No Data No More: A Tool to End the Exclusion of Trans & Gender-Diverse People in HIV Research Brian Minalga (Fred Hutchinson Cancer Center) & Cindra Feuer (AVAC)

Background

X Transgender and gender-diverse (TGD) people face multiple forms of structural exclusion and neglect in the global HIV response.

We sought to quantify the inclusion of TGD people in milestone HIV clinical trials over the course of the epidemic.

We also sought to devise a research and advocacy tool (Scorecard) to promote the meaningful inclusion of TGD people in future HIV research.

Methods

Conducted consultations with global TGD stakeholders to create No Data No More: Manifesto to Align HIV Prevention Research with TGD Realities.

Synthesized the Manifesto into 13 scoreable indicators to assess studies for TGD inclusivity.

Applied the Scorecard to 41 milestone HIV clinical trials conducted from 1991-2023 (protocols, clinicaltrials.gov, publications), including HIV treatment, ARV-based prevention, and

vaccine/antibody studies.

CLINICAL TRIAL SCORING TOOL

SCORING

11-13 points

8-10 points

5-7 points

2-4 points

A

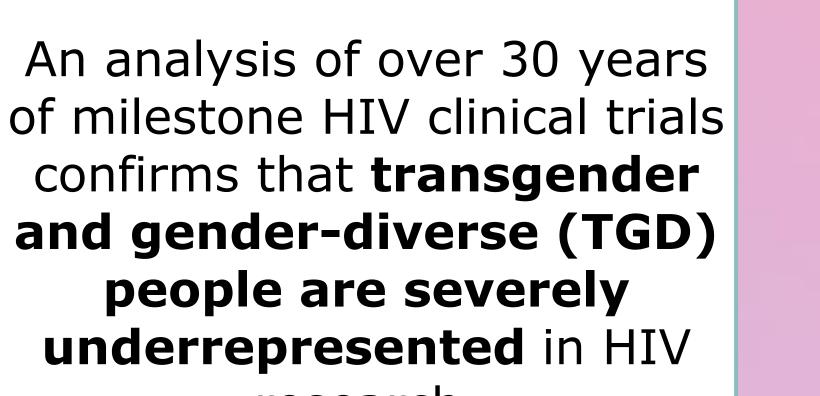
В

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D

ELIGIBILITY

- Selection criteria include trans women, trans men, and gender nonbinary participants, discretely. (1 point)
- If no trans and gender-diverse participants are specified in the protocol, their exclusion is explicitly justified in the protocol and in the results reporting. (1 point)



REPORTING Participant characteristics are reported using the 2-step method such that sex assigned at birth and gender identity can be cross-referenced. (1 point)

Trans-specific safety and efficacy results are reported (when possible). (1 point)

SYSTEMS

Specified trans and gender-diverse enrollment goals—either in absolute numbers or percentage of participants. (1 point) Gender-identity status is assessed using a twostep method (Step 1: sex assigned at birth, Step 2: current gender identity). (1 point)

Outreach, marketing, and recruitment strategies that clearly exemplify trans inclusion (or exclusion). (1 point)

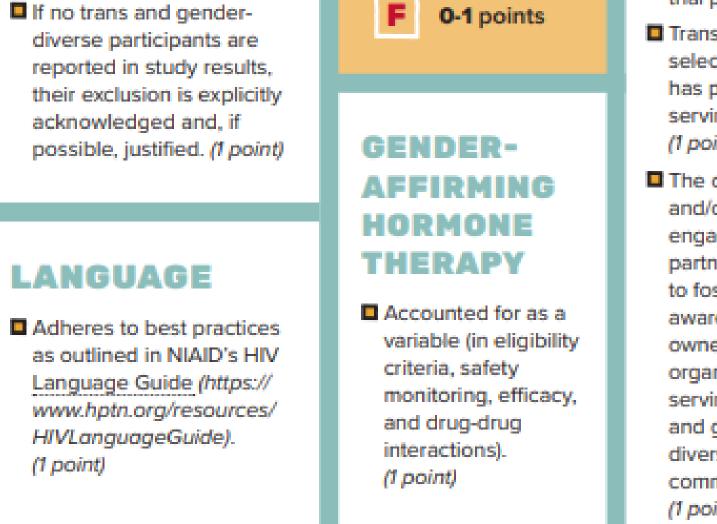
Trans and gender-diverse staff at research sites and/ or as part of the core study team who reflect trial participants. (1 point) Trans-responsive site selection. Each study site has proven experience serving the population. (1 point) The core study team and/or study sites engage in partnerships to foster awareness and ownership with organizations serving trans and genderdiverse communities. (1 point)

A clinical trial **Scorecard** developed by TGD people around the world may help to promote a future of HIV research that **meaningfully** prioritizes TGD people in

research.

Results

Since 1991, TGD people have made up less than 1% of participants in 41 key HIV studies. The vast majority of the <1% were transgender women.



ending the epidemic.

Next Steps

Promote the Scorecard as a research and advocacy tool to increase meaningful TGD inclusion in HIV clinical trials. Download the Scorecard below!

Transgender 1,340 (0.78%) Trans Men 37 (3%) Nonbinary 39 (3%)





HIV/AIDS Network Coordination



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