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## Centring the health of women across the HIV research continuum

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Despite tremendous advances in HIV research, women and gender diverse people—particularly women from racial and ethnic groups under-represented in research, transgender women, and young women—remain disproportionately affected by HIV. Women and gender diverse people face unique challenges and have been under-represented in HIV research. The National Institutes of Health (NIH) is tasked to apply fundamental knowledge about the nature and behaviour of living systems to enhance health, lengthen life, and reduce disability. Rigorous exploration of—and interventions for—the individual, social, biological, structural, and environmental factors that influence HIV prevention, transmission, treatment, and cure is crucial to advance research for women, girls, and gender diverse people across the lifespan. In this Position Paper, we introduce a framework for an intersectional, equity-informed, data-driven approach to research on HIV and women and highlight selected issues for women and gender diverse people, including HIV prevention, HIV cure, ageing with HIV, substance use and misuse, violence, pregnancy, and breastfeeding or chestfeeding. This framework underlines a new HIV and Women Signature Programme from the NIH Office of AIDS Research and Office of Research on Women's Health that advances the NIH vision for women's health, in which all women receive evidence-based HIV prevention, treatment, and care across their lifespan tailored to their unique needs, circumstances, and goals. The time is now to centre the health of women, girls, and gender diverse people across the HIV research continuum.

### Introduction

Over the past four decades, tremendous scientific advances have translated to substantial progress in confronting the HIV epidemic; however, women—particularly women from racial and ethnic groups under-represented in research, young women, and transgender women—and gender diverse people remain disproportionately affected by HIV. Globally, 53% of people with HIV are women.<sup>1</sup> In this Position Paper, the term women is inclusive of cisgender and transgender women. To balance brevity and visibility, we alternate between cisgender and transgender women in some instances and women in other instances.

In the USA, an estimated 44% of Black transgender women and 26% of Latinx transgender women are living with HIV.<sup>1,2</sup> The time is now to focus on the health of cisgender and transgender women and girls, transgender men and boys, and gender diverse people across the HIV research continuum. Advancing HIV research and clinical care for all women who have been or are affected by HIV across their lifespan, and ending the HIV pandemic, requires ongoing, meaningful engagement of women and gender diverse people (panel 1).

Sex, gender, and their intersections influence HIV outcomes for women across the lifespan; these effects should be rigorously investigated throughout the health research ecosystem. However, despite National Institutes of Health (NIH) Inclusion Policies,<sup>7,8</sup> women with HIV and those from disproportionately affected communities remain under-represented across the HIV research continuum. Both publicly funded and industry-sponsored HIV clinical trials frequently fail to have adequate female representation.<sup>9</sup> Pregnant and lactating people are often excluded from clinical research

and contraception requirements are perceived by many participants as onerous.<sup>10</sup> Meaningful engagement of cisgender women and transgender people in HIV research has been suboptimal.<sup>11,12</sup> These and other factors limit the availability and uptake of safe, effective, acceptable, and women-centred HIV prevention, treatment, and cure interventions. In this Position Paper, we summarise key messages that emerged from a 2023 NIH-sponsored symposium exploring

#### Panel 1: Key terminology

- Sex: multidimensional biological construct based on anatomy, physiology, genetics, and hormones (these components are sometimes referred to together as sex traits)<sup>3</sup>
- Gender: multidimensional construct that encompasses gender identity and expression, gender roles and norms, gender relations, and power<sup>3</sup>
- Intersectionality: theoretical framework for understanding how multiple social identities, such as race, gender, sexual orientation, socioeconomic status, and disability, intersect at the micro level of individual experience to reflect interlocking systems of privilege and oppression (ie, racism, sexism, heterosexism, and classism) at the macro social-structural level<sup>4</sup>
- Health equity: continual process of assuring that all individuals or populations have optimal opportunities to attain the best health possible<sup>5</sup>
- Social determinants of health: conditions in which people are born, grow, learn, work, play, live, and age, and the wider set of structural factors shaping the conditions of daily life<sup>6</sup>

considerations affecting women, girls, and gender diverse people across the lifespan. We conclude by describing the current NIH approach to advancing an intersectional, data-driven, equity-informed HIV research agenda (figure) and outline the next steps for consideration.

