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## Eliminating Prevention Counseling to Improve HIV Screening

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The Centers for Disease Control and Prevention (CDC) estimates more than 1.1 million people in the United States are living with human immunodeficiency virus (HIV) infection, including 18% who remain undiagnosed.<sup>1</sup> In July 2010, the Office of National AIDS Policy issued the first National HIV/AIDS Strategy for the United States, with a short-term goal of reducing the number of individuals with undiagnosed HIV infection to 10% by 2015 and a more general goal of creating an AIDS-free generation.<sup>2</sup> Screening and testing for HIV infection is at the forefront of efforts to achieve these goals, and in 2013 the US Preventive Services Task Force (USPSTF) supported a broader HIV screening approach by changing its recommendation for routine HIV screening from grade C to grade A.<sup>3</sup>

When the CDC last modified its recommendations for HIV screening in health care settings in 2006, it called for routine non-risk-based opt-out HIV screening and explicitly removed the requirement for prevention counseling as part of such screening.<sup>4</sup> Prevention counseling is a highly individualized interactive process of assessing risk, identifying specific behaviors that increase risk, and developing a plan to reduce risk and is expected to motivate behavior change.<sup>5</sup> This expanded screening effort was proposed to help accelerate the processes by which individuals with HIV infection are identified. The elimination of prevention counseling, except for those who test positive, was also proposed to reduce a substantial barrier to testing. Prevention counseling was thought to be too resource-intensive, making clinicians less inclined to adopt the practice of routine HIV testing.

In this issue of *JAMA*, Metsch et al<sup>6</sup> report findings from the AWARE randomized clinical trial, a study to evaluate the efficacy of prevention counseling on the incidence of sexually transmitted infections (STIs), including HIV infection, among patients who seek care at sexually transmitted disease (STD) clinics. This study included 5012 patients from 9 STD

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clinics in the United States who were randomized to receive brief patient-centered HIV risk-reduction counseling with a rapid HIV test or the rapid HIV test with information only. At 6 months, there was no significant difference between groups in the composite end point of cumulative incidence of any measured STI (*Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Treponema pallidum*, herpes simplex virus 2, and HIV; women also were tested for *Trichomonas vaginalis*), with incident rates of 250 of 2039 cases (12.3%) in the counseling group and 226 of 2032 cases (11.1%) in the information-only group. The authors concluded that there was no overall benefit from prevention counseling and observed a notable increase in STIs for men who have sex with men (MSM).

Since the mid-1990s, several similar trials have been performed, including populations from both primary care and STD clinics, with the use of different counseling forms and intensities.<sup>7-10</sup> The study samples from these trials are also heterogeneous, with STI outcomes differing substantially among control groups (ranging from 4% to 27%) and with varying follow-up rates. These studies demonstrate that low-intensity counseling (eg, mailings, pamphlets, or informational sessions) does not prevent transmission of STIs. Moreover, there appears to be little difference between moderate- and high-intensity counseling (eg, individualized sessions ranging from 20 minutes to 12 hours), although slightly more than half demonstrated reduced STIs among those who underwent moderate- or high-intensity counseling.<sup>11</sup>

Thus, how definitive is the study by Metsch et al,<sup>6</sup> and how should it be interpreted in light of other studies that have reported benefit from prevention counseling? Despite a number of smaller studies reporting varying results, Project RESPECT<sup>9</sup> was the only clinical trial larger than AWARE, and the number of individuals enrolled in either of these trials exceeds the sum of individuals enrolled in all other studies combined. While these 2 large studies include similar rigorous counseling models and geographically diverse groups of STD clinics, the more contemporaneous AWARE trial has several important advantages: (1) enrollment of a broader study sample (including, in particular, MSM), (2) the use of rapid HIV testing (in lieu of conventional HIV testing), and (3) a higher follow-up rate. Men who have sex with men represent the highest-risk group in the United States,<sup>12</sup> and their inclusion in AWARE enhances understanding of the effect of prevention counseling on a more general population. Also, the use of rapid HIV testing not only involves what is becoming standard practice, but also provides real-time diagnostic results to individuals, thus potentially directly modifying the propensity for risk-taking behaviors through positive reinforcement (ie, a negative test result).

In light of the Affordable Care Act,<sup>13</sup> the National HIV/AIDS Strategy,<sup>2</sup> extensive efforts by the CDC,<sup>14</sup> and most recently, the USPSTF recommendations to routinely screen all adolescents and adults for HIV infection,<sup>3</sup> HIV testing has the potential to shift from a sporadically applied diagnostic tool to a universal screening modality. For this shift to occur, clinicians have to be knowledgeable about when and how to apply screening and must believe that the process, which has historically included prevention counseling, does not impose undue burden on already stretched clinical practices. Prevention counseling is staff-intensive, often perceived as onerous, and often not performed well. Even in the ideal setting of an STD clinic, returns are minimal at best and, in light of new evidence, likely

nonexistent.<sup>6,9</sup> Despite calls to eliminate counseling in the setting of HIV screening so as to increase uptake of tests, counseling remains firmly ensconced in HIV testing programs. The real or perceived need to continue counseling as part of HIV screening remains a barrier to maximizing the penetrance of this prevention intervention.

In contrast, many clinicians believe that counseling in the setting of HIV screening is imperative to motivating patients to change their behavior. Despite the dilemma that exists for these clinicians, an important issue is whether offering counseling simply assuages the clinicians' needs to do something as opposed to nothing. At a population level, to reach a tipping point at which most clinicians screen all their adult patients for HIV infection, the perception that counseling is necessary must not trump the reality that in practice, counseling is typically ineffective. A shift away from counseling, which contrasts with the current standard of care, is crucial to a broader uptake of HIV screening and is consistent with modern advances such as the recent availability of home HIV tests. This shift is also integral to the reduction in the number of those living with HIV who remain unaware of their infection.

The health impact pyramid, as described by Frieden,<sup>15</sup> suggests that public health efforts maximize reach while minimizing resource utilization. If HIV screening is to become routine, barriers such as resource-intensive prevention counseling<sup>16</sup> must be eliminated. The juxtaposition of clinical equipoise of prevention counseling and its relatively large resource burden suggests there may be better ways of channeling limited public health resources when trying to counter the HIV epidemic. Although effective HIV prevention will likely always include a heterogeneous mix of interventions targeted to specific groups, effectively and efficiently identifying patients with HIV infection by widespread completion of HIV testing must remain a principal objective.

In an era of shrinking resources, clinicians and policy makers cannot ignore data that inform efficient clinical practice. Maximizing identification of individuals with undiagnosed HIV infection and reducing viral transmission will require consistent and extensive HIV testing with emphasis, for those identified with HIV infection, on linkage to care, treatment, and adherence. Although utilization of prevention counseling in the context of these post-HIV testing efforts remains to be characterized, results of the AWARE trial support the notion that prevention counseling in conjunction with HIV testing is not effective and should not be included as a routine part of practice.

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