6th Annual National Summit on Health Disparities

The NIAID Integrated Prevention Research Program

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A Comprehensive HIV Prevention “Toolbox”

- Vaccine
- Microbicides
- PrEP
- Education
- ARV therapy
- Partner Reduction
- MTCT interruption
- Circumcision
- Condoms
- Harm reduction
- Drug/alcohol treatment
- Etc.
HIV/AIDS in Washington, DC

- ~3% of adults and adolescents in District living with HIV/AIDS, end-2007

- An underestimate, as between 1/3 and 1/2 of DC residents may be unaware of their HIV infection status

Report released 3/16/2009
Proportion of Washington, D.C. Adults and Adolescents Living with HIV/AIDS by Race and Sex, End-2007

- **White Females**: 0.2%
- **Hispanic Females**: 0.7%
- **Black Females**: 2.6%
- **White Males**: 2.6%
- **Hispanic Males**: 3.0%
- **Black Males**: 6.5%

Threshold for generalized/severe epidemic: 1.0%
Overall DC HIV/AIDS Prevalence among Adults and Adolescents: 3.0%

Source: DC Dept. of Health, 2009; MMWR, 10/3/2008
Comparative AIDS Prevalence, Major Cities

Cases per 100,000

- Detroit
- Chicago
- Philadelphia
- New York City
- Baltimore
- Washington, DC

Source: S. Hader, CROI 2009, Montreal
The HIV Prevalence Rate in Washington DC is Higher than in 22 Sub-Saharan African Countries

- Washington, DC: 3.0%
- Mali: 1.5%
- Niger: 0.8%
- Mauritania: 0.8%
- Senegal: 1.0%
- Gambia: 0.9%
- Guinea-Bissau: 1.8%
- Guinea: 1.6%
- Sierra Leone: 1.7%
- Liberia: 1.7%
- Ghana: 1.9%
- Benin: 1.2%
- Burkina Faso: 1.6%
- Democratic Republic of Congo: 1.4%
- Angola: 2.1%
- Rwanda: 2.8%
- Ethiopia: 2.1%
- Somalia: 0.5%
- Comoros: <0.1%
- Mauritius: 1.7%
- Madagascar: 0.1%
- Burundi: 2.0%
HIV Prevention Research: Guiding Principles

- Multiple strategies needed to assemble a well-rounded “prevention toolkit.”

- No one prevention strategy will be 100% effective, appropriate to or accepted by everyone.

- Multiple prevention strategies must be evaluated in different populations, domestically and globally, to determine the best combinations for a given population.
Estimated Number of New HIV Infections Among Adults/Adolescents, USA, 1977-2006

Health Care Costs of HIV Infection

- Each new HIV infection ultimately costs $300,000 in health care expenses

- At 56,300 new HIV infections a year in the U.S., $17B in health care costs added annually

Source: Medical Care 44:990-7, 2006
Population-Specific Prevention Research Activities in the U.S.

- Three new pilot studies:
  - Two observational studies of women in defined geographic areas at high risk of HIV
  - Multi-faceted intervention in Black MSM

- Question: Can we identify and reach the most at-risk populations in the U.S. and tailor interventions to more effectively prevent HIV
HIV SerolIncidence Study in Women (ISIS)

Objectives:

- Estimate overall HIV incidence rate among women in geographic areas with high HIV prevalence and poverty
- Describe sexual behaviors, alcohol & drug use, prevalence of domestic violence, & mental health indicators
- Assess women’s preferred recruitment and retention strategies for future studies
- Explore facilitators/barriers to HIV testing
HVTN 906

Objectives

- Determine feasibility of recruiting & retaining women at risk of HIV infection
  - Reside or engage in risk behavior in areas with high HIV prevalence
  - Partners of men who are from subgroups with high HIV prevalence
- Assess whether recruitment strategy identifies population with incidence $\geq 1\%$
- Comparison to ISIS will define better method of identifying at risk women

Status

- Study opened in December 2008 in 3 U.S. cities
  - New York, Philadelphia, Chicago
Feasibility of Multi-Component HIV Intervention for Black MSM

Objectives:

- Assess use of interventions
  - Recruit and retain Black MSM
  - % agreeing to HIV and STI testing
  - % who utilize peer health navigation
- Estimate intervention effect in HIV (+/-):
  - HIV/STI incidence at 6 & 12 months
  - ↓ in viral load
  - ↑ in condom use
Approaches to HIV Prevention

- Education and behavior modification
- Condoms, and other barrier methods
- Treatment/prevention of drug/alcohol abuse
- Clean syringes (i.e. needle exchange programs)
- Interruption of mother-to-child transmission
- Circumcision
- HIV/STI Testing
- Antiretroviral treatment as prevention
- Pre-exposure prophylaxis (PrEP)
- Topical microbicides
- Vaccination
Percentage of Individuals at Risk with Access to HIV Prevention

- 8% Harm reduction for injection drug users
- 9% Condom access
- 9% Behavior change programs for men who have sex with men
- 10-12% Adults with access to HIV testing in Africa
- 11% Prevention of mother-to-child transmission
- <20% Behavior change programs for commercial sex workers

Topical Microbicides: Current Status

- A microbicide is a product applied vaginally or rectally that can reduce or eliminate transmission of HIV and/or other STD pathogens
- PRO 2000: 30% effective
- First clinical study suggesting that a microbicide may prevent male-to-female transmission
Topical Microbicides: Future Directions

- **PRO 2000**
  - Ongoing study of PRO 2000 (0.5%) conducted by Microbicides Development Programme; results expected by end of this year
  - Rectal safety study of PRO 2000 planned

- **Tenofovir**
  - CAPRISA 004: phase II B trial, 1% Tenofovir gel vs. placebo in South Africa; results will be available next year

- **Other Research Plans**
  - Devise more acceptable delivery methods
  - Expand efforts to develop rectal microbicides
  - Develop products with outstanding safety and resistance profiles
    - Explore combinations
    - Alternative microbicide strategies e.g., modulation of female reproductive tract (FRT) homeostasis
    - Vaccines and microbicides
  - Evaluate novel clinical trial methodologies
Will people at risk adhere? The importance of understanding behavior!
PrEP Future Directions

- First, prove the concept
- Establish improved dosing schedules to maximize adherence
- Engage partners in operations research social marketing
- Develop and test new agents, combinations and delivery systems
  - Safe, potent, longer half-lives
  - Non-overlapping resistance profiles with existing ART
  - Improved animal models
Voluntary “Test and Treat” Concept

Universal Voluntary HIV Testing with Immediate Antiretroviral Therapy as a Strategy for Elimination of HIV Transmission: a Mathematical Model

RM Granich et al.

- Model indicates that universal and annual voluntary HIV testing followed by immediate antiretroviral therapy treatment (irrespective of clinical stage or CD4 count) could reduce new HIV cases by 95% within 10 years

- Concerns: feasibility, protection of individual rights, drug resistance, toxicity, financing
Test and Treat Hypothesis

Test

- Adoption of safer behaviors by HIV+ persons

Treat with ART + Adherence

- Maintain viral suppression

Decrease in HIV Transmission

Source: S. Vermund, HPTN
Emerging Issues

- Need to expand PEPFAR in the context of “treatment as prevention”
- No new people are starting treatment in PEPFAR
  - These people are still capable of transmitting virus
A Safe and Effective HIV Vaccine

- Critical to the effective control of HIV globally.
- The most important and difficult scientific challenge in AIDS research.
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