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HIV and women in the USA: what we know and where to go from here

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New diagnoses of HIV infection have decreased among women in the USA overall, but marked racial and geographical disparities persist. The federal government has announced an initiative that aims to decrease the number of new infections in the nation by 90% within the next 10 years. With this in mind, we highlight important recent developments concerning HIV epidemiology, comorbidities, treatment, and prevention among women in the USA. We conclude that, to end the US HIV epidemic, substantially greater inclusion of US women in clinical research will be required, as will better prevention and treatment efforts, with universal access to health care and other supportive services that enable women to exercise agency in their own HIV prevention and care. Ending the epidemic will also require eliminating the race, class, and gender inequities, as well as the discrimination and structural violence, that have promoted and maintained the distribution of HIV in the USA, and that will, if unchecked, continue to fuel the epidemic in the future.

Introduction

Powerful social, economic, political, and structural forces promote and maintain the demographic and geographical distribution of HIV among women in the USA.¹ Laws, government policies, and influence groups restrict the electorate,^{2,3} resulting in reduced access to HIV prevention and care (eg, by limiting sex education, restricting the reproductive rights of women, and thwarting attempts to expand health insurance coverage).¹ Mass incarceration, poverty, racism, homophobia, gender norms, and inequity reinforce each other's effects and work together to promote sexual network patterns that spread HIV.⁴ Stigma and violence against women further exacerbate these effects. These forces are among those that increase the susceptibility of cisgender women (cis women) and transgender women (trans women) to HIV infection, worsen their health outcomes, and increase their mortality. In early 2019, the US Department of Health and Human Services announced its goal of reducing incident HIV infections by 90% within 10 years.⁵ With this goal in mind, we outline some important features of the current HIV epidemic among women in the USA and make recommendations for addressing them.

The significance of race and place

At the end of 2016, adult and adolescent women comprised almost a quarter (23·7% or 235004 individuals) of all people diagnosed and living with HIV in the USA.⁶ The US Centers for Disease Control and Prevention (CDC) estimates that an additional 11% of women with HIV were unaware of their infection.⁷ Although 50% of 7401 new cases among women reported in 2017 occurred in women between the ages of 25 and 44 years, new diagnoses occurred among women of all ages, with 14% of these women aged 13–24 years and 16% aged 55 years and older.⁷ Rates of new diagnoses among

women have declined during the past few years (by 21% in 2010–16), with substantial decreases among Black (by 25%) and Hispanic (by 20%) women, and greater declines among Black women born in the USA than among those who were born outside the USA.^{7,8} Nevertheless, stark racial disparities in the incidence and prevalence of HIV infection persist between women of colour and White women in the USA. HIV prevalence per 100000 individuals is 800·9 among women who identify as Black, 442·7 among women who identify as being from multiple races, 191·4 among women who identify as Hispanic, and 77·8 among women who

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Key messages

- Almost a quarter of all people diagnosed with HIV in the USA are women; the incidence of HIV diagnoses has declined among women in the USA overall, but marked racial and geographical disparities persist
- HIV suppression among women varies by region and, within regions, by race; these differences reflect women's access to care, social and economic forces, and the adequacy and distribution of public health efforts and resources, which in turn result from political and economic decisions
- Distinct subgroups of women with HIV are present in the USA, including those who are of reproductive age, older women, or transgender women; each subgroup has unique experiences, challenges, and types and distributions of comorbid conditions
- Among the most frequent and severe comorbid conditions among women with HIV in the USA are those associated with ageing, including obesity, cardiovascular disease, and neurocognitive impairment
- All clinical trials for prevention and treatment of HIV infection should enrol women, including US women, in sufficient numbers to permit meaningful analysis by sex and gender
- Ending the HIV epidemic among women in the USA will require universal access to health care, housing, and other supportive services, and will also require eliminating the race, class, and gender inequities, and the discrimination and structural violence, that have promoted and maintained the disparate distribution of HIV in the USA

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Search strategy and selection criteria

