

How HIV Prevention Research Happens at the NIH

Judith D. Auerbach, Ph.D.
San Francisco AIDS Foundation
CHAMP Research Advocacy for HIV Prevention
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Notes: I've actually worked at the NIH for about 9 years. So this presentation is informed by having worked at this institution. How does HIV prevention research happen? The NIH is the largest research institution in the world, which is funded by your tax dollars.



Notes: The NIH is currently comprised of 27 separate institutes and centers. It's important because AIDS research occurs in most of these, if not all of them, and not in one place. National Institute of Allergy and infectious diseases (NIAID) is the biggest part of that, and mostly biomedical prevention.

Parts of NIH that do other prevention research that we need to pay attention to, especially with regard to behavioral and social research:

National Institute on Aging - those over 50.

Alcohol abuse and Prevention

Child Health and Human development (main funders for social research, particularly innovative research)

National Inst. Of Mental Health (supports behavioral research)

Substance Use - third largest AIDS budget, due to the strong link between substance use and HIV infection.

In addition to these institutes, the Office of AIDS needs to be pay more attention to.

NIH Office of AIDS Research

- ❖ Unique role and legislative authorities
- ❖ Annual trans-NIH strategic plan
- ❖ Annual trans-NIH budget tied to the strategic plan
- ❖ Trans-NIH coordination, management, and evaluation
- ❖ A unified NIH research front against the AIDS pandemic

Notes: Office of AIDS Research (OAR, not NIAID, although confused with it) is very important. Got congressional authority in 1993 to oversee all this research and the funding. It's above all these other institutes. Unique role and legislative authorities. Created because of treatment activism by the community (TAG and other groups) back in the 80s, to have one coordinating agency.

The OAR:

Creates an annual plan, which drives the budget and ties the budget to the strategic plan. And responsible for the coordination, management and evaluation across NIH

OAR Planning Process Participants

- ❖ Trans-NIH Coordinating Committees
- ❖ NIH Institutes and Centers
- ❖ Other government entities with research responsibilities
- ❖ Non-government experts from academia, industry, and the private sector
- ❖ Community representatives
- ❖ OAR Advisory Council

Uses of the Annual Strategic Plan

- ❖ Informs the scientific community, the public, and AIDS-affected communities about the NIH AIDS research agenda
- ❖ Frames the development of the NIH AIDS budget
- ❖ Determines the use of NIH AIDS-designated dollars
- ❖ Coding permits tracking and monitoring of expenditures

Notes: There is a annual process that sets the scientific priorities that involves all these different players. And there is a advisory council that streamline the plan.

You really should read it if you have the time. It actually says what kinds of AIDS research can be supported by the NIH that we won't necessarily think are permitted, such as populations we think they are afraid to name, scientific approaches we think they wouldn't fund. So the permission is there, it then becomes the issue of what actually gets proposed by researchers and if that proposal makes it through peer review - the system by which proposals are evaluated and funding decisions made. This plan is the actual definition of what is AIDS research.

The funding priorities stated in the plan are how the institutes are spending the money, so we can use this to track where the spending is going.

FY 2008 NIH AIDS Scientific Research Areas

- ❖ Foundational Science
 - Natural History and Epidemiology
 - Etiology and Pathogenesis
- ❖ Therapeutics
- ❖ Prevention
 - Vaccines
 - Microbicides
 - Behavioral and Social Science
- ❖ Cross-cutting Resources
 - Training, Infrastructure, and Capacity Building
 - Information Dissemination

Notes: These are the major research areas. Under prevention, there are 3 categories – vaccines, Microbicides, and behavioral & social science.

How can we make sure institutes and communities have people, facilities, etc that can actually do the research? How can we help build capacity for this research? and can we dissemination research info to the public.

NIH AIDS Research Priorities

- ❖ A strong foundation of basic science
- ❖ Prevention research, including development of vaccines, microbicides, and behavioral interventions; prevention of mother-to-child transmission
- ❖ Therapeutics research
- ❖ Relevant research in international settings
- ❖ Research targeting racial and ethnic minorities in the U.S.

OAR Prevention Priority

- ❖ Convened outside experts to advise on how to most effectively redirect funds to catalyze future initiatives and multi-disciplinary endeavors
- ❖ Recommended focus on “next generation” prevention strategies
- ❖ Reestablished Prevention Science Working Group to suggest specific research strategies
- ❖ Set aside OAR funds for Prevention Science Initiative

Notes: Traditionally, there was not a separate area for prevention. OAR created an interdisciplinary view of prevention, and initially created a prevention science working group to define it and jump start the field. This is where the focus on “next generation” of prevention came from. For a long time we have the behavioral strategies, then we have vaccines and microbicides. Recently, we started hearing about treating other STDs, looking at PREP, diaphragms, etc. These became understood as the Next generation of prevention strategies and became prioritized and funding allocated.

Some access is there for community input on the research agenda. The community should get involved before the studies are decided on. You can say to the NIH, these are the issues important to us as a community. These are the questions we have that need answering. Don't just invite us after you decide what research needs to take place.

