



thewellproject

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Comment from the Center for HIV Law and Policy, AIDS United, and The Well Project Regarding the CDC's HIV Testing Recommendations

As advocates for people living with HIV (PLHIV), we are writing to express our continued support of recommendations from the CDC that recognize the vital importance of strong protections of patients' rights to notice of and consent to HIV testing to further progress towards ending HIV transmission.

The CDC's request for comment notes an intention to update the 2006 clinical guidelines for HIV screening based on "contemporary issues and evidence," with a special consideration of "opt-out routine testing." Now more than ever, as advocates and policymakers set their sights on ambitious goals of ending HIV transmission within a generation, we believe that it is essential that HIV testing guidelines reflect contemporary understandings of medical ethics, respect for the dignity and autonomy of all patients, and clinical best practices. We believe that a strong commitment to those values is what will actually facilitate progress towards an end to HIV transmission by addressing concerns about continued criminalizing of alleged HIV exposure, collateral legal consequences of HIV diagnosis, and the legacy of medical mistrust between patients and providers in exactly the vulnerable communities in which we most need to make inroads.

We know that this will require maintaining testing guidelines that make patients feel that testing is safe by protecting them from collateral threats that present serious harm to many, particularly undocumented immigrants and others whose lives are bound up with government agencies that regulate their medical care choice, parenting and other very personal issues. Moreover, in order to be effective, HIV testing guidelines must comply with state and federal law protecting the rights of health care patients and people living with disabilities.

To that end, we urge the CDC to continue to recommend patient protections that ensure that medical treatment is only provided upon informed consent of the patient in the hope that doing so will improve public health. We believe that ensuring a person is fully informed of their testing regimen will best ensure a reduction in HIV as well. For those reasons, the CDC's revised screening recommendations should direct that all jurisdictions

continue to require that providers only conduct HIV testing after directly orally notifying patients and providing them the opportunity to indicate whether or not they consent to testing.

HIV Testing Regulations Should Reflect Modern Understandings of Patient Autonomy and the Critical Importance of Patient Literacy and Engagement in Improving Health Outcomes

HIV testing protocols best reflect the indispensable modern medical concept of informed consent by ensuring that all patients are effectively put on notice, with an explanation of what a proposed test will do and why it is recommended, prior to testing and have the opportunity to indicate whether or not they consent. This situates HIV within the common practice throughout the country to test an individual for a serious chronic disease only following an explanation of the test and an opportunity for a patient to ask questions. Professional and practice standards, as well as state patient bill of rights provisions, require no less.

That is why, as recently as 2015, the CDC's Sexually Transmitted Diseases Treatment guidelines explicitly recognized that "Persons should be notified that testing will be performed, but retain the option to decline or defer testing."¹

To recognize the importance of testing procedures that respect the dignity and autonomy of patients, one must acknowledge the fallacy of two significant fictions often propagated to support a return to nonconsensual testing practices out-of-step with contemporary medicine. Those are that (1) patient-centered care and communications with clients pose a significant barrier to effective diagnosis and treatment; and (2) that it is standard practice to do a wide array of tests unrelated to a patient's symptoms without informing the patient what they are being tested for and why. Arguments such as these have been used most recently to support a lower standard of patient autonomy in HIV testing and diagnosis than is routinely followed for other types of STIs, that are at present far more prevalent and frequently more deadly.²

In fact, testing for HIV only upon notice and consent is completely consistent with best medical practices. Even in the case of basic screening tests done as part of an initial patient panel to assess overall health, most providers will explain what tests are being conducted and for what purpose. That is because providers recognize that an informed patient is more engaged in, and therefore takes more responsibility for, maintaining their

¹ See Sexually Transmitted Diseases Treatment Guidelines, 2015, available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm>.

² See, e.g., Hogan, Bernadette, *New Bill Would Allow Doctors to Test for HIV Without Consent*, New York Post, May 26, 2019, available at <https://nypost.com/2019/05/26/new-bill-would-allow-doctors-to-test-for-hiv-without-consent/>.

health.^{3,4} Such a practice should surely also apply to testing for HIV, which, despite the significant medical progress of the past three decades, still carries categorically different ramifications than basic screening tests. While routine labs like a complete blood count or a comprehensive metabolic panel give a general indication of things going on with any patient, an HIV test is very specific and should be treated no differently from other very specific screening tests, such as those for prostate or breast cancer, which are only conducted with the full input of the patient.

