

# NEW CANADIAN HIV PrEP/nPEP GUIDELINES:

Public health and community  
perspectives

PRESENTED BY

**Camille Arkell, Moderator**

**Dr. Darrell Tan,**

**Gilles Charette,**

**Dr. Joss Reimer**

May 16, 2018



Canada's source for  
HIV and hepatitis C  
information



## Webinar Agenda (1 hour)

- Review of PrEP/nPEP guideline and key messages  
*Dr. Darrell Tan, 20 minutes*
- A perspective on PrEP access efforts in SE Ontario  
*Gilles Charette, 10 minutes*
- A public health perspective on use of the guideline in MB  
*Dr. Joss Reimer, 10 minutes*
- Q & A  
*15 minutes*

## **Dr. Darrell Tan**

MD, FRCPC, PhD  
Scientist, Li Ka Shing Knowledge Institute

Darrell is an infectious diseases physician, clinician-scientist and CIHR/OHTN New Investigator whose research focuses on clinical trials in HIV prevention and HIV/STI co-infection. He is Director of the University of Toronto Clinical Research Unit on HIV Prevention, and is leading multiple projects to optimize the implementation of HIV PrEP and PEP in Canada.





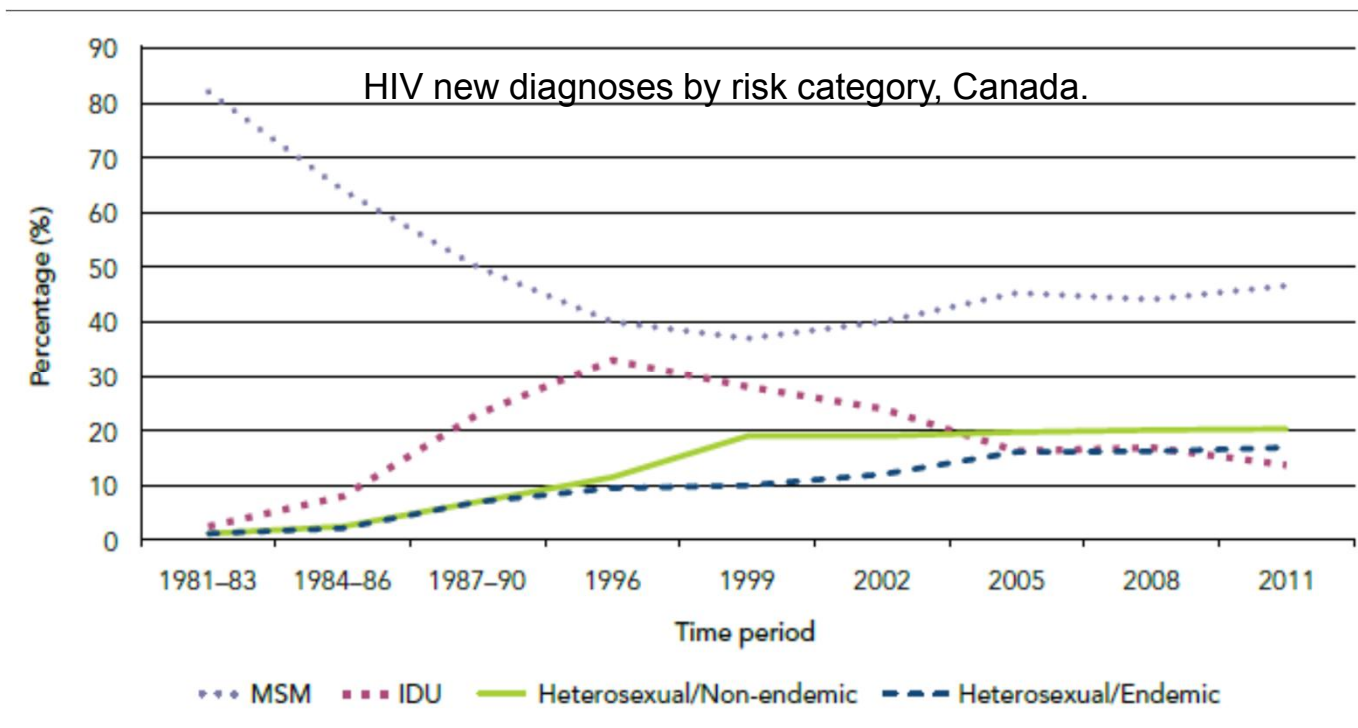
# Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis

