
Presidential Advisory Council on **HIV/AIDS**



May 25, 2016

The Honorable Sylvia Burwell
Secretary Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madame Secretary:

On behalf of the Presidential Advisory Council on HIV/AIDS (PACHA), we write to advise you of the Council's concerns regarding the National Institutes of Health (NIH) transition from the Adolescent Trials Network III (ATN III) to a network formed using the U19 mechanism. As you may know, the ATN III infrastructure has been dismantled, resulting in an abrupt interruption of clinical studies and potential research gaps. The U19 proposals were recently reviewed within the National Institute of Child Health and Human Development and the funding decisions will take place June 8th. We are concerned that the National Institutes of Health (NIH) will fund a much more limited network, one that lacks the capacity to address the individual and structural drivers of the epidemic among adolescents and young adults.

The primary mission of the ATN is to conduct research, both independently and in collaboration with existing research networks and individual investigators, in youth living with HIV and HIV-at-risk pre-adolescents, adolescents, and young adults up to 25 years of age. The ATN has extensive experience in recruiting and retaining understudied youth populations in the United States. Much of the research activity of the ATN has focused on collaboration with Clinical Trials Networks supported by other institutes of the NIH including but not limited to the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute (NCI) through research coordination. The ATN infrastructure consists of developmentally-appropriate adolescent clinical sites with expert clinicians who understand the intricacies of youth development, HIV care, prevention, and research.

We must stem the tide of HIV in our youth. Replacing established and effective research programs with a completely untested new research mechanism seems to us a high-risk strategy at this point in the epidemic. To mitigate this risk, we believe it is important to fund a significant number of adolescent research programs with established expertise in the stages of adolescent development as a prerequisite for a U19 success. PACHA has two specific recommendations to ensure continued and improved success of the U19:

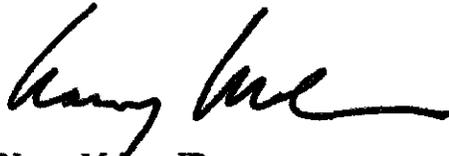
1. Funding a clinical, community and research infrastructure capable of completing the ongoing and needed behavioral, community and biomedical trials. Examples include licensing trials for promising upcoming biomedical prevention interventions and research on adolescent substance abuse, mental health, stigma and other social determinants of health.

2. Establishing an independent and interdisciplinary external advisory group (EAG) with stakeholder representation to monitor and assess the U19 progress. It is imperative that the EAG will involve key community members with expertise in pediatric and adolescent research. Similarly, it is crucial to include youth as they are essential stakeholders and have the greatest increase in new cases of HIV for all age groups.

These recommendations derive from the National HIV/AIDS Strategy action item 1.A.s *which explicitly states that we include stakeholder expertise by inserting specific RFA language and review criteria related to the meaningful involvement of communities and clinical sites with expertise in adolescent development in order to avoid marginalization that may negatively impact the research agenda.*

We respectfully ask for the Administration's support to obtain a commitment from NIH for adequate infrastructure funding and independent monitoring of the new U19 mechanism to ensure results from these important research efforts are maximized.

Best regards,



Nancy Mahon, JD
Chair
PACHA

Enclosure

CC: Robert W. Eisinger, PhD, NIH Acting Associate Director for AIDS Research and Acting Director for the Office of AIDS Research
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