Fully informing patients of their rights need take little or no time away from other treatment, nor do such conversations need to be fraught with discomfort. Busy, successful medical providers repeatedly report that such notice and consent can be accomplished in mere minutes and improves relationships between patients and providers. To the extent that medical providers avoid that conversation because they are uncomfortable discussing HIV testing and treatment, or think it is a waste of scarce time to give options to people they consider at significant risk of HIV, the solution is improved training in best practices. Indeed, such training is essential to solving any issues of provider or patient discomfort, none of which would be addressed by unproductively kicking these important conversations down the road and keeping patients in the dark about their rights and options at a crucial stage in engagement.

As Dr. Jeffrey Birnbaum, a long-time adolescent HIV care provider, founder and director of the HEAT Program at SUNY Downstate/Brooklyn, and one of the most respected physicians in his field recently observed:

It is a kind of bias to assume that there is no time to ask a few simple questions and document verbal consent, especially if the provider perceives the patient to be at risk due to their socioeconomic and ethnic background. Assumptions are being made that all Black and Brown people who are poor are at higher risk for HIV, and so we should just go ahead and give them an HIV test as a "routine" test without a brief, even perfunctory discussion of risk and request for consent. But this simple discussion can be accomplished in under two minutes for most people and individuals who do have higher risk can be engaged in a longer conversation, if appropriate.

Medical Ethics Require Informed Consent to Testing

³ See American Medical Association Code of Medical Ethics Opinion 2.1.1 *available at* <https://www.ama-assn.org/delivering-care/ethics/informed-consent>.

⁴ Brach, Cindy, *Even in an Emergency, Doctors Must Make Informed Consent An Informed Choice*, Health Aff (Millwood) 35(4) 739 (2016) (“There is a growing expectation that doctors should be effective communicators. Medical schools have begun to teach communication skills, especially since the United States Medical Licensing Examination started testing those skills with the use of simulated patients in 2004, and the communication skills component of the exam was enhanced in 2012”).

Respect for a patient’s dignity and right to make affirmative decisions with respect to medical treatment, medical testing, and disclosure of sensitive information is a central tenet of medical ethics.

In New York, that value is so important that it is enshrined in the Patient’s Bill of Rights that New York’s Public Health Law requires that every medical facility post.⁵ The Patient’s Bill of Rights makes it clear that patients are entitled to “receive complete information about your diagnosis, treatment, and prognosis.”⁶ A patient also has the absolute right to refuse treatment.⁷ Notably, these provisions apply to all medical testing and treatment, even for conditions that do not have a specific testing or treatment law of their own. For its part, a New York hospital has an affirmative obligation to afford each patient the opportunity to exercise each of those rights, including the right to refuse treatment.⁸

New York is not exceptional in this regard—the recommendations of the Centers for Disease Control,⁹ the World Health Organization¹⁰ and the American Nurses Association’s Code of Ethics¹¹ also all stress the importance of informed consent to treatment.

HIV testing with effective notice to and consent of patients is consistent with those essential values. Providers who engage in medical testing with a patient’s informed

⁵ Pub. Health § 2803(1)(g).

⁶ 10 N.Y. Comp. Codes. R & Regs. Tit. 10 § 405.7 (c)(9).

⁷ *Id.* at § 405.7(c)(11).

⁸ *Id.* at § 405.7(b)(1) and 405.7(b)(10).

⁹ “CDC Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings,” available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> (“Patients should be informed orally or in writing that HIV testing will be performed unless they decline (opt-out screening). Oral or written information should include an explanation of HIV infection and the meanings of positive and negative test results, and the patient should be offered an opportunity to ask questions and to decline testing.”).

