Potential Contributions of Clinical and Community Testing in Identifying Persons with Undiagnosed HIV Infection in the United States

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Abstract

Background: An estimated 166,155 individuals in the United States have undiagnosed HIV infection. We modeled the numbers of HIV-infected individuals who could be diagnosed in clinical and community settings by broadly implementing HIV screening guidelines. **Setting:** United States. **Methods:** We modeled testing for general population (once lifetime) and high-risk populations (annual): men who have sex with men, people who inject drugs, and high-risk heterosexuals. We used published data on HIV infections, HIV testing, engagement in clinical care, and risk status disclosure. **Results:** In clinical settings, about 76 million never-tested low-risk and 2.6 million high-risk individuals would be tested, yielding 36,000 and 55,000 HIV diagnoses, respectively. In community settings, 30 million low-risk and 4.4 million high-risk individuals would be tested, yielding 75,000 HIV diagnoses. **Conclusion:** HIV testing in clinical and community settings diagnoses similar numbers of individuals. Lifetime and risk-based testing are both needed to substantially reduce undiagnosed HIV.

Keywords

HIV, testing, community testing, HIV unaware

Background

An estimated 162,500 individuals in the U.S. had undiagnosed HIV infection in 2016, representing 14% of the HIV-infected population of 1.1 million.[1] These individuals are at greater risk of developing HIV-related illness, premature death, and transmitting HIV. People who start antiretroviral therapy (ART) immediately after HIV diagnosis have a significantly lower risk of illness and death, according to findings from START, which found a 57% reduction for immediate versus deferred treatment.[2] These findings suggest that HIV causes persistent immune system damage soon after infection, and has led to recommendations that ART be provided for everyone regardless of CD4 count.[3] For prevention, there is compelling evidence for the large benefits of HIV treatment. The landmark 2011 HPTN 052 randomized controlled trial demonstrated that antiretroviral treatment in people living with HIV at CD4 counts 350–500 reduces transmission to HIV-negative partners by 93%, with no new infections linked to patients who were virally suppressed.[4] The broad clinical and prevention effects align in support of universal treatment for HIV-infected persons, and are consistent with the global UNAIDS 90:90:90 targets.[5] The United States has a policy, encompassed in "Ending the HIV Epidemic (EHE)" initiative, to curtail HIV transmission in the US by 90% within 10 years by focusing on

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geographic areas where the majority of new infections are concentrated. Timely diagnosis is the first EHE strategy[6,7] and dedicated resources are available.[8]

Diagnosis is the essential first step in any test and treat strategy. Although the percent of HIV-infected individuals unaware of infection has been dropping over time, the 15% undiagnosed remains a major public health challenge. CDC recommends screening for HIV infection just once for all patients aged 13–64 years who are not at elevated risk.[9] The guidelines for clinical settings suggest routine testing except in contexts with documented undiagnosed HIV prevalence < 0.1%; as reviewed below, implementation appears inconsistent. All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint. Health care providers should subsequently test all persons who disclose one or more risks for HIV infection at least annually. These include people who inject drugs (PWID), persons who exchange sex for money or drugs, sex partners of HIV- infected persons, and men who have sex with men (MSM) or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test. Guidelines also recommend testing during pregnancy (which we do not consider in this analysis). Improved application of HIV screening recommendations in healthcare settings (e.g., provider education and removal of barriers) may facilitate diagnosis. In non-clinical sites, the proposed emphasis is targeted testing, especially for individuals at elevated risk due to injection drug use, exchanging sex for money or drugs, and frequenting venues with high-risk sex.

