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Self-testing for HIV and its impact on public health

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The Centers for Disease Control and Prevention (CDC) estimate that 18% of the 1.15 million persons living with HIV in the United States (U.S.) are unaware of their infection.¹ Without the individual and public health benefits afforded by linkage to care and provision of antiretroviral therapy (ART),² these infected-but-unaware individuals are the source for approximately half of all new sexually transmitted HIV infections in the U.S.³ Minimizing the number of undiagnosed HIV-infected Americans requires expanded coverage of HIV testing and increased testing frequency among those at greatest risk of infection – both of which are important elements of the National HIV/AIDS Strategy's prevention goals.⁴

HIV testing in the privacy of one's home has long been proposed as a way of expanding the number of people tested, by addressing issues of access, stigma, and confidentiality that may keep at-risk individuals from testing through conventional venues.^{5, 6} In 1996, the U.S. Food and Drug Administration (FDA) approved the first over-the-counter HIV test kits,⁷ which relied on the user to prepare dried blood spots and send them to a central laboratory for antibody testing. Results were accessible to the user over the phone, with counseling and referral resources available on demand. In the first year of kit availability, uptake was poor; just 1% of the 16.6 million HIV tests performed in 1996–1997 were from home-collected specimens.⁷ In subsequent years, utilization remained low across key demographics.^{8, 9} With the 2002 approval of the first rapid HIV test¹⁰ and its subsequent waiver for use outside of clinical settings,¹⁰ the goal of true self-testing – having results immediately and directly available to the user – became a possibility.¹¹ Critics of self-tests argued that the potential benefit of expanding access to testing could be offset by the risk of missed diagnoses (false negative results) and the inability to readily link those who test positive to care.¹² Others identified a new potential use of rapid HIV tests for “point-of-sex” testing –

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with negative results giving partners more confidence in decisions to forgo condoms.¹³ In July 2012, after years of dedicated, manufacturer-sponsored studies, the FDA approved the first over-the-counter, rapid self-test for HIV – the OraQuick In-Home HIV Test (OraSure Technologies, Bethlehem, PA; Figure 1).¹⁴

Use of the OraQuick kit for self-testing has three main drawbacks. First, the test's sensitivity in detecting established, antibody-positive HIV infection is substantially lower among unobserved users (92.9%) as compared to the same test administered by trained providers (99.3%).¹⁵ The extent to which this lower sensitivity might result in greater numbers of false negatives depends on the relative numbers of clinic-based tests and self-tests performed, as well as the HIV prevalence among users of each test type – quantities that will vary across settings and are difficult to pin down among self-testers, in particular. These issues with sensitivity in detecting established infection are separate from another drawback of in-home rapid tests (and indeed, all antibody-based tests): their inability to diagnose HIV during the “window” period between initial infection and seroconversion.^{16, 17} False negatives during early infection are particularly problematic, as this period is characterized by increased infectiousness to others;¹⁸ phylogenetic¹⁹ and modeling studies^{20, 21} have suggested that sexual transmission is disproportionately attributable to individuals with early infection. This inability to detect acute infection is a drawback not only of self-tests, but also of most clinic-based tests (which rely on antibody detection); however, educating testers that a negative result doesn't completely rule out the possibility of HIV infection is considerably more challenging in the context of self-testing. In the absence of pre-test counseling, self-testers may not appreciate the limitations of OraQuick's use as a “point-of-sex” test with an acutely HIV-infected partner, or as a “morning-after” test – so early after a transmission event that no available antibody tests for HIV would be positive. Last but not least, self-testing places an important burden on all newly diagnosed users: navigating the often-complicated pathways leading into HIV care. The consumer hotline established for the in-home test kit provides basic counseling and contact information for local clinics, but does not assist in making referrals or ensure the user successfully enters care.

