



Safety Issues in Pre-exposure Prophylaxis for HIV negative individuals, proposals for management of safety concerns, and pending plans for scale-up

Forum for Collaborative HIV Research
August 19, 2011
Washington, D.C.

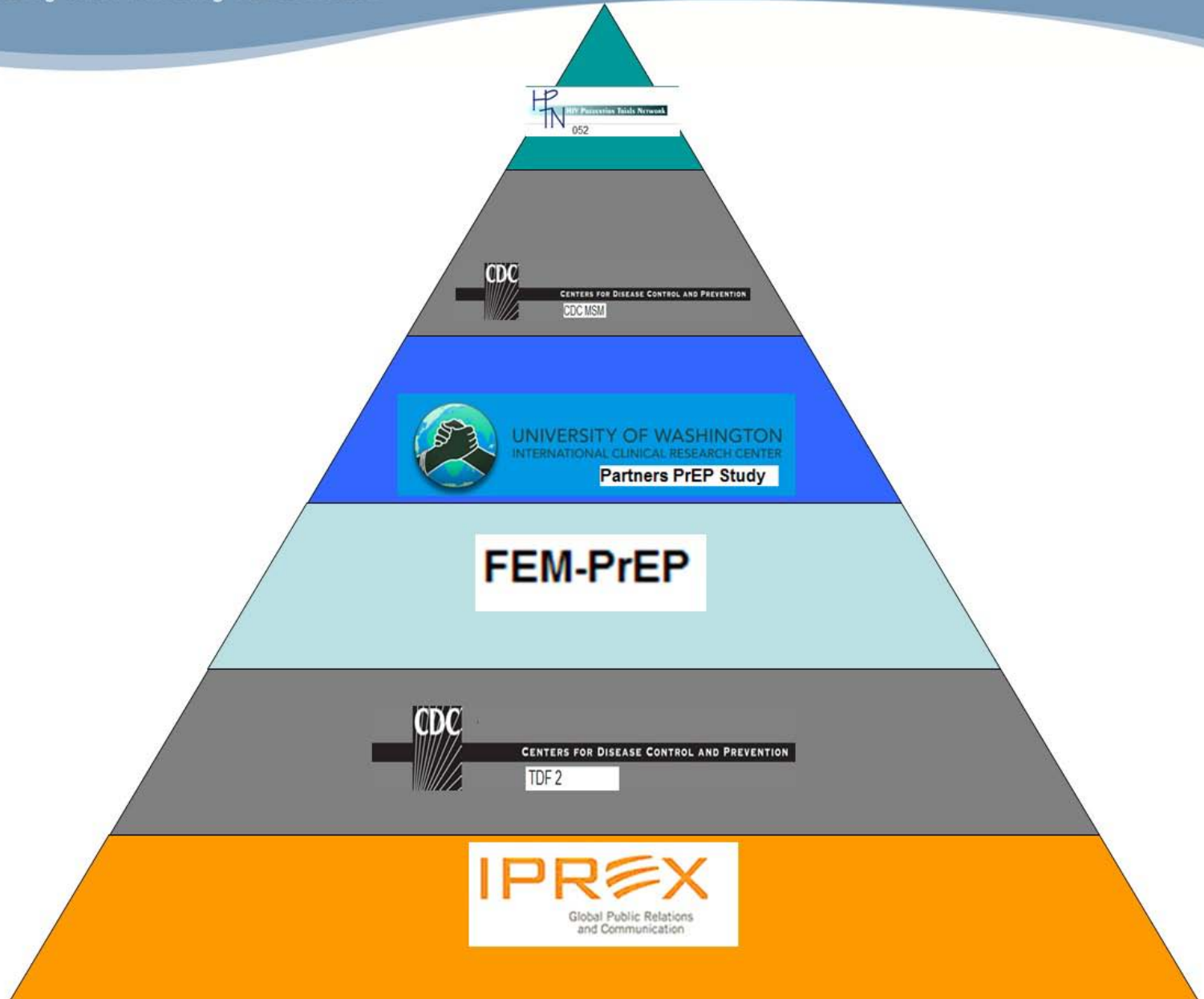
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PrEP Stakeholders