We searched PubMed and Embase on Aug 31, 2019, for English language manuscripts published between Jan 1, 2010, and Aug 30, 2019, focusing on the HIV epidemic among cisgender and transgender women in the USA. Search strategies were based on a combination of controlled vocabulary, including medical subject headings (MeSH) and related keywords. We searched for the keywords “women”, “transgender women”, and related commonly used terms, in combination with “HIV” in MeSH, “human immunodeficiency virus” in MeSH, and “United States” or “US”. We focused on publications from the past 5 years but did not exclude commonly referenced and highly regarded older publications. We reviewed additional references from seminal articles to ensure that important contributions were not inadvertently excluded.

identify as American Indian or Alaskan Native, compared with 45.3 among White women.⁶ In fact, the CDC estimates that 3900 (93%) of the 4200 new infections reported among Black women in 2016 would not have occurred if HIV incidence among Black and White women were the same.⁹ The US South, with 38% of the nation’s population,¹⁰ accounts for a disproportionate number of infections among women. Of 236589 women with HIV residing in the 50 US states and Washington, DC at the end of 2017, 50% lived in the South and 29% in the northeast, whereas much lower proportions lived in the west and midwest.¹¹

Strong links exist between race, poverty, and HIV in the USA. Among heterosexual women who did not inject drugs and lived in census tracts with a high prevalence of poverty in 23 US cities, HIV prevalence was 2.2%, which is 20 times greater than in heterosexual women and men in the general US population.¹² HIV prevalence in these areas of high poverty did not differ substantially by race or ethnicity, suggesting that poverty probably accounts for some of the racial disparities in HIV prevalence, given that 46% of Black women and 40% of Hispanic women live in poverty, compared with 10% of White women.¹²

Most women (86%) with a newly diagnosed HIV infection in 2017 acquired the infection from sex with men,⁷ and the CDC estimates that more than 50% of infections among women between 2010 and 2015 were acquired from sexual contact with men with a previous diagnosis of HIV infection.¹³ Changing sexual practices might contribute to ongoing HIV transmission among women. The percentage of US women who report anal sex has increased over time, and mathematical models estimate that almost 40% of infections among women aged 18–34 years in 2015, who did not inject drugs, were attributable to anal sex.¹⁴ HIV incidence among women who inject drugs has remained stable. However, the HIV outbreak in 2014–15 in a small Indiana county, precipitated

by an epidemic of injection drug use, highlights the potential for rapid spread within communities where HIV prevalence was previously low, including the potential for spread to women who do not inject drugs.¹⁵

Viral suppression also varies by region and, within regions, by race. HIV plasma viral load not only determines health outcomes of women with HIV, but also reflects their access to care and the adequacy and distribution of public health efforts and resources, which in turn result from political and economic decisions. As of 2015, only 58% of women who were diagnosed and living with HIV in the USA had achieved viral suppression.¹⁶ To date, women have been less likely than men to sustain viral suppression over time and have a higher cumulative plasma viral burden (viraemia over time).^{17,18} Women aged 60 years and older were more likely to achieve viral suppression (64.4%) than women aged 20–29 years (46.1%).¹⁶ The prevalence of viral suppression varies by race and ethnicity, with Black women (55.5%) less likely to achieve viral suppression than Hispanic (61.6%) and White (59.6%) women.¹⁶ Moreover, the overall proportion of women with viral suppression was lower in rural areas (55%) than in metropolitan (59%; population of 50000–499000) or metropolitan statistical areas (58%; population of more than 500000); these geographical disparities were observed for Black and Hispanic women, but not for White women.¹⁶ Social forces clearly help drive the distribution of HIV infection and HIV health outcomes among women in the USA.

Diversity among women

Distinct subgroups of women with HIV are present in the USA, and each group has unique experiences and challenges.

