



## Editorial

# New USPSTF Guidelines for HIV Screening and Preexposure Prophylaxis (PrEP) Straight A's

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In the June 11, 2019, issue of *JAMA*, the US Preventive Services Task Force (USPSTF) updates its 2013 recommendations on HIV screening and issues its first published guidance on the prevention of HIV infection with preexposure prophylaxis (PrEP).<sup>1-7</sup> As in 2013, the USPSTF provides a grade A recommendation for routine, voluntary HIV screening among all persons aged 15 to 65 years, all pregnant women, and all individuals at high risk of infection. The USPSTF assigns a grade A for a new recommendation to offer PrEP to all persons at high risk of HIV infection, corroborating similar clinical practice guidelines issued in 2014 and 2017 by the US Centers for Disease Control and Prevention<sup>8</sup> and the International Antiviral Society–USA panel.<sup>9</sup> These new recommendations bolster what we already knew: the evidence in support of expanded HIV screening and PrEP is strong. However, the guidelines do not address some of the hard lessons we are learning: screening and PrEP are merely points of entry to a pathway of care that is riddled with obstacles and opportunities for failure.

The significance of the new recommendations lies in the large number of individuals in the United States whose insurance coverage for HIV preventive services, notably PrEP, will be favorably affected. Most US public and private insurers use the USPSTF grading scheme to guide their decisions about which preventive services to cover. The 2010 Patient Protection and Affordable Care Act (ACA) codified this process, instituting formal requirements and incentives for coverage of preventive services that achieve a grade A or B recommendation from the USPSTF.<sup>10</sup> Since the release of the USPSTF's grade A recommendation for HIV screening in 2013, most individuals in the United States with health insurance have had access to routine HIV testing at no out-of-pocket cost. The new recommendations will open doors to PrEP and its associated services. This is a big step forward and is sufficient cause to applaud the USPSTF for its leadership.

Early detection and treatment of HIV infection was a good idea in 2013; it is an even better idea today. The new recommendations provide a comprehensive update of the many randomized clinical trials and cohort studies that have been conducted in the last 6 years on a global study population that, taken as a whole, includes more than 70 000 people living with HIV. The USPSTF reaffirms the unequivocal benefits of early antiretroviral therapy (ART) initiation and viral suppression, in terms of increased survival of individuals with HIV and in terms of reduced HIV transmission to partners. Routine testing is the most effective gateway through which individuals may be triaged to appropriate follow-up care. Persons with newly diagnosed HIV infections can be linked immediately to social support services, provision of ART, and appropriate counseling to protect their partners. Persons at high risk who have negative HIV test results can be referred either for initiation of PrEP (with repeated quarterly HIV screening) or simply for frequent repeated HIV screening; persons at lower risk who have negative HIV test results can be provided the opportunity to ask questions and then referred for occasional rescreening. The frequency of repeated HIV screening for persons not receiving PrEP remains a research question.

Less well explicated in the new recommendations is the HIV continuum of care—the so-called HIV cascade—and our growing appreciation of how failure to retain patients at every step of the pathway from detection to viral suppression weakens our effort to realize the full, life-saving

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potential of any HIV screening program, no matter how enthusiastically and competently that screening program is implemented. The guidelines state, "Screening for HIV infection...would allow for earlier and expanded detection of HIV infection, *thus resulting* in earlier medical and behavioral interventions and treatment [italics added]."<sup>11</sup> Traversing the continuum from a seropositive test to timely and successful interventions and treatment is neither automatic nor to be taken for granted. Indeed, the Centers for Disease Control and Prevention currently estimates that among US individuals who are aware of their HIV infection, only 73% are in care, and only 60% are virologically suppressed.<sup>11</sup> The barriers include mental illness, substance use disorder, HIV stigma, and the complexity of the health care system.<sup>12,13</sup> The USPSTF offers guidance on the perfunctory mechanics of obtaining consent, delivering results, and providing opportunities for questions. Though the USPSTF acknowledges the importance of ART initiation and the potential barriers to services, the document is silent on the less transactional, more delicate aspects of facilitating linkage to care at the time of a positive test—the word *linkage* does not appear anywhere in the primary recommendations (only in the response to public comment)—despite economic analyses demonstrating that improving linkage is among the most attractive investments to be made in a testing program.<sup>14</sup> Similarly, the USPSTF's description of the potential harms of screening and treatment offers an inventory of ART regimens' adverse effects—cardiovascular, neuropsychiatric, hepatic, renal, and bone—but overlooks the more proximal and care-limiting issues of stigma, gender-based violence, and medical care coverage. By avoiding these key obstacles along the HIV treatment and prevention cascades, the USPSTF undermines its own recommendation—testing is the beginning, not the end, of the process of addressing HIV as both a public health and clinical issue.

