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# **Condoms, PrEP, and the use of ART to prevent the sexual transmission of HIV:**

## **Overview of the science and recommendations for service providers**

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# Overview

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1. Internal and external condoms
2. Oral pre-exposure prophylaxis (PrEP)
3. The use of antiretroviral treatment (ART) and an undetectable viral load



# Internal and external condoms

# What are internal and external condoms?

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- Condoms are barriers that prevent vulnerable parts of the body from coming into contact with HIV
- Materials used to make most condoms (latex, nitrile, polyurethane, polyisoprene) are impermeable to HIV
- Types of condoms
  - External and internal
- Cornerstone of past and current HIV prevention efforts

# How well do condoms work for preventing HIV?

- Biological rationale for 100% effectiveness if condom does not break, slip, or leak
  - Failure rates of condoms range from 0.4-3.4% (breakage), 0.6-1.1% (slippage), and 0.4-6.5% (leakage)
  - Incorrect use of condoms is common
  - Correct use of condoms can reduce rates of breakage, slippage, and leakage

# How well do condoms work for preventing HIV?

- Several observational studies have evaluated effectiveness of **consistent external condom use**
  - Heterosexual serodiscordant couples
    - Three early meta-analyses estimated 69-94%
    - Latest meta-analysis estimated 80%
  - Gay men and other MSM
    - Similar level of effectiveness (70%)
- Observational studies of condoms have **limitations**
  - Inconsistent use, incorrect use, lack of randomization
- **Internal condoms** have not been evaluated for their effectiveness against HIV infection

# Summary – internal and external condoms

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- Condoms can reduce the risk of HIV transmission by 90% or more when used consistently and correctly
- For many people, effectiveness against HIV infection is lower than 90%
- Service providers can play an important role in improving uptake and consistent and correct use

# Recommendations for service providers

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1. Improve awareness of condoms as a highly effective HIV prevention strategy, including the factors important for maximizing its effectiveness.
  - Finding an external condom with the right fit and feel
  - Using a new condom for every act
  - Applying sufficient and appropriate lubrication
  - Using condom for entire act of sex
  - Putting the condom on and taking it off correctly



# Recommendations for service providers

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## 2. Facilitate and support appropriate uptake and use of condoms as a prevention strategy.

- Offer condoms to clients
- Explore – and help clients overcome – barriers to consistent and correct use

# Summary – internal and external condoms

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- Condoms can reduce the risk of HIV transmission by 90% or more when used consistently and correctly
- For many people, effectiveness against HIV infection is lower than 90%
- Service providers can play an important role in improving uptake and consistent and correct use
- Advantages and disadvantages of condoms



# Oral pre-exposure prophylaxis (PrEP)

# What is oral PrEP?

- Ongoing **daily use of Truvada** by HIV-negative individuals, starting before an exposure and continuing after
- **Regular visits with a service provider** to test for HIV/STIs, monitor side-effects and toxicity, and provide risk-reduction and adherence support
- CDC and WHO recommend offer of PrEP to people at “**high-risk**” of **HIV infection**
- **Approved** by the FDA in the United States

# How well does daily oral PrEP work?

- **Several RCTs** have found that the daily use of Truvada works for multiple populations;
  - heterosexual men and women
  - gay men and other men who have sex with men
  - people who use injection drugs
- The overall reduction in HIV risk provided by PrEP in these studies ranged from **0 to 75%**
  - Varying levels of adherence responsible for wide range
  - Adherence so low in two studies of heterosexual women that PrEP provided no protection

# How well does daily oral PrEP work?

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- Additional analyses suggest that the **consistent use of PrEP** can reduce the risk of HIV infection by **90% or more**
- No evidence showing PrEP works less well for one sex compared to the other when used consistently

# How well does daily oral PrEP work?

- Evidence from **‘open label’ studies** support high effectiveness
  - iPrEX open-label extension
    - No HIV infections among gay men and other MSM taking 4 or more pills a week (reduced HIV risk by at least 86%)
  - PROUD study
    - Overall HIV risk-reduction of 86% among gay men and other MSM
  - Partners PrEP
    - “PrEP as a bridge to ART” estimated to reduce HIV transmission risk among serodiscordant heterosexual couples by 96%

# Does intermittent oral PrEP work?

- iPERGAY study
  - RCT among gay men and other MSM in France and Montreal
  - Evaluated an event driven, “on demand” Truvada strategy

**PrEP strategy reduced risk of HIV infection by 86%**  
(Men took an average of 4 pills per week)

- Supports evidence from other studies suggesting occasional missed pill may not have large impact for gay men



