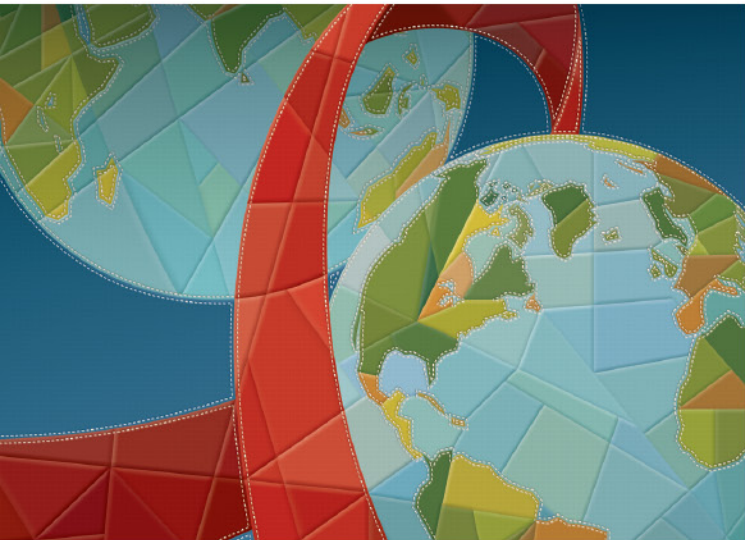




NIH OFFICE OF AIDS RESEARCH (OAR)

U.S. Department of Health and Human Services



AIDS Research Priorities

Jack Whitescarver, Ph.D.
**NIH Associate Director
for AIDS Research and
Director, Office of AIDS Research**

CENTERS FOR DISEASE CONTROL

MMWRTM

MORBIDITY AND MORTALITY WEEKLY REPORT

June 5, 1981

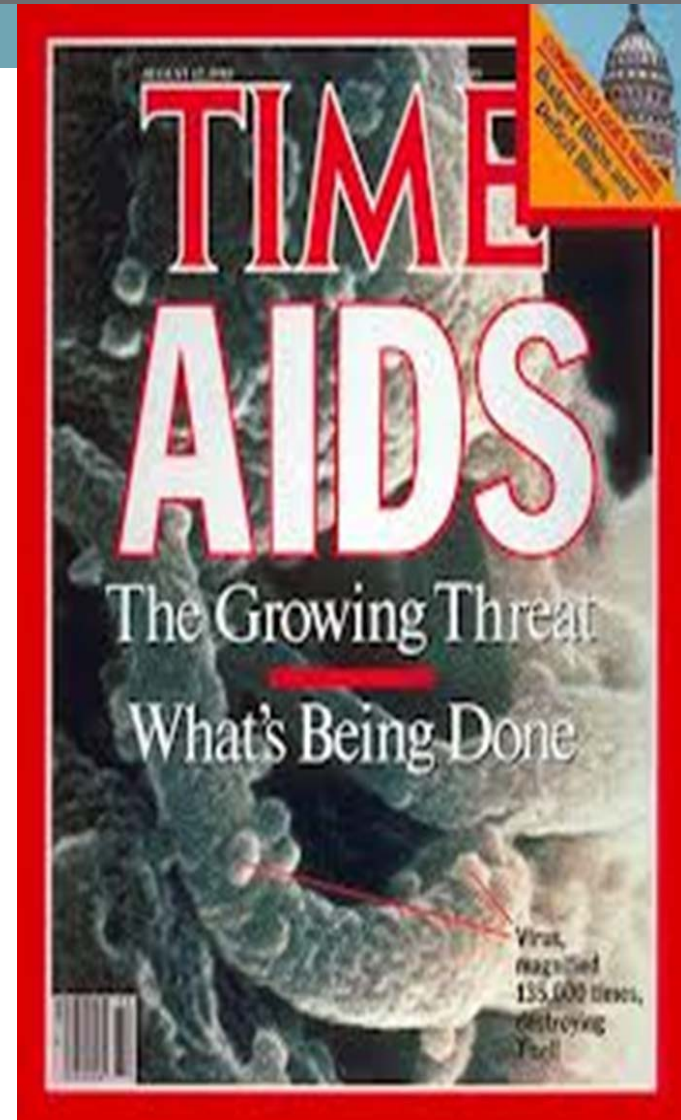
***Pneumocystis Pneumonia –
Los Angeles***