Trans women

Trans women, who comprise about 0.28% of the US population,¹⁹ have a lower socioeconomic status than cis individuals, with lower educational attainment and higher levels of poverty and housing instability.^{20,21} The intersectional issues faced by cis women are compounded for many trans women. Multilevel stigma and discrimination, psychological trauma, gender power dynamics, violence, and decreased occupational opportunities increase the risk of HIV acquisition for trans women.¹⁹ Thus, the estimated HIV prevalence is substantially higher among trans women (14%) than among cis women (less than 1%)⁶ in the USA, and marked racial disparities are apparent (among trans women, HIV prevalence is 44.2% among Black women, 25.8% among Hispanic women, and 6.7% among White women).²² However, many trans women are unaware of their infection; more than half (51.4%) of seropositive Black trans women in a study in six US cities had not been diagnosed.²³

About 1.3% of adults who are HIV-seropositive and who are receiving medical care in the USA are

trans women.²⁰ Although estimates of the prevalence of viral suppression among trans women vary, the available data suggest that the prevalence of suppression in trans women (80%) is somewhat lower than that in cisgender women (83%) and cisgender men (87%).²⁴ In addition to mistreatment in the health-care system, trans women often receive inadequate transgender-related medical care.^{21,25} Unmet needs for social, legal, and medical gender affirmation (eg, through feminising hormone therapy [FHT]) decrease the ability and willingness of trans women to engage in HIV care and have been associated with antiretroviral therapy (ART) interruption.²¹ A survey of trans women with and without HIV in Los Angeles, CA, USA, showed that 64% of all trans women used FHT, including 66% of those with HIV. Only half (49%) of trans women had discussed potential interactions between ART and FHT with their health-care providers, and a substantial proportion (40%) reported not taking FHT, ART, or both, as directed because of concerns about potential interactions.²⁶

Few studies address interactions between FHT and ART.²⁷ One study showed that the rectal tissue ratio of tenofovir diphosphate (the active metabolite of tenofovir disoproxil fumarate) to deoxy-ATP (the competing deoxynucleotide) was seven times lower among trans women who used FHT than among cis women and men, and the ratio inversely correlated with oestradiol concentrations.²⁸ This study raises questions about interactions between drugs, with implications for both ART and pre-exposure prophylaxis (PrEP) among trans women who use FHT.

Women of reproductive age

Women with HIV have diverse pregnancy intentions.²⁹ At least a third of women initiating ART in one study reported a desire to have children in the future, emphasising the need for comprehensive reproductive services.³⁰ The approach of providers to reproductive care often focuses exclusively on contraception and does not always meet the needs of women with HIV who require comprehensive reproductive care, including discussion of sexual health and fertility desires, choice of effective contraception, abortion counselling, and preconception planning.²⁹

About 5000 women with HIV in the USA give birth each year.³¹ Although combination ART has reduced the risk of perinatal HIV transmission to less than 1% in the USA, concerns have been raised about associations, mainly observed outside the USA, between use of ART by pregnant women and adverse birth outcomes, such as preterm delivery.³² A slightly increased prevalence of neural-tube defects was observed among infants of women in Botswana who took dolutegravir at conception.³³ These issues highlight the need for high-quality data on drugs used during conception and pregnancy and good surveillance systems with broad population coverage to monitor pregnancy outcomes.^{34,35}

For many pregnant women, protecting the fetus from HIV infection is a powerful incentive for maintaining adherence to ART. But the post-partum period, with the associated responsibilities of caring for a new infant, challenges the ability of many women with HIV to remain in care. A study of 141 pregnant women with HIV in a prospective university cohort in southeastern USA from 1996 to 2014 revealed that, although 74% showed viral suppression at delivery, only 48% of the women were retained in care and only 25% still showed viral suppression 24 months after delivery. Older mothers and those who had viral suppression at delivery were most likely to have viral suppression at 24 months.³⁶ US perinatal guidelines recommend that women with HIV avoid breastfeeding because of the risk of HIV transmission to the child, but 29% of providers surveyed across the USA reported that their patients continued to breastfeed despite these recommendations, often because of the stigma associated with formula feeding and the possibility of unintentional disclosure of HIV status by formula feeding.³⁷

