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HIV/AIDS Research Portfolio Review Working Groups Submits Science Priorities Report to NIH Director

June 16, 2014

On May 28, the National Institutes of Health (NIH) HIV/AIDS Research Portfolio Review Working Group forwarded its final report, *Optimizing NIH HIV/AIDS Research in a Time of Budget Constraints*, to NIH director Francis Collins. They presented the report at the two-day Advisory Committee to the Director (ACD) meeting on June 5 - 6. The report outlines key science priorities for NIH HIV/AIDS research for the next three to five years and responds to Collins' charge to the working group to identify the highest priority areas of HIV/AIDS research at the November 2013 Office of AIDS Research Advisory Committee (OARAC) meeting.

Collins reviewed his charge to OARAC and noted that he was looking specifically for some bold but achievable goals, specific enough to guide the NIH's decision-making but "avoiding over granularity, comprehensive in consideration of the broad sweep of AIDS research but courageous in identifying major priorities." From his perspective, a laundry list of every conceivable AIDS-related program would not be useful. Collins further noted that he thought that it was the time to assess whether there are priority efforts the agency might want to reconsider in terms of the way it is spending the approximately $3 billion in funding devoted to AIDS research priorities.

Office of AIDS Research (OAR) director Jack Whitescarver noted that his presentation to the ACD not only fell on the anniversary of the D-Day invasion but that June 6 was also the "D-Day" for the recognition of the AIDS pandemic, exactly 33 years ago, when the first cases of what is now known as AIDS were reported in the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report. "Remarkable progress" has occurred due to the research supported by NIH, said Whitescarver. He lauded Congress for not establishing an AIDS institute and instead authorizing the Office of AIDS Research, an institute without walls and located within the Office of the NIH Director. He further pointed out the unique authority provided to the OAR in order to accomplish the goal of establishing a unified and coordinated NIH AIDS research agenda and facilitate collaboration across the NIH, other institutions across the government, and around the world.

Whitescarver explained that as part of its charter, the OAR is required to develop an annual strategic plan and a trans-NIH budget based on that plan. He underscored that the statute, however, gives the responsibility for administering the programs and projects to the NIH institutes and centers (ICs). Fulfilling this requirement, the OAR, Whitescarver reported, has prepared a trans-NIH strategic plan every year since 1993. He explained that during the planning process, the state of the science is reviewed, newly emerging needs and the changing clinical profile of the disease are addressed, and scientific opportunities and priorities are determined. Whitescarver further noted that AIDS research is also coordinated by the

White House and goes across departments and operating divisions in which OAR participates. Therefore, the OAR strategic plan must also reflect the NIH's role in carrying out the president's initiatives.

Whitescarver noted that more than 200 experts participate in this yearly process. The experts come from NIH, other federal agencies, academia, foundations, and community representatives who have played an essential role in the planning and participating in AIDS research.

The director explained that the OAR's trans-NIH plan serves a number of critical functions, the most important one being providing the framework for which the development of the annual AIDS budget request. Institutes and centers submit their AIDS budget request to OAR each year with proposed, new, or expanded program initiatives. The budgets are coded to the plan and the OAR allocates the funding to the ICs. It is not formula-based, Whitescarver pointed out. The OAR values its transfer authority (three percent of the AIDS budget) to move funds across the ICs during the year to meet newly emerging needs. To monitor the use of AIDS funding by the ICs, Whitescarver explained that an annual portfolio review is performed. The Office, he explained, reviews grants and contracts that were previously awarded by the ICs with AIDS funding and are due to expire or re-compete in the upcoming year.

As part of the review, the Office determines which projects are no longer considered of high enough priority to be funded with AIDS dollars. The process has allowed the shifting of funds to meet new priorities. Most recently, Whitescarver noted, the OAR shifted funding to launch a new initiative on research towards a cure announced by the President on World AIDS Day. The Office is also planning to shift additional funding to address new advances in vaccine research.

