



January 24, 2020

Karen Parker, Ph.D., MSW
Director, Sexual & Gender Minority Research Office (SGMRO)
6555 Rock Spring Drive, Suite 220, Room 2SE31K
Bethesda, MD 20817

Re: Request for Information on the Development of the Fiscal Year 2021-2025 Trans-NIH Strategic Plan for Sexual & Gender Minority Health Research

Dear Dr. Parker,

On behalf of Treatment Action Group (TAG), thank you for the opportunity to comment on the strategic plan goals for sexual & gender minority (SGM) health research. TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis (TB), and hepatitis C virus (HCV).

We applaud the National Institutes of Health (NIH) for their commitment to research inclusive of, and responsive to, SGM communities. As an organization that works to address many scientific questions that disproportionately impact LGBTQ+ communities, we are pleased to see the research and operational goal areas from which the NIH strategic plan will be built.

Below we provide a brief outline of topline priorities that we hope will be considered as part of a final Trans-NIH Strategic Plan on SGM Research:

Clinical Research

Continued and increased public investment in clinical trials to develop additional tools in order to create a sustainable end to the HIV epidemic must remain a priority for the wellbeing of SGM communities, especially for those SGM communities most impacted by HIV and coinfections such as HCV. These investments are particularly important to meet the ambitious vision set forth by the administration's End the HIV Epidemic (EHE) initiative, in which new tools that can only be made by strengthening investment in cutting-edge science at NIH and its research institutions. These new tools needed for SGM communities includes the development of event-driven primary prevention modalities, long acting prevention and treatment options, a cure, and a scalable vaccine.

As part of this research, and all SGM-related clinical research, NIH must address the specific concerns of transgender and gender nonconforming (TGNC) communities. While hormone therapy serves a critical role in many people's medical transition, it is rarely included in safety or efficacy measures in clinical trials for other biomedical tools. This limits the accuracy of trial results, due to the fact that many of those who could benefit from such innovation will be less likely to take measures that could negatively impact their transition. Future studies should

measure the impact of treatments on hormone therapy, and vice versa. Delays in this research have led to delayed discovery of possible diminished efficacy of TDF-based PrEP for individuals receiving feminizing hormones and broader scale up of this essential intervention among community members.

Social & Behavioral Research

Many SGM communities, including men who have sex with men (MSM), experience higher rates of methamphetamine addiction. Despite the fact that opioid use disorder is an important research topic, substance misuse affecting marginalized communities – including studies devoted to methamphetamines – are sorely needed as well. New biomedical tools and medication assisted therapies (MAT) to address stimulant misuse and addiction could save lives and have a profound impact on LGBTQ+ people.

Behavioral research has historically focused on interventions for patients and those receiving care, but they are not the only agents in the health care system. In order to more adequately address SGM health care needs, we must address the gap in interventions to modify the behaviors of providers, health care administrators, and medical schools. Health care systems research on improved sexual history taking, extragenital screening, improved sexual health care, and other behaviors would provide a meaningful foundation for such research.

Chronic Diseases & Comorbidities Research

Any strategic plan for SGM research must include robust study of the sexually transmitted infections (STI) that disproportionately impact SGM, and new tools to combat these infections. In particular, better diagnostics are needed to provide more rapid and more convenient options for at-home and point-of-care diagnosis. Recent NIH investment in vaccine research for gonorrhea, chlamydia, and syphilis should be increased, and implementation research for scaling up promising new treatments for drug-resistant gonorrhea should be a priority. Ongoing investment in additional primary prevention tools such as doxycycline as PrEP or PEP will be needed to address bacterial STIs that disproportionately impact SGM communities.

HCV is a leading cause of liver disease and cancer, especially in individuals coinfecting with HIV. Efforts to prevent sexual transmission of HCV among MSM are often overlooked in the broad response to the overdose, infectious disease, and injection drug use syndemics. Research on interventions to address HIV and HCV risk from stimulant injection is also lacking. Public investment in HCV vaccine research to prevent HCV reinfection is critically needed, as the commercial marketplace has little incentive to advance current scientific efforts.

As mentioned previously, although the tools to fight the HIV epidemic have advanced considerably in recent years, there is still a need for new technologies including a vaccine and cure. These innovative products must be effective for SGM, which requires recruitment and inclusion in research. As has been seen in recent studies such as HPTN083, a study of long-acting cabotegravir in MSM and transgender women, better recruitment of transgender research participants will be essential for research on chronic conditions such as HIV.

Methods & Measures Research

Much research focusing on SGM will undoubtedly include sexual health, but the definitions for optimal outcomes have historically been lacking. Most people engage in sexual activity for pleasure, yet any standardized measure of impact of interventions on sexual satisfaction or social interconnectedness is frequently lacking in studies, thereby limiting the accuracy of study results and their applicability in the lives of target demographics.

Research on “healthy sexuality” should be subject to a standardized list of measures including sexual satisfaction, feelings of social interconnectedness, and individual empowerment. Moving research away from a sole focus on disease and towards a focus on wellness will improve the efficacy of research and its impacts on SGM communities.

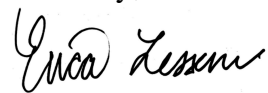
Operational Goals

While inclusion of transgender research participants has improved in recent years, many problematic recruitment practices remain. Studies that aim to recruit MSM and transgender women using the same methods are not only less effective, but perpetuate false narratives that transgender women are not women. In the future, studies should have a specific and dedicated focus on transgender women and other gender minorities, or at the very least should have separate recruitment protocols.

Lastly, more studies should be led by principal investigators representing the communities being studied – not merely as a matter of justice, but as one of efficacy. HPTN073, a study of Black gay and bisexual men, was led by Black gay and bisexual men and consequently resulted in significantly improved rates of retention. This should also incorporate an intersectional lens, as white SGM will not adequately represent or understand the concerns of people of color. Such diverse representation should also extend to key advisory bodies for research and the agencies that fund them. The overall inclusion of these often marginalized and misunderstood communities in all aspects of clinical and behavioral research – from explicit participation in trials to representative leadership in early research protocol formation – ensures that downstream tools and prospective interventions that result from this research take into account the lived experiences of these groups, to maximize success of scale-up and provide value to taxpayer investments in this research aimed at the wellbeing of SGM communities.

We thank you for the opportunity to submit comments on the draft strategic plan research and operational goals. We look forward to continued engagement on the strategic plan as it develops further. Please do not hesitate to contact Erica Lessem, Deputy Executive Director for Programs, at Erica.Lessem@treatmentactiongroup.org with any questions.

Sincerely,



Erica Lessem, MPH
Deputy Executive Director of Programs
Treatment Action Group