Older women

Almost half (47%) of people diagnosed with HIV in the USA are aged 50 years or older. Among people with new HIV diagnoses in this age group in 2016, 24% were women with heterosexually transmitted HIV.³⁸ Many older women have the same risk characteristics as younger women, and older women who no longer worry about pregnancy might be less likely to use condoms and other HIV prevention measures.³⁸ Physiological changes might increase risk of HIV acquisition as well. Postmenopausal women have dryness and thinning of the vaginal epithelium, with more HIV immune target cells than premenopausal women.³⁹ Compared with premenopause, menopause is associated with less anti-HIV innate immune activity in the lower female genital tract.⁴⁰

HIV and other health issues

People with HIV experience many comorbidities that reflect concomitant biological, psychological, and social structural factors in their lives. In the following sections, we highlight a few comorbidities with particular significance for women, especially older women.

Obesity

The prevalence of obesity and overweight has increased among all races and ethnicities in the USA. ART initiation is associated with weight gain, some of which has been regarded as a reflection of improved health.⁴¹ From 1998 to 2008, mean body-mass index (BMI) was lower among people with HIV initiating ART in the USA and Canada than among individuals in the general population, but 3 years after starting ART, the mean BMI of people with HIV increased and became equal to (or exceeded, in the case of White women with HIV) the

mean BMIs of their counterparts in the general population.⁴² Studies of weight gain have focused concern on specific classes of antiretroviral drugs. Integrase inhibitors, especially dolutegravir, have been associated with weight gain among individuals who are initiating ART and among those changing type of ART whose plasma viral loads are suppressed.^{43,44} Some studies have shown more pronounced weight gain among women and Black people with HIV than among the general population with HIV.⁴⁵ South African women who took tenofovir alafenamide and emtricitabine combined with dolutegravir showed even greater weight gain (10 kg) over the course of 96 weeks than those who took either tenofovir disoproxil fumarate and emtricitabine combined with dolutegravir (5 kg) or tenofovir disoproxil fumarate and emtricitabine combined with efavirenz (3 kg).⁴⁶ The mechanisms through which these antiretroviral agents result in weight gain remain unclear, but the implications of weight gain for common comorbidities, such as diabetes, hypertension, and cardiovascular disease, are concerning.

Mental health disorders and neurocognitive impairment

Psychiatric disorders are common among people with HIV in the USA. Among participants in the Medical Monitoring Project, a nationally representative sample of patients receiving care for HIV infection in the USA, the estimated prevalence of depression in the 2 weeks preceding the survey was 23%; 12% of survey respondents had major depression.⁴⁷ Depression, which is common among women in the general population, is even more prevalent among women with HIV. Among 1027 women with HIV in a large multisite cohort, the lifetime prevalence of depression was 32% and the 12-month prevalence was 20%, compared with a lifetime prevalence of 23% and 12-month prevalence of 10% among US women in general.⁴⁸ Depression is strongly associated with non-adherence to ART.⁴⁹ The effect of depression on neurocognition appears to differ by sex; depression is a stronger predictor of impaired executive function among women with HIV than among men with HIV.⁵⁰ Moreover, the duration of depression predicts both virological failure and mortality among women.^{51,52}

HIV-associated neurocognitive impairment is most common among women with evidence of more advanced HIV disease, although the degree of impairment is usually small.⁵³ Moreover, impairment persists despite plasma viral suppression.⁵⁴ Compared with men with HIV, women with HIV in the USA might be more susceptible to HIV-associated neurocognitive impairment because of the higher prevalence of factors that adversely affect the brain and cognitive reserve, such as low education, substance use, and depression.⁵⁵ However, women with HIV have higher odds of impairment than their male counterparts, even after adjustment for age, race, and education.⁵⁶ The pathophysiology of neurocognitive damage is unclear

but might be associated with the previously mentioned sociodemographic factors, adverse cognitive effects of commonly used non-antiretroviral medications, and persistence of HIV-infected cells in cerebrospinal fluid.^{54,57,58}