### Women & HIV Symposium: Considerations From Across the Lifespan

To launch a new, joint signature programme centred on HIV and women, the NIH Office of AIDS Research (OAR) and Office of Research on Women's Health (ORWH) co-sponsored the 2023 NIH OAR-ORWH Women & HIV Symposium: Considerations From Across the Lifespan during the 13th International Workshop on HIV and Women. This workshop is the only annual, international workshop focused on HIV and women that elevates both community and research perspectives. The sponsored symposium paired emerging and established investigators in selected topical areas to highlight gaps, opportunities, and issues for women, girls, and gender diverse people who are living with and affected by HIV. The topical areas highlighted provided an idea of current NIH-wide research activities, including social determinants of health, maternal morbidity and mortality, ageing, and chronic conditions among women. Due to time constraints, the full range of relevant topics could not be adequately addressed. To facilitate a more thorough exploration of the breadth of issues affecting women and girls, transgender boys and men, and gender diverse people across the lifespan, NIH OAR and ORWH will host a 2-day virtual workshop on March 21–22, 2024, open to the public via NIH videocast.<sup>13</sup>

#### Adolescent girls and young women

An estimated 1 million adolescent girls and young women aged 10–19 years were living with HIV in 2021, most located in sub-Saharan Africa.<sup>14</sup> It is estimated that in sub-Saharan Africa, only one in four adolescent girls have been tested and know their HIV status, and every day 1000 young women acquire HIV and 50 adolescent girls die from AIDS-related illnesses.<sup>14</sup> Biological, social, structural, and political factors influence the epidemic among all women and gender diverse people, with unique considerations for younger women and girls. Adolescent girls and young women are not a homogeneous group and effective HIV testing (for diagnosis and monitoring of viral suppression), treatment, and prevention interventions must respond to their diverse vulnerabilities to HIV and include community-informed options that those most vulnerable are willing to use and can easily access.

Barriers to achieving epidemic control persist despite gains in understanding structural and biological factors associated with HIV susceptibility in adolescent girls

and young women and reports of reduced HIV incidence among young women in some nations.<sup>15</sup> These barriers include harmful gender and cultural norms, sexual and reproductive health and rights, gender and racial inequalities, gender-based violence (GBV), intimate partner violence (IPV), and other drivers of HIV transmission. Sub-Saharan Africa is one of the regions with the highest prevalence of both IPV and HIV, with an adjusted population-attributable fraction of incident HIV due to IPV among women ranging from 11.9% to 22.2%.<sup>16</sup>

One exemplar study that centres the needs of adolescent girls and young women is the Females Rising through Education, Support, and Health (FRESH) Study, launched in 2012 in Durban, South Africa. FRESH aims to study the earliest immunological responses after HIV acquisition and guide the development of novel HIV prevention and cure interventions. The study enrolls young sexually active women without HIV aged 18–23 years who undergo HIV-1 RNA testing twice per week, to detect incident infections and initiate treatment during hyperacute infection.<sup>17</sup> Participants are co-enrolled in a life skills and job skills programme paired with the frequent testing schedule. The programme is inclusive of computer training, career exploration, CV and job interview preparation, and trauma, GBV, and intensive HIV prevention support, including access to oral pre-exposure prophylaxis (PrEP).<sup>17</sup>

In addition to the unique HIV prevention, treatment, and social considerations affecting adolescent girls and young women, they have been substantially under-represented in HIV cure trials. A 2019 analysis of HIV cure-related trials found that only 17% of participants were female.<sup>18</sup> In 2022, the first HIV cure trial in Africa was launched at the FRESH clinical research site to assess a regimen of dual broadly neutralising antibodies (bNAbs) and a toll-like receptor agonist. Recruiting young women from FRESH who initiated antiretroviral therapy (ART) during acute infection and

