HIV Prevention Trials Network Plenary

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National Institute of Allergy and Infectious Diseases

NIAID HIV Language Guide

NIAID Strives to End the Use of Stigmatizing Language

- Certain language is insensitive to people and their basic human dignity; it can be offensive and stigmatizing, and alienates study participants and the communities in which we work
- Using person-first, inclusive, and respectful language emphasizes humanity, highlights autonomy, and promotes the idea that someone's health and health determinants are only facets of their full life and identity
- NIAID strongly supports and requests the use of person-first, non-stigmatizing language at all NIAID-supported meetings
- The NIAID HIV Language Guide can be found at: https://www.niaid.nih.gov/research/hiv-language-guide

NIAID HIV Language Guide and Related Materials

Research › Resources for Researchers

NIAID HIV Language Guide

NIAID is making every effort to eliminate the use of stigmatizing terminology and advance the use of person-first, inclusive, and respectful language. This updated HIV Language Guide (May 2024) is an important step toward that end. This resource is applicable to all communications, including but not limited to grant applications, contracts, publications, presentations, abstracts, and press materials.

It should be noted that the NIAID HIV Language Guide has relevance beyond HIV. It includes language related to other areas of research, diseases and conditions, gender and sexuality, general research terminology, and more. NIAID urges all staff, collaborating researchers, and stakeholders to review the Language Guide and make use of it for all written and oral communications.

Download the NIAID HIV Language Guide

Credit: NIAID

Supporting Materials

The following slide and invitation templates may be used to reiterate the importance of eliminating the use of stigmatizing terminology in NIAID-supported meetings, workshops, and conferences.

- HIV-specific Template Introductory Slide PDF (PowerPoint Version PPT)
- Generic Template Introductory Slide PDF (PowerPoint Version PPT)
- Meeting Invitation Template Language PDF (Word Version DOC)
- Speaker Invitation Template Language PDF (Word Version DOC)

NIH National Institute of Allergy and Infectious Diseases

White House Office of National AIDS Policy – New Director

Francisco Ruiz, MS, DrPH (‘25)

HIV Clinical Trials Networks Competition

Network Competition Timeline

- **Spring 2024: Launch process with network presentations to SWG**
- **Summer 2024: Input from the stakeholders (investigators, community, etc.)**
  - Webinars, thematic discussions, townhalls
- **Fall 2024: Preliminary discussion at ARAC and other advisory committees**
- **Jan 2025: Formal presentation to ARAC of the refined network and units structure for approval**
- **2025: Begin RFA writing**
- **Jan 2026: Publish RFAs**
- **Fall 2026: Applications due**
- **Winter/Spring 2027: Review**
- **Sept 2027: Applications to Council**
- **Dec 2027: Earliest start date**

Finishing the Current Cycle and Moving Towards 2027 and Beyond

- What can be accomplished prior to the end of the current grant cycle?
- What adjustments in structure and scientific direction should be made to accelerate the pace of discovery?
- How should we build implementation strategies into our plans?

What Does the Future Hold?

- NIAID/DAIDS remains committed to HIV prevention across the lifespan
- Facilitate implementation and evaluation of HPTN 096
- Continue to advance novel prevention strategies, plan and then complete studies to demonstrate impact
- Establish pathways for implementation science research evaluations
- Work within NIAID and the NIH to be part of a coherent plan for evaluating treatment and prevention strategies for STIs
- Engage in advancing the Ending the HIV Epidemic agenda

HIV Vaccines Scientific Foci

Establish vaccine efficacy

- Evaluate vaccines against sites of vulnerability
- Initiate pediatric studies once efficacy is established

Define correlates of protection

- Partner to evaluate the most efficacious vaccine based on progress in the field

Beyond preventive HIV vaccines*

- Integration of Px Vx products with HIV Tx and Cure
- Evaluation of TB vaccine candidates

* With collaborating network partners

Pandemic preparedness and response

Prevention Scientific Foci

Novel biomedical methods of HIV prevention

Behavioral and social science partnerships

Protection in key populations, including adolescents, cisgender women, GBMSM, and U.S. minorities