Based on reported HIV diagnoses and transmission risk nearly all the persons who are HIV- infected but undiagnosed in the US belong to one of 3 groups: MSM, PWID, and high-risk heterosexuals.[10] Failure to screen individuals earlier is largely explained by 3 factors: physician knowledge, attitude, and behaviors, e.g. even if guideline knowledge is present, the provider may perceive insufficient time to consent and test[11,12]; high-risk individual fear, fatalism, confidentiality concerns, and failures to disclose risk,[13] as well as denial of HIV risk and practical issues in accessing tests; and broader structural barriers whereby clinics do not systematically implement testing guidelines.[14]

In this study, we review the clinical use and testing behaviors of persons with undiagnosed HIV infection, in both low and high-risk groups, in order to quantitatively estimate the opportunities for diagnosing individuals in health care settings, as currently recommended. Those estimated to not interact with the health care system or to be untested despite medical contacts comprise the numbers needed to be reached in community-based settings. Understanding this has important policy and programmatic implications, informing the optimal relative contributions of clinical and community-based settings. If more HIV+ unaware (i.e., individuals who have undiagnosed HIV infection) could be diagnosed in health care, this might argue for enhancing efforts in this context. To the extent that the HIV+ unaware have no real opportunity to be diagnosed in clinical settings, this could suggest strengthening community-based testing.

Methods

We estimated the number of HIV tests needed and the potential of diagnosing persons with HIV in clinical and community-based settings. For clinical settings, we estimated the numbers based on the likelihood of clinical contact, uptake for offered tests, and for screening based on risk, the likelihood of disclosing risk. For community-based settings, the number needing HIV tests was calculated as the number needing testing minus the number of tests calculated for clinical settings, and thus reflects the population size that has no clinical contact, declines clinical-based testing or, for high-risk individuals, fails to disclose risk. We did not consider age at testing.

Our approach to estimating the maximum benefits of fully implementing the testing guidelines proceeded in 2 steps. First, we estimated the number of HIV tests that would be required to fully implement the national testing guidelines in healthcare settings for individuals in low- and in high-risk groups. Second, we estimated the number of existing infections that could be diagnosed by fully implementing testing. We reference Tables 1 and 2 (for number of tests and newly diagnosed infections, respectively) both to describe methods and present results.

For these estimates, we assumed the coverage of HIV testing guidelines[6] included one test over the lifetime for low-risk individuals, and annual testing for the 3 high-risk populations: men who have sex with men (MSM), people who inject drugs (PWID), and high-risk heterosexuals (HRH). For simplicity, we examine only 1 year; i.e. we do not consider the strategy for or benefits of ongoing testing to diagnose new HIV infections in future years.

HIV Tests Required to Fully Implement National Guidelines

The number of HIV tests required by risk group and setting (Table 1) begins with the population size of each risk group, as provided in demographic reports of population statistics for the general population and high-risk group sizes ages 15–44.[15-18] (Each table entry is precisely cited and detailed in an online Technical Supplement.) We extracted the number of people known to be living with HIV in each risk group from CDC surveillance reports.[19] We use the difference between the population size and the size of the HIV-infected population in each group to estimate the number of people who are potentially eligible for HIV testing. The number already tested (lifetime for general population and annual for high-risk populations) is estimated from HIV testing trends,[20] and National HIV Behavioral Surveillance (NHBS) surveys,[21-23] and the National Survey of Family Growth.[24] The number needing testing (lifetime for general population, annual for high-risk) is calculated as the difference between those who are potentially eligible for testing and those already tested.

Table 1. Number of HIV Tests Required in Clinical and Community Settings.

