



Current and Future Directions for PrEP Research

Carl W. Dieffenbach, Ph.D.
Director
Division of AIDS, NIAID, NIH, HHS
April 2, 2009



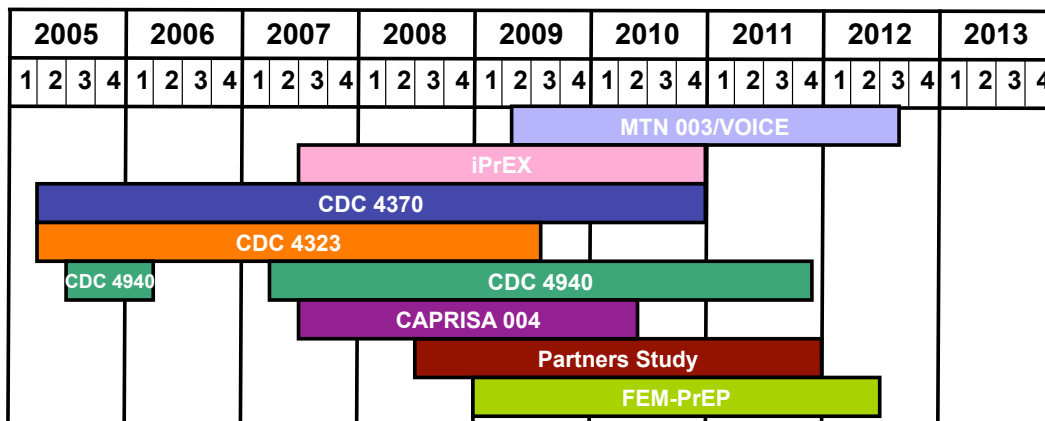
Areas of Emphasis for Prevention

- **New Biomedical Interventions**
 - Current clinical trials
 - Basic and preclinical framework for microbicide, PrEP pipeline
- **Treatment as Prevention**
 - Optimizing “test and treat” programs
 - Other prevention strategies with positives
- **Combination Prevention Packages**
 - Determining optimal methods for designing and testing prevention packages for specific target populations
- **Refocusing on Domestic Epidemic**
 - Feasibility of accessing most at risk populations
 - Piloting components of appropriate prevention packages

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 and Post-exposure prophylaxis (PrEP, PEP)**
- **Topical microbicides**
- **Vaccination**

Timeframe for Ongoing & Planned PrEP Trials



MTN 003/VOICE – Phase IIb, topical Tenofovir, oral Tenofovir, oral Truvada vs. placebo (multi-country)

iPrEX – Phase III, Truvada among MSMs in Peru, Ecuador, South Africa, Brazil, Thailand, US

CDC 4370 –Phase II/III, daily Tenofovir or placebo among IDUs in Thailand

CDC 4323 – Phase II safety study, daily Tenofovir or placebo among MSMs in US

CDC 4940 – Phase III, daily Truvada or placebo in Botswana

CAPRISA 004 – Phase III, 1% Tenofovir gel or placebo in South Africa

Partners Study – Phase III, daily Tenofovir, Truvada, or placebo in discordant heterosexual couples (Kenya and Uganda)

FEM-PrEP – Phase III, daily Truvada or placebo in high risk women (multi-country)

Future Directions for PrEP

- **First, prove the concept**
- **Propose and evaluate rationally designed alternative dosing schedules that maximize acceptance, 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
- **Address potential negative outcomes**
 - Adherence
 - Drug toxicity/resistance
 - Behavioral disinhibition

A Comprehensive HIV Prevention “Toolbox”

