

HIV Testing and Written, Informed Consent:

An Analysis of Current Debates

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GMHC

Executive Summary

Numerous barriers to HIV testing exist. Patients have fears, misconceptions, and misgivings about HIV testing that dissuade them from getting tested. Doctors and health care providers face time constraints, lack of access to testing technologies, and a dearth of proper testing environments. Advocates struggle to reach those most at risk for contracting HIV and who have never been tested.

Upon reviewing various studies on barriers to HIV testing, from the point of view of every stakeholder involved, written informed consent has not presented itself as an obstacle to HIV testing. New York's statutes on HIV testing, as outlined in article 27-F of the public health law, seek to encourage greater testing while protecting patients' rights and doctors' against liability.

The revised guidelines of the Centers for Disease Control and Prevention (CDC) serve simply as that—guidelines. The complex cornucopia of laws governing testing among the 50 states was put in place to protect patients and doctors, not to hinder the eradication of HIV/AIDS. The CDC guidelines should act as a floor in a solution to expanded testing, not a ceiling. State laws, by design, seek to tackle societal problems in a manner appropriate to the state, as they best see fit. What works in one state may not work in another and differing tactics may be the most appropriate response to a complex public health epidemic.

Written informed consent is the law in New York and not one study or report has indicated that such a requirement acts as a barrier to testing. Indeed, this report points to a number of real barriers to testing—attitudes, waiting periods, lack of offering, or lack of access to rapid tests to name a few.

Written informed consent is doing what it was designed to do—protect patients and protect health care providers. It is not a barrier to testing and no one has proven as much. The CDC guidelines and written informed consent need not be mutually exclusive. Instead, the application of both could work to significantly bridge the gap in the awareness of an individual's HIV status. Greater outreach and the routinization of HIV testing can occur under both.

Introduction

In New York City, in New York State, and throughout the United States, public health officials, HIV/AIDS advocates and health care providers are grappling with the desire to expand HIV testing into routine medical and diagnostic practices. However, implementation of routine testing is extremely complicated and raises numerous concerns.

This is a matter subject to much debate from City Hall to the State Capitol to the White House, from local sexually transmitted disease (STD) clinics to large hospitals, and from medical records to law books. Answers vary, stakeholders collide, and embroiled debate reaches every corner of the argument.

Some in the debate would like to see anyone visiting a doctor's office or hospital tested for HIV without their consent and without counseling. Others wish for patients to be well informed and affirmatively consent to testing, first knowing full well what they are entering into. Yet others seek to have HIV tests offered universally and accompanied by pre- and post-test counseling. Defenders of civil liberties want to protect patients' rights and ensure consent remains a key prerequisite to testing. And yet others disagree on what consent itself even entails—a nod, the simple act of giving one's blood or saliva, or a signature. Some debate the universality of testing—should we test everyone or only those in high-risk categories?

Testing is nuanced and includes multiple points of patient/provider interaction. Testing is complex and the debate surrounding it is heated. However, one immutable truth applies on which all those involved can agree—more people need to be tested in order to stem the tide of HIV/AIDS.

Gay Men's Health Crisis (GMHC) has long believed that testing individuals for HIV acts as both treatment and prevention. One in four New Yorkers who test positive for HIV are dual diagnosed with AIDS. We know this means that HIV infection had occurred in the individual many months or years prior to discovery. Early detection of HIV serves to move people into proper care sooner and set them on a path to manage their HIV infection.

Early detection also serves to make one aware of his or her own HIV status. Some studies suggest that individuals who test positive are more likely to curb behavior that can spread HIV. Other studies indicate that over half of new infections are caused by people who are unaware of their HIV status and who have been infected themselves for less than two years. The number could be as high as 70 percent.¹ Untreated, newly infected individuals exhibit high viral loads and are at greater risk for spreading the disease.

It is estimated that 20,000 to 30,000 New Yorkers—approximately one in four New Yorkers living with HIV—are infected with HIV and unaware of their status. Many such New Yorkers are in higher risk categories, such as men who have sex with men (MSM) and intravenous drug users. Other communities, such as black and Latina women and low-income New Yorkers are also at elevated risk. In 2003, the Centers for Disease Control and Prevention (CDC) estimated that one in four people living with HIV in the U.S. is undiagnosed.²

Because of the growing and comprehensive societal impact of HIV/AIDS, many believe that making HIV testing a routine aspect of any medical visit will reach the one in four who are currently unaware of their HIV status, and slow the progress of HIV infection in all communities.

