THE FENWAY INSTITUTE

May 15, 2017

Paul Gaist, PhD, MPH
Office of AIDS Research
National Institutes of Health
Room 2E40
5601 Fishers Lane
Rockville, MD 20852

RE: Notice Number NOT-OD-17-053

The Fenway Institute provides public comment regarding the National Institutes of Health's Request for Information on the Development of the FY 2019 Trans-NIH Plan for HIV-Related Research

Dear. Dr. Gaist,

The Fenway Institute works to make life healthier for those who are lesbian, gay, bisexual, and transgender (LGBT), as well as people living with HIV and the larger community. We do this through research and evaluation, education and training, policy analysis, and public health advocacy. We are the research division of Fenway health, a federally qualified health center and Ryan White Part C HIV clinic in Boston, MA. We would like to make the following recommendations regarding the fiscal year 2019 Trans-NIH Plan for HIV-Related Research.

HIV Research Funding

We would first like to emphasize the need for continued funding of HIV research in general. Recent investments in expanding access to health care for people with preexisting conditions like HIV, as well as a renewed focus on the domestic HIV epidemic (e.g. the National HIV/AIDS Strategy) have led to success. Between 2005 and 2014, new HIV diagnoses in the U.S. decreased by 19%.[1] With some populations hard hit by HIV, we saw even greater improvements: new diagnoses declined 42 percent among mostly heterosexual Black women over the past decade, fell 35 percent among heterosexual women and men of all races, and dropped 65 percent among people who inject drugs. More people living with HIV (PLWH) in the U.S. are connected to care and virally suppressed. Recent biobehavioral research breakthroughs such as PrEP are vital tools that could dramatically lower new HIV infections. It is important to continue to fund innovative HIV prevention research and keep this momentum going.

[1] Centers for Disease Control and Prevention. HIV diagnoses decline almost 20 percent, but progress is uneven. Press release, December 6, 2015. https://aidsinfo.nih.gov/news/1631/hiv-diagnoses-decline-almost-20-percent--but-progress-is-uneven

Biomedical Interventions for HIV Prevention

Given the major role PrEP is already playing in HIV prevention in the U.S.,[2] NIH should continue funding research into injectable PrEP, implants, transdermal patches, and other long-lasting treatments as biobehavioral intervention approaches that could significantly increase adherence and efficacy. NIH should also continue funding research into vaginal and rectal microbicides, which have been shown to have potential.

Demonstration projects should be funded to understand real-world implementation issues and develop best practices. Among the most critical issues is how to improve rates of PrEP uptake among African Americans. Non-Hispanic Blacks were 45% of those newly diagnosed with HIV in 2013.[3] While about 80,000 individuals in the U.S. have accessed PrEP, its use among Black and Latino gay and bisexual men, youth, women, and Southerners has lagged.[4] Of 79,684 individuals on PrEP at the end of 2015 for whom race/ethnicity data were available, 74% were White, 10% Black, 12% Latino, and 4% Asian.[5] Implementation research to improve uptake of PrEP among Black gay and bisexual men, heterosexual women, and transgender women is urgently needed.

Research Studies Focused on Vulnerable Populations

NIH should fund research studies that focus specifically on populations that are disproportionately affected by the HIV epidemic, so that effective interventions to reduce these health disparities can be developed and implemented. Vulnerable populations that should be prioritized in HIV research include serodiscordant same-sex and opposite-sex partners, young men who have sex with men (YMSM)–particularly YMSM of color, young women, transgender women, people who inject drugs, and sex workers. Research studies should include members of these vulnerable populations as participants and as community partners in planning in order to ensure success. Studies of intermittent PrEP, non-tenofovir-based regimens, and non-oral modes of administration are important with these populations so that the safest, most cost-effective, and most acceptable regimens are available to a diverse array of potential consumers.