Turning to PrEP, the USPSTF reviews a decade's worth of evidence on efficacy in alternative settings and demographic populations. The US Food and Drug Administration approved the use of emtricitabine/tenofovir for this indication among adults in 2012. The recommendations provide useful guidance on who should be considered a candidate for PrEP, by demographic subgroup (eg, men who have sex with men, heterosexual women, and persons who inject drugs) and by risk (eg, serodiscordant sex partners, recent sexually transmitted infection, and sharing injection equipment). They also provide references for behavioral counseling, including abstinence, reducing the number of sexual partners, and condom use.

As with its recommendations on HIV testing, the USPSTF focuses on the mechanics of entry. The document acknowledges stigma and racial/ethnic disparities as barriers to care but refers to Centers for Disease Control and Prevention recommendations for guidance about 2 key obstacles to sustained and successful PrEP implementation: access and adherence.<sup>8</sup> Coverage of PrEP across the United States is low, especially in the south, where medical mistrust looms large in the context of an expansive and growing epidemic.<sup>15</sup> Recipients of PrEP are disproportionately white men living in the Northeast and on the West Coast. Adherence among those at highest risk (notably, African American individuals and young men) is poor. Further, recent data suggest very high rates of attrition among PrEP recipients.<sup>16</sup> While the USPSTF acknowledges that fewer than 7% of those in need of PrEP received it in 2016, it offers little insight toward overcoming the implicit implementation challenge of engaging and retaining the patients at the highest risk, who are most refractory to a prolonged PrEP commitment.

However, downstream obstacles must not dampen enthusiasm for expanding PrEP. If anything, the USPSTF understates the ancillary benefits of engaging individuals at high risk in a PrEP intervention. Notable among these are the provision of a trusted clinician and quarterly HIV and sexually transmitted infection screenings, important mechanisms for the early detection of disease and referral in a population of patients that is at particular risk of breakthrough infections. Further, for persons in serodiscordant partnerships, PrEP offers a unique opportunity to link an identifiable, seropositive partner to care and (ideally) virologic suppression that would subsequently render PrEP superfluous in that relationship.

Economic considerations—although highlighted in the 2013 HIV screening guidance—are now deemed outside the USPSTF scope of consideration. We and others have demonstrated the cost-effectiveness of both interventions in the United States.<sup>17-19</sup> However, cost-effective does not imply affordable. Testing for HIV, at about \$25 per test, may be cheap, but each case of infection that is detected and successfully linked to care triggers a lifetime of ART, costing at least \$40 000 annually.<sup>20</sup> At an annual cost of \$20 000 per person, the drug component alone of a complete PrEP rollout for all those eligible would cost \$24 billion annually. With generic emtricitabine/tenofovir disoproxil fumarate available soon, affordability will improve, but attempts are already being made to shift prescribing to emtricitabine/tenofovir alafenamide, which will entail higher costs with relatively modest differences in clinical outcomes.<sup>21</sup>

The USPSTF has taken an important step in securing access to services that will hasten the end of the HIV epidemic in the United States by 2030.<sup>22,23</sup> But this is by no means sufficient. Where HIV screening and PrEP interventions have long failed is in their execution among our nation's communities that are most marginalized and stigmatized—and correspondingly, most at risk. Ending the HIV epidemic is a worthy aspirational target; a number of attainable intermediate objectives seem equally worthy as milestones of our progress, including ensuring that virtually all adults in the United States know their HIV infection status, linking all persons with identified HIV infection to ART, and achieving rates of virologic suppression in excess of 90% among individuals in the US living with HIV. Attainment of these treatment targets could eliminate the need for PrEP—when high levels of virologic suppression are achieved in the population, there will be almost no one at high enough risk to warrant PrEP. Now wouldn't that be the best public health report card the nation could bring home?

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#### ARTICLE INFORMATION

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