FY 2008 Microbicide Research Priorities

- ❖ Conduct basic science research that targets viral and/or cellular elements of HIV transmission
- ❖ Develop methodologies to assess preclinical/clinical safety and efficacy of microbicides
- ❖ Develop combinations of multiple active compounds of different chemical classes, specificities, and mechanisms of action
- ❖ Develop acceptable formulations and modes of delivery
- ❖ Expand research capacity, infrastructure, and coordination to conduct clinical trials
- ❖ Conduct behavioral and social science research on use and acceptability

Notes: Microbicides was not on the agenda in early years. Because of advocacy and advances in the science, it's now it's own special scientific area, given more importance, and structures to make sure the science move forward and invested in.

FY 2008: New Microbicide Priority

- ❖ New OAR staff dedicated to enhancing microbicide research and developing strategic plan
- ❖ New coding to track and monitor microbicide research
- ❖ Trans-NIH Coordinating Committee
- ❖ New branch in NIAID
- ❖ New Microbicide Research Working Group to advise NIH and other funders
- ❖ India agreement with priority to microbicides
- ❖ Joint efforts with Gates Foundation and other funders

FY 2008 Vaccine Research Priorities

- ❖ Support basic and preclinical research on innovative vaccine concepts
- ❖ Conduct studies on mucosal immunity, antibody responses, and correlates of immunity
- ❖ Conduct expanded clinical trials
- ❖ Expand research infrastructure, training, and cohort development

Behavioral and Social Science Priorities

- ❖ Develop and evaluate interventions to reduce HIV acquisition and transmission associated with sexual behavior as well as with drug and alcohol use
- ❖ Integrate basic behavioral and social science research into the design and evaluation of HIV prevention and care interventions
- ❖ Develop and test innovative models and interventions that reflect the cultural and social context of the lives of racial and ethnic minorities

Budget Development Process

- ❖ Institutes and Centers (ICs) develop new/expanded program initiatives, with budget requests, for each scientific area
- ❖ OAR reviews IC initiatives in relation to the Plan and OAR priorities
- ❖ Consultations between IC and OAR throughout process
- ❖ Budget is developed in consultation between the OAR Director and NIH Director
- ❖ OAR allocates budget levels to each IC

NIH Office of AIDS Research Funding by the Trans-NIH Plan for HIV-Related Research (dollars in thousands)

**NIH Office of AIDS Research
Funding by the Trans-NIH Plan
for HIV-Related Research
(dollars in thousands)**

Area of Emphasis	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2007 Joint Resolution	FY 2008 President's Budget
HIV Microbicides ¹	\$85,693	\$85,453	\$86,453	\$96,400
Vaccines	581,450	591,679	591,695	596,194
Behavioral and Social Science	406,217	398,761	403,256	398,761
Therapeutics	635,434	633,100	642,001	622,427
Etiology and Pathogenesis	716,239	709,107	717,168	709,107
Natural History and Epidemiology	269,835	264,311	267,496	261,463
Training, Infrastructure, and Capacity Building	160,686	169,591	171,078	168,211
Information Dissemination	27,723	26,422	26,655	25,349
Subtotal	2,883,277	2,878,424	2,905,802	2,877,912
Roadmap	18,582	24,859		27,307
TOTAL	\$2,901,859	\$2,903,283	\$2,905,802	\$2,905,219

Notes: Total NIH AIDS research budget is close to \$3 Billion, hasn't increased in some years. Allocation can change from year to year. OAR helps other countries build capacity for research too. These categories and allocations can change from year to year based on the research priorities.

Q: How are funding decisions made?

A: Most \$ goes to research that has been proposed by the scientists who want to do them. Peer review groups of scientists who know the field evaluate the grants and decide whether it would be useful. The institute decides how many of those chosen studies can actually be funded. There are a few other ways, like cooperative agreements, call for applications – where the gov asks researchers to apply for the grant. Review is the same for that. There are some politics involved, we all have our biases, there is an attempt to counter those biases. We need to get to know the system better so we can influence the decision-making as community advocates.

Trans-NIH Management and Coordination

- ❖ Facilitate trans-Institute programs
- ❖ Manage multi-Institute research
- ❖ Foster research through designated funds, targeted workshops
- ❖ Identify areas that require focused attention
- ❖ Non-human primates
- ❖ Prevention research
- ❖ International research

Q & A

Q: Can you talk about how people can get involved? Like protesting the attacks on certain research from the religious right.

A: Political currents in the world, pressure on all federal agencies to not support certain kinds of research, by religious conservatives who went after the NIH. They heard about work with gay men, Asian women who work in massage parlors, drug users, young people who have sex before marriages, and used congress to take away the money from those research projects. An attack on science based on the populations being studied should not prevail. What we all celebrate in science is that decisions get made by peers, it's not a political person or your pastor. So what unites activists with the scientists is the outrage against these kinds of attacks. The scientists that are doing the work are on our side, don't worry about NIH director. Go meet the program directors, tell them what your concerns are. It's another place to do your advocacy.

[comment from CDC researcher] Once the science is in, it's hard to say what we've found without taking out things that are politically sensitive or changing it due to the political climate.