Transgender women have 49 times the odds of being infected with HIV compared with all adults of reproductive age.[6] This glaring disparity is even

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[2] Anonymous (2016, July 21). U.S. PrEP users likely exceeded 80,000 by end of 2015. *Poz*. https://www.poz.com/article/us-prep-use-likely-80000-end-2015

[3] Dasgupta S, Oster AM, Li J, Hall I (2016, February 5). Disparities in consistent retention in HIV care—11 states and the District of Columbiua, 2011-2013. *MMWR* 65(4);77-82.

[4] Anonymous (2016, July 21). U.S. PrEP users likely exceeded 80,000 by end of 2015. *Poz*. https://www.poz.com/article/us-prep-use-likely-80000-end-2015

[5] Presentation by Alex Rinehart, PhD, Director, Global Prevention Strategy, ViiV Healthcare, ViiV Community Summit, Fort Lauderdale, Florida, November 12, 2016.

[6] Baral, S. D., Poteat, T., Stromdahl, S., Wirtz, A. L., Guadamuz, T. E., & Beyrer, C. Worldwide burden of HIV in transgender women: A systematic review and meta-analysis. *The Lancet Infectious Diseases*. 2013. 13, 214–222. doi:10.1016/S1473-3099(12)70315-8

more apparent in transgender women of color.[7] Transgender people also experience widespread discrimination, including discrimination in health care settings, which contributes to lack of access to current HIV prevention methods such as PrEP. Previous large clinical studies of PrEP have only included a small percentage of transgender women within their study samples, despite the disproportionate burden of HIV on transgender women. Because of this, there is a strong need for more research in the area of PrEP and other HIV prevention interventions for transgender women. Also, there is concern among some transgender women that estrogen therapy could interfere with the effectiveness of PrEP.[8] While leading transgender health and PrEP researchers do not think there are interactions between PrEP and feminizing hormones[9,10] intentional, focused research on interactions between antiretroviral medications and cross-sex hormone therapy would clarify whether there is any interaction between the two classes of drugs.[11]

Research on structural drivers of vulnerability to HIV is needed. Structural factors that can increase vulnerability to HIV and decrease access to care include intimate partner violence,[12] criminalization of sex work,[13] gender-based violence,[14] and victimization in childhood[15] and adulthood.[16]

Chronic disease and disability among older people living with HIV

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[7] The Foundation for AIDS Research. *Trans population and HIV: Time to end the neglect*. 2014. Accessed at: http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/

[8] Marquez S, Cahill S (2015, December 1). *Transgender women and pre-exposure prophylaxis for HIV prevention: What we know and what we still need to know*. National Center for Innovation in HIV Care.

[9] University of California, San Francisco. (2011) *Review of literature relating to possible drug interactions between antiretrovirals and estrogen therapy used for MTF gender transition*. http://transhealth.ucsf.edu/trans?page=protocol-hormones-arvs. Accessed October 22, 2015. Cited in Marquez and Cahill, 2015.

[10] Dr. Bob Grant on transgender women and pre-exposure prophylaxis. Interview, June 19, 2015. https://www.youtube.com/watch?v=08YEm7YcaIk. Accessed October 22, 2015. Cited in Marquez and Cahill, 2015.

[11] Human Rights Campaign. (n.d.). Transgender people and HIV: What we know. Retrieved from: http://www.hrc.org/resources/entry/transgender-people-and-hiv-what-we-know

[12] Jewkes R, Dunkle K, Nduna N, Shai N. Intimate partner violence, relationship power inequity, and incidence of HIV infection in young women in South Africa: A cohort study. *The Lancet* 376, no. 9734 (2010): 41-48. doi: 10.1016/S0140-6736(10)60548-X.

[13] Cowan F, Mtetwa S, Davey C, et al. Engagement with HIV prevention, treatment and care among female sex workers in Zimbabwe: A respondent driven sampling survey. *PLoS One*. 2013 Oct 15;8(10):e77080. doi: 10.1371/journal.pone.0077080.

