



NO DATA NO MORE

Manifesto to Align HIV Prevention Research with Trans and Gender- Diverse Realities

The *No Data No More Manifesto*, written and informed by trans and gender-diverse (TGD) advocates from Cape Town to Cologne, with support and solidarity from AVAC, offers practical and essential priorities to manifest meaningful change. We believe the future must include peer-led HIV prevention research with true ownership, acceptability and viability in TGD communities.

Specifically, this declaration sheds light on the TGD experience and the role of gender-affirming therapy, and the HIV prevention research landscape, including its historical gaps and recent progress. *No Data No More* provides a vision for a relevant and inclusive TGD research agenda, offering public recommendations to finally fulfill an inclusive HIV research future where TGD people flourish in all our diversity.

LIVED TGD EXPERIENCES

The stakes are high: Efforts to bring an end to the global HIV pandemic will fail if effective, accessible HIV prevention interventions don't reach TGD communities. Yet our people—who often face crushing stigma, marginalization, criminalization and violence, along with a disproportionate burden of HIV—continue to be overlooked, subsumed, underrepresented or excluded altogether from HIV prevention research and programs. Though there's been a recent uptick of TGD-inclusive scientific literature and trans-led research, it falls gravely short of what's needed.

Trans women bear a disproportionate burden of HIV globally with 19 percent living with HIV—49 times greater than the general population. HIV in trans men

is woefully understudied and the absence of data leads to a false assumption that they bear little to no burden of the virus. Gender nonbinary people face even greater underrepresentation in HIV surveillance and research and related syndemics (the confluence of two epidemics with the potential to worsen outcomes for both). As such, we envision an HIV TGD research agenda that:

- Considers diversity, including the full range of participants along the gender spectrum.
- Tracks epidemiological data on HIV incidence and prevalence that accurately reflects the large and growing HIV acquisition rates of TGD populations, including in regions where little to no data has been collected thus far.
- Supports best practices in language use, informed by TGD researchers, TGD community advisory board members and TGD trial participants.
- Undertakes a global analysis of the data gap from TGD-relevant health programs and prevention research.
- Addresses structural barriers that limit TGD people's access to HIV prevention and the HIV research process.

ROLE OF GENDER-AFFIRMING HORMONE THERAPY (GAHT)

Gender-affirming hormone therapy (GAHT) in all its forms is a building block of TGD health and well-being, including HIV prevention. Improved uptake and retention are a direct result of GAHT as it enhances an individual's self-worth and self-esteem. And yet,

gender-affirming hormone therapy remains an unmet need and priority for many. Furthermore, for too many years, a lack of research into hormone and ARV drug interactions has raised concerns among some TGD people at risk for HIV and slowed their uptake of PrEP. As such, we call for an HIV research agenda that:

- Ensures all new PrEP compounds in development undergo drug-drug interaction studies with feminizing and masculinizing hormones to examine any possible drug variances.
- Resolves efficacy and safety questions about on-demand oral PrEP for trans people on GAHT.
- Provides GAHT across the continuum of HIV care and prevention, from early clinical trials through delivery.

The historic failure to conduct meaningful HIV prevention research with TGD populations is yet another act of systemic and institutionalized violence against TGD people.

It exacerbates the very health disparities that the HIV field has committed to addressing.

HIV PREVENTION RESEARCH

Further, when TGD groups are included in research, their numbers are typically too small to measure statistically significant outcomes in the trans subgroup. While there are growing commitments to TGD-inclusion, this goodwill doesn't stretch far enough to ensure needed research is adequately funded or developed in partnership with TGD communities and answers critical questions. As such,

For more information on advocacy for TGD HIV prevention, go to avac.org/no-data-no-more

About AVAC

AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic. For more information, visit www.avac.org.

Illustrations: Rory Midhani

we envision an HIV research agenda to overcome this historic disparity that:

- Improves TGD-inclusion in randomized clinical trials that is comprehensive and studies the differences among trial participant sub-groups.
- Adapts gender-inclusive enrollment criteria from the UNAIDS/World Health Organization's guidance (*Ethical considerations in HIV prevention trials*) to local contexts.
- Provides inclusion criteria for TGD people in clinical trials and reports how gender is defined by the study protocol, and how it is explained and communicated to potential participants.
- Explicitly includes trans men and other assigned female at birth (AFAB) trans people in the eligibility criteria of all PrEP trials—and all other HIV clinical trials.
- Includes TGD leadership in clinical research. TGD representatives must participate in study design and implementation through direct and meaningful inclusion in protocol teams, special advisory committees, trial teams and even as principal investigators.
- Funds and strengthens capacity of local research sites to recruit TGD participants and follow the Good Participatory Practice Guidelines by engaging with the local LGBTQ community, including transgender-led organizations.

To advance this vital work, **we offer our detailed global manifesto to HIV researchers, site-level staff and funders. This work demands immediate and sustained action. Join with TGD communities to envision, fund, and launch a body of research to finally redress decades of negligence. No data, no more!** Forty years into the global HIV pandemic, which is endemic to most trans communities, it's beyond time to align HIV prevention research with trans and gender-diverse realities.