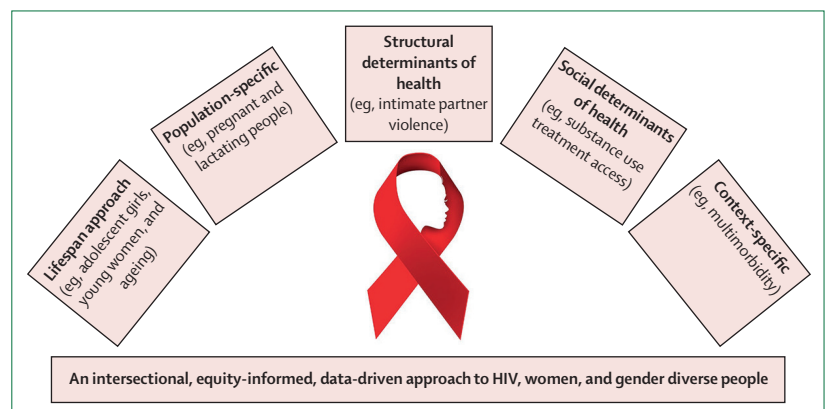


Figure: The NIH's approach to HIV, women, and gender diverse people

The five different areas that make up the NIH's approach to HIV, women, and gender diverse people.<sup>13</sup> NIH=National Institutes of Health.

have viral reservoirs limited in size and diversity might increase their likelihood of achieving HIV cure or post-treatment control. It is imperative that the enrolment and retention of women, especially adolescent girls and young women who are disproportionately affected, are prioritised as part of equitable access to HIV cure research studies—and that community voices are prioritised throughout study development.<sup>19</sup>

Documented barriers to participation in HIV cure trials include requirements to attend frequent and often prolonged study visits, invasive sampling, and consent to pause ART during analytic treatment interruptions.<sup>20</sup> For trials in some settings enrolling adolescent girls and young women, analytic treatment interruptions can pose ethical dilemmas between optimising partner protection and risk of harm to participants from disclosure.<sup>21</sup> Additional challenges include restrictions on pregnancy and lactation and increased risk for perinatal transmission of HIV if pregnancy occurs. To better understand the challenges for young women enrolled in HIV cure trials with analytic treatment interruptions, FRESH is conducting a sociobehavioural research study—nested within the bNAb trial—to inform women-centred approaches in future trial protocols planned in high-burden countries in sub-Saharan Africa. Additional work will be required to develop standards for participant and partner protections, address the unique regional challenges facing adolescent girls and young women (including high levels of poverty compared with young men and boys, gender power dynamics, and gender-based violence), and to promote equitable global enrolment of women in cure-related research to ensure the safe and ethical inclusion of those in need of effective interventions.<sup>22</sup> As cure-related research scales up globally, additional structural considerations related to cost-effectiveness, ethics, and infrastructure will require attention, necessitating sustained community engagement.<sup>23</sup>

#### **HIV prevention and pregnant and lactating people**

Uptake of PrEP by cisgender and transgender women is increasing globally (although robust data are not available for gender diverse people), but remains suboptimal to end the HIV pandemic.<sup>24–26</sup> Racism, discrimination, and HIV stigma are identified barriers for PrEP access for women and gender diverse people.<sup>24,25</sup> Globally, where gender data of PrEP users are available, data suggest that women account for approximately 60% of PrEP users.<sup>27</sup>

In sub-Saharan Africa, women and girls face a high likelihood of HIV acquisition during pregnancy, in the postpartum period, and while breastfeeding or chestfeeding. For example, South Africa's estimated HIV incidence among women is 4.51 per 100 person-years,<sup>28</sup> with an estimated maternal HIV incidence of 3.3 per 100 person-years.<sup>29</sup> Acute maternal HIV infection is associated with significantly increased likelihood of perinatal HIV transmission, contributing to the majority

of infant HIV acquisitions and making primary prevention of HIV among pregnant and lactating people an urgent global health priority.<sup>30</sup> Scaling up PrEP—with emphasis on access and uptake among pregnant and lactating people—could increase progress to the 2025 UNAIDS targets of reducing new HIV infections to under 375 000 and eliminating perinatal transmission.<sup>31</sup>

