Challenges and Opportunities in HIV Prevention

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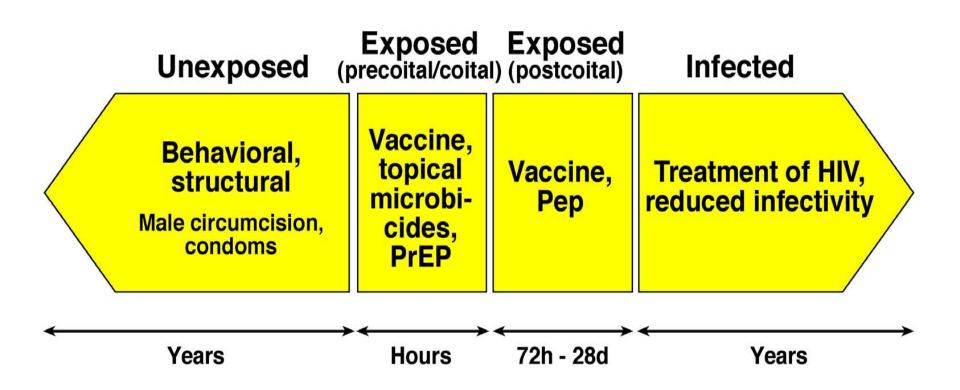
Director, Division of AIDS, NIAID, NIH

March 28, 2011

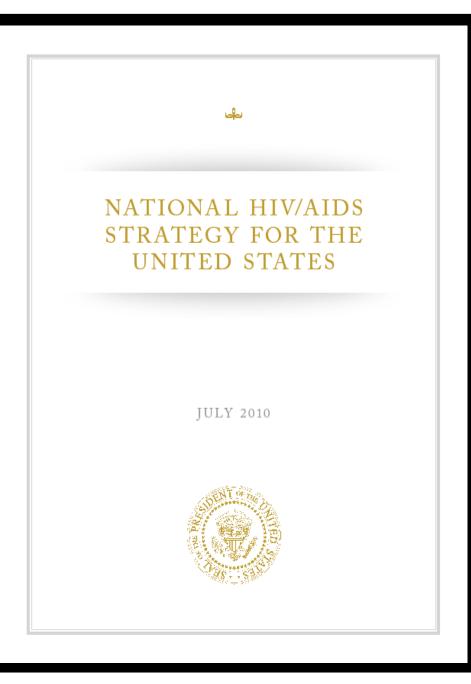


Know the Epidemic in the Community

Opportunities for Preventing HIV Infection



Source: M Cohen et al. J. Clin. Invest. 118:4, 2008



- Reducing HIV incidence
- Increasing access to care and optimizing health outcomes
- Reducing HIV-related health disparities

HIV Prevention Research: Guiding Principles

- Multiple strategies needed to assemble a wellrounded "prevention toolkit."
- No one prevention strategy will be 100% effective, appropriate to or accepted by everyone.

Approaches to HIV Prevention

Validated Approaches

- Clean syringes (i.e. needle exchange programs)
- Condoms, and other barrier methods
- Education and behavior adaptation
- Treatment/prevention of drug/alcohol abuse
- Interruption of mother-tochild transmission
- Circumcision
- HIV/STI Testing

Research Needed

- Topical microbicides
- Pre-exposure prophylaxis
- Vaccines
- Antiretroviral treatment as prevention (Test and Treat)
- Integrated combination prevention strategies

Selected HIV Prevention Strategies Under Development

ARVs as Prevention

- Microbicides
- Pre-Exposure Prophylaxis (PrEP)
- "Test and Treat" / TLC +

Next Steps

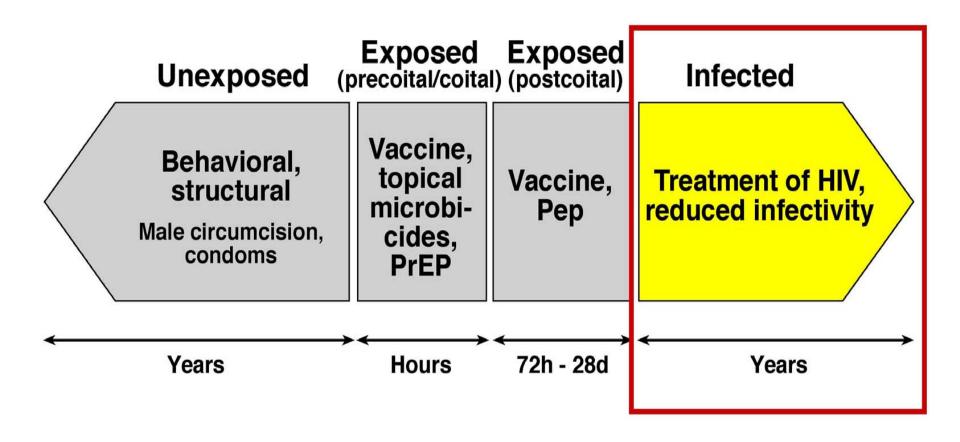
Topical Microbicides: Future Directions

- Complete VOICE move 1% Tenofovir gel to licensure
- Expand efforts to develop rectal microbicides
- Devise more acceptable, less behaviorally sensitive delivery methods
- Explore combinations
 - Alternative microbicide strategies e.g., modulation of female reproductive tract (FRT) homeostasis
 - Vaccines and microbicides?
- Evaluate novel clinical trial methodologies

PrEP Future Directions

- Now that the concept is proven complete VOICE!
- Engage partners to define adherence strategies and approaches to social marketing
- Develop and test combinations pills and gels?
- Devise means of incorporation of ARVs as prevention into combination packages

Opportunities for Preventing HIV Infection



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Selected Research Issues Related to the Voluntary "Test and Treat" Approach