Improve implementation of new biomedical and behavioral prevention strategies

Pandemic preparedness and response

Maternal Child Scientific Foci

Optimized therapeutics for HIV and infectious co-morbidities

- Pharmacology, drug formulations
- Long-acting formulations of ART and bNAbs
- Postnatal prophylaxis
- Therapeutics for key co-infections (HCV, CS)

Cure and immunotherapy

- Very early newborn treatment incl. bNAbs
- Combination Immune-based therapies to clear, control or silence reservoir
- CNS and tissue reservoir targeting
- Gene/cell therapies
- Vaccine response against priority pathogens

Tuberculosis

- Shorter therapies for DS and DR
- Improve TB preventive therapy
- Pharmacology, drug formulations
- Optimized diagnostics, Biomarkers

Brain and mental health

- Optimal TB neurocognitive development and mental health
- Neuroprotective therapeutic approaches or those targeting neurocognitive and mental health disorders

Pandemic preparedness and response

Therapeutic Scientific Foci

Novel and durable therapy

- Pharmacology, drug formulations
- Long-acting formulations of ART, bNAbs and other novel therapeutic modalities

Cure or ART-free remission

- Clear, control or silence reservoir
- Immune-based interventions
- Gene/cell therapies

Tuberculosis

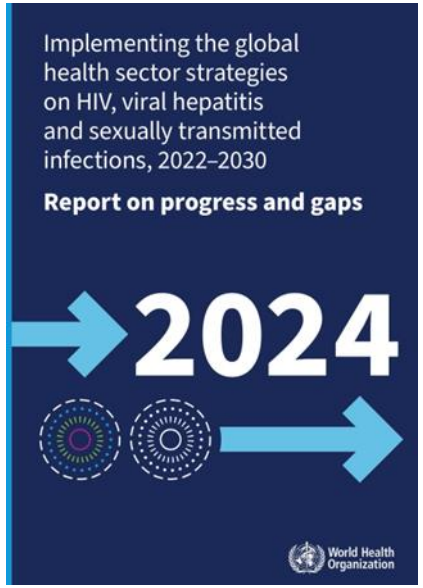
- Shorter and safer therapies for all forms of TB
- Diagnostics, drug susceptibility testing
- Biomarkers

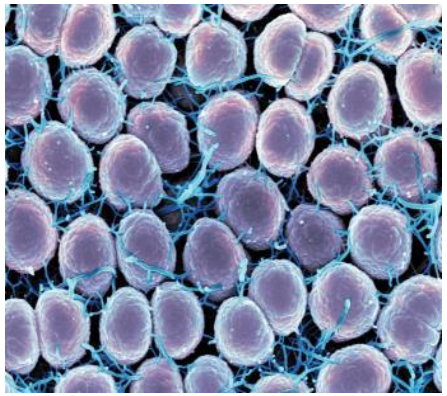
Complications and co-infections

- HBV cure strategies
- Long-acting formulations of HCV
- Cellular and immune dysregulation
- Prevent and treat end organ disease

Pandemic preparedness and response

WHO Situation Report on HIV, Hepatitis & Sexually Transmitted Diseases





~1.3 million new HIV infections; higher incidence among MSM, IDUs, sex workers, transgenders, people in prisons; 630,000 HIV-related deaths

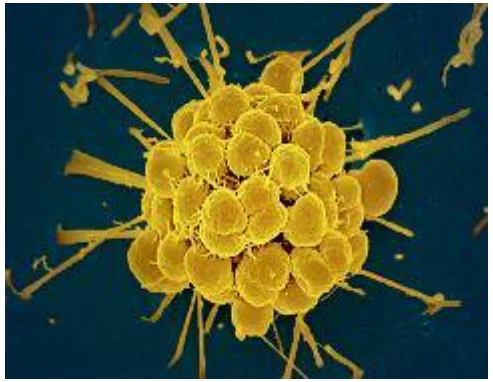
~8 million new syphilis cases among adults aged 15-49 years; increases in congenital syphilis; 220,000 syphilis-associated deaths

>1 million infections daily of four curable STIs – syphilis, gonorrhea, chlamydia, and trichomoniasis

>80 countries reporting gonorrhea antimicrobial resistance

~1.2 million new hepatitis B infections; ~1 million new hepatitis C infections; 1.3 million deaths associated with viral hepatitis

