Interpreting and Implementing the 2006 CDC Recommendations for HIV Testing in Health-Care Settings

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On September 22, 2006, the Centers for Disease Control and Prevention (CDC) announced recommendations to expand the role of health-care providers in human immunodeficiency virus (HIV) testing.[1] These clearly justified guidelines aim to remove traditional testing barriers, and thereby increase the rate of earlier diagnosis. This overarching strategy to increase testing in all health-care settings also includes less traditional sites such as emergency departments and correctional health-care facilities.

The motivation for the guidelines is intuitive, as the need for augmented testing is well supported. Of those infected with HIV in the U.S., approximately one-quarter are unaware of their disease status.[1] People who are unaware of their infection disproportionately account for new transmissions[2] and are unable to benefit from treatment. The HIV incidence has not fallen below approximately 40,000 new diagnoses per year, of which approximately 40% are diagnosed late in the course of infection.[1] Universal screening, even in populations with a disease prevalence of 0.1%, has been shown to be cost-effective.[3,4]

While the guidelines have been reviewed in depth,[5,6] current interpretations do not adequately outline a structure for further debate or facilitate incremental or partial implementation of the recommendations. This must be remedied, as comprehensive implementation of the guidelines will be controversial or logistically impossible in many settings for the foreseeable future. Herein, we provide a clarified interpretation by outlining the core guideline elements individually and within the context of current barriers to implementation. We then discuss potential combinations of the core elements that would enable increased testing in settings where comprehensive guideline implementation is not possible.

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CORE GUIDELINE ELEMENTS

The justifications for guideline recommendations are well described in the original publication in *Morbidity and Mortality Weekly Report*.[1] In brief, the core recommendation elements include:

(*1*) Emphasis on expansion to all health-care settings. It is clear that there are missed opportunities for testing disadvantaged populations at high risk for HIV in nontraditional health-care settings.[7–9]

(*2*) Screening of all people aged 13–64 years regardless of risk profile unless the documented site-specific prevalence of undiagnosed infection falls below 0.1%. Targeted testing according to an established risk profile misses those without self-reported risk,[9–12] and the process of targeting may result in stigma that inhibits consent.[13–15] Testing until the yield is proven to be low would circumvent the fact that disease prevalence statistics are generally unavailable; the threshold of 0.1% conforms to recent cost-effectiveness analyses.[3,4]

(*3*) Voluntary opt-out testing whereby patients are notified that testing will be performed unless they decline, and there is no separate written consent for HIV testing. Opt-out consent mirrors the lack of special requirements for other diagnostic testing[6,16] and has been shown to increase consent for testing.[17–20]

(*4*) Elimination of the requirement for prevention counseling in conjunction with testing. Although the importance of prevention counseling may be debated,[1] divorcing this time- and resource-intensive requirement from the testing process will remove an identified barrier to testing.[1,21–23]

INTERPRETATION AND APPROPRIATENESS

The new recommendations, although necessarily controversial, are to be commended for their relevant response to an important public health need. Each component of the overarching strategy is well justified and logically addresses barriers to increased testing and earlier diagnosis. Combining these recommendations into a comprehensive strategy is intuitive. Each component recommendation independently serves the central goal of increased testing. There are also important interrelationships between the guideline components that support their juxtaposition. For example, if testing becomes easier with the removal of exceptional requirements for consent and counseling, then universal testing regardless of identified risk will seem more feasible. Conversely, nontargeted testing without risk assessment may reduce the stigma that fuels the desire for exceptional consent and counseling protections.

Although the combination of these component recommendations in an overarching strategy is understandable, there is a need for precise and detailed consideration of each recommendation in isolation. Each component of the guidelines is supported by a unique rationale with similarly unique controversies and barriers to implementation. However, in discussion and presentation, individual components are rarely distinguished. Rather, an aggregate interpretation is almost universally given as "routine testing should be implemented." A typical article from the lay press might read, "The CDC Urges HIV Tests as Routine in Health Care."[24–26] The guidelines themselves seem to have promoted this generalization, as they refer to multiple recommendations with the singular characterization of "routine." For example, it is recommended that ". . . diagnostic HIV testing and opt-out HIV screening be a part of routine clinical care . . ." and that ". . . screening for HIV infection should be performed routinely for all patients aged 13–64 years."[1] Both quotations refer to routine testing, but two distinct recommendations are being made. The first is in reference to making testing less exceptional by removing special counseling and consent requirements. The second quotation refers to universal screening without respect to an individual risk profile as a criterion for testing.