¹⁰ “Consolidated Guidelines on HIV Testing Services,” available at https://apps.who.int/iris/bitstream/handle/10665/179870/9789241508926_eng.pdf;jsessionid=B9A60A216A0A64036011E9A7D29EE81C?sequence=1 (“HIV testing for diagnosis must always be voluntary, consent must be informed by pre-test information, and testing must be linked to prevention, treatment, care and support services to maximize both individual and public health benefits.”).

¹¹ *Code of Ethics for Nurses*, available at <https://www.nursingworld.org/coe-view-only> at Section 2.1 (“The nurse’s primary commitment is to the recipients of nursing and health care services.... When the patient’s wishes are in conflict with those of others, nurses help to resolve that conflict. Where conflict persists, the nurse’s commitment remains to the identified patient.”).

consent have, by definition, fulfilled their legal obligation to fully counsel the patient with respect to the risks and benefits of the procedure and secure informed consent. By contrast, a patient who has been tested without their knowledge and consent has by definition been deprived of the opportunity to assert their own rights as that patient was not made aware of the testing when it occurred.

Indirect, Written Forms of “Notice” are not Sufficient for HIV Testing and Violate the Americans with Disabilities Act

In order for patients to assert their rights to direct their own medical treatment, and for doctors to fulfill their ethical and legal obligations to provide them with an opportunity to do so, patients must be provided verbal notice prior to any HIV testing. Indeed, oral advisement is the only form of notice that ensures that patients will be effectively put on notice of testing and be provided a real opportunity to indicate that they do not consent to testing.

One can easily imagine why written notices on the walls of busy urban clinics and emergency rooms alone would not constitute sufficient notice to a person presenting for care that they must assert an objection at some point in their admission and testing process to avoid being tested for HIV. Indeed, one can think of numerous daily examples in modern life--from fine print in contracts, to street signs and notices on the walls of subway stations, to terms and conditions of in-app purchases on smartphones--in which one encounters, and glosses over, boilerplate notices.¹²

Providing notice only through signage or buried in boilerplate forms would further ignore the needs of those who may not have functional vision, cannot read, are not fluent in English or other posted languages, or have mental or cognitive impairments. Others might present in the emergency department in the kind of physical distress from acute pain or illness that precludes simultaneously understanding that at some unidentified point they must speak up and object or be tested for HIV. Oral notification is a common sense measure to protect such people with disabilities and patients in distress from a process that would otherwise effectively deprive them of their right to refuse unwanted testing by giving treatment staff the opportunity to directly assess a patient’s needs and comprehension of their treatment options. For persons with disabilities, oral notification is a vindication of protections of the Americans with Disabilities Act as well as other state and federal anti-discrimination laws.

Exercise of the right to know of and consent to HIV testing is far from academic for many people. Indeed, for some communities, the right to determine which care they receive when is essential to their safety. A majority of states still have criminal laws or

¹² See, e.g., Greenberg, Andy, *Who Reads the Fine Print Online? Less Than One Person in a Thousand*, Forbes, April 8, 2010, available at <https://www.forbes.com/sites/firewall/2010/04/08/who-reads-the-fine-print-online-less-than-one-person-in-1000/#3ade69f67017>.

sentencing enhancements for which an element in HIV status -- HIV testing without strong notice and consent provisions could facilitate additional prosecution in those states.¹³ For some with undocumented immigration status, testing for HIV while being treated for the flu or other acute health care needs may place their ability to stay in or return to this country in peril.¹⁴ ¹⁵ Or take the too frequent scenario of mentally ill or minority individuals being brought into an ER for injuries sustained after “resisting arrest,” often in states with laws that continue to criminalize HIV exposure or transmission; if they can be tested for HIV without their knowledge or consent, arresting officers will now have HIV test results which can turn a mishandled arrest of a person on the basis of a disability into a felony charge for the arrested individual. In short, there are multiple reasons why replacing direct oral notice with indirect forms of notification will be meaningless for most individuals, and why it may be in the best interest of many individuals to choose to test for HIV at another time and in another setting.

