



# Risk Mitigation Considerations: Pre-Exposure Prophylaxis (PrEP) for Prevention of HIV Infection

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# Agenda

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- Background of PrEP for HIV Infection and Risks
- Potential Strategies to Mitigate Risks with PrEP
- Potential Challenges and Considerations with Strategies for Mitigation of Risks



# What is Required with PrEP for Prevention of HIV Infection?

# PrEP for Prevention of HIV Infection

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- Adherence with a daily regimen
- Adherence with safer sex practices
- Adherence with HIV testing *prior to* PrEP treatment and *periodically monitoring* HIV status while treated with PrEP



# What are the Risks with PrEP for Prevention of HIV Infection?

# Risk - Development of Drug Resistance

- If PrEP resistance develops, it results in loss of treatment options proven to prolong life for individuals infected with HIV
- Spread of resistance to PrEP in high-risk communities risks loss of achieved public health benefits for high risk individuals

**Question:**

How could HIV prophylaxis be offered to the public and, concurrently, mitigate the risk of developing PrEP treatment resistance and losing PrEP treatment options for patients with disease (infected with HIV)?

# Inconsistent Adherence with PrEP for Prevention of HIV Infection

- Adherence with PrEP
  - Risk of intermittent adherence to:
    - Consistent safer sex practices
    - Daily treatment
- Adherence with periodic HIV testing

## Question:

How to motivate individual *adherence* to daily PrEP as prophylaxis *and* periodic HIV testing?



# Potential Strategies to Mitigate Risks with PrEP for Prevention of HIV Infection



# Potential Education and Training For Prescribers

- Development of resistance to PrEP if:
  - PrEP is continued after an individual seroconverts from HIV negative to HIV positive
    - PrEP is not taken consistently
    - Inconsistent safer sex practices
  
- Need to counsel individuals treated with PrEP for HIV infection
  - Adherence with daily treatment
  - Adherence with safer sex practices
  - Importance of periodic HIV testing

# Potential Approach to Monitoring HIV Testing

- Require periodic monitoring of HIV status
  - *Prior to initiating* PrEP
  - *Throughout* treatment with PrEP
- Counsel individuals who seroconvert from HIV negative to HIV positive
- Treat individuals who seroconvert to HIV positive according to CDC Guidelines



# Potential Challenges and Considerations with Risk Mitigation Strategies

# Potential Challenges for Consideration

- Who are target prescribers for PrEP for HIV negative individuals?
  - Primary care physicians and/or infectious disease specialists or other physicians?
- How to target the HIV negative population, at risk, to benefit from PrEP for HIV infection?
- How to impact human behavior and the need for strict adherence with daily treatment, safer sex practices, and periodic HIV testing for chronic use?

# Potential Challenges for Consideration

- How often should HIV testing be monitored?
  - *Draft* CDC Guidelines recommend HIV testing q 3 mos.
  
- How to achieve prescriber and individual user adherence with PrEP for prevention of HIV infection?
  
- How to ensure medication access if HIV testing is required for both populations?
  - HIV positive individuals with disease
  - HIV negative individuals using PrEP for prevention of HIV infection

## Potential Challenges for Consideration

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- How to measure the impact of education, training, and, potentially, adherence with these risk strategies and monitoring?
- What is the burden of these and other potential risk strategies for PrEP for HIV infection on healthcare systems?



# Panel Discussion