We contend that the ambiguous use of the term "routine" and the tendency to consider the CDC guidelines as a single recommendation will hinder progress for two reasons. First, discourse becomes confused on all levels. As stated by the Scottish philosopher, Thomas Reid, "There is no greater impediment to the advancement of knowledge than the ambiguity of words." Second, it inhibits the consideration of incremental or partial adoption of the guidelines. If one component of the guidelines is found impractical, rejection of the entire set of recommendations occurs unless the components are considered independently. This is unfortunate, since implementation of selected recommendations might still increase testing, even if other recommendations are not considered acceptable or feasible.

IMPLEMENTATION

Because the individual recommendations are diverse in their scope, attendant controversies, and corresponding barriers to implementation, we will first discuss the

implementation of each guideline element in isolation. This step is required prior to contemplating the complex interplay between the component recommendations that is likely to be an issue when the guidelines are applied incompletely or in less familiar settings.

Expanded testing in health-care settings

Enlisting the health-care system to help fight the spread of HIV is clearly justifiable and strategically desirable, but it is debatable whether this initiative will ever reach the laudable goal of universal screening. The U.S. health-care infrastructure is frequently criticized for not providing adequate and systematic prevention interventions.[27–29] Additionally, any lack of contact between those most at risk and the health system will attenuate the effectiveness of health-care screening initiatives.

The benefit of expanded testing is widely trumpeted, but any potential risks from testing, even if small in comparison, should also be discussed and monitored. For example, although the specificity of rapid assays has been reported as high as 99.9%,[1,30–32] the positive predictive value of any test necessarily falls with lower disease prevalence.[31,33,34] One recent estimate for a universal screening scenario suggested that a false positive result would be 10 times as likely as a true positive result with positive predictive value falling to only 9%.[31] Although comparatively rare,[30,31] such events have the potential to be problematic given the inherent delay in obtaining a confirmatory test by Western blot.[30] The risks of adverse consequences for patients with preliminarily false positive diagnoses have yet to be fully elucidated.[30]

It also seems quite possible that just a few preliminarily false positive results could have a chilling effect on initial provider enthusiasm in low-prevalence settings, particularly when combined with barriers to efficient confirmatory testing and subsequent result notification. The tolerance for these events from the provider perspective when testing patients without identified risk is likely to be low.[31]

Testing without respect to risk

Justification of the increased resources required to expand testing beyond those with identified risk is clearly informed by the disease prevalence within the population. The new guidelines recommend a prevalence threshold (or established testing yield) for nontargeted testing of 0.1%. However, defining prevalence for a given practice setting requires either implementing a testing program to establish the yield, or estimating the prevalence of undiagnosed disease within the patient population. The latter requires data that are rarely, if ever, available. The resources to support expansion of testing in a given site, either to establish the yield is below 0.1% or to maintain testing if the yield is sufficient, have yet to be identified.

Regardless, questions remain as to whether risk-targeted testing remains preferable in high-prevalence settings where nontargeted screening, though ideal, is resource prohibitive. For example, a medical setting with a large patient volume and high prevalence of undiagnosed HIV should aim to test without respect to risk. However, if patients cannot afford to pay for testing and other resources only allow a minority of eligible patients to be tested, risk targeting may still be the best use of limited resources for maximal yield. In lower-prevalence settings, this approach will continue to be even more justifiable.

Consent

Objections have been raised that are specific to the proposed removal of the exceptional requirements for written opt-in consent, the need for which is legislated in many states.[35] The societal and medical context in which such patient protections were initially recommended has changed,[1] but the importance of understanding HIV and the testing process is not obviated. Ethicists, privacy advocates, and those focused on individual patient protections object to opt-out consent due to the possibility of inadvertent or intentional abuse.[36,37] When contemplating how the opt-out consent process may work in practice, particularly in busy health-care settings, it is easy to imagine that a patient could be tested without his/her knowledge, fail to comprehend his/her right to refuse, or be otherwise coerced. Even if not the reality, any perception to this effect might deter some patients from seeking necessary health care.