[14] Ellsberg M, Betron M. *Preventing gender-based violence and HIV: Lessons from the field.* U.S. Agency for International Development, 2010. http://www.aidstar-one.com/sites/default/files/AIDSTAR-One_Gender_Spolight_Gender-based_violence.pdf

[15] Boroughs MS, Valentine SE, Ironson GH, Shipherd JC, Safren SA, Taylor SW, Dale SK, Baker JS, Wilner JG, O'Cleirigh C. 2015. Complexity of childhood sexual abuse: predictors of current post-traumatic stress disorder, mood disorders, substance abuse, and sexual risk behavior among adult men who have sex with men. *Arch. Sex. Behav.* 44(7): 1891-902.

[16] Operario D, Nemoto T. 2010. HIV in transgender communities: Syndemic dynamics and a need for multicomponent interventions. *J. Acquir. Immune Defic. Syndr.* 55(Suppl 2): S91-93.

As people living with HIV live into middle age and older adulthood thanks to improvements in treatment and care, more research on health issues affecting older people living with HIV is needed. About half of the HIV-positive population in the United States is now age 50 or older.[17] Older adults living with HIV are more likely to have comorbidities than other older adults.[18] As people grow older with HIV, their ability to metabolize antiretroviral medications is diminished, resulting in increased toxicity.[19] Taking antiretrovirals for a long time may increase the risk of heart attack[20] and heart disease.[21] HIV infection and antiretroviral therapy are associated with obesity,[22] which presents additional risk factors for heart disease.[23] Preexisting cardiovascular, hepatic, and metabolic complications can be exacerbated by HIV infection itself, immunodeficiency, and by metabolic syndrome and other adverse effects of antiretroviral therapy.[24] Research into disability and chronic disease issues affecting long-term survivors of HIV living into old age and other older adults living with HIV is needed.

The Centers for Disease Control and Prevention should improve epidemiological surveillance systems and data collection on older adults delineated by age and risk category to better inform HIV preventionists and gerontological health providers with information on the proportion of older HIV-positive adults who contract HIV through homosexual sex, heterosexual sex, and injection drug use. It should also analyze HIV prevalence among the young-old, old-old, and oldest-old.

The National Institutes of Health should fund large-scale, national, longitudinal studies that investigate how antiretroviral medications and HIV disease interact with aging bodies, and how they interact with treatments for comorbidities such as high cholesterol medication; to what extent normal aging processes result from viral infection and immune activation; and the incidence and determinants of cognitive decline in aging HIV-positive individuals.

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[17] Effros, R.B., C.V. Fletcher, K. Gebo et al. Aging and Infectious Diseases: Workshop on HIV Infection and Aging: What Is Known and Future Research Directions. *Clinical Infectious Diseases.* 2008. 47(4):542–53. (Cited in Cahill, S., and R. Valadez. 2013. Growing Older with HIV/AIDS: New Public Health Challenges. *American Journal of Public Health* 103(3):e7–e15. doi:10.2105/AJPH.2012.301161.)

[18] Deeks, S.G., and A.N. Philips. HIV Infection, Antiretroviral Treatment, Aging, and Non-AIDS Related Morbidity. *BMJ.* 2009. 338(7689):288–92. (Cited in Cahill and Valadez, 2013.)

[19] Gebo, K.A. HIV and Aging: Implications for Patient Management. *Drugs and Aging*. 2006. 23(11):897–913. (Cited in Cahill and Valadez, 2013.)

[20] Bhavan, K., V. Kampalath, and E.T. Overton. The Aging of the HIV Epidemic. *Current HIV/AIDS Reports*. 2008. 5(3):150–8. (Cited in Cahill and Valadez, 2013.)

[21] Deeks and Phillips, 2009.

[22] Bhavan et al., 2008.

[23] Simone, M., and J. Appelbaum. HIV in Older Adults. *Geriatrics*. 2008. 63(12):6–12. (Cited in Cahill and Valadez, 2013.)