WHO, 2024



What if We Had a Vaccine that Prevents *Neisseria gonorrhoeae*? Inspiration, Assumptions, and Aspirations

Myron S. Cohen[1] **and Jeanne M. Marrazzo**[2]

[1]UNC Chapel Hill, SOM Institute for Global Health and Infectious Diseases, Chapel Hill, NC, USA; and [2]The National Institute of Health, The National Institute of Allergy and Infectious Diseases, Bethesda, MD USA

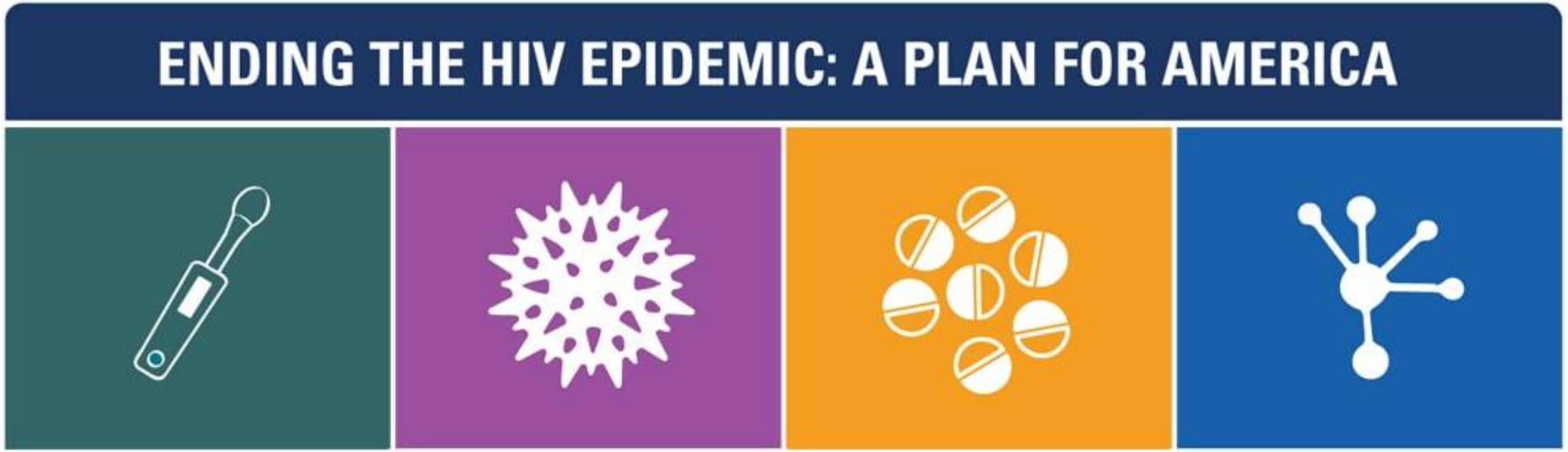
"The [mathematical] models presented suggest that successful deployment of a vaccine with even modest efficacy could reduce the spread of *N. gonorrhoeae*."