Given the high HIV incidence in southern and eastern Africa among people who are pregnant and breastfeeding or chestfeeding, effective interventions to prevent HIV acquisition during these periods have substantial potential benefits. HIV counselling and testing, risk reduction counselling, and promoting condom use for pregnant people during antenatal care have proven to be insufficient to address HIV acquisition during pregnancy and lactation.<sup>10</sup> PrEP is an effective HIV prevention strategy that WHO recommends offering to pregnant and postpartum people who are behaviourally susceptible to HIV acquisition as a person-controlled prevention strategy.<sup>32</sup> A 2022 review found no safety-related rationale to prohibit PrEP during pregnancy or lactation.<sup>33</sup> The use of oral PrEP is increasing among pregnant and lactating people with successes in Kenya, Zimbabwe, and demonstration sites in South Africa. A 2019 mathematical model found that meeting the unmet need for PrEP in pregnant and breastfeeding or chestfeeding people could help avert more than 90 000 maternal and infant HIV infections in South Africa over the next decade.<sup>34</sup>

Innovative, community-led, and well resourced strategies are needed to optimise and implement PrEP among pregnant, breastfeeding, or chestfeeding people. PrEP persistence and adherence are low among women in southern and eastern Africa, with specific barriers identified for those who are pregnant, breastfeeding, or chestfeeding. The effectiveness of PrEP depends on the ability of individuals to effectively access, adhere to, and maintain available PrEP options. A global systematic review and meta-analysis that included more than 24 000 participants found that women had lower adherence to PrEP than men (31% among women vs 71% among men) and younger populations (aged <30 years) had lower adherence to PrEP than older populations (35% among people <30 years vs 70% among people ≥30 years).<sup>35</sup> In-depth interviews with postpartum women who had poor PrEP persistence in a South African cohort study revealed that more than 90% perceived themselves as at high risk of HIV acquisition and wanted to continue taking PrEP, but they expressed key barriers to continued use.<sup>36</sup> Those who were pregnant and breastfeeding or chestfeeding referenced pill burden, side-effects, and challenges of PrEP use disclosure to family members and partners as barriers affecting adherence.<sup>37</sup>

Long-acting injectable PrEP is a promising strategy for cisgender and transgender women and girls, transgender

men and boys, and gender diverse people. Long-acting injectable cabotegravir (CAB-LA), an integrase inhibitor administered via intramuscular injection every 8 weeks to prevent HIV, has shown high efficacy, safety, and superiority over available oral PrEP options in global cohorts of both men and women.<sup>38</sup> CAB-LA reduced risk of HIV infection by 89% compared with daily oral emtricitabine and tenofovir disoproxil fumarate in a cohort of cisgender women in sub-Saharan Africa.<sup>38</sup> Preliminary data show that CAB-LA is well tolerated during pregnancy and the postpartum period, has a similar pharmacokinetic profile among pregnant and non-pregnant people,<sup>39</sup> and shows no substantial increases in adverse pregnancy or birth outcomes, including neural tube defects.<sup>40</sup> The potential for detectable concentrations of CAB-LA for 1 year or longer following administration of the last dose (pharmacokinetic tail)<sup>38</sup> suggests the need for ongoing, rigorous monitoring for HIV seroconversion and possible development of ART drug resistance.<sup>41</sup>

The 2023 regulatory approval of CAB-LA in South Africa and Zimbabwe, with ongoing review in other countries, underscores the need for community engagement and implementation strategies specific to pregnant and breastfeeding or chestfeeding people.<sup>42</sup> However, access remains a barrier to CAB-LA use, along with other structural and facility-based factors (eg, need to return to the clinic every 2 months for injections) and individual-level factors (eg, personal fear of injection).<sup>38</sup> Despite—or due to—these barriers, there is a strong rationale for expanding PrEP options for women and gender diverse people, particularly for long-acting antiretrovirals with proven safety, effective prevention benefit, and interest among women, especially for young people, women with caregiving responsibilities, and other groups.<sup>43</sup>