Cardiovascular disease

Cardiovascular disease has emerged as a comorbidity of major concern for older women with HIV. Among the 2187 women in the Veterans Cohort Study,⁵⁹ the risk of cardiovascular disease (ie, acute myocardial infarction, unstable angina, ischaemic stroke, and heart failure) in women with HIV was almost 3 times higher than in HIV-seronegative women (hazard ratio 2.8).⁵⁹ Women with HIV also have increased risk of ischaemic stroke (hazard ratio 1.89), even after adjustment for demographic factors, traditional stroke risk factors, and sex-specific risk factors, such as menopause status and oestrogen use.⁶⁰ HIV infection is associated with an increased risk of incident heart failure among women,⁵⁹ and women with HIV in a US health-care system-based cohort had increased rates of hospitalisation for heart failure and all-cause cardiovascular mortality.⁶¹ The pathophysiology that drives this increased risk has not been completely elucidated, but might relate, in part, to increased immune activation due to HIV.⁶² Cardiac imaging has shown that women with HIV were more likely to have myocardial fibrosis, decreased diastolic function, and elevated markers of immune activation with resultant inflammation.⁶³ The relative risk of both myocardial infarction and stroke is greater among women with HIV than among men with HIV—an observation that some people have attributed to sex-based differences in immune mechanisms,⁶⁰ given that women generally mount stronger immune responses than men.⁶⁴ As in other morbidities, gender inequities in care have been reported: compared with men with HIV in the Data Collection on Adverse Events of Anti-HIV Drugs cohort (a combination of cohorts in Australia, Europe, and the USA), women were less likely to receive most interventions to prevent and treat cardiovascular disease (eg, lipid-lowering drugs, angiotensin-converting enzyme inhibitors, and invasive cardiovascular procedures), even after adjusting for cardiovascular risk.⁶⁵

Cure

Persistence of the HIV reservoir that harbours latent HIV in CD4 memory T cells in the peripheral blood and tissues has frustrated efforts to cure HIV infection. Research suggests that sex differences exist in HIV latency and the size of the HIV reservoir.⁶⁶ Oestrogen inhibits HIV transcription, and oestrogen receptor 1 has a key role in maintaining HIV latency. Ex-vivo administration of oestrogen inhibits T-cell receptor activation of transcription, whereas oestrogen-receptor antagonists enhance reactivation of latent HIV proviruses. Both of these effects are more pronounced in women than in men. Moreover,

the total inducible HIV RNA reservoir is smaller in women than men.⁶⁶ Another study identified sex differences in immune phenotype and HIV persistence among men and women of reproductive age on suppressive ART, with increased cell-associated HIV RNA, increased plasma HIV RNA, and greater programmed cell-death protein 1 expression and T-cell activation in men than in women.⁶⁷ These findings have important implications for HIV cure efforts and highlight the crucial need to include women in these studies.⁶⁷

Prevention: treatment-as-prevention and PrEP

Many studies have shown that sexual contact with people whose plasma HIV loads are undetectable does not result in HIV transmission.^{68–71} This recognition underpins the undetectable equals untransmittable initiative of the Prevention Access Campaign.⁷² This message has the potential to drastically decrease HIV-related stigma and improve the quality of life for women and men with HIV,⁷³ and should be widely and rapidly disseminated.⁷⁴

PrEP is the other major biomedical HIV prevention strategy. To date, the only PrEP agent approved by the US Food and Drug Administration (FDA) is daily oral tenofovir and emtricitabine. The efficacy of tenofovir and emtricitabine for PrEP among women has varied substantially in randomised controlled trials. In studies in African women, tenofovir and emtricitabine had no efficacy when adherence was low,^{75,76} but prevented 62–66% of infections in a study in which adherence was higher,⁷⁷ and 90% of infections among women whose plasma drug concentrations were consistent with high adherence.⁷⁷

The CDC has outlined recommendations concerning PrEP⁷⁸ and estimates that, of the 1144550 people in the USA who had indications for PrEP use in 2015, 176670 (15.4%) were heterosexual women.⁷⁹ Despite the expansion in PrEP use since 2012, uptake among women has been poor; only 3678 (4.7%) of the people who received PrEP in 2016 were women, and more White women used PrEP than Black women did.⁸⁰ Although the estimated annual percent of change in prevalence of PrEP use among US men increased by 68.1% from 2012 to 2017, use among women during the same period only increased by 5.4%.⁸¹