The CDC should take special care to preserve patient protections in the current political environment. While there is significant optimism within the HIV treatment community about the accelerating potential of progress towards an end to HIV transmission, we must not lose sight of the persistence of HIV-specific criminal laws or sentence enhancements,¹⁶ the new and serious possibilities for collateral legal consequences to HIV diagnosis opened by the ever-changing landscape of immigration policy, and the dramatic expansions of public health surveillance utilizing personal health data which have heightened existing anxieties about collateral legal consequences.¹⁷ In such a context, community concerns about the risks of HIV testing are both valid and ever-present; a successful end-the-epidemic strategy must take them seriously.

Changing HIV Testing Recommendations May Not Even Result in More Testing, nor Will it Increase Engagement in Care Needed to Prevent Further HIV Transmission

¹³ See “Map: HIV Criminalization in the United States,” Center for HIV Law and Policy, available at <http://www.hivlawandpolicy.org/resources/map-hiv-criminalization-united-states-center-hiv-law-and-policy-2018>.

¹⁴ See “HIV Criminalization in California: What We Know,” The Williams Institute, available at <https://williamsinstitute.law.ucla.edu/wp-content/uploads/HIV-Criminalization-What-We-Know-2017.pdf> (“Based on the data available, it did appear that there were some individuals who had deportation proceedings brought immediately after an HIV-specific criminal incident.”).

¹⁵ See Gruberg, Sharita, *How Policy Entanglement with Immigration Enforcement Puts LGBTQ Lives at Risk*, Center for American Progress (April 12, 2017), available at <https://www.americanprogress.org/issues/lgbt/reports/2017/04/12/430325/police-entanglement-immigration-enforcement-puts-lgbtq-lives-risk/>.

¹⁶ See “HIV Criminalization in the United States,” the Center for HIV Law and Policy, available at <http://www.hivlawandpolicy.org/sites/default/files/CHLP%20HIV%20Crim%20Map%20030119.pdf>.

¹⁷ See “Is HIV Molecular Surveillance Worth the Risk?,” Center for HIV Law and Policy, available at <https://medium.com/@CtrHIVLawPolicy/is-hiv-molecular-surveillance-worth-the-risk-dfa7b0a4bd33>.

HIV testing recommendations should also continue to enshrine strong notice-and-consent protections because it is far from clear that the public health benefits of changing them outweigh the considerable risks. In assessing this, we must keep in mind that the ultimate goal of HIV testing is successfully connecting newly diagnosed persons with treatment; testing alone is of no clinical benefit. To that end, while advocates may stress the potential benefits of increasing the number of people engaged in treatment from additional testing, they offer little evidence that reducing patient protections will accomplish that.

To the extent that some providers have reported that it is challenging to offer pre-test counseling about sensitive topics in emergency departments, for example, it is hard to imagine that eliminating that conversation will result in good clinical outcomes. Should we expect that providers who now fail to orally offer HIV testing for fear of becoming embroiled in embarrassing or time-consuming conversations will now have meaningful and productive conversations with patients testing positive about the meaning of those results, the benefits of ART and regular physician visits, and how to connect with appropriate providers and treatment options?

There is scant evidence that eliminating notice of and consent to HIV testing will actually result in higher rates of testing or engagement in treatment, and the evidence most commonly marshaled in support of such proposals is often confounded by other barriers to testing and treatment, such as the reluctance of many medical providers to engage in open conversations with patients about HIV and the effects of HIV stigma on both providers and patients.¹⁸ Nor does any such proposal take into account the myriad ways that testing without notice, consent, or transparency could erode trust between patients and medical providers, especially given the HIV stigma and discrimination that many patients will have experienced both in the medical and legal establishment.¹⁹

A balanced analysis of the merits of notice of and consent to HIV testing would fully consider the possibility that—far from increasing access to and engagement with medical

¹⁸ For example, proponents of eliminating effective notice from New York’s testing law often point to successes in increasing the rate of Hepatitis C testing since New York reformed that law in 2014, but that testing regimes differs in key ways from the proposed reform to the HIV testing law; most notably, New York does *not* permit persons to be tested for Hepatitis C without notice or consent, so it is unclear how any improved rates testing for Hepatitis C over the past five years militate for dispensing with notice and consent for HIV testing. Rather, improved rates of Hepatitis C testing may stem from the new requirement that tests be automatically offered to certain individuals, a reform that brought that statute in line with current laws around HIV testing. *Compare* Pub. Health §§ 2171 and 2781. As that example illustrates, more rigorous empirical study is needed in order to establish whether there is actually clinical benefit prior to modifying HIV testing guidelines.

