Ending the Pandemic: NIH Directions in HIV Prevention Research

HIV Prevention Trials Network Annual Meeting
June 3, 2019

Maureen M. Goodenow, Ph.D.
Associate Director for AIDS Research and Director, Office of AIDS Research
Vision for NIH-wide HIV Research

End the HIV/AIDS pandemic

AND

Improve the health of people with, at risk for, or affected by HIV.
Office of AIDS Research: in the Office of the NIH Director

Secretary of Health and Human Services (DHHS)

NIH Director

Office of AIDS Research

NIA
NIAAA
NIAID
NIAMS
NCI
NICHD

NIDCD
NIDCR
NIDDK
NIDA
NIEHS
NEI

NIGMS
NHLBI
NHGRI
NIMH
NINDS
NINR

NIBIB
NCCIH
FIC
NCATS
NLM
NIMHD

CC
CIT
CSR
Collaborative HIV Research at NIH

- Multidisciplinary, global
- Research, training, infrastructure, information dissemination
- Flexible
Legislation authorizes OAR to:

- Establish scientific priorities for the NIH HIV/AIDS research agenda
- Determine and allocate budgets for NIH HIV research aligned with scientific priorities
- Plan, coordinate, and evaluate HIV/AIDS research across the NIH
- Consult with the advisory councils of the agencies
NIH Priorities for HIV and HIV-Related Research
## NIH HIV Priorities Align with the National HIV/AIDS Strategy

### NIH Priorities vs. NHAS Goals

<table>
<thead>
<tr>
<th>NIH Priorities</th>
<th>NHAS Goals</th>
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<tbody>
<tr>
<td></td>
<td>Reduce new infections</td>
</tr>
<tr>
<td>Reduce Incidence</td>
<td>✔</td>
</tr>
<tr>
<td>Next-Generation Therapies</td>
<td>✔</td>
</tr>
<tr>
<td>Comorbidities &amp; Coinfections</td>
<td>✔</td>
</tr>
<tr>
<td>Cure</td>
<td>✔</td>
</tr>
<tr>
<td>Cross-Cutting</td>
<td>• Basic research ✔</td>
</tr>
<tr>
<td></td>
<td>• BSSR</td>
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<tr>
<td></td>
<td>• Health disparities ✔</td>
</tr>
<tr>
<td></td>
<td>• Implementation science ✔</td>
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<tr>
<td></td>
<td>• Training/capacity building ✔</td>
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</table>

**“More coordinated national response to the epidemic”**
NIH HIV/AIDS Funding History, 1983 – Present

Dollars in Millions

Fiscal Year

OAR established

Reflects $45M increase in 2019
FY 2018 HIV/AIDS Portfolio by Research Priority

- **Reduce Incidence**: $714.6
- **Next-Gen Therapies**: $364.5
- **Research Toward HIV Cure**: $175.8
- **Comorbidities, Coinfections**: $517.9
- **Cross-Cutting**: $1,222.7

Dollars in Millions
Estimated FY 2019 HIV/AIDS Portfolio

- **Reduce Incidence**
- **Next-Gen Therapies**
- **Research Toward HIV Cure**
- **Comorbidities, Coinfections**
- **Basic Science**
- **Cross-Cutting**

* Reflects $45M increase in FY 2019

Dollars in Millions

- $0
- $50
- $100
- $150
- $200
- $250
- $300
- $350
- $400
- $450
- $500
- $550
- $600

- **Vaccine**
- **Non-Vaccine**
- **Translational**
- **Clinical**

Dollars in Millions

- Estimated FY 2019
  - Reflects $45M increase in FY 2019
# Professional Judgment FY 2020 Budget Request

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</thead>
<tbody>
<tr>
<td>Reduce Incidence</td>
<td>$714.5</td>
<td>$741.2</td>
<td>14.9%</td>
<td>$957.2</td>
<td>29.1%</td>
</tr>
<tr>
<td>Next-Gen HIV Therapies</td>
<td>364.5</td>
<td>369.7</td>
<td>1.1%</td>
<td>370.9</td>
<td>0.3%</td>
</tr>
<tr>
<td>Research Toward A Cure</td>
<td>175.8</td>
<td>190.7</td>
<td>3.5%</td>
<td>190.9</td>
<td>0.1%</td>
</tr>
<tr>
<td>Comorbidities, Coinfections, Complications</td>
<td>517.9</td>
<td>537.5</td>
<td>17.6%</td>
<td>587.5</td>
<td>9.3%</td>
</tr>
<tr>
<td>Cross-Cutting Areas</td>
<td>1,222.7</td>
<td>1,206.0</td>
<td>19.6%</td>
<td>1,395.3</td>
<td>15.7%</td>
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<tr>
<td>TOTAL</td>
<td>$2,995.4</td>
<td>$3,045.1</td>
<td>15.0%</td>
<td>$3,501.8</td>
<td>15.0%</td>
</tr>
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* Dollars in Millions
FY 2018 NIH HIV/AIDS Prevention Portfolio
Total = $1.23B