| | | | High risk Populations | | | |
	Sum	Low risk population	MSM	PWID	High risk hetero	Sources
Number in group in U.S.	198 140 457	185 299 124	2 873 037	594 421	9 373 875	15–18
Number living with HIV[a]	952 605	14 511	554 018	137 727	246 349	19
Number not known to be HIV-infected (eligible for testing)	197 187 852	185 284 613	2 319 019	456 694	9 127 526	calculated
Percent already tested (lifetime)		43%	94.1%	91%	81.0%	20–23
Percent already tested (per year)		n/a	40%	58%	41%	24, 25
Percent needing testing (lifetime for low risk, annual for high risk)		57%	60%	42%	59%	calculated
Number needing testing	112 581 606	105 612 229	1 391 411	192 725	5 385 240	calculated
Percent with clinical contact (5 y for low risk, annual for high risk)		95.7%	67%	72%	75%	24, 26
Percent agreeing to testing (low risk) / disclosing risk to provider		75%	59%	25%	50%	27, 34, 35
Percent reachable in clinical setting (including disclosure, if relevant)		72%	40%	18%	37%	calculated
Number needing testing, reachable in clinical setting	78 403 374	75 803 178	551 667	34 450	2 014 080	calculated
Number needing HIV tests in community settings	34 178 232	29 809 052	839 744	158 275	3 371 160	calculated

[a]Adults and adolescents. All infected via heterosexual contact are included in "High Risk hetero." Low risk population includes perinatally acquired and other.

Table 2. Number of Individuals with Undiagnosed HIV Identifiable in Clinical and Community Settings.

| | | | High risk populations | | | |
	Sum	Low risk population[a]	MSM	PWID	High risk hetero	Sources
Number of individuals HIV(+) unaware	166 155	370	110 328	9 265	46 192	10, 36
Percent with clinical contact (5 y)		95.7%	92%	81.0%	80.8%	21, 23, 26, 37
Never previously tested	55 421	47.8%	26.0%	48.5%	47.8%	38, 39
Percent taking up an HIV test if offered		75%	75%	75%	75%	27
Number identifiable as HIV(+) through once in lifetime (non-risk-based) testing in clinical settings	35 937	127	19 716	2 729	13 365	calculated
Number not identifiable (no clinical contact or no uptake)	19 484	50	8 969	1 764	8 702	calculated
Previously tested	110 734	52.2%	74.0%	51.5%	52.2%	calculated
Percent disclosing risk to health care provider		n/a	59%	25%	50%	34, 35
Number identifiable as HIV(+) through risk-based testing in clinical settings	54 852	n/a	44 145	966	9 741	calculated
Number not identifiable (not in risk group, no clinical contact, no risk disclosure)	55 882	193	37 498	3 807	14 384	calculated
Identifiable in clinical settings	90 789	127	63 861	3 695	23 106	calculated
Number requiring identification in community settings	75 366	243	46 467	5 570	23 086	calculated

[a]Some estimates for Low risk population from entire population.

To assess the potential for testing in clinical settings, we start with the percent with clinical interaction (visiting any health care provider). That is, we assume that clinical contact is a necessary condition for HIV testing in these settings. This is based on the National Health Interview Survey (NHIS)[25] for general (low risk) populations, and NHBS for high-risk populations.[26] We assume that 75% of individuals offered non-risk-based testing will agree, based on studies which show a range of acceptance of point-of-care testing from 50–90%.[27] confirmed by our review of identified articles.[2,28-32] We also assume that disclosure of risk (that is, letting the health care provider know that one belongs to a high-risk group) is a necessary and sufficient condition for annual testing. We derive the portion of high-risk individuals who disclose their risk from a Canadian study for MSM[33] and data from MSM in Chicago using findings from the 2014 NHBS[34] and additional calculations (available from authors). We were unable to find relevant data for PWID with a literature search and consultation with experts, and use an estimated value that we test in sensitivity analysis. The percent of each risk group that is potentially reachable in clinical settings is then calculated as the product of the portion that have clinical contact and the portion that disclose belonging to a high-risk group. The total tests assumed in clinical settings equals the number needing testing times the percent reachable.

The number of tests required in community settings is defined as the number of individuals needing testing, minus the number of tests estimated for clinical settings. This

Table 3. Sensitivity.