The Journal of Infectious Diseases

EDITORIAL COMMENTARY

2024 April 17; published online ahead of print

Seeking Input on Implementation Science



https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

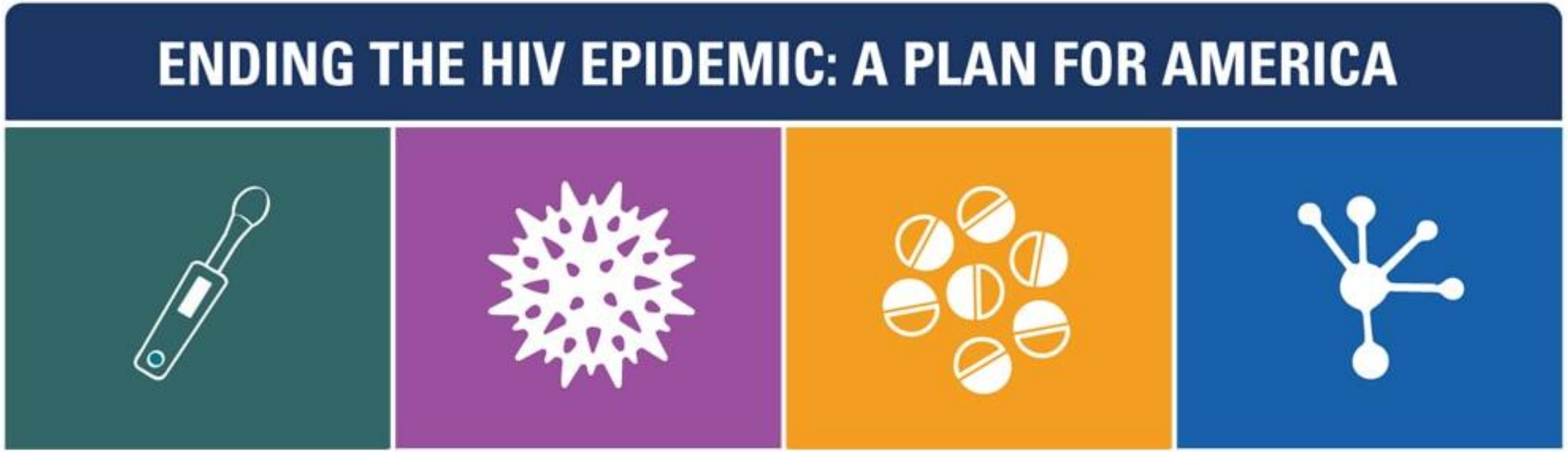
Building an Implementation Plan Prior to Starting an Efficacy Trial

- A detailed development plan will be required for clinical trials that will lead to label change or licensure
- There must be a plan to establish post trial access, open label extension studies and equitable access for the product in the countries where the trials are performed
- The plan must include all relevant stakeholders and clearly defined roles and responsibilities

Implementation Science Principles

- Priorities are defined by implementers
- Projects are jointly led by NIH investigators and implementing agency/organization
- Joint funding by NIH and implementing organization
- Projects need to start and complete in a timely manner with defined milestones
- Implementation development plans will be required

Seeking Input on Implementation Science



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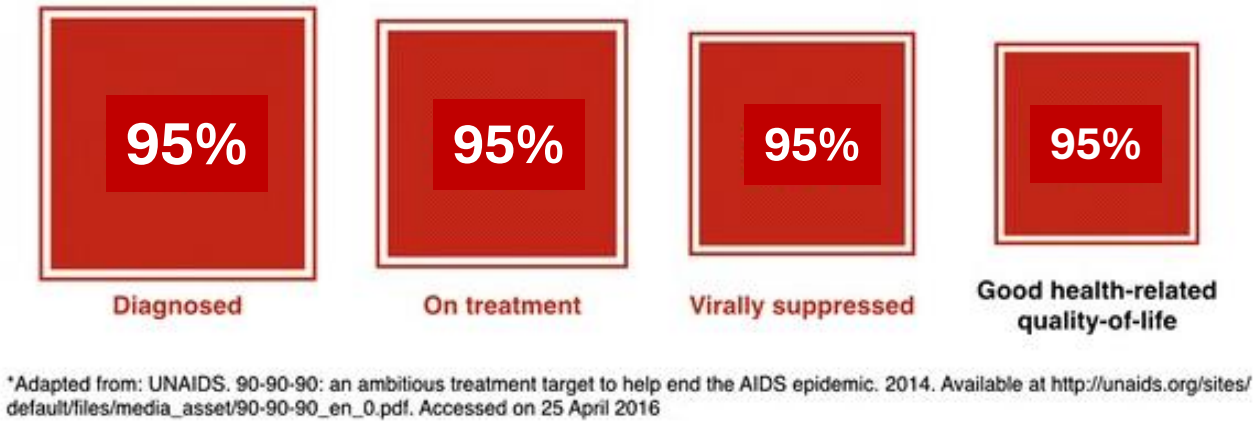
CTSG Research in the Next Grant Cycle



*Adapted from: UNAIDS. 90-90-90: an ambitious treatment target to help end the AIDS epidemic. 2014. Available at http://unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf. Accessed on 25 April 2016

What *is* 'good health-related quality of life'?

Health-related quality of life (HRQOL) is an individual's or a group's perceived physical and mental health over time.

Can we achieve the 'fourth 95' for those who are living with HIV, through cross-institute NIH collaboration?

Netanya Utay and Kristine Erlandson

ACTG