Darrell H. S. Tan MD PhD, Mark W. Hull MD MHSc, Deborah Yoong BScPhm PharmD, Cécile Tremblay MD, Patrick O'Byrne RN (EC) PhD, Réjean Thomas MD, Julie Kille RN, Jean-Guy Baril MD, Joseph Cox MD MSc, Pierre Giguere BPharm MSc, Marianne Harris MD, Christine Hughes BScPharm PharmD, Paul MacPherson MD PhD, Shannon O'Donnell MD MPH, Joss Reimer MD MPH, Ameeta Singh BMBS MSc, Lisa Barrett MD PhD, Isaac Bogoch MD MSc, Jody Jollimore MPP, Gilles Lambert MD, Bertrand Lebouche MD PhD, Gila Metz MD, Tim Rogers PhD, Stephen Shafran MD; for the Biomedical HIV Prevention Working Group of the CIHR Canadian HIV Trials Network

■ Cite as: *CMAJ* 2017 November 27;189:E1448-58. doi: 10.1503/cmaj.170494

*CMAJ* Podcasts: author interview at <https://soundcloud.com/cmajpodcasts/170494-guide>

# Ongoing HIV Transmission in Canada



Source: Public Health Agency of Canada. HIV/AIDS Epi Update October 2014.

# Overview

- Why guidelines?
  - Improve quality of care, raise awareness
  - Reduce inappropriate variation in practice
- Intended audience
  - Primarily clinicians (ED, ID, FP, RN, NP, Pharm...)
  - Also relevant for policy-makers & community
- Methods
  - 25-member panel from a range of backgrounds
  - Supported by CIHR, CTN; no industry funding
  - Evidence-based, rigorous methodology: GRADE

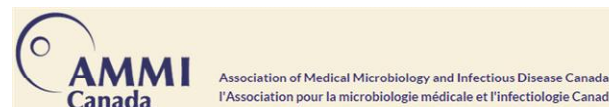
# Grading of recommendations

- Strength of recommendations
  - Reflects the extent to which the panel is **confident that the desirable effects of an intervention outweigh undesirable effects**
  - 1 = “Recommend”, 2 = “Consider”
- Quality of evidence:

Quality of Evidence	Symbol	Letter	Example study designs
High	⊕⊕⊕⊕	A	Starting point for RCTs
Moderate	⊕⊕⊕	B	
Low	⊕⊕	C	Starting point for observational
Very low	⊕	D	

# Endorsements

- Association of Medical Microbiology & Infectious Diseases Canada (AMMI)
- Canadian Association of Emergency Physicians (CAEP)
- Canadian Association of Nurses in AIDS Care (CANAC)
- Canadian HIV/AIDS Pharmacists Network (CHAP)
- Canadian Public Health Association (CPHA)



- PENDING: College of Family Physicians of Canada (CFPC)





# Key Topics for Today

- Eligibility for PrEP (“Indications”)
- Recommended Regimens for PrEP
- Practical advice for delivering PrEP
- Roles for CBOs and public health

## Box 2: Summary of recommendations

### Pre-exposure prophylaxis (PrEP)

#### *Indications*

#### **Men who have sex with men (MSM)**

- PrEP is recommended for MSM (*strong recommendation; high quality of evidence*) and transgender women (*strong recommendation; moderate quality of evidence*), who report condomless anal sex within the last six months and who have any of the following:
  - Infectious syphilis or rectal bacterial sexually transmitted infection (STI), particularly if diagnosed in the preceding 12 months;
  - Recurrent use of nonoccupational postexposure prophylaxis (nPEP) (more than once);
  - Ongoing sexual relationship with HIV-positive partner with substantial risk of transmissible HIV; or
  - High-incidence risk index (HIRI)-MSM risk score  $\geq 11$  (Appendix 1, supplemental Table 2).

# Targeting PrEP in gbMSM, British Columbia

## HIV Incidence

Prior dual STI diagnosis (rectal gonorrhea/syphilis) <sup>b</sup>



Inconsistent condom use and STI <sup>b</sup>

Recurrent NPEP use <sup>c</sup>

HIRI score > 25 <sup>a</sup>

Rectal gonorrhea <sup>b</sup>

Syphilis <sup>b</sup>

HIRI score > 10 <sup>a</sup>

CaHR 2016:

Hull, M. EPH 1.2

Lachowsky, N. EPHP 5.04

Samji, H. EPHP 2.02

0 5 10 15 20  
Incidence rate (per 100 person-years)

<sup>a</sup> Momentum Cohort  
<sup>b</sup> BCCDC STI Clinic Seroconverter Study  
<sup>c</sup> BC-CfE NPEP Evaluation Study

## Box 2: Summary of recommendations

### Pre-exposure prophylaxis (PrEP)

#### *Indications*

#### **Heterosexual exposure**

- We recommend PrEP for the HIV-negative partner in heterosexual serodiscordant relationships reporting condomless vaginal or anal sex where the HIV-positive partner has a substantial risk of having transmissible HIV (*strong recommendation; high quality of evidence*).
- PrEP may be considered for the HIV-negative partner in heterosexual serodiscordant relationships reporting condomless vaginal or anal sex, where the HIV-positive partner has a non-negligible risk of having transmissible HIV (*weak recommendation; moderate quality of evidence*).