Scenario	Sum	Low risk population	High risk populations MSM	PWID	High risk hetero
Number of HIV tests required in community settings					
Base case	34 178 232	29 809 052	839 744	158 275	3 371 160
Previously tested 25% higher	27 776 528	24 187 169	699 787	104 079	2 785 493
25% lower	40 579 936	35 430 934	979 702	212 472	3 956 828
Clinical contact higher (non-contact 50% lower)	31 994 466	28 106 055	705 112	151 410	3 031 890
lower (non-contact 50% higher)	36 361 998	31 512 049	974 377	165 141	3 710 431
Test uptake / disclosure of risk to clinical provider 20% higher	18 497 557	14 648 416	729 411	151 386	2 968 344
20% lower	49 858 907	44 969 687	950 078	165 165	3 773 976
Number of HIV+ unaware individuals requiring identification in community settings					
Base case	75 366	243	46 467	5 570	23 086
Clinical contact higher (non-contact 50% lower)	69 265	240	43 556	5 137	20 333
lower (non-contact 50% higher)	81 467	246	49 378	6 004	25 839
Previously tested 25% higher	70 638	208	43 474	5 087	21 868
25% lower	80 095	278	49 460	6 053	24 304
Test uptake / disclosure of risk to clinical provider 20% higher	68 179	218	42 524	5 025	20 413
20% lower	82 554	269	50 410	6 116	25 759
Disclosure of risk to clinical provider 25% higher	61 653	243	35 431	5 329	20 651
25% lower	89 079	243	57 503	5 812	25 521

represents the population that has no clinical interaction, declines testing, or for high-risk individuals, fails to disclose risk to clinical providers. We make no assumptions about the ability to actually reach all these individuals in community settings; i.e. we did not (and could not) estimate the number of people who do not want to know their HIV status and thus turn down all testing opportunities.

Identified Infections

The number of HIV infections identifiable in health care settings by full implementation of testing guidance, by risk group, is examined in Table 2. We start with the number of individuals who are HIV+ unaware in each risk group, estimated from analyses of HIV surveillance data.[10,35] The proportion of people who obtain clinical care at least once over a 5-year period is estimated from NHIS data[25] for the low risk population, and using the ratio of 5 year to 1 year clinical contact in NHIS to adjust the 1-year estimates in NHBS[21,23,36] for high-risk groups.

We next focus on the number of identifiable infections with once-in-lifetime testing. The number of persons with undiagnosed HIV never previously tested is estimated from individuals with newly identified infection in HIV surveillance data.[37,38] Of note, in the data we use, prior testing is less common among persons recently diagnosed than among all individuals with undiagnosed HIV, suggesting an association between non-testing and non-diagnosis. The number of never-tested individuals accepting offered tests (uptake) in clinical settings is based on literature review as noted for Table 1. The number identifiable through once-in-lifetime testing is the product of number unaware, percent never previously tested, and test uptake.

The next section of Table 2 focuses on the number of infections identifiable in high-risk individuals with previous testing. The percent disclosing risk to health care providers, and thus eligible for annual testing, is as described above. The number identifiable only through risk-based testing in clinical settings is the product of prior testing and disclosure. This is the increment in annual testing, above current annual testing.

Sensitivity Analyses

Due to substantial uncertainty in inputs, we conducted sensitivity analyses for our 2 main outcomes: number of HIV tests required in community settings, and number of HIV+ unaware individuals requiring identification in community settings. We varied input values plus or minus 20–25% (low uncertainty) or 50% (high uncertainty) as noted in Table 3.

The analytic tables are available from the authors upon request; all analyses were performed using Excel. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Ethical Approval and Informed Consent

Neither ethical approval nor informed consent was needed, due to reliance entirely on published reports and publicly available aggregate data.

Results

Required Tests

We estimate that there are 197.2 million individuals potentially eligible for testing (that is, not known to be HIV-infected),

made up of 185 million low risk individuals, 2.3 million MSM, 0.46 0 PWID, and 9.1 million HRH (Table 1). Of these, 106 million low risk individuals have never been tested and thus need one lifetime test per national guidelines. The number in high-risk groups who are eligible for annual testing and have not been tested in the last year is 1.4 million MSM, 0.19 million PWID, and 5.4 million HRH.