Routine Testing

In 2006 the federal Centers for Disease Control and Prevention (CDC) revised its recommendations regarding HIV testing in medical settings. Consistent with its prior recommendations the CDC maintains that 1) testing must be voluntary, 2) testing must not be conducted without the knowledge of the patient, and 3) obtaining written informed consent is an ethical obligation.³

The CDC further recommends:

- Testing should be offered and the patient required to opt out if he/she does not want a test. Specific signed consent for HIV testing need not be required.
- Consent for HIV testing should be incorporated into the patient's general informed consent for medical care.
- "Prevention" counseling should not be required prior to testing.
- Prior to testing patients should receive either written or oral information on HIV testing, including the meaning of both positive and negative test results.
- Lastly, patients should be offered an opportunity to ask questions, as well as an opportunity to refuse the test all together.⁴

New York State has a number of guidelines and statutes governing HIV testing and written informed consent, most of which are outlined in Article 27-F of the public health law. The recommendations by the CDC, a federal agency, are not legally binding and therefore do not supersede state and local law.

Written Consent

Currently in New York State, written consent must be obtained from an individual undergoing an HIV test, and proper pre-test and post-test counseling must be provided.

Some have cited written consent as a barrier to testing, and have further claimed that having different requirements for HIV testing contributes to the stigma that surrounds HIV and AIDS.⁵ Such claims have proven baseless and have not been empirically documented in any major peer reviewed academic journal. Stigma associated with HIV and AIDS is directly related to homophobia, racism, and the fear of being associated with drug users and low-income individuals. Simply requiring written consent does nothing to reinforce such discriminatory attitudes.

Instead, many believe that the routine offering of HIV tests in diagnostic settings could help to decrease stigma by effectively reaching every individual regardless of one's characteristics, community, or behavior. Patients being tested for HIV will be freed from revealing personal behaviors that they are uncomfortable discussing with their doctor. Similarly, doctors will no longer fear asking patients about behaviors that may not be readily apparent. However, as professionals, it is critical that physicians receive training to overcome such fears which serve to perpetuate stigma. The routine offering of an HIV test is a win-win situation for the doctor/patient relationship, and works to cement the bonds of trust critical to encouraging testing and care.

When discussing routinization of testing and consent, despite some critical differences associated with HIV/AIDS, it is important to consider protocols related to other diseases. Over the past seven years epidemiological data has shown an increase in the incidence of syphilis cases among gay men.⁶ One main contributor to the continued rise is that doctors are not offering the recommended annual screening as prescribed by the CDC. This is a disease where written informed consent is not required and where stigma is considered less severe than HIV/AIDS, partly due to the curable nature of the disease. However, cases of syphilis continue to rise because testing is not being routinely offered in diagnostic settings.⁷

Another argument to maintain written informed consent is an assurance that pre- and post-test counseling will be performed. Physicians have complained about having a lack of time to conduct proper counseling related to HIV testing. Without government guidelines to safeguard and properly inform the public, there is a risk that health care providers may skip pre-test counseling altogether, particularly for those patients considered to be in a low risk category for HIV transmission. Further, providers may also forgo post-test counseling for those patients with a negative result, therefore surrendering a key opportunity to reach patients with critical prevention information. This would be an extremely dangerous practice that could lead to the further transmission of HIV due to a clear deficiency of information.

Additionally, assurance must be made that patients are aware of the true meaning of an HIV test and its results. An opt-out provision, as recommended by the CDC, is not ideal. An opt-in provision would give greater choice to people wishing to be tested for HIV, and would better enable patients to consent to an HIV test, while preventing physicians from testing without the patient's knowledge. However, many advocates concede that opt-in testing in a general environment will result in fewer people being tested. The opt-out version, while not optimal, could yield a higher rate of those getting tested.⁸

Pre-Test & Post-Test Counseling

Pre- and post-test counseling are key components of consent requirements. This is essentially the "informed" portion of written informed consent. Many doctors have complained that they simply do not have time to provide the information required. However, neither the CDC nor the State of New York has outlined specific time parameters, staffing, or media for imparting such information.⁹

Doctors must ensure that patients are provided with information necessary to decide to take an HIV test. This is a critical part of a doctor's obligation to their patient and can be done by either the doctor or by proxy. In fact, a study conducted by the New York State AIDS Institute shows that less than 2% of those conducting HIV counseling were physicians. More than 77% of counselors in the survey were either a nurse, nurse practitioner, HIV counselor and tester, case manager, social worker, or therapist.¹⁰ The fact that other health care professionals provide most pre- and post-test counseling belies doctors' claims that this requirement is burdensome.

Despite the need for their medical expertise, physicians may not be in the best position to actually perform counseling for HIV testing. In a survey of physicians throughout New York State conducted by the AIDS Institute, nearly 32% of physicians have reported never diagnosing a patient with HIV since the inception of the HIV Reporting and Partner Notification law (HIVRPN) in 2000. And only 31% of physicians had diagnosed HIV in the last year. Also, roughly 24% of doctors incorrectly identified the HIVRPN law in pre- and post-law surveys.¹¹ Clearly, health care professionals who work regularly with HIV testing may be better suited to counsel patients during HIV testing than doctors.