# How safe is PrEP?

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- PrEP **increased risk** of side effects including diarrhea, nausea, headache, fatigue and dizziness
- Some participants experienced **small decreases** in kidney, liver and bone health
- Drug resistance was **generally rare**
- **Limited evidence** of risk compensation

# Summary – oral PrEP

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- Daily oral PrEP is currently available in Canada
- The daily use of Truvada as PrEP can reduce the risk of HIV transmission by 90% or more when used consistently and correctly
- For many people, effectiveness of PrEP against HIV infection may be lower than 90%
- Service providers can play an important role in improving uptake and consistent and correct use

# Recommendations for service providers

1. Improve awareness of PrEP as a highly effective HIV prevention strategy, including the factors important for maximizing its effectiveness.

Emphasize that PrEP:

- should only be used by people who are HIV negative
- should only be accessed through a healthcare provider
- requires the daily use of a pill called Truvada
- requires that people should be screened for the hepatitis B virus before taking Truvada
- requires regular clinic visits with a healthcare provider every three months

# Recommendations for service providers

2. Facilitate and support appropriate uptake and use of PrEP as a prevention strategy.
  - Support clients to decide whether PrEP is right for them
  - Be aware of – and develop partnerships with – local healthcare providers, clinics, health centres and demonstration/pilot projects that are willing to prescribe PrEP
  - Support clients in talking to a healthcare provider and determining whether insurance can cover the cost
  - Support consistent and correct use



# **Use of ART and an undetectable viral load as prevention**

# What is the use of ART as prevention?

- In addition to improving the health of people living with HIV, it is now clear that ART **also has important HIV prevention benefits.**
- The amount of virus (viral load) in the bodily fluids is the **most important predictor** of whether an exposure to HIV leads to infection
- Successful ART can reduce the viral load in the bodily fluids to undetectable levels and this can **dramatically reduce the risk of HIV transmission**

# How well does the use of ART as prevention work?

- **Nine observational studies** have evaluated the prevention benefits of ART among heterosexual serodiscordant couples
  - Overall risk-reduction ranged from 0 to 92%
  - Meta-analysis estimate of 42%
- The **HPTN 052 RCT** conclusively demonstrated that ART has prevention benefits
  - Early initiation of ART reduced the risk of HIV transmission among heterosexual serodiscordant couples by 96%

# How well does the use of ART as prevention work?

- **PARTNER study** interim analysis demonstrated that ART also has prevention benefits for MSM
  - Enrolled heterosexual and same-sex male serodiscordant couples
  - No HIV infections despite over 44,000 condomless anal and vaginal sex acts when viral load undetectable
- **Opposites Attract study** interim analysis also found no HIV infections among gay men in serodiscordant relationships
  - Over 5,000 condomless anal sex acts when viral load undetectable



# How well does the use of ART as prevention work?

- Impact of STIs and viral load blips remains unclear
- All participants in the HPTN 052, PARTNER, and Opposites Attract studies were in stable relationships and engaged in regular care
- In the above studies, no HIV transmissions occurred between the couples when the viral load was undetectable
  - However, HIV infections did occur from sex outside of the main relationship

# Summary – ART as prevention

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- ART has prevention benefits
- ART and an undetectable viral load can reduce the risk of HIV transmission by 90% or more when used consistently and correctly
- For many people, the prevention benefits of ART may be lower than 90%
- Service providers can play an important role in improving uptake and consistent and correct use

# Recommendations for service providers


1. Improve awareness of ART and an undetectable viral load as a highly effective HIV prevention strategy, including the factors important for maximizing its effectiveness.

Maximizing prevention benefit requires:

- an HIV-positive individual to have had an undetectable blood viral load (defined as less than 40 or 50 copies per ml of blood) for at least six months
- both sexual partners to have no untreated sexually transmitted infections (STIs).

# Recommendations for service providers

2. Facilitate and support appropriate uptake and use of ART as a prevention strategy.
  - Support client decisions related to ART initiation
  - Link clients to HIV care, if needed
  - Support clients on ART with consistent and correct use
  - Encourage and support clients to communicate openly with their sex partners (viral load and STI test results, outside sex partners, disclosure of HIV status)



# **Additional recommendations for service providers related to condoms, PrEP, and use of ART as prevention**

# Recommendations for service providers

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3. Encourage combination prevention methods.
4. Address underlying risk of HIV transmission.
5. Offer comprehensive couples-based counselling.
6. Incorporating information into all prevention programming will increase its impact.
7. Be prepared to discuss the legal issues around HIV disclosure.

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**Thank you!**