July 4, 1981

***Kaposi's Sarcoma and
Pneumocystis Pneumonia Among
Homosexual Men –
New York City and California***

Office of AIDS Research: “Institute without Walls”

- Unified research agenda
- Coordinate AIDS research across all ICs
- Develop annual trans-NIH strategic plan
- Develop annual trans-NIH budget
- 3% transfer authority
- Domestic and international agreements
- OAR Director: “primary Federal official with responsibility for overseeing all AIDS research”
- But “does not remove the responsibility of the heads of the ICs for the approval of specific programs or projects, or for other details of the daily administration of these activities.”

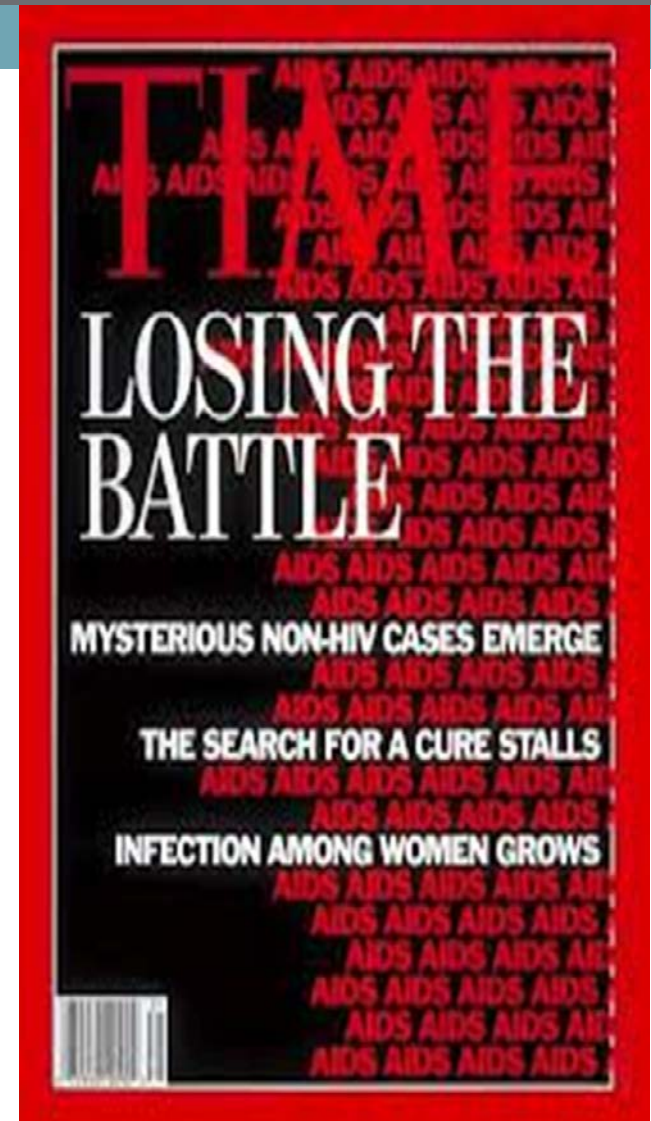


OAR Priority-Setting Processes: Annual Strategic Plan



OAR Priority-Setting Processes: Annual Trans-NIH Strategic Plan

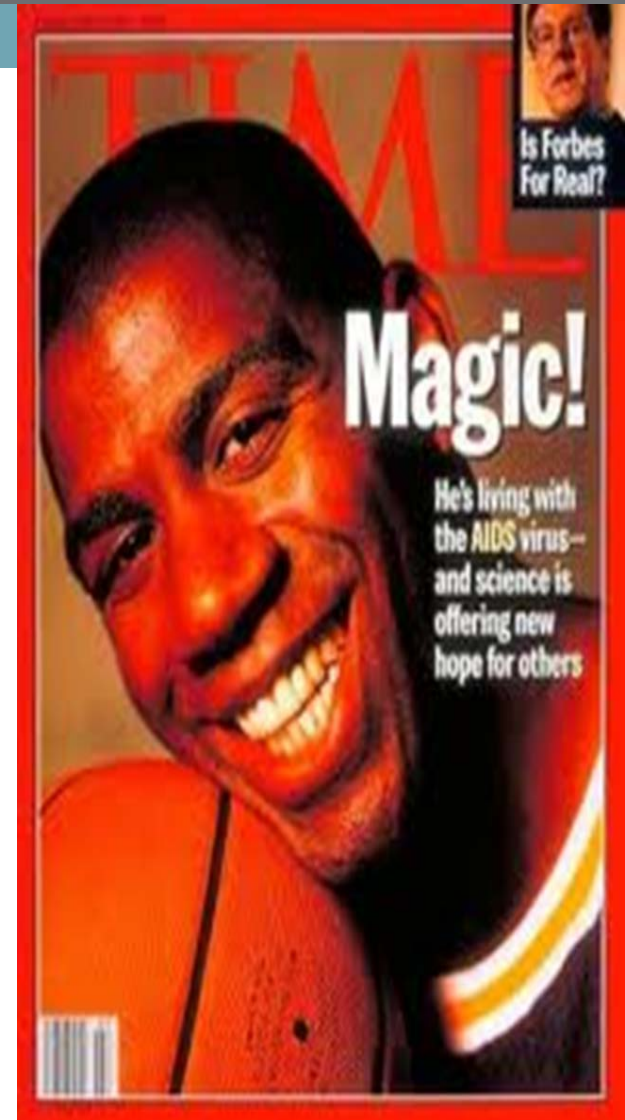
- Reviews state of the science; assesses newly emerged needs and changing clinical profile; and identifies scientific opportunities
- Addresses priorities of President's National AIDS Strategy and White House HIV Care Continuum Initiative
- ICs required to code all intramural and extramural AIDS expenditures (including RMS) by objectives of Plan
- Frames development of the trans-NIH AIDS budget



OAR Planning Process:

