NIH HIV/AIDS Prevention Priorities

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Discovery → Delivery: The Path to Combination Prevention

How do we move from single products to integrated combination prevention programs?
Combination HIV Prevention

- Harm Reduction
- Vaccines
- Condoms
- STI Treatment
- Testing/Counseling
- Treatment as Prevention
- PrEP
- Microbicides
- Male Circumcision
- Drug/Alcohol Treatment
- PMTCT
- Education
Opportunities for Preventing HIV Infection

- **Unexposed**
  - Behavioral, structural
  - Male circumcision, Vaccine, Condoms

- **Exposed (precoital/coital)**
  - Topical microbicides, PrEP, Vaccine, Condoms

- **Exposed (postcoital)**
  - Vaccine, PEP

- **Infected**
  - Treatment of HIV, reduced infectivity

HIV Prevention Research: Guiding Principles

- No single prevention strategy is enough
- HIV testing is the entry point for individually-focused prevention interventions
- HIV treatment is a critical component of prevention
- Know your epidemics within the community and select prevention interventions based upon effectiveness and cost
- Evolve prevention strategies with changes in the epidemic
Lessons Learned From Prevention Research

- The active agent must be at the site of exposure in sufficient concentration for ample duration to abrogate infection
- New agents
  - Does it work for all routes of exposure?
  - How is it administered?
  - Is it behaviorally dependent?
The Dynamic Tension in the Prevention Field

- Given the efficacy of treatment as prevention, what is the future niche for PrEP and microbicides in combination prevention?
- Do we seek to optimize what we have shown to be effective or do we seek a better next generation?
  - Current products are strikingly behaviorally dependent and adherence is a significant issue
- Can behavior be changed and adherence improved?
- Will coitus-dependent gels will be part of the prevention armamentarium?
- Can we develop long-acting formulations with improved treatment and/or prevention outcomes (e.g. rings, implants, injectables)?
Role of Social and Behavioral Science in Biomedical Prevention Research

- Social science research must inform product development in an iterative way.
- Strategies and messages must be developed that promote:
  - Social acceptance of knowing your HIV status.
  - Understanding of the social responsibility for getting treatment.
- An integrated approach is required to create interest and demand for HIV prevention.
Applying this paradigm to:
- Prevention of acquisition
- Co-infections and co-morbidities
- Drug formulation and novel interventions
- Cure and/or functional cure
- Vaccines

Partnership is an essential tool
Incredibly diverse portfolio
Where on this cascade does NIH fit?
Combination HIV Prevention

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- Education
- PrEP
- Harm Reduction
- PMTCT
The Virtual Elimination of Mother to Child Transmission of HIV is Possible

Estimated new infections in children in 25 countries with largest numbers of HIV+ women

- No ARV prophylaxis for PMTCT
- Constant 2009 coverage of ARV prophylaxis
- 90% of women reached with services matching WHO guidelines
- 90% of women with WHO services, incidence ↓50%, family planning ↑, restrict breastfeeding to 12 months

Source: Adapted from Mahy et al, 2010
Research Needed to Get to Zero

- What are the research innovations needed to eliminate perinatal transmission?
  - Long-acting formulations for therapy or infant prophylaxis

- What areas require partnerships?
  - Implementation
  - Integration
  - Health systems strengthening
Research Needed to Get to Zero

- What are the research innovations needed to eliminate tuberculosis (TB), especially in special populations?
  - Improved diagnostics and formulations
  - Preventive vaccine

- What partnerships are needed in TB research?
Ethics Review of the “Promoting Maternal and Infant Survival Everywhere (PROMISE)” Study

June 18, 2012
Questions to the Panel

1. Given the changing landscape of the PMTCT guidelines, could PROMISE be conducted (or under what conditions can PROMISE be conducted) in a country that has chosen a national policy for PMTCT that recommends initiation of ART for life in all HIV-infected pregnant women regardless of CD4 count (Option B+)?
YES, the Panel believes that the PROMISE study could be conducted ethically in countries that have chosen option B+
Questions to the Panel

2. Given diverse implementation challenges and current policy developments in PMTCT programs, does the PROMISE study still have sufficient value for informing clinical, policy, or program decisions, now or in the future? If no, is there a design modification that would provide sufficient value to continue the study?
Answer

YES
Our Common Goal:
Controlling and Ultimately Ending the HIV/AIDS Pandemic