### Substance use and HIV

Substance use increases vulnerability to adverse health, social, and behavioural outcomes, is highly prevalent among people with HIV,<sup>44</sup> and is more common among women with HIV than women without HIV.<sup>45</sup> In the USA, an estimated 29% of women living with HIV acquired it through injection drug use, and an additional 15% acquired it through sexual intercourse with a person who injects drugs.<sup>45</sup> Global data suggest a high prevalence of alcohol or other substance use and misuse among women with HIV, including in South Africa,<sup>46</sup> Tanzania,<sup>47</sup> Uganda,<sup>48</sup> Peru,<sup>49</sup> and India.<sup>50</sup> These prevalent and persistently high rates of substance use and misuse underscore the importance of integrating substance use treatment with the prevention and management of HIV.

In the US context, evidence suggests substance use treatment can be effective in reducing behavioural vulnerability to HIV acquisition through increasing needle exchange and decreasing injection drug use.<sup>51</sup> Programmes that integrate HIV and substance use treatments might be more successful at reducing HIV transmission than those focused on substance use alone.

Data from the USA suggest that, overall, women with HIV are less likely to begin substance use treatments than women without HIV, with variation depending on specific substances.<sup>52</sup> Although evidence continues to show the success of addressing behavioural vulnerability associated with HIV acquisition and drug use concurrently, access to substance use treatments remain a challenge for many women in the USA, especially marginalised groups. In particular, geographical access poses a substantial barrier to substance use treatment participation and adherence.<sup>53</sup>

Although most research has focused on the USA, a systematic review of the integration of HIV and substance use services found that care integration, including colocation of treatment for HIV and substance use, can benefit patients.<sup>54</sup> The possibility of simultaneously reducing substance use and HIV acquisition among women is a promising and cost-effective use of resources and underscores the importance of taking a comprehensive person-centred approach to HIV that accounts for the complexity of lived experience. Global evidence suggests that person-centred care has the potential to engage diverse populations, including diverse populations of women, and improve outcomes.<sup>55</sup>

### Intimate partner violence

The experience of IPV, defined as physical (eg, slaps or assault with a weapon), sexual (eg, rape or forced sex), or psychological (eg, belittling or intimidation) violence perpetrated by a current or former partner or spouse, has been substantially associated with HIV acquisition among women.<sup>56</sup> Available data indicate that 36–55% of women with HIV experience IPV, although there is scarce data from African settings and low-income and middle-income countries.<sup>57</sup> Data from sub-Saharan Africa suggest that women with a lifetime history of IPV are three times more likely to acquire HIV,<sup>16</sup> and longitudinal work in Uganda shows a 1.5 times higher incidence of HIV infection for women who have experienced IPV compared with women who have not.<sup>58</sup> Forced sex or sexual IPV (ie, condomless sex via physical force, coercion, or threat) with a partner with HIV directly links HIV acquisition to IPV.<sup>59</sup> Indirect associations occur at biological (eg, chronic stress response, chronic inflammation, and immune dysfunction), behavioural (eg, individual and perpetrator sexual and drug-related risk behaviours), and societal (eg, social norms and gender power imbalances) levels.<sup>59</sup> Conversely, IPV can be a consequence of HIV infection, with a review finding considerable disclosure-related risk of HIV for women in sub-Saharan Africa.<sup>60</sup> Although most studies focus on US settings, some global data support the idea that IPV interferes with women's engagement and adherence to HIV care and is associated with lower ART use, self-reported ART adherence, and viral suppression.<sup>61</sup>

Most IPV interventions target individual factors (eg, IPV screening and risk identification, safety



planning, skills building related to condom use, and safer sex negotiation), followed by interpersonal factors (eg, couples communication and reduced alcohol use within couples).<sup>62</sup> Few interventions focus on structural drivers of IPV and HIV (eg, criminalisation of drug use or sex work, structural racism, and income inequality) across key populations or address community factors, such as neighbourhood segregation and culturally tailored services (eg, youth-friendly combination IPV screening, safety planning, referrals, and integrated HIV care). In addition, the accumulation and different types of violence and traumatic experiences and their contexts can vary by key population subgroups.