#### **People who inject drugs (PWID) exposure**

- PrEP may be considered for PWID if they share injection drug use paraphernalia with a person with a non-negligible risk of HIV infection (*weak recommendation; moderate quality of evidence*).

## Box 2: Summary of recommendations

### Pre-exposure prophylaxis (PrEP)

#### Indications

- PrEP is not recommended in the context of a stable closed relationship with a single partner with no or negligible risk of having transmissible HIV (*strong recommendation; moderate quality of evidence*).



# PrEP Regimens

- Daily TDF/FTC (Grade 1A)



PARTNERS PrEP STUDY



- gbMSM only: On-demand TDF/FTC (Grade 2A)



- TDF alone not recommended
- TAF-based regimens not recommended

## “Practical advice”

Lab tests	Screening	Baseline	30 days	Q3 mo	Q 12 mo
HIV Serology	X		X	X	
Hepatitis A & B screen <sup>a</sup>	X				
Hepatitis C Screen	X				X
Gonorrhea, chlamydia & syphilis screen	X			X	
Complete Blood Count	X				
Creatinine	X		X	X	
Urinalysis	X				X
Pregnancy screening	X			X	
<b>Counseling</b>					
Medication adherence	X	X	X	X	X
Risk reduction strategies	X	X	X	X	X

<sup>a</sup> provide vaccination if non-immune)

- Routine DXA is not recommended unless otherwise indicated according to Osteoporosis Canada guidelines
- If PrEP prescribed in HBV co-infection, monitor as per HBV

Guidelines



## “Practical advice”

- Regular quarterly HIV testing prior to each prescription is ESSENTIAL
- Routine STI screening at all relevant anatomic sites is part of routine PrEP care

**Dr. M.D., CCFP**  
\_\_\_\_\_  
*Firstname Lastname*  
*DOB*  
\_\_\_\_\_  
*Date*  
\_\_\_\_\_  
*Tenofovir disoproxil fumarate/emtricitabine*  
*300/200 mg (Truvada) 1*  
*po daily x 3 months*  
\_\_\_\_\_  
☒ Do NOT refill  
☐ Refill \_\_\_ times at \_\_\_ day intervals  
\_\_\_\_\_  
*Signature*





# Roles for CBOs & public health

**Box 3: A health systems approach to pre-exposure prophylaxis (PrEP) and nonoccupational postexposure prophylaxis (nPEP)\*<sup>5</sup>**

- “...attention to syndemic conditions that may predispose people to high-risk behaviour (eg. depression, substance use)”
- “...ensure the availability of other harm reduction interventions for people who inject drugs...”
- “Nonprescribing health care and service providers should be encouraged to play roles in PrEP/nPEP delivery...”
- “...should be counselled about and considered for PrEP”



# Thinking about PrEP?

<http://bit.ly/2qmZv4X>

**Step 1:** Check out this 20-minute video

**Step 2:** Take a screenshot of these cards and your unique ID code to your doctor.

A code is needed to access the module:

Email or call Alex Schnubb to get an access

code: [schnubba@smh.ca](mailto:schnubba@smh.ca) (416) 864-6060 x77105

*Don't lose the code!*

For gay or bisexual guys & trans people considering PrEP, this research study can help you...

- Learn more about **PrEP**
- Help figure out whether **PrEP** is right for you
- Talk to your doctor about **PrEP**
- Connect your doctor with reliable medical information about **PrEP**



For physicians:

## How to Prescribe PrEP: The Basics

- **Pre-exposure prophylaxis (PrEP)** is an evidence-based, Health Canada-approved strategy for preventing HIV infection in individuals at high risk.
- **PrEP** reduces the risk of HIV acquisition by >90% when taken regularly.
- **PrEP** is a safe and effective primary prevention strategy.
- **PrEP** can be easily prescribed by family physicians.

**Learn** how to effectively prescribe and monitor PrEP in your patients in this one-hour online CME module, grounded in evidence-based Canadian Guidelines.

This **Self-Learning** program has been certified by the College of Family Physicians of Canada for up to 2 Mainpro+ credits.