Many opportunities exist to shorten the time and lessen the staffing required for such counseling. Neither the CDC nor the State of New York requires that a physician must administer the totality of pre- and post-test counseling. Such requirements can be fulfilled by a variety of health care professionals—nurse practitioners, registered nurses, HIV counselors, or physician's assistants, among others.

Pre- and post-test counseling is important for an array of reasons, not all related to medical implications. In New York State, as in 44 other states, health providers are required to report the name of every individual diagnosed with HIV or AIDS. Such information is held in confidence by the State. Proper pre-test counseling makes patients aware of important legal obligations and appries them of the option of testing at an anonymous testing site. Since mandatory names reporting became law in 2000 in New York State, fewer anonymous testing sites exist. However most medical professionals would agree that getting a patient tested, whether confidentially or anonymously, is the most important step toward making a person aware of his/her HIV status. Through such awareness, an individual can begin to make decisions about personal behavior and treatment options.

Further, counseling is needed to make patients aware of the true meaning of an HIV test. Unlike most diseases, HIV has a window period in which a typical antibody test will not detect the presence of HIV antibodies. This period can extend for three months after infection. Therefore a negative result does not accurately reflect the HIV status of a patient on the day the test is administered, but only reflects the patient's status approximately three months prior to the test.

In the event of a positive HIV antibody test, whether the test is administered orally or through the drawing of blood, a confirmatory test must be administered. It is important for health care providers to explain the meaning of a positive HIV test result, as there is a tremendous amount of misconception surrounding HIV/AIDS. An HIV diagnosis has not been considered a death sentence for well over a decade, thanks to the advent of antiretroviral drugs in the mid-1990s. However, such notions remain prevalent among the general public. Health care providers must counsel patients on treatment options and explain that, thanks to advances in HIV medications, people can live with HIV for many years.

Hospitals and other health care facilities that have attempted to independently routinize HIV testing have often relied on the distribution or display of HIV testing education materials to adequately inform patients who consent to testing. Pamphlets, brochures, and posters have significantly lessened the staff time dedicated to disseminating information essential to proper testing. This passive form of pre-test counseling allows patients to absorb information at their own pace and permits a greater rumination for the formulation of questions a patient may have.

Another distinct aspect of the process of receiving test results includes post-test counseling. A 2005 study reveals that among those utilizing the standard blood test, which typically requires one to two weeks for a lab result, slightly less than 70 percent of individuals returned to receive their results, and therefore did not complete the necessary counseling. Of those who utilized the rapid test, 99 percent stayed for their results and counseling.¹²

The importance of counseling cannot be overstated. There continues to be a lack of basic information about HIV transmission throughout the general public.

- 37% mistakenly believe HIV can be transmitted through kissing.
- 22% mistakenly believe HIV can be transmitted by sharing a drinking glass.
- 16% mistakenly believe HIV can be transmitted by touching a toilet seat.
- Over 40% of adults held at least one of the above misconceptions.¹³

In fact, HIV is generally transmitted primarily through unprotected sex or the sharing of injection drugs or needles.¹⁴ Such lack of basic HIV information promulgates stigma and serves to marginalize people living with HIV/AIDS.

With the inception of New York's HIV Reporting and Partner Notification Law (HIVRPN), significant changes occurred in the information given to New Yorkers getting tested. Remarkably, even after the law was enacted, only 60% of those who tested anonymously reported having a discussion about HIVRPN. Similar numbers were reported for those who tested confidentially. Two out of five people getting tested for HIV continue to not receive sufficient information regarding the laws that govern HIV testing, names reporting, and its full implications. However, there is a clear disconnect between what is being heard by patients and what is being said by those providing the counseling, because approximately 85% to 98% of counselors reported discussing different facets of HIVRPN.¹⁵

Additionally, a 1998 study by the CDC found that certain counseling tactics that encourage specific and tailored prevention strategies to the individual are more effective than other tactics that only seek to lecture the patient. A 20% decrease in new STDs was shown among participants overall, and that number is doubled among adolescent participants.¹⁶ Such clearly documented behavioral changes supports the argument against eliminating pre-test counseling.

Barriers & Attitudes

Following the implementation of HIVRPN, the New York State Department of Health AIDS Institute commissioned a report on the new law and its general implications. The study was updated in 2006 and revealed some notable findings regarding attitudes and practices surrounding HIV testing. The AIDS Institute surveyed a broad number of New Yorkers on their views on HIV testing, pulling from various sources, including gay bars, STD clinics, and syringe exchange programs. The population also included those who tested positive, those who have tested within the past year, and those who have never been tested.