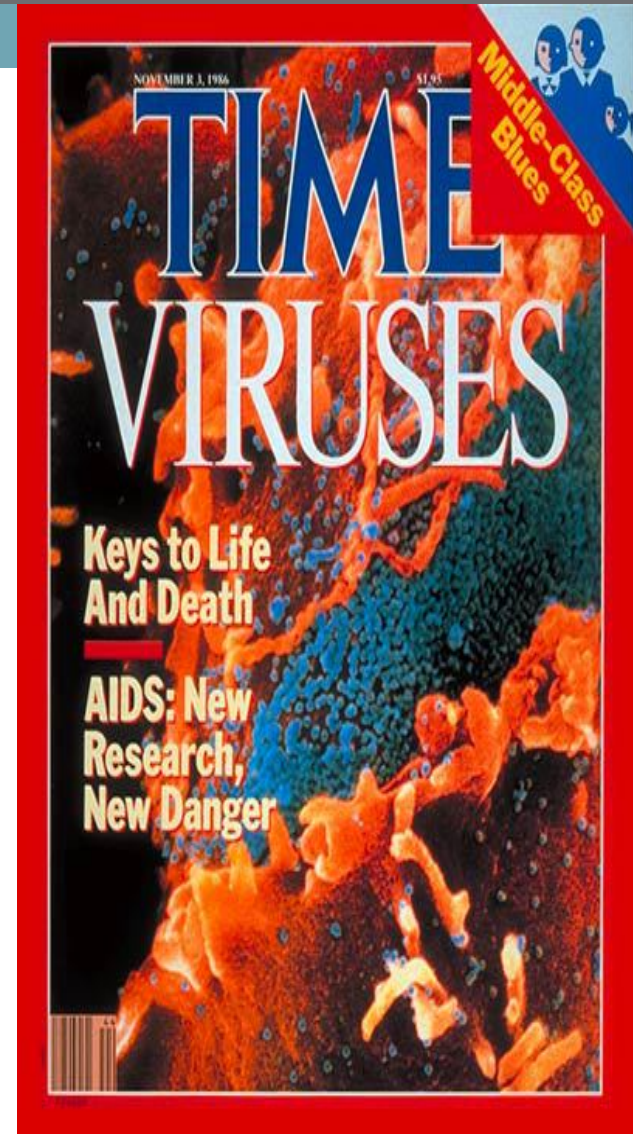
More than 200 Participants each year

- NIH IC AIDS Coordinators
- Other government entities (CDC, USAID, PEPFAR, FDA, VA, DoD)
- Non-government experts from academia, foundations, etc.
- Community representatives
- Trans-NIH Coordinating Committees
- OAR Advisory Council



OAR Planning Process: OAR Advisory Council

- Experts from academia and foundations
- Community representatives
- Ex officio members:
 - Advisory Councils of NCI, NIAID, NIMH, NIDA
 - DoD, VA, CDC
- 5 Guidelines Working Groups on Clinical Practices for the Treatment of HIV Infection



OAR Priority-Setting Processes: Budget Development Process

- Based on priorities and objectives of the strategic Plan
- Built from the commitment base