<http://bit.ly/2qkfuQM>

Email Alex at [SchnubbA@smh.ca](mailto:SchnubbA@smh.ca)  
for a unique access code



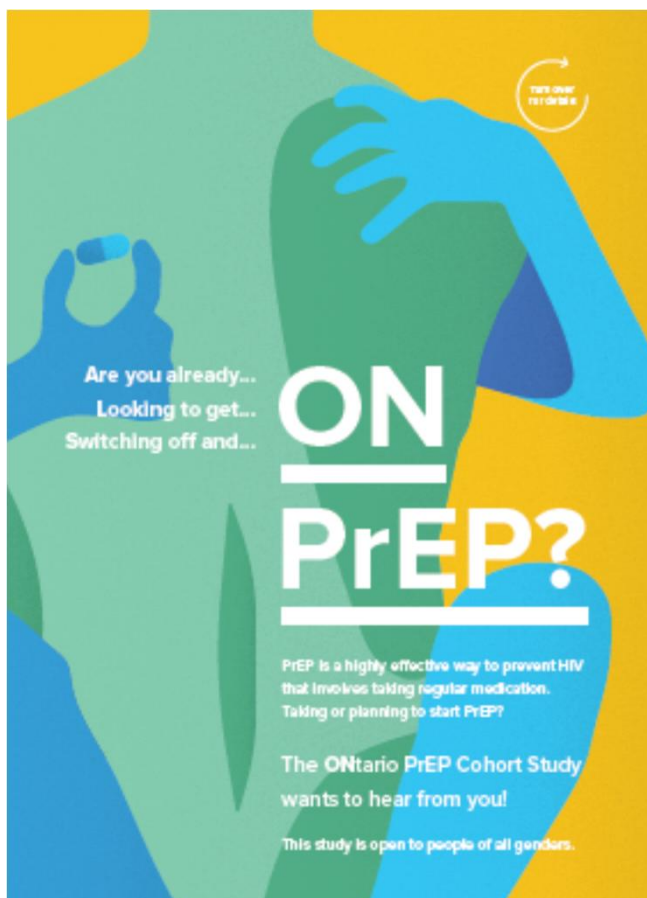
St. Michael's  
Inspired Care.  
Inspiring Science.



the CTN  
CIHR Canadian  
HIV Trials Network

le Réseau  
Réseau canadien  
pour les essais VIH des BRSC





Are you already...  
Looking to get...  
Switching off and...

# ON PrEP?

PrEP is a highly effective way to prevent HIV that involves taking regular medication. Taking or planning to start PrEP?

The **ON**tario PrEP Cohort Study wants to hear from you!


This study is open to people of all genders.

## THE ONTARIO PrEP COHORT STUDY

Is exploring the experiences, health and wellness of people taking HIV pre-exposure prophylaxis (PrEP)\* in Ontario.


Participation is open to any adult starting or using PrEP in Ontario. Participation includes regular surveys every 6 months and permission to access your health information. Compensation is provided.

To get involved, visit [ONPrEP.ca](http://ONPrEP.ca) for details about connecting with an affiliated PrEP Provider, or contact the ONPrEP study coordinator at 416-864-6060 ext 77395 or [mohrj@smh.ca](mailto:mohrj@smh.ca)

 **PARTICIPANT CODE** \_\_\_\_\_

\*PrEP is a new, Health Canada-approved and effective way of preventing HIV infection that involves taking anti-HIV medication on a regular basis. Want to know more? Talk to your healthcare provider or contact us for more information!

**St. Michael's**  
Inspired Care.  
Inspiring Science.

 **act**



**The End**



## RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

# GRADE: going from evidence to recommendations

The GRADE system classifies recommendations made in guidelines as either strong or weak.

### Quality of evidence

High quality	⊕ ⊕ ⊕ ⊕ or A
Moderate quality	⊕ ⊕ ⊕ ○ or B
Low quality	⊕ ⊕ ○ ○ or C
Very low quality	⊕ ○ ○ ○ or D

### Strength of recommendation

Strong recommendation for using an intervention	↑ ↑ or 1
Weak recommendation for using an intervention	↑ ? or 2
Weak recommendation against using an intervention	↓ ? or 2
Strong recommendation against using an intervention	↓ ↓ or 1

## **Gilles Charette**

M4M Sexual Health Coordinator at HARS

Gilles does program coordination, education, and outreach to the M4M community in SE Ontario. He has developed an online outreach program, facilitates discussion groups for MSM, delivers a counselling program and leads a monthly support group for LGBTQ+ offenders. He also works closely with health units in the region to improve access to HIV testing and treatment for the MSM community.