Overwhelmingly, most consumers of HIV testing cite the belief that they are not at risk for contracting HIV as the biggest deterrent to getting a test. Other concerns include the fact that their doctor did not recommend the test, which often means that the doctor does not consider the individual to be in a high risk category for contracting HIV. Further, people express worries of confidentiality, as well as a simple aversion to needles and giving blood as a barrier to testing. A small segment is fearful that they will test positive.^{17,18}

In a survey conducted by the Kaiser Family Foundation in 2006, over 60% of people believe that HIV testing should be part of routine medical testing, as with other diseases. However, those same people

did not view written consent to be a barrier to testing. Additionally, one in five people surveyed felt that people would think less of them if they tested positive for HIV. Despite calls for routinization of HIV testing, it is clear that stigma and discrimination associated with HIV play a significant role in people's decision whether to get tested.¹⁹

Self assessment continues to be an overwhelming barrier to testing. Nearly half of respondents to the AIDS Institute survey (46.4%) reported thinking that they were unlikely to be positive as a reason for avoiding or delaying testing. Nearly 36% gave that response as the most important reason. Approximately 29% of respondents indicated that they avoided or delayed getting tested for HIV either due to fear of being positive or because they did not want to think of their own serious illness or death.²⁰ Clearly a need for greater in-depth pre-test counseling is needed to assuage people's fears and anxieties surrounding testing, and to get people tested without delay. Any postponement of diagnosis could be detrimental to the health and well being of a patient, as well as perpetuate the spread of HIV if behavior is not altered.

Of note, 5% of respondents expressed concern about potentially reporting their name to the government in the event of a positive result as a reason for avoiding or delaying testing. When HIV counselors were asked their beliefs as to why a patient avoids or delays testing, a much higher two-thirds indicated that they felt patients were worried that their name would be reported to the government if they tested positive. The AIDS Institute study also shows that while nearly half of people are aware that HIV results are reported in some manner, only 18% knew the results were reported by name. Also, while over 75% of those who have tested since HIVRPN's inception knew that anonymous testing is available in New York State, only 43.5% of those who have never tested for HIV knew of such availability.²¹ Education about this important legal distinction and availability of this critical service must be more pronounced in pre-test counseling. Providing this information is vital to gaining the trust of patients and putting them in a better position to get tested on their own terms.

Another possible deterrent to getting tested is the partner notification aspect of HIVRPN. Prior to the law's inception, nearly 60% of respondents who tested knew that partner notification was not required if they tested positive. However, for those who tested after the law less than 48% reported knowing for certain that partner notification is not required. Further a full third of respondents who have tested after the law claim they do not know that health workers do not report the name of the patient when conducting partner notification. Also, over one-third of respondents feel that partner notification is an invasion of one's privacy for both the patient and the person being notified.²² One could imagine that this would be a significant deterrent to testing, particularly if there is a history of physical or psychological domestic abuse.

Progress is certainly being made with the minds and attitudes of people testing for HIV; however, more work is needed. While 39% of respondents feel that testing is not at all stressful, nearly 41% express feeling stressed on some level, with over 25% of them indicating that testing for HIV is extremely stressful.²³

One aspect of knowing one's HIV status is a potential shift in behavior for those who have been tested. The AIDS Institute study reveals that nearly 25% of those testing positive report not having sex in the past year. That is more than double the rate for those who test negative or who have never been tested. Also, roughly 28% of those who have never tested report having six or more sexual partners, compared to approximately 21% of those who got tested for HIV.²⁴

On average, those who had never been tested had eight sexual partners in the course of a year, while those who did test had an average of five partners. Further findings associated with condom use clearly illustrate changes in behavior. Only 18% of those who have never tested for HIV report always using a condom during anal or vaginal intercourse, while nearly 43% of those who have tested positive report always using a condom. Conversely, nearly 25% of those who have never been tested report never using a condom, as opposed to just under 11% of HIV-positive respondents who report never using a condom during sex.²⁵

When discussing barriers to testing, one of the main aspects discussed is the patient's ability to get tested and impediments to his or her actions toward getting tested. However, another aspect of testing barriers is on the side of the doctor. Some doctors have reported experiencing barriers to the actual administering of the consent and therefore the test itself. Some alleged administrative barriers include lack of availability of forms in languages other than English or a lack of opportunity and time for a doctor to properly deliver completed consent forms to the necessary officer in the laboratory.

Due to state guidelines already in place in New York and others states, as well as medical ethics regarding linguistic competencies surrounding the administering of health care and information sharing, forms in a variety of languages must be made available in order to quickly initiate HIV testing. Some doctors have complained that if a form is required in another language other than English, it becomes cumbersome to obtain the proper form and therefore significantly delays testing. In truth, the New York State Department of Health provides consent forms in more than 20 languages, all of which can be easily accessed on the Department's website.

GMHC does not view this as a significant barrier for physicians. HIV test consent forms are no different than a variety of other forms necessary to gain consent for other tests and procedures. Doctors do not complain about providing those forms in languages other than English. Linguistic competency is a basic human right for accessing health care and should not be compromised for the sake of expediency or convenience.