Evidence from the USA suggests that the most effective strategies to address IPV are integrated in clinical and community-based organisation spaces.<sup>62</sup> Implementation research approaches to evaluate the efficacy, scale-up, and cost-effectiveness of different strategies can advance a coordinated response to HIV and violence against women. These approaches should be geography-specific and target specific populations to achieve maximum reductions in HIV-related outcomes, IPV, and other forms of gender-based violence. Data from the USA support trauma-informed care or healing-centred engagement as a path forward for responding to IPV and HIV.<sup>63</sup>

### Multimorbidity

Multimorbidity, the co-occurrence of two or more chronic conditions, is common across the lifespan, although cisgender women have a greater risk of multimorbidity than cisgender men in the general population—a sex difference that is exacerbated among people with HIV.<sup>64</sup> Given the substantial individual and public health effects of multimorbidity burden, including affected quality of life and functional status, premature mortality, and increased health-care use and cost, evidence-based screening and prevention initiatives are needed for people with HIV and potentially at an earlier age than people without HIV. To date, most risk assessment tools are limited by their focus on singular conditions (such as cardiovascular or fracture risk scores) and their inaccuracy among people with HIV, particularly women and young individuals.<sup>65,66</sup> Development of innovative, HIV-specific, sex-tailored tools and strategies that holistically assess and mitigate the risk of ageing-related multimorbidity development and progression are urgently needed.

Granular data on multimorbidity from low-income and middle-income countries is generally unavailable. Moreover, assessment tools for common conditions might be inappropriate or unvalidated for settings in these countries. For example, a cross-cultural screening test for dementia, developed for use in both industrialised and resource-limited settings, produced a 90% false-positive rate when applied to a longitudinal cohort study in Africa.<sup>67</sup> For some conditions, normative reference

values are unavailable for specific populations. For example, studies of osteoporosis often use WHO T-score thresholds based on the National Health and Nutrition Examination Survey (NHANES) non-Hispanic White population.<sup>68</sup> In a study in Zimbabwe, bone mineral density values for Black Zimbabwean women were closer to that of US White women than those of US Black women when the NHANES data were used as a comparator.<sup>69</sup> Similarly, in a study comparing Ugandan women aged 18–35 years with untreated HIV and without HIV, an analysis using NHANES reference ranges identified a higher prevalence of osteoporosis among the women with HIV (93 [20.6%] of 452) than those without HIV (6 [8.7%] of 69), respectively, at the same Z-score cut off.<sup>70</sup>

In the era of ART, morbidity and mortality among people with HIV are increasingly due to ageing-related chronic conditions, such as cardiovascular, kidney, and neurocognitive disease.<sup>71</sup> People with HIV have a higher prevalence and decade-earlier onset<sup>72</sup> of ageing-related comorbidities than people without HIV, even though initial studies substantially under-represented female participants (range 12–21%).<sup>73</sup> Data from enrolment to April, 2019, from the Multicenter AIDS Cohort Study and the Women's Interagency HIV Study—an ageing cohort of men and women with and without HIV—revealed that overall burden of ten ageing-related comorbidities was significantly higher in women with HIV than men with HIV (3.4 vs 3.2;  $p=0.015$ ), particularly compared with people without HIV (3.0 in women vs 3.0 in men;  $p=0.37$ ).<sup>64</sup> Furthermore, distribution of comorbidities significantly differed by sex, with women having an overall higher prevalence of diabetes, bone disease, and lung disease than men.<sup>64</sup>