To date, a major reason for the slow uptake of PrEP by US women has been low awareness of this type of treatment.⁸² In a Rhode Island sexually transmitted disease clinic, only 77 (17%) of 446 women were aware of PrEP in 2016, and Hispanic (42 [11%]) and Black (33 [14%]) women were significantly less likely to be aware of PrEP than White women (127 [21%]). Only one (1%) of the 84 women who met CDC eligibility criteria had used PrEP.⁸³ Similarly, among 500 women surveyed at family planning clinics in Atlanta, GA, USA in 2017, only 18% were aware of PrEP,⁸⁴ and only 48 (21%) of 232 street-based female sex workers interviewed in Baltimore, MD, USA, between 2016 and 2017 were

aware.⁸⁵ Among 201 Black and Hispanic trans women in Baltimore and Washington, DC, interviewed between 2015 and 2017, PrEP awareness was high (174 [87%]), but only 30 (17%) of those who had heard of PrEP had ever used it; the most common reason for not using PrEP was concern about interactions between ART and FHT.⁸⁶

Studies have also revealed providers' low awareness of PrEP. A CDC review of factors affecting PrEP implementation for women in the USA suggests that, once informed about PrEP, women have generally been willing to use it and providers have been willing to prescribe it. Medication cost, stigma, and concern about potential side-effects are among barriers to PrEP use by women.⁸² Moreover, many women who begin taking PrEP discontinue its use. Among 7148 people who initiated PrEP through a large US pharmacy chain, only 84 (34%) women (compared with 3944 [57%] men) continued use for 1 year, and 49 (20%) continued for 2 years (compared with 2901 [42%] men).⁸⁷

The pharmacokinetics of tenofovir favour protection from rectal HIV acquisition more than vaginal acquisition. The active metabolite of tenofovir, tenofovir diphosphate, is 100 times more concentrated in colorectal tissue than in female genital-tract tissue. In addition, the competing host-cell endogenous nucleotides, deoxy-ATP and deoxycytidine triphosphate, are more concentrated in female genital-tract tissue than in colorectal tissue, a phenomenon that results in lower uptake of tenofovir diphosphate by female genital-tract cells and lower drug concentrations in those tissues, compared with colorectal tissue.⁸⁸ These characteristics require daily adherence to tenofovir and emtricitabine to protect against vaginal acquisition of HIV, and they limit forgiveness for non-adherence. Considerable interest in agents that provide long-acting protection against HIV is rising, as is interest in multipurpose technology for prevention of HIV infection, pregnancy, and in some cases, sexually transmitted infections other than HIV. If these new products are safe, effective, and appropriately publicised and marketed, women might be receptive to them. Surveys show that women have diverse preferences concerning the type of multipurpose technology: respondents in one survey of 829 US women reported their interest in using multipurpose technology in the form of injectables (46%), vaginal gels (34%), vaginal rings (26%), and diaphragms (17%).⁸⁹

Clinical trial designs present a barrier to the development and licensure of new products, especially those for women in the USA. The annual HIV incidence of 0.3% observed among US women at high risk for HIV acquisition⁹⁰ would require enrolment of 10000 participants in a randomised trial to show an efficacy of 44% for a new drug, when compared with a placebo.⁹¹ Moreover, an active control group would be required because the availability of tenofovir and emtricitabine for PrEP, with its demonstrated efficacy, renders a placebo group unethical in almost all settings. The low-effect size further inflates the necessary number of trial participants. These problems

demand new strategies for research design, such as bridging studies and other innovations to establish product effectiveness, and acceptance of these new strategies by regulatory agencies to permit drug licensure.^{91–93}

Recommendations

The pillars of the Ending the HIV Epidemic initiative include early diagnosis, rapid and effective administration of ART to maintain durable viral suppression, and use of PrEP to prevent HIV infection among people at high risk.⁵ Much of the approach involves ensuring effective implementation and scale-up of the strategies already available in the nation's considerable armamentarium for HIV prevention and care. We outline a number of issues that are particularly relevant to features of the HIV epidemic among US women.

