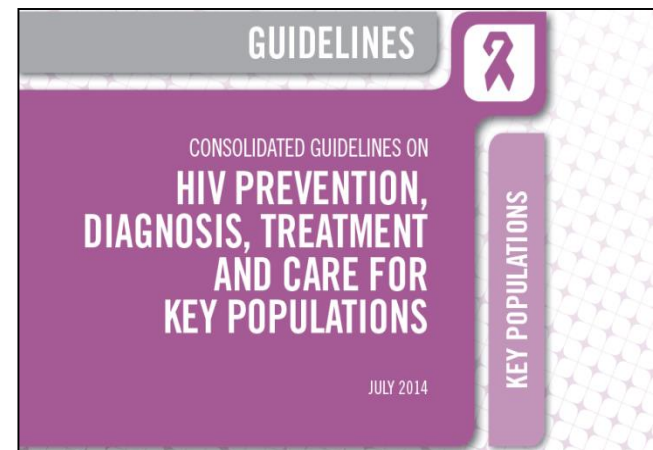
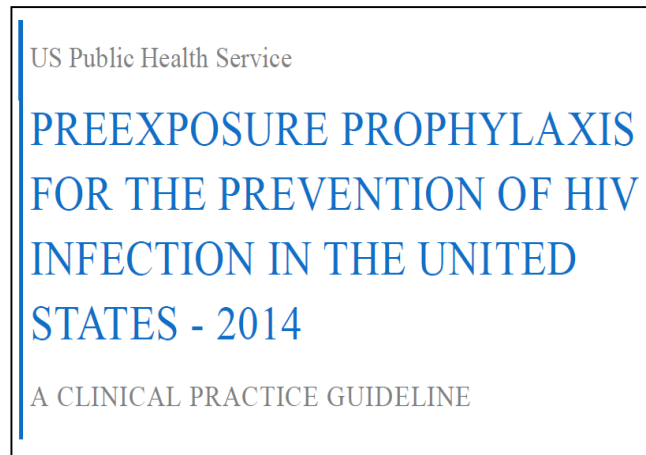
# Moving PrEP into practice

- 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



# 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?

# 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

Ongoing and Planned PrEP Trials and Demonstration Projects, as of November 2014						
Trials/Project	Sponsor/Partner	Type/Category	Location	Population	Objectives/Interventions	Status
PRELUDE Study	Kirby Institute, AIDS Council of New South Wales (ACON) and Positive Life New South Wales.	Demonstration Project	Australia	Men and women at high and ongoing risk of HIV	To look into how clinicians can provide PrEP. It will study whether people find it easy and agreeable to take PrEP every day, why they take it, what it is like to take it, and whether it changes how they have sex. It will 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 at 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.
Sisters Antiretroviral Therapy Programme for Prevention of HIV –an Integrated Response (SAPPHare)	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 20,000 highly-biased 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 ineligibility based on country guidelines or personal decision.	Ongoing, fully enrolled. Expected completion 2016.
PrEP(Bras)	University of Sao Paulo, Centro de Referência 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.

- 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
  - iPrEX OLE and PROUD

**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.

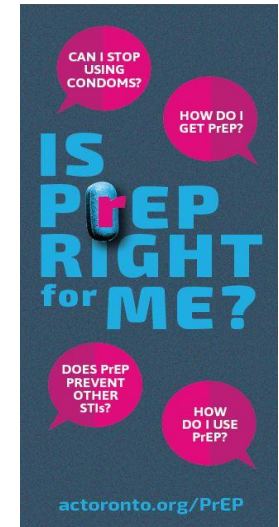
For CTN 279 Contact Us: [www.ctn279.com](http://www.ctn279.com)

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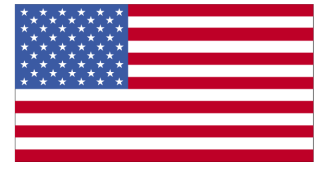
# Moving Forward

# 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



**Thank You!**