# PrEP access efforts in Southeastern Ontario

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GILLES CHARETTE

M4M SEXUAL HEALTH COORDINATOR

HIV/AIDS REGIONAL SERVICES (HARS)





# Current state of PrEP locally

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- ☐ 2<sup>nd</sup> most common online outreach question
- ☐ Awareness of PrEP among health-care providers seems low
- ☐ Issues around 'coming out'
- ☐ Full patient rosters
- ☐ Currently, access via referral to Infectious Disease Clinic

# Strategies to address gap

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- ☐ Local sexual health clinics (health units)
- ☐ Helping patients inform and advocate for themselves
- ☐ PrEP mailer to health care providers

# PrEP info mailer to primary care

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- ☐ Mailer to 300 primary care practitioners
- ☐ Package contents:
  - ☐ Letter re: PrEP and local need with link to online module
  - ☐ CTAC “Providing HIV PrEP” brochure
  - ☐ CMAJ article: “Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis”
  - ☐ Business Card and ‘The Sex You Want.ca’ postcard

# Progress

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- ☐ Inquiries from physicians
- ☐ Requests from MSM
- ☐ Meetings with Health Units/CHCs

## **Dr. Joss Reimer**

MD, MPH, FRCPC  
Medical Officer of Health, Winnipeg Regional  
Health Authority and MB Health

Joss' work as a Medical Officer of Health focuses on health sexuality and the prevention of drug related harms. She also maintains a clinical practice in the areas of sexual and reproductive health. Her research interests include assessing barriers to improving sexual health and reducing drug related harms for vulnerable populations both in Canada and in Colombia.



**GUIDELINE**  VULNERABLE POPULATIONS 



the CTN  
CIHR Canadian  
HIV Trials Network

le Réseau  
Réseau canadien  
pour les essais VIH des IR



CIHR IRSC

## Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis

# The Manitoba Experience

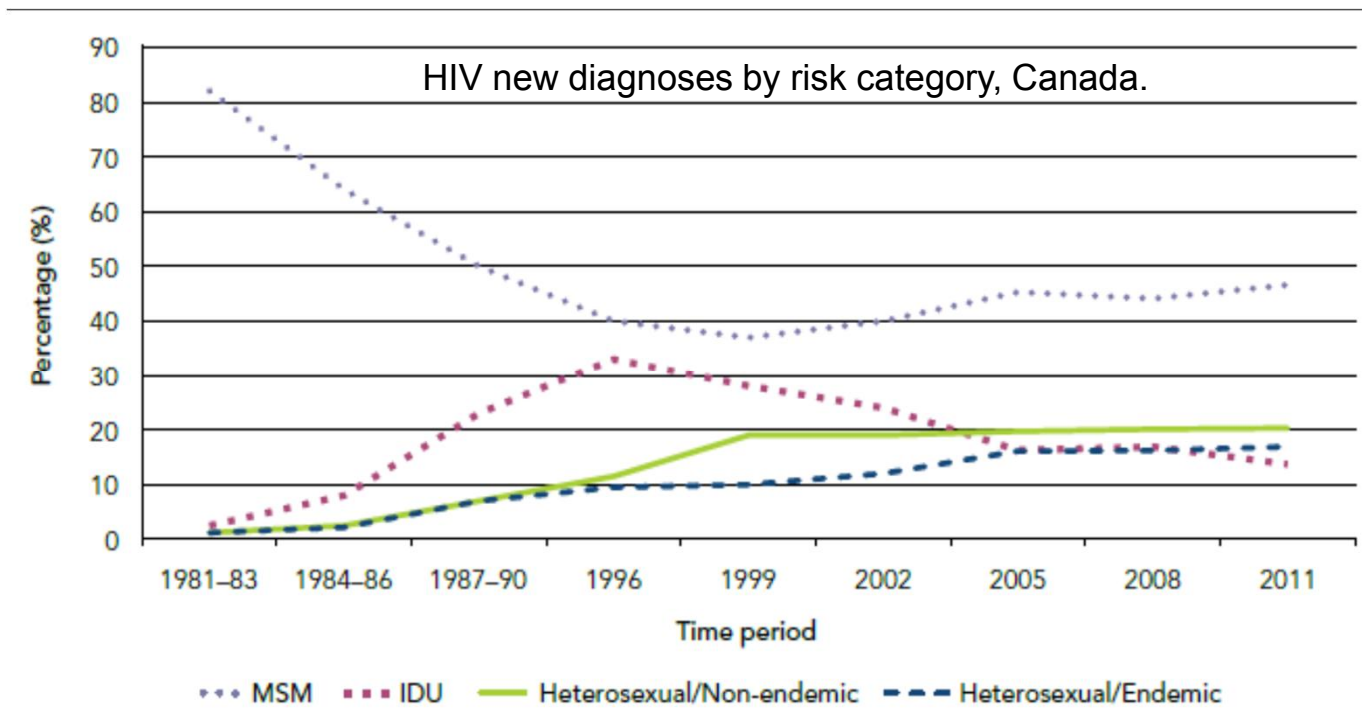
Dr Joss Reimer MD MPH FRCPC



# Key Topics for Today

- Epidemiology in Manitoba
- Situation before guidelines
- Provincial PEP guidelines
- Applying guidelines
- PrEP use in Manitoba