¹⁹ See e.g., McAllister, Carolyn, Susan Reif, and Elena Wilson, *Perceptions and Impact of HIV Stigma Among High Risk Populations in the US Deep South*, Journal of HIV and AIDS (April 6, 2018), available at <https://www.hivlawandpolicy.org/sites/default/files/Perceptions%20and%20Impact%20of%20HIV%20Stigma%20among%20High%20Risk%20Populations%20in%20the%20US%20Deep%20South.pdf>.

treatment—nonconsensual testing risks further alienating exactly the communities that the proposal aims to engage from pursuing further care. Patients might think twice about seeking other medical treatment that they need for fear that they might be subjected to further testing or interventions without their notice and consent.

This concern is particularly acute in communities of color, who have long suffered disparate health outcomes—including substantially increased mortality from many chronic diseases when compared to white peers—borne of diminished access to treatment and agency within treatment settings.²⁰ In response, far from suggesting that standard practices of notice and consent should be discarded, social scientists have proposed working even more closely and openly with members of affected communities to design more effective policies.²¹ That specific recommendation has been echoed with respect to people living with HIV—as one article notes, “Legal protections for people living with HIV and AIDS, together with appropriate reporting and enforcement . . . have provided powerful and rapid means of mitigating the worst effects of the unequal power relations, social inequality and exclusion that lie at the heart of processes of HIV and AIDS-related stigmatization and discrimination.”²²

Countering a Worrisome Trend

This opportunity to reiterate that our HIV testing regulations should be guided by what will actually result in engaging currently undiagnosed persons in care comes in the midst of a worrying trend of state regulations that threaten to erode patient rights. These incursions have come in the form of both proposed revision of HIV testing regulations -- most notably in New York²³, explored in more detail below -- and a proposal in Louisiana to dramatically broaden the reach of public health surveillance by maintaining databases of both positive and negative HIV tests for eighteen months.²⁴ These seemingly disparate policies all sit at the intersection of three worrisome trends: first, a belief that because the end of the HIV epidemic appears to be within reach, any and all means to reach that end are justified, even if they fly in the face of medical ethics and respect for the dignity of

²⁰ *In Focus: Reducing Racial Disparities in Health Care by Confronting Racism*, The Commonwealth Fund, September 27, 2018, available at <https://www.commonwealthfund.org/publications/newsletter-article/2018/sep/focus-reducing-racial-disparities-health-care-confronting>.

²¹ *Id.*

²² Aggleton, Peter and Richard Parker, *HIV and AIDS-related Stigma and Discrimination: A Conceptual Framework and Implications for Action*, *Social Science & Medicine* 57 (2003), 13–24.

²³ *The Wrong Way To Improve HIV Testing*, New York Post, available at <https://nypost.com/2019/05/17/the-wrong-way-to-improve-hiv-testing/>.

²⁴ *Policy Change Could Lead to Medical Privacy Policies*, KTBS-TV, available at https://www.ktbs.com/news/3investigates/policy-change-could-lead-to-medical-privacy-problems/article_c17c5ad2-7836-11e9-9fda-937b16210aae.html?fbclid=IwAR0CnWIWj4STWZtC5i-m0xYSAan-ZEtizprOXSPRjUyOpl_9d1d4LKPOGs.

people living with HIV; second, a mistaken perception that increased cultural representation of people living with HIV means that policymakers do not need to consider persistent HIV stigma and legal risk, evidenced by the fact that a majority of states still have criminal laws that punish HIV nondisclosure; and finally, a political moment in which vulnerable peoples' basic legal rights to bodily autonomy are up for debate, as evidenced by the recent and increasingly frequent attacks on abortion access in many states.

We embrace the goal of Ending the Epidemic, and we do not question the good intentions of those proposing this radical exemption to modern principles of patient autonomy in medical decision-making. Our concern is not with motives but with consequences. We do not believe that eliminating legal requirements that HIV testing be voluntary and consensual is the appropriate response to proponents' frustration with persistent provider refusal to follow state law and to encourage patients to test for HIV.