Cancer is a substantial source of morbidity for people with HIV. Despite availability of human papillomavirus (HPV) vaccine as primary prevention of cervical cancer since 2006, cervical and other HPV-related malignancies remain common in low-income and middle-income countries.<sup>74</sup> In Africa, age-standardised incidence of cervical cancer is 27.1 per 10000 people (double that of any other geographical region) and the mortality rate is six times higher than in the USA.<sup>75</sup> Comorbidities are aptly termed the lingering challenge for the estimated 38.4 million people with HIV living in the world in 2021, of which 54% were women and girls.<sup>71</sup>

Risk assessment of comorbidities in women with HIV should ideally integrate evaluation of both traditional (eg, age, BMI, and substance use) and HIV-related factors,<sup>76</sup> such as cumulative HIV-1 non-suppression despite ART use.<sup>77</sup> Additional research is needed to ascertain the age at which risk assessments and interventions should be initiated among women with HIV, and how sex-associated and gender-associated factors could be considered in screening and prevention strategies. These factors include menopausal status, inflammatory burden (higher in women on ART than in

men on ART at any given HIV-1 viral load), and social determinants of health (often over-represented among women, particularly women with HIV).<sup>78</sup>

### Ageing and older women

People with HIV who have access and adhere to ART have an average life expectancy ranging from 70 years to 80 years.<sup>72</sup> The most recent data (2020) from the US Centers for Disease Control and Prevention estimated that more than 50% of people with HIV in the USA were aged 50 years or older,<sup>79</sup> and modelling work in the Netherlands indicates that by 2030 this proportion will increase to equal to or greater than 70%.<sup>80</sup> In high-income countries, estimated life expectancy among people with HIV varies on the basis of geography, CD4 count at time of ART initiation, HIV acquisition route, race, sex, and gender, among other factors.<sup>81</sup> In low-income and middle-income countries, 23% of the US President's Emergency Plan for AIDS Relief (PEPFAR) population was older than 50 years in 2023; this proportion is expected to grow. Women outnumber men in every age band supported on ART by PEPFAR. Yet, despite the increasing proportion of older women with HIV, data on menopause among women with HIV is insufficient, including how menopause transition affects the health of women with HIV.<sup>82</sup>

Among people living with HIV, the dramatic gains in longevity enabled by ART are lower for cisgender women (data are scarce for transgender and gender diverse individuals) and cisgender women with HIV have more years of life lost compared with cisgender men with HIV and with the general population.<sup>81</sup> The multifactorial reasons for this gap probably include biological and social factors, such as delayed HIV diagnosis, increased disease progression, and decreased access to or use of quality HIV care, including ART.<sup>83</sup> Additional research among people with HIV is needed to elucidate sex-differential and gender-differential factors contributing to disparities in mortality rates and lifespan, including quality of life and functional status among women and men.

Additionally, although individuals with HIV worldwide have higher rates of ageing-related comorbidities than those without HIV, distribution of geriatric conditions for people with HIV in Africa remains unclear and understudied. Rates of common comorbidities are high in people older than 50 years, disease burden of non-communicable diseases is rising in Africa, and the number of years of life lost due to premature death and years lived with a disability are rising.<sup>84</sup> Cause of death data collected by the South African Government show that, as of 2023, non-communicable diseases have overtaken infectious diseases as leading causes of reported deaths.<sup>85</sup>

Structural barriers constrain the complex clinical management of older adults with multiple chronic conditions, including HIV. Specialty care is often siloed,

with clinics focused on care of diabetes, cardiovascular disease, and other common ageing conditions separated from those that focus on HIV management. In PEPFAR-supported programmes, all ART is free and care is provided without user fees, in contrast to other medical illnesses or non-communicable diseases in which the supply chains for drugs and diagnostics are often complex, irregularly available, and expensive.<sup>86</sup> Integrated models of care have been recommended and efforts are under way to explore how best to implement different models.