Treatment: ensure sustained, high-quality health-care coverage

Implementation of the Affordable Care Act (ACA), which constitutes the biggest structural intervention for HIV prevention and care in the USA to date, greatly decreased the number of people in the country without health-care insurance, by 41% in 2013–16.⁹⁴ In addition to the many provisions for general health care and prevention, the ACA addresses several issues that are relevant to women living with or at risk of acquiring HIV, such as interpersonal violence. The ACA provides screening and counselling for interpersonal violence at no cost and ended some abusive practices of insurance companies, such as denial of insurance because of a history of interpersonal violence (as a pre-existing condition) and the setting of premium rates on the basis of a history of interpersonal violence.⁹⁵ Legislative attempts to undermine the ACA threaten women's health and the goal of ending the HIV epidemic.

Medicaid, the joint federal and state health insurance programme for people on low incomes, provides comprehensive prevention and care benefits, including PrEP and ART, and is an important source of health-care coverage for many women with HIV. However, about 10·2% of the US non-elderly population remains uninsured, in large part because of the refusal of some states to expand Medicaid.⁹⁴ Of the 12 states that had not expanded Medicaid by November, 2020, eight were in the South, where the prevalence of poverty and HIV infection among women is high.⁹⁶ Medicaid expansion in these states would substantially improve women's access to prevention and care and help end the HIV epidemic.

Prevention: improve integration of services and maintain the reproductive rights of women

Several federal and state policies are especially relevant to the health of women with and at risk of HIV infection. Family planning sites are an important entry point for reaching women and provide a range of prevention and care services, including PrEP, HIV testing, and

contraceptive services. Integration of family planning, reproductive health, and HIV prevention and care services has been recognised as being crucial for optimising clinical outcomes and achieving public health goals. Federal policy decisions that reduce access to these services compromise these goals.⁹⁷

Research: increase inclusion of women and enforce the requirement of the FDA for their enrolment in trials

Women have been consistently under-represented in research, given that they comprise more than 50% of people with HIV globally and more than 20% of people with HIV in the USA, and that sex differences have been reported in biological response to HIV and HIV treatment, immunological response, and pharmacokinetics.⁹⁸ One review from 2016 showed that women represented a median of 19% of participants in ART studies, 38% of participants in vaccination studies, and 11% of participants in cure studies.⁹⁹ All clinical trials for prevention and treatment of HIV infection should enrol women, including US women, in sufficient numbers to permit meaningful analysis. The FDA should require inclusion of women in all trials, not only for drug licensure but also for labelling new indications. Pregnant women should be included in drug trials to enable collection and analysis of sufficient, high-quality data on the use of these drugs during pregnancy, and appropriate surveillance should be done to monitor the effect of drugs on birth outcomes. New research design strategies should be developed and used to enable elucidation of PrEP efficacy in settings in which HIV incidence does not allow use of traditional randomised controlled trials.

Conclusion

Ending the HIV epidemic among women in the USA and improving the lives of women with HIV will require universal access to health care. This process will also require unfettered access to behavioural health care, housing, food security, child-care programmes, and other supportive services that allow women to exercise agency in their own HIV prevention and care. Yet these services alone will not end AIDS. Ending the HIV epidemic in the nation will also require eliminating the race, class, and gender inequities, as well as the discrimination and structural violence, that have promoted and maintained the distribution of HIV in the USA, and that will, if unchecked, continue to fuel the epidemic in the future.

Contributors

All authors contributed to conceptualising, drafting, and editing the manuscript, and approved the final version for publication.

Declaration of interests

AAA has received consulting fees from Merck, ViiV, and Gilead, and research funding from Gilead and Merck. JC served on a scientific advisory board for Merck. ALA has received consulting fees from Merck and Gilead. TP reports grants from ViiV and Gilead Sciences. DA reports personal fees from Merck and ViiV Healthcare. JDA has received consulting fees from Gilead. All other authors declare no competing interests.

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