- Universal testing
- Relationship of the stage of HIV infection to efficiency of transmission
- Efficacy of ART in preventing HIV transmission
- Drug resistance
- Behavioral "disinhibition"
- Benefit to the individual
- Cost-effectiveness for society

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ART Reduces the Risk of Heterosexual HIV-1 Transmission in HIV-1 Sero-discordant African Couple Study (Abstract #136)

Deborah Donnell, Fred Hutchinson Cancer Research Center

| ART in HIV- infected partner | Linked Transmissions | Person-years of follow-up | HIV Seroincidence |
|---------------------------------|-------------------------|---------------------------|------------------------------|
| Post ART initiation | 1 | 256 | 0.39 (95%CI 0.09 to 2.18) |
| No ART | 102 | 4851 | 2.23 (95%CI 1.84 to 2.70) |

EPIDEMIOLOGY AND PREVENTION

HIV Transmission Risk Among Serodiscordant Couples: A Retrospective Study of Former Plasma Donors in Henan, China

Lu Wang, MD, PhD,* Zeng Ge, BS,*† Jing Luo, BS,*‡ Duo Shan, BS,*† Xing Gao, MD, PhD,* Guo-wei Ding, MD,* Jian-ping Zhou, BS,§ Wen-sheng He, BS,§ and Ning Wang, MD, PhD*

COMMENTARY

HIV Treatment as Prevention: To be or not to be?

Myron S. Cohen, MD

"Second, and perhaps most important, transmission events occurred with equal frequency in couples regardless of whether the partner was provided free ART."

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National Institutes of Health June 8, 2009

National Institute of Allergy and Infectious Diseases (NIAID)

http://www.niaid.nih.gov/

Starting Antiretroviral Therapy Earlier Yields Better Clinical Outcomes

Interim Review Leads to Early End of Clinical Trial in Haiti

~4-fold increased risk of death for patients deferring ART until CD4 count dropped below 200 vs. initiating ART at CD4 count between 200-350 (n=816)

START

HIV-infected individuals who are ART-naïve with CD4+ count > 500 cells/mm³

Early ART Group

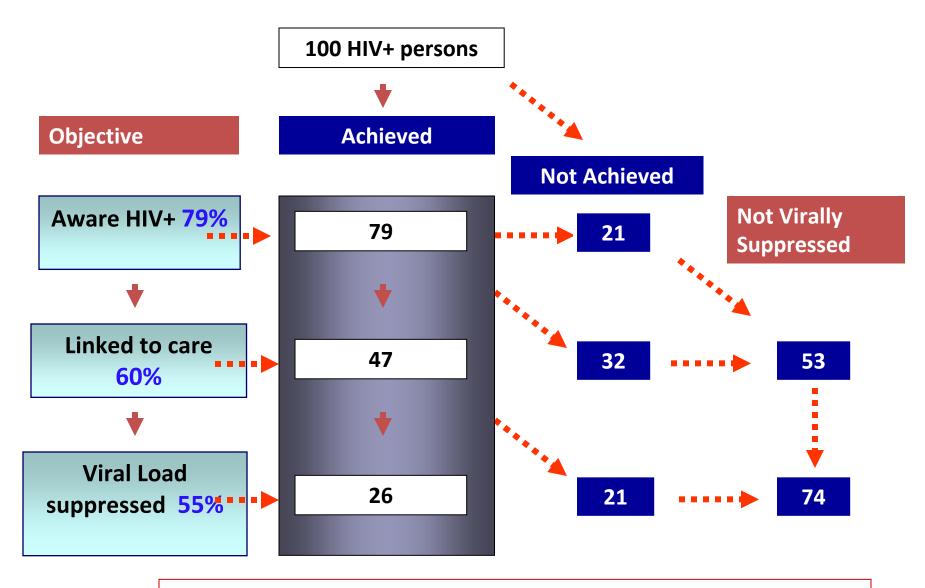
Initiate ART immediately following randomization

Deferred ART Group

Defer ART until the CD4+ count declines to < 350 cells/mm³ or AIDS develops

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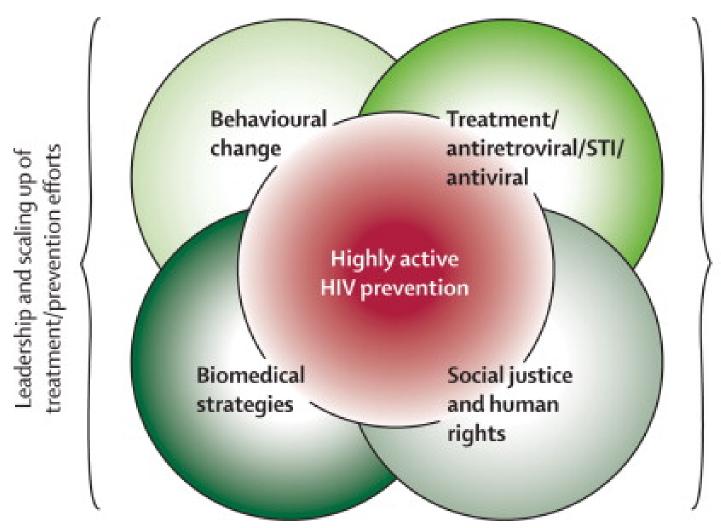
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Overall: ~26% of HIV+ persons were in care and estimated to have a viral load <500 copies/ml

HPTN 065 update

- HPTN 065 (TLC-Plus): A study to evaluate the feasibility of an enhanced test, link to care, plus treat approach for HIV prevention in the US
 - Study open to accrual: September 2010
 - Enrolling: March 2011
 - Anticipated results: 1Q 2014



Our Common Goal:

Controlling and Ultimately Ending the HIV/AIDS Pandemic