New Portfolio Analysis Launched

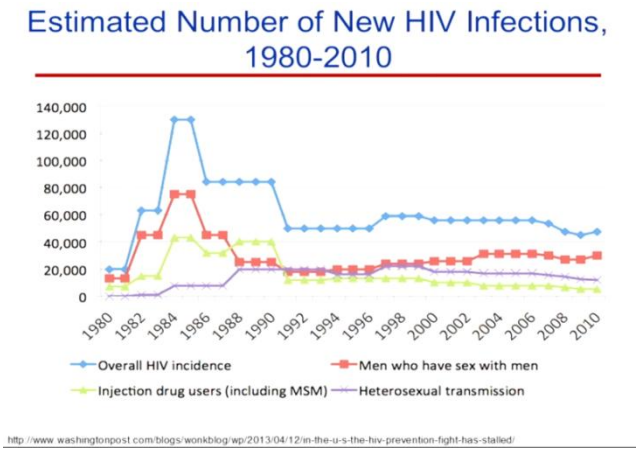
Whitescarver informed the ACD that at the same time the OARAC working group was fulfilling the charge given to it by the NIH director, OAR also launched a new portfolio review with the assistance of the working group. OAR is reviewing the entire NIH AIDS portfolio, grant by grant—not just those projects due to expire. The working group is meeting with the ICs' program staff to agree on AIDS relevant research. Whitescarver shared that in the process of conducting this new review, the working group confronted a number of significant challenges. One of the biggest challenges is reviewing the basic science portfolio, where it is difficult to determine what is relevant to AIDS. A second challenge, he noted, is addressing how the ICs fund their AIDS research and the inconsistency in how the ICs code their projects. Coordination and further analysis is being done by the NIH's Division of Program Coordination, Planning, and Strategic Initiatives, he noted. ICs will be informed of projects that can no longer be supported with AIDS-designated funding, and the funding will be shifted accordingly. The OARAC working group will be used to adjudicate projects for which there is no consensus between the OAR and the ICs. Completion of the process is anticipated by early fall, which will allow the OAR to turn its concentration to the 2016 budget, Whitescarver stated.

The OARAC working group also recommended that the OAR assess the existing NIH processes and develop new procedures that allow it to proactively determine the use of AIDS funding. These processes include addressing the OAR approval process for funding announcements; developing criteria for what constitutes HIV/AIDS research; developing receipt and referral guidelines for the Center for Scientific Review (CSR); developing trans-NIH policy regarding proportional funding of grants and/or portfolios with AIDS dollars; and conducting an assessment of training, mentoring, and capacity-building mechanisms for HIV/AIDS research. OAR intends to work with CSR and the NIH leadership to identify the best way to move forward on these issues, he stated. Finally, Whitescarver noted that every member of the council and its

working group signed the *Optimizing NIH HIV/AIDS Research in a Time of Budget Constraints* report. Comments were also received from a series of key stakeholders, he noted. He concluded his remarks by emphasizing that "this global pandemic is far from over, and it is too soon to declare victory."

Optimizing NIH HIV/AIDS Research in a Time of Budget Constraints

Rochelle Walensky, Harvard, presented the working group's priorities and recommendations to the ACD. She began by acknowledging the remarkable progress made over the last 33 years but also noted the "formidable challenge ahead." She provided a snapshot of the state of the epidemic to the ACD. Walensky reported that there were 35.3 million people living with HIV in 2012, 2.3 million new infections, and 1.6 million deaths, reflecting an increase in prevalence.



According to Walensky, those in the HIV field think about HIV prevention in multiple ways: prevention for people who are positive—people who are infected with HIV—prevention for those who are negative, and behavioral interventions for when those two populations meet.

In *Optimizing NIH HIV/AIDS Research in a Time of Budget Constraints*, the OARAC working group highlighted the fact that HIV/AIDS remains "a critical component of the NIH research portfolio, as a number of scientific questions in HIV prevention, treatment, and co-morbidities remain to be answered before the pandemic can be abated in the U.S. and internationally." The working group also stressed that while it has answered its charge as directed, it does not think that the priorities identified are the only "important areas of science for the NIH to support." The working group further pointed out that the recommendations were similar to those in the current *Trans-NIH Plan for HIV-Related Research*, as well as reports from recent scientific workshops supported by NIH and others.

The report stresses that "few other areas of NIH investment have paid off such dividends in discovery and health than those devoted over the last three decades to HIV/AIDS. Yet HIV/AIDS remains the most challenging and complex pandemic of this generation." The principles articulated by the working group that informed its recommendations include:

- Basic biomedical, behavioral, and social science underlies the identification, development, testing, and implementation of prevention, care, and treatment strategies.
- The most effective of these strategies are evidence-based, and evidence is best formulated when derived from multiple methods and sources.
- The co-occurring and intersecting biological, social, and environmental factors that influence HIV transmission, acquisition, pathogenesis, and treatment must be addressed simultaneously.
- Effective HIV research and its application and public health impact require collaboration among scientists, industry, governmental and non-governmental organizations, community-based organizations, policy-makers, patients, and advocates.

The working group emphasized that it did not prioritize the report's recommendations because it feels that the recommendations are all part of "an interconnected, comprehensive approach to HIV/AIDS." The report stresses that "preventing new HIV infections remains the fundamental way to end AIDS" and

therefore requires a focus on both transmission and acquisition and the biological, behavioral, and social contexts in which these occur.