- ICs submit budget requests to OAR with proposed new/expanded initiatives coded to the Plan
- OAR allocates budgets to ICs based on priorities of the Plan and new scientific opportunities -- not on a formula.



OAR Priority-Setting Processes: Budget Allocation Process

- OAR allocates final budget levels to each IC at the time of appropriation.
- Total NIH funds for AIDS research made available to the OAR account.
- The Director of OAR transfers to ICs amounts necessary to carry out the Plan.
- Transfer Authority: may transfer up to 3 percent among ICs from AIDS funds. Requires notification (not approval) to the House and Senate Appropriations Committees at least 15 days in advance of any transfer.



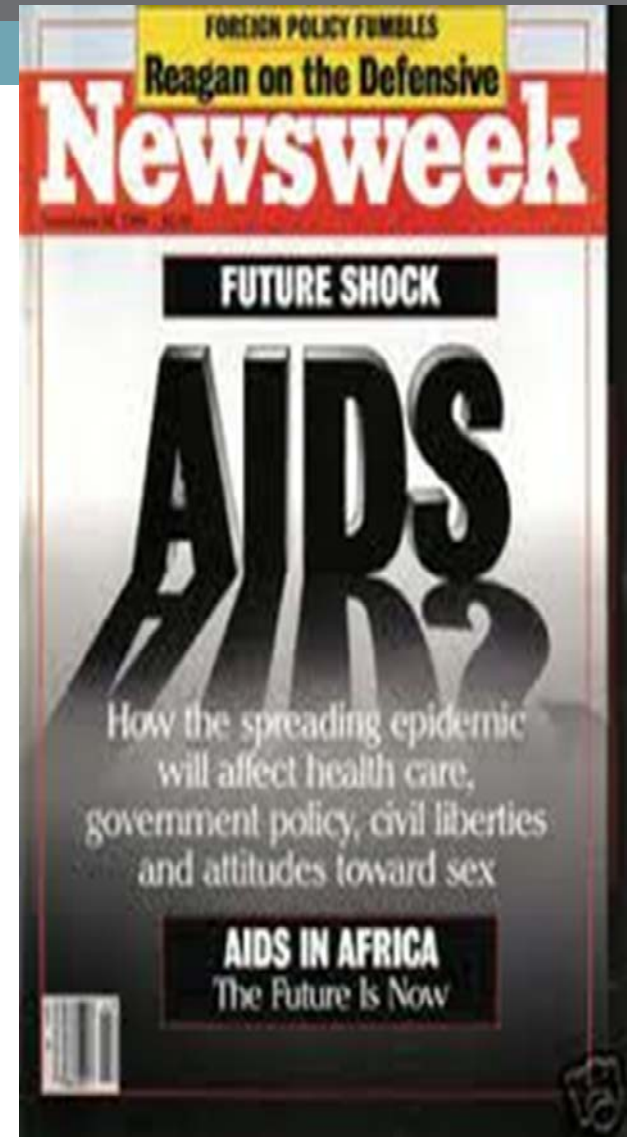
OAR Priority-Setting Processes: Annual Portfolio Review