Investments to expand and apply the field of geroscience—the intersection of ageing biology, chronic disease, and health—to the context of HIV will allow for the refined and harmonised evaluation of sex and gender differences in drivers of multimorbidity and other conditions associated with ageing, as well as biomarkers to guide treatment and prevention interventions. Efforts are needed to build integrated health systems that foster multidisciplinary care of ageing women with HIV, emphasise women's health needs across the lifespan, and that develop and sustain the capacity of the HIV health-care workforce trained in ageing conditions and care.

### Future directions

Rigorous exploration of—and interventions for—individual, social, biological, structural, and environmental factors that influence HIV prevention, transmission, treatment, and cure is crucial to advance research of relevance for cisgender and transgender women and girls, transgender boys and men, and gender diverse people across the lifespan. The Women & HIV Symposium: Considerations From Across the Lifespan was an important first step towards this goal. To further ensure accountability to the communities the NIH serve, NIH OAR and ORWH published a request for information<sup>87</sup> to elicit public input on a preliminary set of gaps, opportunities, and research approaches of relevance to women, girls, and gender diverse individuals (panel 2).

Much of the research highlighted here focuses on cisgender women and girls in the US context. Although these data have been essential to drive NIH programmatic activities, it remains imperative to ensure that robust, inclusive, and rigorous efforts are made to address gaps in existing data, including the scarcity of research centred on transgender and gender diverse individuals and women from under-represented and understudied populations and contexts (eg, the ORWH Understudied, Underrepresented, and Underreported programme).<sup>88</sup> Additional opportunities to support a data-driven approach to HIV and women include appropriate use of sex and gender terminology and adherence to existing NIH and journal policies on sex and gender data collection and reporting.

The March, 2024 scientific workshop Centring the Health of Women in HIV Research will explore the

For the US President's  
Emergency Plan for AIDS Relief  
see <https://data.pepfar.gov/library>

### Panel 2: Preliminary topics and research approaches of relevance to HIV and women

- Access to HIV prevention, including pre-exposure prophylaxis and multipurpose technologies
- Behavioural and social science research
- Community-led research
- Comorbidities and multimorbidity in women
- Early childhood consequences of HIV exposure
- Gender-affirming and trauma-informed HIV care and research
- Gender-based violence and intimate partner violence
- HIV and ageing, including opportunities for future research during menopause
- HIV prevention research focused on social, behavioural, and structural risk factors (eg, child maltreatment, trauma, mental illness, stress, and alcohol and substance misuse)
- Implementation science research
- Role of sex and gender in HIV cure-related research
- Sex and gender considerations related to polypharmacy, and drug–drug interactions
- Structural factors influencing HIV prevention, treatment, and outcomes
- Treatment and prevention during pregnancy, lactation, and the postpartum period
- Unique considerations for long-term survivors

breadth of research considerations affecting women and girls, transgender boys and men, and gender diverse people. The workshop planning has been equity-informed: the planning committee includes community members who contributed to the agenda development and speaker selection, each workshop session features community perspectives, and the 2-day virtual event will be archived via NIH videocast to ensure wide reach and global access. Meaningful engagement of affected communities is a key principle of equity-informed research and we invite continued engagement and ongoing discussion.

The NIH OAR and ORWH look forward to centring intersectionality, data, and equity as pillars of this new collaboration on women and HIV in 2024, and beyond. We are grateful to the communities of women who live with and are affected by HIV who have advocated tirelessly for these issues. Each member of the health research ecosystem—federal partners, funders, journal editors, health sciences researchers and clinicians, industry, advocates, and community members—plays a role in advancing this agenda. The time is now to ensure cisgender and transgender women and girls, transgender men and boys, and gender diverse people are centred in the NIH research agenda to prevent, treat, and cure HIV so that clinical care and outcomes can be advanced for all, at all stages of the lifespan.

### Contributors

EB and LJM conceptualised this Position Paper. EB, LJM, LFC, CG, NSV, JKS, DLJD, and KD wrote the original draft. EB, LJM, SMT, MTG, and CB reviewed and edited the manuscript. JAC and MMG supervised the development, writing, and revision of the manuscript. EB and LJM contributed equally to this Position Paper.

### Declaration of interests

We declare no competing interests.

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