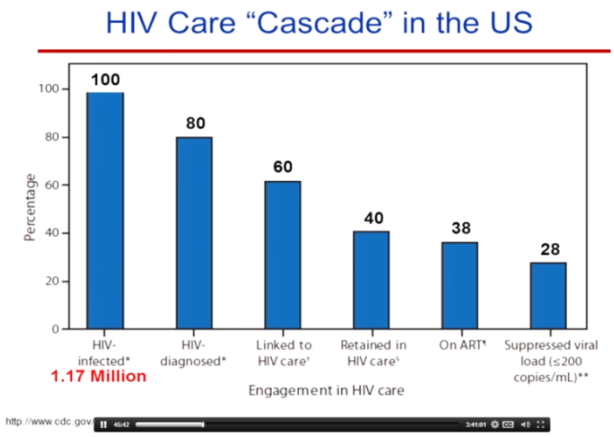
Recommendations

Among the recommendations included in the report are those for prevention, the prevention and care continua, behavior and social science, implementation science, and training.

Prevention – Among the areas that the NIH should prioritize to prevent transmission and acquisition of HIV infection focused on people/communities most at risk of/most affected by HIV in different locales, is the recommendation to *address behavioral and social/structural issues to increase access to, adoption of, and adherence to efficacious prevention methods*.

"It is essential that the NIH maintain its commitment to supporting a robust basic biomedical, behavioral, and social science program to support these HIV prevention (and related) priorities, and thus, among other things…Support basic behavioral and social sciences research to better identify, understand, and address social determinants and cultural drivers of HIV infection, resultant health disparities, and associated social stigma(s) in various settings."

Prevention and Care Continua – The report highlights the fact that NIH-supported research has shown that anti-retroviral therapy is also effective in preventing the transmission of HIV, "thus solidifying the intertwining of prevention and treatment." It also notes that at the same time, in the U.S. and internationally, there "continue to be significant gaps, attrition, and inequalities in the prevention and care continua, from HIV testing, to linkage to and engagement in services, to uptake of effective interventions, to adherence to effective regiments, to achievement of optimal health outcomes." Accordingly, the working group recommends that the agency prioritize inter- and multi-disciplinary research to:



- Develop, test and implement strategies to improve HIV testing, entry into prevention and treatment services, retention in these services, and achievement and maintenance of optimal prevention and treatment responses; and
- Address unique characteristics (e.g., gender, sexual orientation, race/ethnicity, age, geographic location, nutritional status, substance use, mental illness, socioeconomic status, acute infection, genetics, pregnancy status, history of violence and trauma, etc.) that influence individuals' experiences along the prevention and treatment continua.

Behavioral and Social Science – Employing a social-ecological framework to better understand and address simultaneously key individual, institutional, community, and social (including economic) factors that fuel or mitigate HIV epidemics in diverse populations and settings is essential to ending AIDS and associated health and social disparities. The report recommends that NIH prioritize the following areas:

- Innovative methods and frameworks to guide social and behavioral science interventions (e.g., adaptive interventions, new social media, mathematical modeling, economic value/policy impact/return on investment frameworks);
- Comparative effectiveness research; and
- Optimizing HIV prevention synergy.

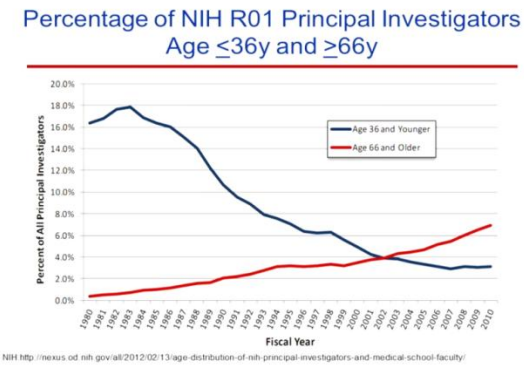
Implementation Science – Walensky noted that the field contains a lot of discussion of implementation science, the study of methods to promote the integration of research findings and evidence into health policy and practice. It addresses what the field calls the "Know-Do gap" or the "Evidence-to-Program gap."

The working group's report also calls for the prioritization of implementation science related to addressing gaps in the HIV prevention and care continua to allow the research to have the greatest impact on HIV both in the U.S. and internationally. Specifically, it recommends that the NIH support research to assess interventions and combinations of strategies to address obstacles to access, uptake of, retention in, and scale-up and sustainability of efficacious, evidence-based HIV prevention, care and treatment intervention in diverse settings.

Information Dissemination – Highlighting the essential need for a robust HIV/AIDS research information dissemination strategy to promote evidence-based and culturally-competent practice, the working group recommended that in order to optimize the dissemination of HIV/AIDS research information, the agency should:

- Support meetings and conferences in which the latest research findings are presented and exchanged among scientists, community members, patient advocates, industry representatives, policy-makers, program implementers, and the media; and
- Support research to enhance the public understanding of science, with HIV research and its crossover benefits as the example.

Training – Walensky pointed out that there is a pipeline problem in terms of the aging of researchers without enough young researchers to carry on the work, which is not only true for HIV but throughout the research workforce.



The working group report recommends that over the next five years HIV-related science must focus on the development of new investigators to achieve the potential of prevention, treatment, and their intersection.

A videocast of the ACD meeting is available.