[24] Kirk, J.B., and M.B. Goetz. Human Immunodeficiency Virus in an Aging Population, a Complication of Success. *Journal of the American Geriatrics Society*. 2009. 57:2129–38. (Cited in Cahill and Valadez, 2013.)

A 2009 Kaiser Family Foundation survey found that more than one third of Americans believed that HIV could be transmitted by sharing a drinking glass, touching a toilet seat, or sharing a swimming pool with an HIV-positive person.[25] Older Americans are more likely than members of younger age cohorts to hold inaccurate beliefs about the casual transmission of HIV.[26] Older Americans are also more likely to hold anti-gay views than younger age cohorts.[27] Consequently, many LGBT older adults express concern about how they will be treated in mainstream senior settings.[28] Research should be conducted to study the experiences of HIV-positive elders, older gay and bisexual men, and transgender women in senior service settings, including congregate living facilities, to inform services and best practices to ensure that they can access elder services.

Community-Based Sites

Community-based sites for HIV treatment and management have been shown to be effective in improving health outcomes and ensuring sustained access to care for people living with HIV. Community-based programs are especially helpful in more resource-limited, rural areas. Better funding and use of community-based sites for HIV prevention and treatment research could help these essential programs become more sustainable.

Research That Analyzes Clinical Data to Improve Care for People Living with HIV

The CFAR Network of Integrated Clinical Systems (CNICS) is a research infrastructure that supports HIV clinical outcomes and comparative effectiveness research using electronic medical records data from 8 Centers for AIDS Research (CFARs). As of 2017, CNICS contains data on 32,727 individuals living with HIV. CNICS data directly reflects the health outcomes of HIV treatment options and clinical decisions made every day in the care of people living with HIV. This data is immensely useful in developing effective HIV care management protocol. CNICS data has significantly contributed to new clinical, translational, and biobehavioral HIV research, with 230 peer-reviewed PubMed publications citing CNICS data as of May 2017. Another example is the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD). Some 200 clinical sites contribute data on 157,701 HIV-infected patients. Research focused on epidemiology, treatment and clinical care has been published in 51 peer-reviewed publications and presented at many dozens of professional research conferences. The 2012 Institute of Medicine report *Monitoring HIV Care in the United States: A Strategy for Generating*

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[25] Kaiser Family Foundation. *2009 survey of Americans on HIV/AIDS*. Washington, DC: 2010. http://www.kff.org/kaiserpolls/7890.cfm. Accessed September 12, 2012.

[26] Ibid.

[27] Anderson R, and Fetner T. Cohort differences in tolerance of homosexuality: Attitudinal change in Canada and the United States. *Public Opinion Quarterly*. 2008;47(2):311-330.

[28] Orel, N. Community needs assessment: Documenting the need for affirmative services for LGB older adults. *Lesbian, Gay, Bisexual, and Transgender Aging: Research and Clinical Perspectives*. Edited by Kimmel D, Rose T, and David S. New York, NY: Columbia University Press. 2006. 227-246.

National Estimates of HIV Care and Coverage cites CNICS and NA-ACCORD as critically important data sets on clinical health outcomes for people living with HIV.[29] We encourage NIH to continue to fund multisite clinical outcomes research on HIV treatment and clinical care.

We thank you for this opportunity to provide feedback on the FY 2019 Trans-NIH Plan for HIV-Related Research. Should you have any questions or require more information on any of the suggestions made here, please contact Sean Cahill, PhD, Director of Health Policy Research at scahill@fenwayhealth.org or Tim Wang, MPH, Health Policy Analyst at twang@fenwayhealth.org.

Sincerely,

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[29] Institute of Medicine; Board on Population Health and Public Health Practice; Committee to Review Data Systems for Monitoring HIV Care; Morgan A. Ford and Carol Mason Spicer, Editors. *Monitoring HIV Care in the United States: A Strategy for Generating National Estimates of HIV Care and Coverage.* Washington, DC: The National Academies Press. 2012. https://www.nap.edu/catalog/13408/monitoring-hiv-care-in-the-united-states-a-strategy-for