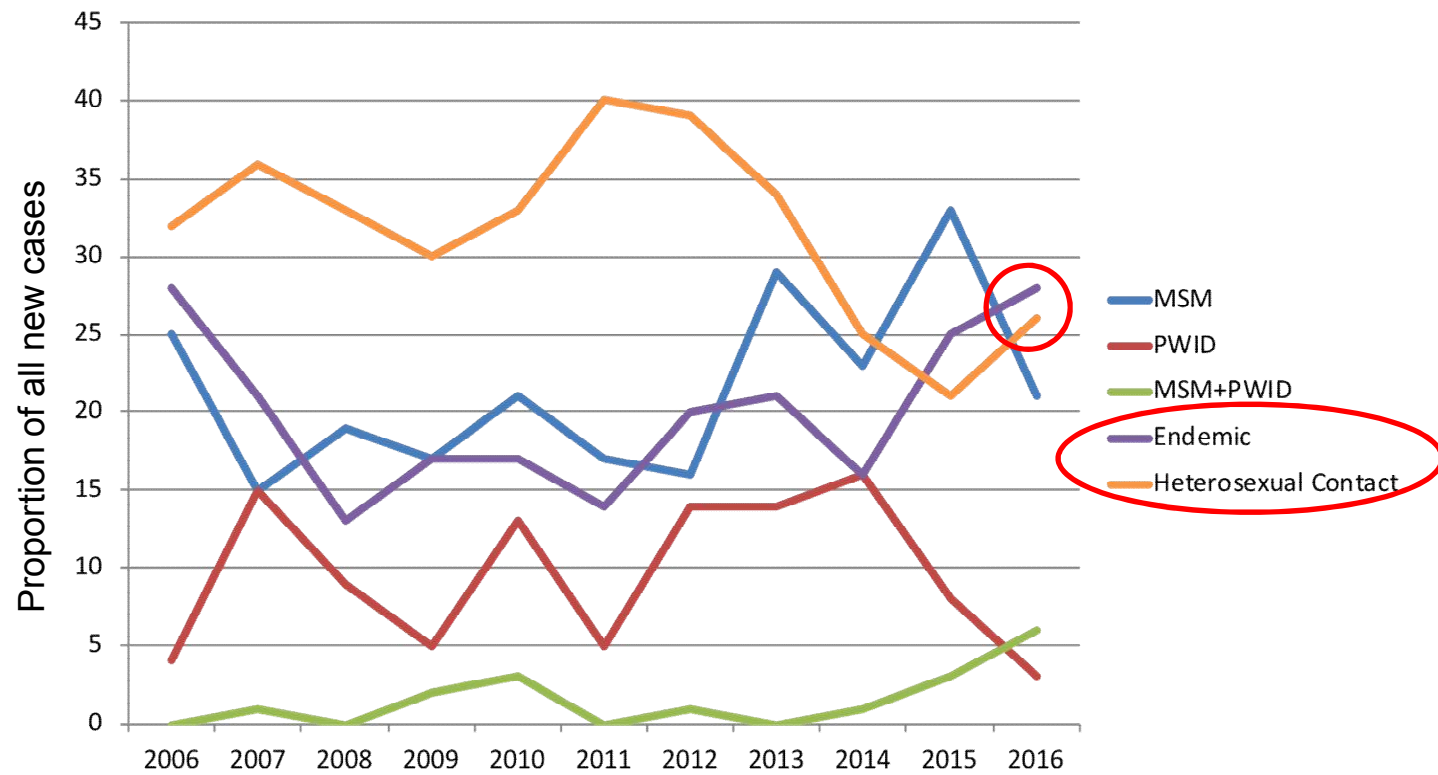
# Ongoing HIV Transmission in Canada



Source: Public Health Agency of Canada. HIV/AIDS Epi Update October 2014.