- **Vaccines**
  - $561,739,192 (45%)
  - $393,141,355 (32%)
- **Microbicides**
  - $194,581,439 (16%)
  - $88,702,099 (7%)
- **BSSR**
  - $561,739,192 (45%)

Total = $1,230,000,000
HIV/AIDS Prevention Projects by NIH Reporting Category
A Combination Approach to Effective HIV Prevention
HIV Prevention Toolbox

- PMTCT
- Condoms
- Blood Supply Screening
- Education/Behavior Change Strategies
- Socio-Structural Facilitators
- HIV Testing/Counseling
- STI Treatment
- Microbicides
- PrEP/PEP
- Syringe Services Programs
- Treatment as Prevention
- Prevention/Treatment of HIV-Associated Comorbidities
- Prevention/Treatment of Mental Health Conditions
- Voluntary Medical Male Circumcision

Combination HIV Prevention

Goodenow and Gaist, 2019
Considerations for HIV Prevention

- Behavioral, structural, and biological factors
- Communities/populations
- Clinical issues
  - Uptake of HIV testing & prevention strategies
  - Adherence & retention
  - Diagnosis & treatment of STIs, other co-morbidities
- Health system and regulatory considerations
  - Ethical &/or legal barriers
  - Improving awareness & demand
  - Age-appropriate, culturally competent counseling & service provision
  - Stigma
Recent HIV Combination Prevention Trials

Five large universal test and treat community-based trials:

• Sustainable East Africa Research in Community Health, **SEARCH** (Uganda)

• Population Effects of Antiretroviral Therapy to Reduce HIV Transmission, **PopART**–HPTN 071 (Zambia, South Africa)

• Botswana Combination Prevention Project, **BCPP** (Botswana)

• Treatment as Prevention, **TasP** (South Africa)

• MaxART Early Access to ART for All, **MaxART** (Swaziland)
The Potential of PrEP

• Highly effective

• Delivered as part of a comprehensive package (e.g., condoms for other STI protection)

• Next step: long acting delivery methods
Long-Acting HIV Prevention and Treatment Regimens in Progress, 2019 – 2022

Now advancing through clinical trials:

- Long-acting injectable PrEP
- Long-acting maintenance ART
- Broadly neutralizing monoclonal antibodies (bNAbs)
- Extended-release vaginal rings & sub-dermal implants
- Extended-delivery prime-boost vaccine regimens
Looking to the Future:
Behavioral Aspects of Long-acting and Extended Delivery
HIV Prevention and Treatment Regimens

May 13-14, 2019

Location: 5601 Fishers Lane
Conference Room 1D13,
Rockville, MD 20892

THINKING
OUTSIDE
THE
PILLBOX
Dual Pathway to Control and End the HIV Epidemic

Implementation of Existing Interventions → Treatment and Prevention → Discovery of New Interventions

Implementation Science Complements Discovery Science
Breakthroughs Lead to Improved Prevention and Better Health Outcomes

UNDETECTABLE = UNTRANSMITTABLE

PWH who take ART as prescribed:

- Can achieve & maintain undetectable viral load.
- Have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

Game changer; reduces stigma
Breakthroughs Lead to Improved Treatment and Health Outcomes

Past

Present

Future

Basic
Clinical
Translational
Implementation
Public Health & Policy
Ending the HIV Epidemic: A Plan for America

Overall goal is to reduce new infections:

• By 75% in the next 5 years; and
• By 90% in the next 10 years
Ending the HIV Epidemic in the U.S.

Focus resources in:

- 48 highest burden counties
- Washington, D.C.
- San Juan, Puerto Rico
- 7 states with a substantial rural HIV burden
A Collaborative National Response to the HIV Epidemic

Basic Research to Public Health

Basic
Clinical
Translational
Implementation
Public Health & Policy
Directions in HIV Prevention Research

- Vaccine
- Non-vaccine biomedical
- Behavioral and socio-structural prevention
- Integrative scientific research
- Stigma, scale-up, adherence
- Community-based partnerships and participatory research (CBPR)

What directions would you add?

21st century solutions for 21st century challenges
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