January 2, 2025

U.S. Department of Health and Human Services (HHS)

Centers for Disease Control and Prevention

Re: Docket No. CDC-2024-0100, draft Recommendations for HIV Screening in Clinical Settings

Submitted to: https://www.regulations.gov

Dear colleagues,

The Fenway Institute at Fenway Health appreciates the opportunity to submit the following comment regarding CDC's draft Recommendations for HIV Screening in Clinical Settings, that update portions of CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings," published in 2006.

The Fenway Institute is the research, education and training, and policy arm of Fenway Health, a federally qualified health center and Ryan White Part C HIV clinic in Boston, Massachusetts. We provide care to about 35,000 patients every year. Half of our patients identify as lesbian, gay, bisexual, transgender, queer, intersex, asexual, or another identity (LGBTQIA+), and about 6,000 are transgender and nonbinary. About 2,300 of our patients are people living with HIV (PLWH), and 3,500 are on PrEP for HIV prevention. A main focus of our work is providing healthcare for sexual and gender diverse people, as well as HIV and STI prevention, screening, care, and research.

Here are our responses to the questions in the Federal Register notice about the draft recommendations:

- Does the evidence presented support the proposed recommendations for HIV screening in clinical settings, including the benefits and harms of HIV screening? If not, please state the reason why and, if available, provide additional evidence for consideration.

The evidence for eliminating the upper age limit for HIV testing, currently 64 years of age, is sound. NHSS data showing just over 1,000 diagnoses among individuals 65 and older in 2022, and an estimated 3800 undiagnosed individuals age 65+, are compelling reasons to remove the upper age limit. These data show a clear need for testing of older adults. We also encourage

CDC to include some of the following information from NIH about HIV among older adults, which describes higher rates of AIDS diagnoses among older age cohorts:

> *For several reasons, older people are less likely to get tested for HIV:*
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> - *In general, older people are often perceived as being at low risk of getting HIV. For this reason, health care providers may not always recommend testing for older people for HIV.*
> - *Some older people may be embarrassed or afraid to be tested for HIV.*
> - *In older people, signs of HIV may be mistaken for symptoms of aging or of age-related conditions. Consequently, testing to diagnose the condition may not include HIV testing.*
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> *For these reasons, HIV is more likely to be diagnosed at an advanced stage in many older people. According to an HIV Surveillance Supplemental Report from CDC, in 2021, 34% of people aged 55 and older in the U.S. already had late-stage HIV (AIDS) when they received a diagnosis. That is, they received a diagnosis later in the course of their disease.*
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> *Diagnosing HIV at a late stage also means a late start to treatment with HIV medicines and their benefits and possibly leads to more damage to the immune system. Studies have shown that delaying treatment can increase the chances that people with HIV will develop AIDS and other serious illnesses. Late start to HIV treatment also increases the chance of getting immune reconstitution syndrome, which can cause worsening of some infections when people with HIV and low CD4 cell counts begin taking HIV medicines.*[1]

As for raising the lower age of testing from 13 to 15, it's important to clarify that CDC guidance to raise the lower age limit from 13 to 15 years old does not preclude a clinician offering testing earlier if they feel it is indicated. Please be clearer that if a clinician sees a 13- or 14-year-old who provides information suggesting risk or who has an STI, then HIV testing should be done. Providers should also discuss prevention approaches, including PrEP for HIV prevention.

Any CDC guidance that would turn the routine screening of 13- and 14-year-old adolescents to a risk-based decision-making model needs to couple that change with a strong push for the development of robust systems within Electronic Health Records (EHRs) that can guarantee adolescent medical confidentiality. Lab orders, lab results, communication of lab results, and follow up messaging and notes all need to be protected from unauthorized review by guardians. This is particularly important as we know that LGBTQIA+ youth have outsized risks for homelessness and abuse from close family members if their queer identities are disclosed.

[1] HIVinfo.nih.gov. HIV and older people. https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-and-older-people#:~:text=Your%20health%20care%20provider%20may,low%20risk%20of%20getting%20HIV. Accessed December 19, 2024.

And guidance should also encourage health care providers to have a clear understanding of their responsibilities as mandatory reporters and the ability to access social resources to support youth who might be subject to abuse, neglect, or human trafficking.

- Are CDC's proposed recommendations for HIV screening in clinical settings clearly written? If not, what changes do you propose to make it clearer?

The CDC guidance should also be more clear about describing a risk-based assessment process for 13- and 14-year-olds. The data mentioned in the CDC draft guidance obscures particular communities and populations that may actually reach an incidence meeting the cost benefit assessment. Female gender, low levels of schooling, Black ethnicity, multiple sexual partners, inconsistent use of condoms, alcohol consumption, and early sexual onset constitute risk factors for HIV infection in adolescents. Risk-based assessments of 13- and 14-year-olds should be recommended if routine screening is stopped. HIV testing shouldn't be abandoned wholesale for that age group.

- If implemented as currently drafted, do you believe these recommendations would improve HIV screening in clinical settings, improve diagnoses and linking patients with undiagnosed infection to clinical care; relinking persons with previously diagnosed HIV to clinical care; diagnosing HIV infection earlier; and reducing HIV transmission in the United States? If not, please provide an explanation and supporting data or evidence.

Yes.

- How should CDC disseminate the final recommendations to effectively reach end users such as healthcare providers in clinical settings?

CDC should broadly disseminate the final recommendations to a broad swath of health care providers, including adolescent health care providers and geriatricians. We also recommend publishing widely in academic and professional journals, presenting at academic and professional conferences, and partnering with community health centers and other safety net care providers through webinars with the Fenway Institute and other education and training providers. Given the disproportionate burden of HIV among sexual and gender minority populations and communities of color, it is important that HIV screening be provided in a context of culturally responsive and affirming care for these populations. Continued federal government support training providers in LGBTQI+ responsive and clinically competent care is essential if we are to reduce new HIV infections and reduce striking racial and ethnic and sex disparities in HIV and STI incidence, prevalence, and health outcomes.

- After the recommendations are finalized, CDC is planning to publish an implementation guide for healthcare providers to supplement the updated recommendations. What should the implementation guide include?

Given the disparities described above, it is important that HIV screening be provided in a context of culturally responsive and affirming care, especially for gay and bisexual men and other men who have sex with men, transgender women, and Black and Latino individuals. This includes adolescent patients who are sexual and gender minority individuals.

We strongly support the proposal to remove the upper age limit for HIV screening in CDC's draft Recommendations for HIV Screening in Clinical Settings. This is a change that Fenway Health, SAGE, Gay Men's Health Crisis, and other organizations have been advocating in support of for many years. It represents an important step forward for health equity for older adults, especially older Black and Latina women, gay and bisexual men, and transgender people. We welcome this proposed change in guidance. Should you have any questions, please contact Sean Cahill, PhD, Director of Health Policy Research, at scahill@fenwayhealth.org. Thank you for considering this comment.

Sincerely,

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