Case Study: New York

A legislative proposal last year in New York which, if passed, would have completely eliminated consent and even effective notice to an individual that was about to be tested for HIV is exemplary of the current threat to patient autonomy. In a state that has prioritized evidence-based approaches to HIV care, it is shocking that this proposal was advanced with a striking lack of data to support it. In fact, there was no reason to expect that the proposed change would do anything more than accommodate those doctors who, despite state law, outreach, and offers of assistance, failed to offer or support HIV testing to those who present for care.

The proposal would have removed the provisions of New York's Public Health Law that currently require a medical provider to provide direct, oral notice of an HIV test—including informing the patient about several crucial medical facts as well as the patient's rights—and obtain explicit consent. The rationale for testing, along with limited HIV education, would be provided to the individual only after testing were conducted.²⁵

Proponents of the proposed elimination of oral notice of HIV testing cited high rates of dual diagnosis (diagnosis of HIV and AIDS at the same time) in upstate New York. But tellingly, they offered no data suggesting that eliminating notice of HIV testing would actually solve that problem. In fact, it was completely unclear whether persons who are dually diagnosed have not previously had substantial contact with medical providers, have been offered and declined HIV testing in the past, or have not been offered HIV testing at all. If such persons have not been offered HIV testing at all—in violation of the

²⁵ Pub. Health § 2781.

provision of New York’s Public Health Law²⁶ which required that patients presenting for care in many clinical environments be offered testing—it was unclear that advocates or public health officials had made any effort to enforce the mandatory offer of HIV testing, though officials said that it would be possible for the state to identify which doctors are not routinely offering HIV tests. Despite those logical flaws in the arguments in support of drastically modifying the HIV testing law, proponents put forward legislation before undertaking common sense public health measures like enforcing the current law’s mandatory offer requirement.

In New York, eliminating the notice-and-consent requirement of the HIV testing law would have a dramatic effect on the structure of the statute, undermining provisions which codify other crucial tools in combating HIV. Other crucial sections of the law, including the mandatory offer of testing²⁷ and the requirement that anonymous testing be made available,²⁸ depend on patients receiving effective notice of testing. Notably, if patients are not effectively provided notice of testing, it would not be possible for them to opt for anonymous testing. The importance of providing patients the option to test anonymously as a public health measure cannot be overstated in a context in which many patients fear the stigma and legal consequences of HIV testing. Such collateral consequences include evolving legal issues such as changes in immigration enforcement and discretionary policies and new molecular HIV surveillance.

Thankfully, the proposal, filed in the New York state legislature last year as Senate Bill S6082 and Assembly Bill A7862, did not advance out of committee. However, absent strong guidance from the CDC reaffirming the importance of respecting patient autonomy as we strive for an end to HIV transmission, we fear that that this proposal is but a harbinger of things to come not only in New York but also in states around the country. Indeed, the push to change New York’s HIV testing law to erode patient protections without any empirical support was a cautionary tale in bad policymaking that the CDC should heed in considering its own recommendations.

Our Recommendations

We believe that in this context, the CDC must take a leadership role in asserting the importance of effective notice in implementing testing regimes that respect patients and facilitate meaningful progress towards ending the epidemic:

1. The CDC should issue strong guidance that effective notice and consent are essential to effective HIV testing. The most effective forms of notice are oral

²⁶ Pub. Health § 2881-a requires that medical providers offer testing to all individuals over thirteen years old with limited exceptions.

²⁷ Pub. Health § 2881-a.

²⁸ Pub. Health § 2881(4).

- notice because they permit doctors to assess patients' actual communication needs.
2. The CDC should issue strong guidance that facilities should utilize non-medical staff, especially peer health educators, to increase the effectiveness of pre- and post-test counseling and decrease the burden on medical staff.
 3. The CDC should recommend that all states require medical professionals receive continuing education regarding sexual health, the routes and risks of STD/STI transmission, and best practices for counseling and treatment.

Respectfully,

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