# HIV Transmission in Manitoba



# Current (old) Manitoba PEP Protocol

# Current PEP in Manitoba

Exposure Type	Condition	Recommendation based on HIV Status of Source		
		HIV Positive. Class 1 <sup>8</sup>	HIV Positive. Class 2 <sup>9</sup>	HIV Status Unknown or Unknown Source
Percutaneous Exposures (including human bites, i.e., person bitten)	Less Severe <sup>10</sup>	Basic PEP	Expanded PEP	Generally no PEP <sup>11</sup>
	More Severe <sup>12</sup>	Expanded PEP	Expanded PEP	Consider Basic PEP
Mucous membrane and Non-intact Skin Exposures (including human bites, i.e., biter)	Small Volume <sup>13</sup>	Consider Basic PEP	Basic PEP	Generally no PEP
	Large Volume <sup>14</sup>	Basic PEP	Expanded PEP	Consider Basic PEP
Needle-sharing (e.g., IDU equipment)	Refer to Percutaneous Exposures category above. An injection drug user who routinely shares IDU equipment is unlikely to present for PEP unless they are planning to change IDU practice.			
Community Exposures to Abandoned Needles/Sharps	Less Severe <sup>10</sup>	Not applicable	Not Applicable	Generally no PEP <sup>11</sup>
	More Severe <sup>12</sup>	Not Applicable	Not Applicable	Generally no PEP <sup>11</sup>
Consensual Sex (serodiscordant partners)	Receptive anal/vaginal sex or oral receipt of semen, vaginal fluid or blood	Basic PEP	Expanded PEP	Not Applicable (see Sexual Assault)
	Other sexual exposures	Generally no PEP <sup>15</sup>		Not Applicable (see Sexual Assault)
Sexual Assault	Receptive anal/vaginal sex or oral receipt of semen, vaginal fluid or blood	Basic PEP	Expanded PEP	Consider Basic PEP
	Other sexual exposures	Generally no PEP <sup>15</sup>		Generally no PEP

# Current PEP in Manitoba

## Basic PEP

Zidovudine/lamivudine (Combivir®)  
1 tablet orally twice a day x 28 days

Supplied as zidovudine 300 mg plus lamivudine 150 mg tablet

## Expanded PEP (Administer in addition to the Basic regimen)

Lopinavir/ritonavir (Kaletra®)  
2 tablets orally twice a day x 28 days

Supplied as lopinavir 200 mg plus ritonavir 50 mg tablet

# Draft New Manitoba PEP Protocol



# New Risk Assessment Protocol

**Table 1 – HIV risk assessment for PEP initiation**

Risk from the exposure type	Likelihood that source person has transmissible HIV		
	Substantial	Low	Negligible / None
High / Moderate	Initiate PEP	Consider PEP	Consider PEP / PEP not required <sup>1</sup>
Low	PEP not required	PEP not required	PEP not required
<sup>1</sup> Consider PEP if occupational setting, unless source is confirmed HIV negative;(USPHS) PEP not required if non-occupational setting			

<b>Exposure Risk Categories</b>	
<b>High</b>	Anal (receptive), needle sharing, <i>percutaneous, mucous membrane, vertical</i>
<b>Moderate</b>	Anal (insertive), vaginal (receptive, insertive), <i>percutaneous, mucous membrane, vertical</i>
<b>Low</b>	Oral sex (giving, receiving), oral-anal contact, sharing sex toys, blood on compromised or non-intact skin

<b>Likelihood Source has transmissible HIV</b>	
<b>Substantial</b>	HIV+ and viremic (VL >40 copies/mL) OR HIV status unknown but source from population with high HIV prevalence (e.g., MSM, PWID)
<b>Low</b>	HIV+ believed to be VL<40 with concomitant sexually transmitted infection (STI) present at the time of exposure
<b>None/Negligible</b>	Confirmed HIV negative OR HIV+ with confirmed VL<40 and no known STI present at time of exposure OR HIV status unknown, general population

# New Drug Regimens

Table 4 –HIV PEP starter kit recommendations for adults and adolescents aged ≥ 13 years			
Age group	Kit	Drug content	Dosage
With normal renal function			
Adults and adolescents aged ≥ 13 yrs	A	TDF/FTC 300/200 mg tablet	One tablet once daily
		RAL 400 mg tablet	One tablet twice daily
With renal dysfunction*			
Adults and adolescents aged ≥ 16 yrs	B	ZDV/3TC 300/150 mg tablet	One tablet twice daily
		RAL 400 mg tablet	One tablet twice daily
*Renal dysfunction is creatinine clearance ≤ 59 ml/min.			
Abbreviations: 3TC = Lamivudine, FTC = Emtricitabine, RAL = Raltegravir, TDF = Tenofovir, ZDV = Zidovudine			



# Application

# In progress

- nPEP prescribers should be readily accessible from multiple access points, including emergency rooms, HIV/STI counselling/testing centres, student health facilities, prenatal and family planning clinics and pharmacies.
- “...attention to syndemic conditions that may predispose people to high-risk behaviour (eg. depression, substance use)”
- “...ensure the availability of other harm reduction interventions for people who inject drugs...”
- “Nonprescribing health care and service providers should be encouraged to play roles in PrEP/nPEP delivery...”
- “Screening for non-consensual sex is advised”
- “Specific interventions may include patient counselling, education, medication reminders, behavioural feedback and reinforcement, peer support, follow-up telephone calls or text messages and minimization of out-of-pocket expenses.”