So what impact will self-testing have? Just from its potential to expand the number of persons aware of their HIV status, one might expect a net positive benefit – but a mathematical modeling study by Katz, *et al.* in this issue of *Sexually Transmitted Diseases* suggests just the opposite.²² In a highly stylized mathematical model of HIV transmission among Seattle's men who have sex with men (MSM), total replacement of clinic-based testing – with neither a corresponding increase in testing rates nor delayed ART initiation among those testing positive – results in substantial increases in endemic HIV prevalence (from 18.6% to 27.5%) and incidence (from 1.18% to 1.79% per year). When mixtures of clinic-based testers and self-testers are modeled along with increases in testing frequency, HIV incidence and prevalence still rise – but not as dramatically. Model outcomes are predictably worse when self-testing leads not only to more false negatives, but also to delayed initiation of ART among newly diagnosed true positives.

Though these predictions seem dire, basic structural features of the model are likely to have exaggerated the negative public health impacts of self-testing. Prior testing patterns and levels of risk behavior do not inform men's initial selection of test modality in the model –

and once men begin using one type of test, they can never switch. The model does not account for individuals who might self-test in between visits to clinical settings in which they are routinely tested. Such augmentation seems less likely to cause public health harm than wholesale replacement of clinic-based testing, as modeled. Furthermore, if self-testing is adopted disproportionately by those who are reticent to test in a clinic, then the detrimental effects of self-testing are likely to be smaller than those predicted. Indeed, uptake of the original home specimen collection HIV tests was strong among never-tested individuals,⁷ and in an FDA model evaluating uptake of rapid self-testing only among those never tested, use was associated with a net benefit: 44,000 new diagnoses that would not have occurred otherwise, resulting in 4,000 fewer HIV transmissions in the first year alone.²³

The authors' sensitivity analyses around key parameters suggest additional reasons why the principal findings may overstate potential harms from self-testing. When the assumed window period is shortened from 90 days (as conservatively stated in the OraQuick package insert) to 42 days (a window period that is closer to estimates from clinical studies^{24, 25}), the model predicts a smaller increase in prevalence. If testing frequency increases among self-testers to twice the rate of clinic-based testers, a 42-day window period is associated with *decreased* prevalence. Additionally, it remains unclear whether the same ART-associated reduction in HIV transmission observed among heterosexuals²⁶ can be expected among MSM – a gray area summarized recently by Muessig, *et al.*²⁷ If ART is indeed less protective for MSM, then identifying new cases (through self-testing or clinic-based testing), linkage to care, and provision of early ART would confer less public health benefit; thus, replacement of clinic HIV testing with self-testing would have an overall less detrimental impact in MSM populations than predicted by the main results of the Katz model.

Finally, as Katz, *et al.* point out, the epidemiological context in Seattle is unique, limiting generalizability of the model's predictions. HIV incidence and testing rates are both high among Seattle's MSM, and clinic-based testing throughout King County is nucleic acid-based. In settings with antibody-based testing and a lower burden of HIV infections, as is the case throughout much of the U.S., differences in test performance between clinic-based testing and home-based self-tests will be smaller, as will the likelihood of testing during acute HIV infection – leading to a less dramatic, less negative public health impact of rapid self-testing.

As we learn how to incorporate self-testing into our overall strategy for managing the domestic HIV epidemic, it will be important to understand how such tests are utilized and to determine what factors drive selection of this modality over conventional, clinic-based testing. Both empirical data and modeling studies will be essential for estimating the impacts of preferential self-test uptake by previously untested persons, differential uptake according to levels of risk behavior, supplementation of clinic-based testing with home-use tests, and both “point-of-sex” and “morning-after” testing. With their model, Katz, *et al.*, have outlined one set of possibilities for self-testing in high-risk populations. Although the results of the model may well exaggerate the likely effects of self-testing in many settings, the availability of this option for testing is still very new; many questions about its use remain unanswered. It is up to us in the prevention, research, and advocacy community to monitor

actual patterns of use, predict their impacts, and carefully determine the optimal role for self-testing in our overall testing strategy. Only then can we ensure that the harms of self-testing predicted by Katz, *et al.* remain unrealized, worst-case scenarios.

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Figure 1.

The OraQuick In-Home HIV Test. The kit contains one paddle-shaped test device (essentially identical to the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test administered in clinical and outreach settings), a vial of developer fluid, detailed English and Spanish instructions in the form of flip-cards, and two booklets: one describing HIV transmission risks and another detailing interpretation of results.