Also, some doctors have noted that due to the nature of their jobs, once written consent is obtained, they may not be able to physically deliver the form to the proper hospital administrator in order for the processing of the test results to commence. GMHC firmly believes that such "barriers" can easily be remedied through small administrative changes in procedures surrounding documentation transfer and patient records.

Implementation Feasibility

The Centers for Disease Control and Prevention (CDC) has frequently made recommendations regarding health policy. In some cases, such recommendations are not feasible or advisable to implement due to various circumstances in state and local jurisdictions. The 2006 CDC revised recommendations on HIV testing, while sometimes a helpful guideline, are impossible to implement because of such circumstances. In this instance, state law does not permit strict implementation because the legislature has already spoken on the matter of HIV testing, and created its own laws and regulations to govern testing. Health policy has long been under the purview of state and local law, and recommendations made at the national level will not always have the most advantageous results or reflect the specific values of various localities.

Age

One aspect of the CDC's recommendation is the age range. The CDC currently recommends routine testing for those 13 to 64. GMHC is in firm agreement that the lower end of the range should be 13. Evidence has shown, particularly in New York State, that teenagers are increasingly engaging in sexual activity. Pregnancy and sexually transmitted infections are on the rise among young adults. The pregnancy rate among teenagers is as high as 15% in some counties in New York.²⁶ Testing is a critical factor in a comprehensive strategy to ameliorate this worsening situation among young people.

On the other end of the age spectrum, GMHC believes New York State should go beyond the CDC guidelines. With baby boomers remaining sexually active later in life and life expectancy increasing, we recommend extending the range from 64 to 72.

Voluntary Routine Testing

In 2005, with money granted by the New York City Council, the New York City Health and Hospitals Corporation (HHC) implemented a pilot program to routinize and expand HIV testing throughout its various facilities, taking a proactive lead to test more New Yorkers for HIV.

HHC had three main goals in mind for this new initiative:

- Increase the number of patients who know their HIV status (with a target of testing 150,000 unique patients);
- Increase the proportion of patients who enter care early, in the hopes that the number of dual AIDS diagnoses will decrease; and
- Retain patients in care with a target of 80% or greater of the patients attending two medical visits within 12 months, with at least one visit in the last six months.

While serving approximately 1.3 million New Yorkers in nearly 100 facilities annually, HHC estimates that it sees nearly 4,000 patients who are HIV-positive and unaware of their status.²⁷

Throughout the HHC facilities enrolled in the pilot program, there were varying degrees of success with the testing initiative. HHC witnessed an increase of 8% to 28% of unique patients being tested among its individual sites without compromising patient volume. While prenatal testing remained steady, HHC saw the number of patients being tested go from 62,023 in 2005 to 133,859 in 2007. That represents an increase of 116% in just two years. From 2006 to 2007, there was a 12% increase of those patients who were newly diagnosed with HIV. This represents a significant number of people accessing proper care earlier, while simultaneously stemming the further spread of HIV by those most infectious.²⁸

It is important to note that the mode of testing utilized by HHC changed significantly within this period as well. In the first quarter of 2005 approximately 7% of tests administered were rapid HIV tests, as compared to the conventional blood test. Within just two years, in the last quarter of 2007, that percentage rose to 83%.²⁹ This tremendous shift in the way testing is conducted throughout HHC facilities is most likely a significant factor contributing to the overall increase in testing and the likelihood of patients consenting to testing. At the very least, the issue of the waiting period between test and result has been significantly managed, no longer allowing patients to use that interim period to decide to not return for the results.

In a detailed study of a specific HHC facility in the north Bronx, 7,028 patients were approached for HIV testing, with 87% consenting to the test. Of those tested, .08% tested positive.

Three main accomplishments from the pilot project were cited by HHC, including:

- Successful identification of a significant number of individuals who would not likely otherwise have taken an HIV test;
- Availability of the rapid HIV test at the largest HHC facilities, as well as those most utilized by high-risk patients; and
- Universal offering an HIV test at all HHC facilities.

HHC identified the following three drivers that positively impacted the expansion of HIV testing:

- Widespread availability of a rapid HIV test;
- Consistent use of the streamlined HIV counseling model accompanied by regular monitoring and evaluation; and
- Clinical and executive level commitment to the HIV testing expansion initiative.

HHC further identified three obstacles that worked against the initiatives expansion, including:

- The need for a higher percentage of clinicians who offer the HIV test;
- The difficulty in maintaining and tracking interdisciplinary teams during tours; and
- A lack of dedicated, private space for counseling patients who test positive.

In its conclusion, the New York City Health and Hospitals Corporation stated, “Written informed consent has not been a significant barrier to achieving exceptional increases in the number of unique patients testing for HIV.”³⁰

Contrary to claims by New York City Department of Health and Mental Hygiene Commissioner Thomas Friedman, HHC did not find written informed consent to be a barrier to testing. It is certainly worth noting that this entire HIV testing expansion initiative may not have been possible without the \$3 million of funding from the New York City Council. In fact, funding is a critical component for any expansion of HIV testing. Government entities, health care facilities, and insurance companies must decide a course of action that will fund expanded testing and work toward sound public health policy.