- Multi-tiered review of all grants and contracts supported with AIDS-designated funds due to expire or recompete in the coming fiscal year
- Panel of non-government experts participates
- Identifies projects now considered of lower priority for their impact on AIDS research -- based on changing clinical profile, scientific advances, and new priorities
- ICs are informed of projects that should not be funded with AIDS-designated dollars if they recompete
- Funds are reallocated for higher priority AIDS research



Priorities and resources have shifted over time

- Funds shifted:
 - from research on OIs no longer important for AIDS patients to new complications
 - from epidemiology to prevention research
 - from drug development to therapeutics as prevention
- Funds shifted to new initiative on cure research
- Funds will be shifted for new advances in vaccine research



Dr. Collins' Charge to OAR Advisory Council (OARAC) November 14

- Develop a blueprint that identifies AIDS research priorities over the next 3 – 5 years
- Outline highest priority AIDS research in:
 - Prevention: including vaccines, microbicides, ARV-based prevention, behavioral research focused on risk reduction, stigma, and adherence
 - Treatment: including advances in therapeutic interventions and research toward a cure
 - Co-morbidities: neurologic, cardiovascular, oncologic, accelerated aging
- Identify high priority research in cross-cutting areas: basic science, training (including capacity building), and information dissemination
- Use whatever means necessary to obtain expert input



Process to carry out new charge

- Working Group of OARAC: eminent experts and community representatives
- November OARAC meeting on AIDS research priorities
- Meetings, teleconferences, emails
- Considered multiple sources of information: OAR Strategic Plan, meeting and workshop reports, OARAC discussions, etc.
- April OARAC meeting devoted to further discussions
- AIDS advocacy/stakeholder organizations comments presented



Public Stakeholders

- AIDS Action Baltimore
- AIDS Foundation of Chicago
- AIDS Treatment Activist Coalition
- American Psychological Association
- amfAR, The Foundation for AIDS Research
- AVAC: Global Advocacy for HIV Prevention
- Elizabeth Glaser Pediatric AIDS Foundation
- HIV Medicine Association
- HIV Prevention Justice Alliance
- National Minority AIDS Council
- Project Inform
- Treatment Action Group



Additional Steps: New Portfolio Analysis Launched

- Led by OARAC Working Group
- Grant by grant review of entire AIDS portfolio
- Discussions and meetings with IC program staff to agree on AIDS-relevance
- Biggest challenge: determining AIDS relevance of some basic science projects and infrastructure
- Projects lacking consensus adjudicated by Working Group
- Coordination and further analysis with DPCPSI
- ICs will be informed of projects that can no longer be supported with AIDS-designated dollars; funds will be shifted
- Process/policy changes recommended



Assessment of suggested additional NIH processes

- Develop process for OAR approval of funding announcements (FOA, RFA, etc.)
- Develop criteria for what constitutes HIV/AIDS research
- Develop receipt and referral guidelines for CSR
- Develop trans-NIH policy regarding proportional funding of grants and/or portfolios with AIDS dollars
- Conduct assessment of training, mentoring, and capacity-building mechanisms for HIV/AIDS research



NIH AIDS Research

- NIH investment in AIDS research has produced groundbreaking scientific advances across ICs that have benefited not only patients with HIV, but those with other diseases as well.
- OAR has shifted AIDS research program priorities and resources to meet the changing epidemic and scientific opportunities.
- AIDS is not over, and it is far too soon to declare victory. New challenges and exciting opportunities lie ahead, as outlined in the Working Group Report.



AIDS Drugs Have Saved 3 Million Years of Life in the United States

July 1, 2006
Volume 194

The Journal of
Infectious
Diseases

The Survival Benefits of AIDS Treatment in the United States

RP Walensky et al.