# PrEP in Manitoba



# PrEP in Manitoba

- Template in EMR
  - Prompts to review eligibility & financial issues
  - Intake, follow up, letters to primary care
  - Requisitions
- Mail-out to primary care – link to guidelines
  - Referral form

## PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION

### What is PrEP?

- Pre-Exposure Prophylaxis (PrEP) is a way for an HIV-negative person at risk of HIV infection to reduce their risk.
- One form of PrEP involves taking the anti-HIV medication Tenofovir DF 300 mg/Emtricitabine 200 mg (brand name = Truvada) on a daily basis.
- Tenofovir/Emtricitabine (Truvada) for PrEP has been approved by Health Canada.

### How much does PrEP cost?

- The cost of Tenofovir/Emtricitabine (Truvada) ranges from \$250-\$1000/month depending on the brand.
- This cost is NOT covered by Manitoba Pharmacare, but may be covered by some third party/private insurance companies.
- The cost is covered for people who have First Nations & Inuit Health Branch benefits.

### How should PrEP be used or prescribed?

- PrEP should be used together with other prevention strategies like condoms.
- Before starting PrEP, a detailed assessment of risks and benefits should be done by a health care provider.
- PrEP requires daily adherence to the medication and HIV/STI testing, urine and blood work monitoring every three months.
- There are potential side effects to the medication.
- There are risks for developing drug resistance if a person becomes infected with HIV while taking PrEP.

### More Information on PrEP:

For patients: [http://bit.ly/PrEPFacts\\_CATIE](http://bit.ly/PrEPFacts_CATIE)

For health care providers: <http://bit.ly/CdnPepPrepGuide>

**If you are interested in starting PrEP, talk to your primary care provider or come to Nine Circles and talk to one of our testing nurses. You can walk in during our testing clinic on Wednesdays from 1-7 pm at 705 Broadway, or call 204-940-6000 to book an appointment.**



## PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION Health care provider

### What is it:

- Pre-Exposure Prophylaxis (PrEP) is a way for an HIV-negative person at risk of HIV infection to reduce their risk.
- One form of PrEP involves taking the antiretroviral medication Tenofovir DF 300 mg/Emtricitabine 200 mg (brand name = Truvada) on a daily basis.
- Tenofovir/Emtricitabine (Truvada) for PrEP has been approved by Health Canada.

### Dose:

- Tenofovir DF 300 mg/Emtricitabine 200 mg one tablet once daily.
- For PrEP to be effective, daily adherence is needed.

### Cost:

- The cost of Tenofovir/Emtricitabine (Truvada) ranges from \$250-\$1000/month depending on the brand.
- Tenofovir/Emtricitabine (Truvada) for PrEP is NOT an eligible benefit under Manitoba Pharmacare, but may be an eligible benefit under some third party or private insurance companies.
- It is important to confirm that the third the party or private insurance company provides coverage for Tenofovir/Emtricitabine (Truvada) when prescribed for the indication of PrEP (preventing HIV) versus treating HIV.
- The cost of Tenofovir/Emtricitabine (Truvada) is covered for people who have First Nations & Inuit Health Branch benefits.

### Assessment and Monitoring:

- Before starting PrEP, a detailed assessment of risks and benefits should be completed by a health care provider. PrEP may be indicated for someone who is at high risk for HIV and who has no contraindications to the medication and is likely to adhere to the medication and to follow up.
- PrEP should be recommended together with other prevention strategies like condoms.
- There are potential side effects to the medication including renal toxicity.
- There are risks for developing drug resistance if a person becomes infected with HIV while taking PrEP. HIV/STI testing, urine and blood work monitoring should be done every three months.

Canadian guidelines for PrEP and nPEP are available at: <http://www.cmaj.ca/content/189/47/E1448>

Information for patients: [http://bit.ly/PrEPFacts\\_CATIE](http://bit.ly/PrEPFacts_CATIE)



## PrEP ongoing challenges

- FUNDING
- Competing priorities
- Treatment gaps
- Disadvantaged populations



## Questions?

Please type your question or comment into the chat box.



# Thank You

PRESENTED BY  
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