At one facility in the north Bronx, HHC estimated that the 6,081 tests that were administered cost \$183,000, not including staffing time. This amounts to approximately \$30 per patient.³¹

In an article written by a spokesman for the CDC’s Division of HIV/AIDS Prevention, implementation recommendations were made regarding the new CDC guidelines on HIV testing. In his argument, Dr. Robert Janssen discusses ways to successfully eliminate political barriers to HIV testing, such as written informed consent. In his example he points to the New York City Health and Hospitals Corporation’s pilot program designed to routinize HIV test among its facilities. Dr. Janssen points to the program’s success. However, he fails to realize that in this instance, written informed consent was maintained, all the while the number of tests performed increased nearly 60 percent in the first year alone.³²

Legal

Beyond the medical issues that arise during comprehensive HIV testing, legal concerns also play a significant role and must be taken into consideration by patients, doctors, and health care facilities. The revised CDC guidelines outline a broad set of recommendations for implementation on the statewide level. However, there is vast patchwork that currently exists, governing HIV testing guidelines throughout the states in the form of statutes, codes of ethics, regulations, and constitutional considerations. Additionally, there are federal laws that prohibit discrimination against persons with disabilities that apply to persons living with HIV/AIDS. The Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) are chief among them. According to the ADA, providing adequate linkages to care for those who test HIV-positive is not simply an ideal to live up to, but the law. There are additional considerations regarding one’s right to privacy, which are also governed by a myriad of state and federal statutes.³³

Consequently, any attempt to circumvent or minimize counseling during an HIV test could result in potential liability under a variety of laws. A one-size-fits-all model will not work given the array of jurisdictions, as well as the local beliefs surrounding HIV testing. The legal hazards that could incur are numerous. This complex legal landscape underlines the need for written informed consent.

Informed consent speaks to the critical need for communication between the health care provider and the patient. Any protocol that would allow silence as consent potentially compromises the patient’s ability to receive information and calls into questions ethical standards. Any guideline that does not support written informed consent where it already exists does not fully address the issue of written informed consent itself.

According to the revised CDC guidelines, “[l]inking patients who have received a diagnosis of HIV infection to prevention and care is essential. HIV screening without such linkage confers little or no benefit to the patient.”³⁴ This is a clear signal from the CDC that testing without counseling is medically and ethically negligent.

Another aspect of the legal ramifications faced by those administering HIV tests is the simple task of knowing that a patient can absorb the information. To ensure informed consent is legally provided a physician must do the following:

- Confirm the patient has the mental capacity to understand the procedure;
- Ensure that the mental and emotional aspects of the test are adequately addressed; and
- Convey the information in a manner that is understandable to a lay person.³⁵

By assessing the patient for such mental and cognitive capacity, subsequently imparting information in a reasonable way, and obtaining written consent, doctors and hospitals can avoid future legal liability.

In 2003, pursuant to the CDC’s desire to fully implement and advance its new HIV prevention initiative, “Advancing HIV Prevention: New Strategies for a Changing Epidemic,” the CDC commissioned a study to review state laws that could support or hinder the strategy. Working with the National Conference of State Legislatures and the Center for Law and the Public’s Health (CLPH) at Georgetown and Johns Hopkins Universities, an analysis was conducted to identify those statutes that would directly impact AHP.

A series of 20 different questions was analyzed in four major areas of HIV/AIDS law: 1) personnel; 2) pre-test requirements; 3) testing; and 4) post-test requirements. There were some questions of particular note to this analysis. Chief among them were limitations on who can request and perform a test, who can provide pre- and post-test counseling, requirements for written consent, and requirements for anonymous testing. One notion that was posed, but later ruled not applicable, is “prohibition of opt out consent forms.” The research conducted concluded that this issue did not produce relevant state statutes that would interfere with the implementation of the CDC’s Advancing HIV Prevention initiative.³⁶

With regard to statutes governing pre-test counseling and informed consent, 35 states and the District of Columbia have laws that either require pre-test counseling and the provision of specific information before testing or require informed consent before testing. Such regulations typically require counselors to provide, the following:

- An explanation of the HIV test, as well as its potential uses and limitation;
- An assurance of confidentiality;
- An explanation of HIV transmission and risk management options; and
- A disclosure of results.

CLPH concluded that meeting these requirements “would not likely be prohibitive for most health care providers in a routine medical setting.”

Further, some states do specify who can conduct such counseling and testing. However, all provisions include doctors, as well as other health care providers. Providing a full complement of HIV counseling has the potential to increase the time it takes for the HIV testing process. However, it does not necessarily mean more time for the doctor, as other health care providers are eligible to impart such information.³⁷

Efficacy & Cost

Once written consent is obtained and counseling provided, administering the HIV test is but one aspect of the overall testing process. Results are fairly meaningless unless a patient actually receives their results. It is at that moment when post-test counseling can occur, and if necessary, referrals to appropriate medical care can be made.