Counseling

Potential problems arising from a lack of adequate counseling include the possibility of false reassurance from a single negative test, adverse reactions to a positive diagnosis, or failure to understand the implications of a positive test result.[33,38] Testing also represents an important opportunity to promote risk reduction.[39] A proposed solution is referral for risk-reduction counseling to complement HIV testing in the health-care setting, yet the success of referral for risk-reduction counseling is as yet unknown and may be questionable given that referral for testing has not been successful.[40] Despite the permission afforded by the 2006 CDC guidelines, it is possible that any perceived need for counseling might continue to prompt clinicians to avoid testing altogether rather than expend scarce resources to adequately educate patients.

Integrating individual guideline recommendations

The most obvious format for implementing the CDC guidelines is to fully employ all recommendations. Frequently, however, this will simply not be feasible or desirable as previously outlined. Rather than rejecting the guidelines outright, we suggest that partial implementation via the adoption of individual recommendations that are feasible will have significant public health benefit. Having detailed the concerns that are specific to individual guideline components, their interaction can be logically considered and acceptable strategies for overcoming barriers to expanded testing can be more clearly elucidated.

One option would be to implement nontargeted patient selection, even if traditional counseling and consent requirements are retained. At first this seems nonintuitive, since such a strategy would be profoundly resource intensive. However, we have noted that the process of risk assessment and risk targeting takes time, is imperfect, and likely augments stigma that may inhibit consent. Therefore, important gains might be realized with the simple removal of the risk-targeted patient selection strategy even if testing a majority of patients remains impossible.

Another strategy would be to adopt the recommendation for opt-out consent, even if resources are insufficient to test universally without respect to risk. While this could free resources for testing itself, and increase consent rates, a rigorous consideration of the ethical justification for opt-out consent must be applied when combining opt-out consent with targeted testing. The critical foundation of the opt-out process is a care standard in which the patient can decline participation. If testing is offered consistently and without respect to risk, the care standard is apparent. However, if patients are differentially or inconsistently selected for testing, then patients could reasonably question why they were selected when other identical patients were not.[37]

For example, an emergency department with 100,000 patient visits per year might functionally test 5,000 patients, but if those tested are selected, then the ethical foundation for an opt-out approach might be questioned; the alternative is to judge the care of those not tested as substandard. One possible solution to this dilemma would be to define a subgroup of patients at high risk among whom it would be feasible to consistently conduct testing using opt-out consent. This delineation might allow practitioners with limited resources or in low-prevalence settings to focus their efforts to have greatest impact and justify an opt-out process for a subset of patients. While this strategy has yet to be validated and may be controversial, it would mirror other health-care testing that is conducted after provider assessment of sufficient risk for a condition to justify further evaluation according to prevailing standards of care.

In many settings, public opposition or legal barriers to opt-out consent may remain insurmountable for some time. Nonetheless, it might still be possible to divorce formal risk-reduction counseling from the testing process, even if a relatively lengthy informed consent process is required. This is perhaps the most broadly and immediately feasible change in current practice. Removal of the resource-intensive counseling requirement may directly facilitate testing and indirectly reverse perceptions that obtaining consent is time-prohibitive. Of note, this change would be possible regardless of whether or not patients are selected according to identified risk.

Other combinations of testing in nontraditional care settings, testing without respect to risk, opt-out consent, and reduced counseling requirements are likely to be appropriate for the individual setting in which they are applied. We suggest that where any individual component of the guidelines can be integrated into a health-care setting, either alone or in conjunction with other components, the overarching goal of the guidelines is likely to be achieved: the number of people tested for HIV will increase.

CONCLUSION

Over time, we can hope to meet the challenges of expanded HIV testing: the need for greater resources, increased participation by medical providers, and societal acceptance of novel consent strategies and of HIV testing itself. Ideally, the expansion of testing and associated public health benefits will become so overwhelmingly apparent that our proposed clarification of the independent components of the recommendations will become irrelevant. Until then, we encourage the use of unambiguous terminology and individualized consideration of the components to facilitate productive public discourse and foster, at a minimum, partial adoption of the well-justified CDC recommendations to reduce the impact of HIV on public health.

This work was supported in part by NIAID K23 AI068453.

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