Turning the Corner on the AIDS Pandemic:
Focusing the Science-Driven HIV Research Enterprise

September 2017
Setting the 2027 Research Agenda

- Every 7 years, NIH competitively reviews its HIV network funding, addressing significant changes in research priorities that have occurred since the last competition.

- By establishing a forward-looking agenda now, NIH will determine the focus and structure of its HIV clinical trial networks through 2027.
We Stand on the Shoulders of Past Successes

- Therapeutics
- Development of PrEP
- Sex-specific protection
- Virtual elimination of perinatal and breastfeeding transmission
- Building on RV144
- Development of long-acting technologies
High priority areas of HIV/AIDS research are those that:

- Reduce incidence of HIV/AIDS through the development of better PrEP and safe and effective vaccines
- Develop the next generation of HIV therapies with improved safety and ease of use
- Discover and develop a cure for HIV/AIDS
- Improve prevention and treatment of HIV-associated co-morbidities and co-infections
- Foster cross-cutting areas of basic research, health disparities research, and training
Goals for 2027

▪ Ten years from now, imagine that we have:
  – Long-acting and durable prevention and treatment strategies effective for at least 6 months
  – HIV vaccines with an efficacy greater than 60 percent
  – A functional cure in large subsets of HIV-positive people of all ages
  – Normalized life expectancy for HIV-positive people
  – Reduced the burden of infectious and non-infectious co-morbidities, including TB co-infection
To achieve these goals in 2027, how should we refine the clinical trials networks today?
What Levers Can NIH Pull?

- Biomedical innovation
- Identify behavioral patterns and interventions
- Forge and nurture partnerships to extend reach
- Facilitate hand-off to implementers
  - PEPFAR, health systems, Ryan White, HRSA, CDC, foreign governments
Science Levers

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Fostering Biomedical Innovation

- Three key areas of research emphasis will be driven by intervention, covering all target populations:
  - Prevention
  - HIV vaccines
  - Therapeutics

- Form follows function. NIH will move to a triad of clinical trial networks:
  - Prevention
  - HIV vaccines
  - Therapeutics
Prevention Scientific Foci

- Novel biomedical methods of HIV prevention
- Behavioral and social science partnerships
- Protection in populations most at risk, including adolescents, young adults, and U.S. minorities
Prevention

- Develop tools that are:
  - Safe
  - Acceptable
  - Desired
  - Highly effective in preventing HIV acquisition
  - Protective system-wide
  - Next generation, where appropriate (e.g., PEP)

- Define the needs of vulnerable populations and tailor-fit prevention strategies
  - Interventions will focus on populations most at risk including adolescents, young adults, and U.S. minorities
What will be the criteria to move a vaccine concept forward for licensure?

- Establish efficacy
- Define correlates of protection
Vaccines

- **Evaluate vaccines to prevent HIV acquisition**
  - Once reasonable safety is determined, initiate studies in adolescents and younger children

- **Define correlates of HIV risk and protection**

- **Bridge from phase 2b/3 studies to licensure and market**
  - Partnerships required
Therapeutic Scientific Foci

- Novel and durable therapy
- Cure
- Tuberculosis
- Complications and coinfections
Therapeutics

- **Novel and durable therapy for HIV**
  - Establish efficacy of long-acting formulations that are fully suppressive and dosed infrequently
  - Newer ART during pregnancy, at birth, through childhood and adolescence

- **Establish virologic control in the absence of sustained therapy from infancy through adulthood**
  - Immune-based interventions, including therapeutic vaccines
  - Immune activation as a driver of persistence
  - Gene/cell therapies

- **Novel and durable therapy for TB**
  - Define new TB treatment and prevention strategies across the lifespan, including a vaccine
  - Newer TB medications during pregnancy, at birth, through childhood and adolescence

- **Complications and co-infections in adults**
  - Define and address mechanisms
  - Partner to prevent and treat end organ disease
  - Define curative strategies for Hepatitis B co-infection
Leveraging Partnerships

- Biomedical innovation
- Identify behavioral patterns and interventions
- Forge and nurture partnerships to extend reach
  - Facilitate hand-off to implementers
    - PEPFAR, health systems, Ryan White, HRSA, CDC, foreign governments
Partnerships: The Next Required Step

- NIH’s role is innovation, moving from bench to bedside, with the goal of public health impact
- Maintain existing and foster new collaborations and partnerships
  - Within NIH, HHS and the Federal Government
  - Foundations and NGOs
  - Private sector
- Partnering with implementers, facilitating the hand off
- Team approach required for partnership formation
Partnerships for Implementation Research

Develop combination prevention and treatment strategies

Prevent and treat infectious and non-infectious co-morbidities

Improve initiation and adherence to prevention and treatment

Address cross-cutting issues in infants, children, adolescents and young adults
Imagine in 2027
What to Expect

- September 2017-January 2018: Requesting feedback
- January 2018: Formal presentation to AIDS Research Advisory Committee
- 2018: Begin Funding Opportunity Announcement (FOA) authorship
- 2019: FOAs issued, peer review
- 2020: Awards made (FY 2021)
We Want to Hear from You

- Tell us what you think. Share a big vision or a specific note.
- Input deadline: November 30, 2017

- NIAIDnetworkrefinement@mail.nih.gov