With any plan or proposal introduced to routinize HIV testing, there is always a discussion of the efficacy and the cost of the rapid HIV test. When reviewing the many barriers to testing, many patients cite fear as a significant factor. The conventional blood test is often seen as compounding that fear because a patient must wait several days before acquiring the results of the test. At the same time, many doctors cite time as a significant barrier. Again, the conventional blood test necessitates the need for at least two visits to the doctor or other health care professional. The rapid test removes such impediments for both the patient and the health care provider, as the time needed to ascertain a result could be as little as 20 minutes.

Prior to the introduction of rapid testing an estimated 2.3 million of 17.5 million U.S. residents tested annually for HIV did not return to receive their results, approximately 13 percent. Interestingly, the rate of those not receiving their results was highest among those whose tests were required—24 percent. Among those who purposely sought testing only five percent did not return for their results. This directly speaks to the issue of mandatory testing and refutes the notion of its effectiveness.³⁸

In an analysis of the National Health Interview from 1994 and 1995, it was found that eight percent of patients who did not receive their test results were infected. The analysis further concluded that had those who did not return for their results actually done so, as many as 29 percent of HIV-positive individuals and half of HIV-negative individuals would have learned their status.³⁹

In 2000, the CDC estimated that 31% of patients who tested HIV-positive through a conventional blood test did not return to receive their results. In a study conducted to gauge the rate patients receive their results, rapid tests were offered at various needle exchange programs and bathhouses in Dallas, Texas. The study found that 83% of participants at a needle exchange site using the rapid test stayed to review their results, compared to 56% of similar participants using the conventional blood test. Additionally, for those who were tested at a bathhouse, 99% of participants using the rapid test stayed to review their results, compared to 74% who used the conventional blood test. In a separate study conducted in New York and Utah, 13% of patients indicated they would not have tested that day had the rapid test not been available.⁴⁰

In a 2006 study conducted by the National Alliance of State and Territorial AIDS Directors, health departments were asked about their attitudes toward the rapid test and their priorities for expanding its use. The respondents included 39 state health departments, three city health departments, and one territorial health department.⁴¹

Of the 43 respondents, over 81% indicated limited availability of the rapid test as a reason for not implementing its routine use. Of the remaining eight departments that indicated otherwise, six cited a lack of resources as a primary barrier to offering the rapid test. Two respondents indicated statutory or regulatory barriers.⁴²

Availability of rapid testing is an area where the CDC could be most helpful and where state laws could be more easily changed to promote rapid tests, compared to the complexity of laws governing informed consent. The efficacy rate of the rapid test is a marked improvement over the blood test. Providing a more universal availability of the rapid test should be central to any effort to routinize HIV testing. Patient and provider satisfaction is fairly clear on the issue.

Another significant factor to making the rapid test more universal is the cost. The introduction of the rapid test also gave consumers the opportunity to compare the cost of rapid tests versus the

standard blood test. While the CDC and many states across the country have expressed their desire to increase testing, additional resources to providers performing tests have not been forthcoming.

The cost of a rapid test varies from \$8 to \$25.⁴³ The cost of the actual test along with staff costs are generally the only costs associated with the rapid test, as it does not require costly laboratory analyses. However, given the relatively new nature of the test, many state and local health departments have not adapted and many have not determined a system to incur the cost of the rapid test. Over half of the health departments responding to the NASTAD survey indicated a need for assistance in evaluating the cost-effectiveness of rapid testing.⁴⁴

In 1997 the cost savings for the rapid test compared to the conventional blood test was \$11 simply for the test itself, while the cost savings per person receiving results and counseling was as high as \$280. Given the rate of inflation, compounded by a staggering rise in gasoline prices in the past year, along with wider availability of the rapid test, one could conclude that the cost differential is far greater now, over a decade later.⁴⁵

Overall, there has been great satisfaction among patients for the rapid HIV test. A recent study addressing barriers and misgivings of the rapid test found that three out of four patients did not find the rapid test stressful. Nearly 9 of 10 actually preferred the same-day results. And an overwhelming 97% of patients would recommend the test to their friends. Such satisfaction rates can only work to assuage misgivings as the rapid test becomes more widely available and help the general population become more comfortable getting tested.⁴⁶

In the effort to reach the 1 in 4 people with HIV who are unaware of their status, one of the driving forces is the desire to get those who are HIV-positive into proper care and treatment as soon as possible following seroconversion. In 1993 the life expectancy of an HIV-positive adult was 6.8 years. The lifetime healthcare costs were then estimated at nearly \$120,000 (\$150,000 in 2004 dollars). Of those costs, approximately half was for inpatient care, while medications accounted for 14 percent.⁴⁷

Today those numbers are quite different. For a newly diagnosed person just beginning to enter care, his/her life expectancy is now estimated to be 24.2 years. With the tremendous advancements in AIDS treatment, particularly with the introduction of antiretroviral therapy (ART), lifetime health care cost is estimated to range from \$385,200 to as high as \$618,900 per person. The breakdown of costs includes 73% for ART, 13% for inpatient care, 9% for outpatient care, and 5% for other medications and laboratory costs.⁴⁸ Clearly there is a significant shift in the cost of health care for people living with HIV/AIDS, which represents the advances in treatment technology.