Adjusting for clinical contact and test acceptance by patients, we estimate that 76 million low risk individuals are reachable in clinical settings. Adjusting for clinical contact and disclosure of 7 high-risk status, each year 0.55 million MSM, 34,000 PWID, and 2.0 million HRH are reachable in clinical settings.

Thus, the estimated number of low-risk people who would need an HIV test to fully implement the national guidelines, but who are not reachable through the health care system, is 34 million. We estimate that annual high-risk testing need in non-clinical settings is 0.84 million MSM, 0.16 million PWID, and 3.4 million HRH.

Identified Infections

Of the 166,155 estimated to have undiagnosed HIV infection, 370 are low risk, 110,000 MSM, 9,300 PWID, and 46,000 HRH (Table 2). Clinical contact over 5 years is estimated at 81–96%, depending on the risk group.

We estimate that 55,000 individuals with undiagnosed HIV have never been tested. Allowing for 2 a 75% likelihood of accepting an HIV test if offered, we estimate that 36,000 individuals could be diagnosed though once-in-lifetime testing. Among those, the largest group is MSM (20,000), followed by HRH (13,000) and PWID (2,700).

Approximately 110,000 persons with undiagnosed HIV are estimated to have been previously tested. Those at low risk (estimated n = 50) will not be discovered by testing guidelines. When adjusting for clinical contact and risk disclosure (assuming that those who disclose get tested), we estimate that 55,000 individuals are identifiable from risk-based annual testing in clinical settings, including 44,000 MSM, 9,700 HRH, and 1,000 PWID.

In sum, combining those reached through one-time or risk-based annual testing yields an estimated of 91,000 individuals (64,000 MSM; 23,100 HRH; 3,700 PWID; and 127 low risk) who could be tested and diagnosed with HIV in a clinical setting if the HIV testing recommendations were fully implemented.

We estimate that the remaining 75,000 persons with undiagnosed HIV would not be tested for HIV in a health care setting, and would require testing and diagnosis in community settings. This includes 46,000 MSM, 23,000 HRH, and 5,600 PWID.

Sensitivity Analyses

Uncertainties in inputs result in a range in the estimate of required HIV tests outside of health care settings of plus or minus 46% (from 18.5 to 49.9 million) (Table 3). With 70%

of MSM tested annually (from NHBS, instead of the study we used), 400,000 fewer tests are needed. The uncertainty for number of persons with undiagnosed HIV that would need to be identified outside of health care settings is smaller, plus or minus 18%, from 61,600 to 89,000.

Discussion

We estimate that following current testing guidelines in clinical settings over one half (91,000) of the 166,155 persons with undiagnosed HIV could be diagnosed. This is an optimistic estimate that assumes that current guidelines of lifetime testing for all individuals and annual testing for high-risk individuals are fully offered to those who interact with the health care system, if they agree to one-time testing or disclose high-risk. By extension, we estimate that at present nearly half of the persons with undiagnosed HIV in the US are not identifiable through the health system-based HIV testing paradigm in the US, and could potentially be reached via community testing. Coverage in clinical settings could be increased by improving access to health care and interventions to increase patient willingness to disclose HIV risk behavior via a discrete and nonjudgmental environment that ensures patients are aware of confidentiality safeguards and of the importance of disclosing accurate risk information.[39,40]

We further estimate that diagnosing these individuals in clinical settings would require 2.6 million HIV tests above current testing levels for high-risk individuals and 78 million tests for low risk individuals. The number of tests required in community settings is lower, 34 million, due to the relatively high likelihood of clinical contact and testing. These estimates exclude testing outside of official recommendations, such as individuals who seek repeat testing but are actually at low risk and more frequent than annual testing among persons who are at increased risk for HIV.