- Academia
- Government
- Pharmaceutical companies
- Advocacy groups
- Insurance companies

PrEP

- Explore its place in the prevention toolbox
 - For use with other prevention modalities such as condoms, etc.
 - For use with patient and physician education about benefits and risks and importance of adherence
 - To reduce risk of acquisition of HIV
 - Test and bring more people into treatment



PrEP Benefit/Risk

- Balance protective benefits with:
 - Risk of development/acquisition of resistant HIV-1 variants
 - Toxicity of long term ARV therapy
 - Behavioral compensation
 - Additional public health issues



Panel Discussions

- Safety and public health concerns
- Access and implementation
- Regulatory, CDC, insurance and industry perspectives
- Next steps

Other Considerations

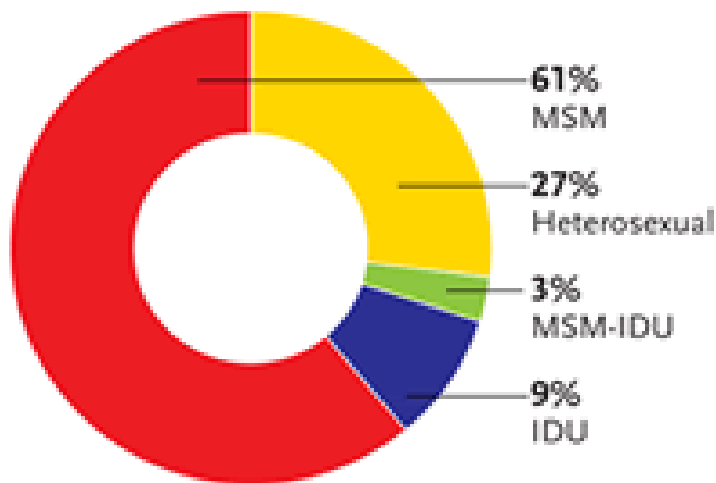
- If approved ARVs for treatment are being considered for PrEP, then
 - access to PrEP should not negatively impact access to treatment
- Need to provide context in addition to CDC guidance
 - In-depth review of data sets and inspection of clinical trial sites

PrEP Matters

- Overall, PrEP would encourage more HIV testing among high risk groups
 - Many HIV-infected persons are unaware of their serostatus
- With more HIV testing, then more HIV positive patients would be brought into treatment
- With more treatment, then decrease in new infections

Gay and bisexual men remain the population most heavily affected by HIV in the United States

Estimated New HIV Infections, 2009,
by Transmission Category



Source: CDC

CDC estimates MSM represent approximately 2% of the US population, but accounted for more than 50% of all new HIV infections annually from 2006 to 2009

- 56% in 2006 (27,000)
- 61% in 2009 (29,300)

Young, black MSM is the only population in the US to experience a statistically significant increase in new HIV infections from 2006 - 2009



NATIONAL HIV/AIDS STRATEGY FOR THE UNITED STATES

JULY 2010



“We must also move away from thinking that one approach to HIV prevention will work, whether it is condoms, pills, or information. Instead, we need to develop, evaluate, and implement effective prevention strategies and combinations of approaches including efforts such as expanded HIV testing (since people who know their status are less likely to transmit HIV), education and support to encourage people to reduce risky behaviors, the strategic use of medications and biomedical interventions (which have allowed us, for example, to nearly eliminate HIV transmission to newborns), the development of vaccines and microbicides, and the expansion of evidence-based mental health and substance abuse prevention and treatment programs. It is essential that all Americans have access to a shared base of factual information about HIV. The Strategy also provides an opportunity for working together to advance a public health approach to sexual health that includes HIV prevention as one component. **To successfully reduce the number of new HIV infections, there must be a concerted effort by the public and private sectors, including government at all levels, individuals, and communities, to:**

Intensify HIV prevention efforts in communities where HIV is most heavily concentrated.

Expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches.

Educate all Americans about the threat of HIV and how to prevent it.”