Given that a disproportionately large number of new infections are caused by people who are unaware of their HIV status, if more people are tested and discover their HIV status sooner, the rate of new HIV infections could decrease exponentially. The CDC estimates that there were nearly 53,000 new HIV infections in 2006.⁴⁹ If the routinization of HIV testing could result in a modest 10% decrease in new infections, besides the incredible impact on public health and humanity, there could be a savings of health care costs totaling \$2.4 billion to \$3.3 billion. If such savings were redirected to prevention services, even more lives and money could be saved.

Emergency Departments

Since the early 1990s many public health experts have looked to emergency rooms as a venue for early diagnosis of HIV. For many low-income Americans and people of color, many of whom have no health insurance, visiting an emergency room may be the only visit with a health care provider that they experience. This use of acute care for primary care underscores the vital need to conduct HIV screenings in emergency rooms. Of the many studies reviewed on the subject of HIV testing in emergency department settings, none have shown written, informed consent to be a significant barrier to testing.

According to findings by the Society for Academic Emergency Medicine Public Health and Education Task Force, of the 17 specific prevention initiatives newly considered in routine emergency care, HIV testing was one of five to receive a top rating. During the study, when routine HIV testing was offered half of the patients consented. This is a comparable rate of consent to other test sites.⁵⁰ It is important to note that this study, conducted in 2003, was in the early days of rapid HIV testing. Given improvements in rapid testing and its greater availability today, the rate of consent might be even higher.

In a review of seven emergency rooms with various demographics and varying degrees of seroprevalence, the rate of new HIV diagnoses ranged from 2% to 17%, with a mean average of 8%.⁵¹ It has long been recommended that HIV screening be offered among the routine offerings in emergency department settings for those living in high prevalence areas. In addition, studies have suggested that HIV counseling and testing can also be successful in such a setting in low prevalence areas.⁵²

In a study of HIV testing in Emergency Departments where patients did not consent to testing, the overwhelming reason for avoiding testing was they had previously been tested. Another significant factor was that people did not feel they were in a high risk category. The actual aspect of granting consent was not listed as a barrier to testing.⁵³

Regardless of prevalence level however, HIV testing is almost always accompanied by counseling. The premise that awareness of one's HIV status alters risk behaviors is generally accepted and holds true for those receiving diagnosis during acute care. Particularly in an emergency department setting, health care providers point to the greater need for pre- and post-test counseling, as well as the need to provide private physical space to conduct such confidential counseling, as areas in need of greater resource allocation. Historically emergency departments have not been equipped with an infrastructure that is needed for such an intervention. However, small and deliberate structural changes can be made to address the realities of acute care and the role of HIV testing.⁵⁴

Emergency rooms play a unique role in the move to routinize HIV testing. With populations at greater risk for HIV infection, taking the opportunity to test for HIV is critical. While there are clear acute needs that may take precedence in an emergency setting, testing patients presenting in the emergency room often yields a higher incidence of HIV than in other settings. And due to the irregularity of emergency room visits such a patient may experience, identifying those who are positive and transitioning them into care is all the more critical.

Conclusion

Beyond prevention methodologies traditionally applied—sex education, the distribution of condoms, the creation of sexy and poignant social marketing campaigns, providing access to clean needles—testing is proven to reduce the spread of HIV. It is through testing, along with screening, that the transmission of HIV through the nation's blood supply has been nearly eradicated. It is through testing, and subsequent treatment, that the incidence of mothers passing HIV to their children through birth or nursing has nearly disappeared in the United States.

Expanded and targeted testing can help to identify a greater number of people living with HIV and successfully connect them to care. This effort can be implemented without the dismantling of written informed consent. Testing is no panacea, but it is a valuable piece of the puzzle from which we can build a successful prevention initiative that targets every American. A responsible, yet deliberate dismantling of true barriers to testing, both economic and structural, must be hastened forthwith.

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Gay Men's Health Crisis (GMHC) is a not-for-profit, volunteer-supported and community-based organization committed to national leadership in the fight against AIDS. Our Mission is to reduce the spread of HIV disease, help people with HIV maintain and improve their health and independence, and keep the prevention, treatment and cure of HIV an urgent national and local priority. In fulfilling this Mission, we will remain true to our heritage by fighting homophobia and affirming the individual dignity of all gay men and lesbians.

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