The number of tests per new diagnosis is higher in clinical settings (864) than in community settings (453). This is due to high access and testing acceptance by low risk individuals in care settings, resulting in a higher proportion of high-risk individuals in community testing settings. Because community testing often includes costs for client recruitment and the testing venue, these costs are often 2-4 times those of clinical testing.[41-45] Analyses of testing suggest that it is cost-effective for very low prevalence,[46] and guidelines since 2006 suggest health care-based testing when the prevalence of undiagnosed HIV infection is >0.1%[9] (which in practice may mean universal, since seroprevalence surveys to reliably detect such low levels are technically demanding and expensive).

The findings also suggest the value of focused testing of high risk individuals. In clinical settings, 60 percent of identified infections are from annual testing of those at high risk, and most of the remainder from once-in-lifetime testing of these individuals. The pattern is similar in community settings.

Our analysis has several key strengths. We created the first comprehensive framework to assess testing needs and opportunities. We were able to assemble and incorporate high quality

empirical data for most model inputs, such as likelihood of clinical contact, current testing patterns and gaps, and risk disclosure for MSM. Although some inputs values were imprecise (e.g., risk disclosure for PWID), our results are qualitatively robust to uncertainty in most assumptions.

The analysis also has important limitations. It is static and indicative: we examine what is required to identify the currently unaware. We do not consider the real-world implementation challenges of testing everyone within 1 year or over several years, nor testing needs and yield for individuals who become infected in future years (a number that will drop if most of the currently unaware are identified). Second, we could not exclude geographic settings with an undiagnosed HIV prevalence of less than 0.1%, the recommended threshold for routine testing in clinical settings. We could find no evidence of jurisdictions applying this rule. Thus we may be overestimating testing needs, although we are unaware of jurisdictions that have suspended routine clinical testing based on this measure. Third, we did not explicitly consider testing in pregnant women, for whom HIV testing is recommended and who have very high testing rates, nor in STI clinics. Fourth, we used data on testing likelihood in clinical settings that is imperfectly aligned with our analysis: uptake of rapid point-of-care tests for general testing uptake, and a Canadian (non-U.S.) study of risk disclosure. Both were the closest available to our desired inputs, and examined in sensitivity analyses. Fifth, we assume that among high-risk individuals, risk disclosure is accompanied by an HIV test being offered and accepted, whereas likely there is some attrition for both steps. Sixth, we could not include a role for self-testing, a relatively new technology which in clinical trials shows impressive potential to increase testing and detection of infections[47,48] but for which we could find no use statistics.

Perhaps most importantly, we portray a high capacity to deliver testing. As noted above, for clinical settings we assume full provider adherence to testing recommendations. For community testing, our estimates of tests and diagnoses are based on need rather than demonstrated capacity. 7 Many individuals may decline to be tested in any setting. Actions to enhance testing levels include education of providers about testing guidelines and methods to support patient risk disclosure, providing clinical tools such as alerts that remind providers of patients in need of testing, and expanding the reach and capacity of community testing programs. Nonetheless, we believe that the analysis importantly quantifies the potential yield and value of following testing recommendations. Recent changes in testing context (e.g., rapid tests, routine testing, lower emphasis on counseling, and pre-exposure prophylaxis) have the potential to increase testing rates.

Future research on HIV testing programs might focus on the practical pursuit of testing levels described in this paper. What strategies can best increase adherence to clinical testing recommendations by providers and by patients? How will health insurance changes affect access to care and thus testing patterns? What are the capacity and funding requirements for community testing? How much will the costs of increased testing be offset by savings in future HIV medical care costs? An optimal national HIV testing effort will benefit from these practical investigations in pursuit of ambitious testing goals. We also hope that as self-testing becomes more widespread, it is incorporated into analyses and planning.

Our major finding is that an approach that a national testing strategy requires 3 major legs—routine screening in health care, high-risk testing in health care, and community-based testing. Together, these elements have the potential to greatly advance our efforts to increase awareness, reduce new HIV infections, and improve health outcomes.

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Supplemental Material

Supplemental material for this article is available online.

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