The End of Written Informed Consent for HIV Testing: Not With a Bang but a Whimper

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In 2014, only two states in the United States still mandated specific written informed consent for HIV testing and, after years of controversy, New York ended this requirement, leaving only Nebraska. New York's shift to opt-out testing meant that a singular feature of what had characterized the exceptionalism surrounding HIV testing was eliminated. We trace the history of debates on written informed consent nationally and in New York State. Over the years of dispute from when HIV testing was initiated in 1985 to 2014, the evidence about the benefits and burdens of written informed consent changed. Just as important was the transformation of the political configuration of HIV advocacy and funding, both nationwide and in New York State. What had for years been the subject of furious debate over what a rational and ethical screening policy required came to an end without the slightest public protest. (*Am J Public Health*. 2017;107:1259–1265. doi:10.2105/AJPH.2017.303819)

In 2014, New York and Nebraska were the only states that still required written informed consent for HIV testing, a signature element of public policy that dated from the 1980s. New York then abandoned the requirement. Remarkably, despite a long and often bitterly contested past that engaged public health officials, clinicians, AIDS advocacy groups, and civil liberties organizations, the final elimination of written informed consent for HIV testing occurred with little public debate.

Conventionally, the story of HIV testing policy involves the commitments that began when the evidence for addressing both the clinical and public health challenges of AIDS was still very uncertain. The conventional narrative argues that public health officials slowly became convinced by evidence demonstrating that written informed consent impeded the rollout of HIV testing on a mass scale, a process that culminated in 2006 when the Centers for Disease Control and Prevention (CDC) issued recommendations for an opt-out approach without written informed consent. Those who opposed this opt-out approach were equally certain that the evidence did not support the claim that written informed consent was a barrier to sound public health practice. In time, however, the overwhelming evidence—coupled with political and funding shifts—convinced many individuals who had been most deeply committed to written consent. Deeply rooted opposition did not, however, vanish.

We seek to locate the controversy over written informed consent in a broad political context. We take account of how and why groups that had confronted each other for years came to see the evidence so differently and why the advocacy community eventually yielded. Although the evidence about the burdens and benefits of written informed consent had not significantly changed in the last years of the controversy, the political configuration surrounding HIV/AIDS policy had. What may appear to be remarkable was, in fact, a long time in coming.

LOOKING BACK

When HIV antibody testing first became possible in 1985, there was considerable uncertainty about the significance of a positive finding and the prognosis of HIV-infected individuals. Within a year public health officials embraced HIV testing as a potentially significant contribution to confronting the evolving epidemic, but many of the first generation of AIDS activists greeted the test with alarm.[1] The psychological impact of the diagnosis in the context of therapeutic impotence, coupled with very realistic concerns about discrimination, stigmatization, and anxiety about the prospect of a turn to coercive public health policy, shaped the worldview of activists who sought to protect vulnerable populations from privacy intrusions and the deprivation of the fundamental right to choose whether to be tested. Advocates argued that written informed consent would provide necessary protection for those who might otherwise be dragooned by public health officials. The national AIDS activist movement quickly succeeded in making written informed consent, along with pre- and posttest counseling, the standard of care nationwide. The first ethical framework for confronting the challenge of AIDS and HIV testing embraced this position[2]; HIV exceptionalism defined the moment.[3]

New York State's experience exemplified the situation. Looking back after three decades, the director of New York State's AIDS Institute, part of the State's Health Department, wrote,

> New York State was an early adopter of strong statutory protections for persons seeking HIV testing, including required pretest counseling and written informed consent.[4]

Under a 1989 law, written consent became the legal norm, and violations could result in civil and criminal sanctions, including fines of up to $5000 and imprisonment for one year.

By the early 1990s public health officials were increasingly able to manage opportunistic infections and create targeted prevention programs, which challenged the empirical and ethical justifications for the protective framework grounded in written informed consent. The discovery in the mid-1990s that highly active anti-retroviral therapy could prolong the lives of HIV-infected individuals shifted the national conversation. Nevertheless, it would take years of debate before the requirements of pre- and posttest counseling and written informed consent could be dislodged.[5] In the face of ongoing sociopolitical anxieties and the persistence of stigmatization, evidence alone could not override the politics of HIV exceptionalism.

The erosion of the earlier consensus was powerfully underscored by the 2005 World AIDS Day editorial by Thomas Frieden, then commissioner of health in New York City. Written five years before the passage of the Affordable Care Act provided protection against denial of insurance coverage on the basis of preexisting conditions, the editorial asserted,

> Given the availability of drugs that can effectively treat HIV infection and progress on antidiscrimination initiatives perhaps society is ready to adopt traditional disease control principles and proven interventions that can identify infected persons, interrupt transmission, ensure treatment and case management and monitor infection and control efforts throughout the population.[6]

Policies that made such identification difficult could no longer be justified from the perspective of public health or clinical medicine. The failure to adopt more aggressive testing policies and eliminate written consent and routinize opt-out testing would entail a wholesale denial of the evidence that, "routine voluntary screening for HIV is indicated on the basis of clinical efficacy and cost-effectiveness."[7]

Two months after Frieden's editorial, the New York City Department of Health and Mental Hygiene issued a detailed set of recommendations that mirrored his views.[8] It made clear that the recommendations did not call for mandatory testing but instead proposed the routinization of HIV testing; HIV testing laws would continue to require that all testing be voluntary with specific documented oral consent. Penalties for HIV testing without consent would be increased.

Frieden's forceful move received backing from the *New York Times* editorial board:

> While there is a danger that some patients might be hoodwinked into taking a test they would otherwise shun, it seems reasonable to treat AIDS like any other infectious or sexually transmitted disease. Wider testing might save some lives and alert people not to spread the virus. . . . Surely most patients would rather get life extending treatments than languish in neglect.[9]

Deeply concerned by the estimate that 20% of HIV-infected Americans did not know their status, the CDC worked to update its practices and policies. In September 2006, after a careful review of the evidence, the CDC issued new recommendations for the routinization of HIV screening that involved an opt-out approach to consent and the elimination of specific written informed consent.[10] "These new recommendations," said Kevin Fenton, director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, "will make routine HIV screening feasible in busy medical centers where it previously was impractical."[11]

Thus the stage was set for a cascade of regulatory and legislative changes across the nation. The speaker of the American Medical Association's House of Delegates called on states "to reexamine legislation to allow physicians to carry out the new CDC recommendation."[12] Before the publication of the CDC's recommendations, 20 states required separate written informed consent for HIV testing. A review published in the *Journal of the American Medical Association* in 2011 concluded,

> Nearly all states' laws and administrative codes were compatible with current CDC HIV testing recommendations on consent and counseling.[13]

Some individuals, such as Peter Staley, a founder of the AIDS Coalition to Unleash Power, supported this shift:

> I realize that abandoning written informed consent raises issues. People are worried about privacy and stigma. But the bottom line is that this would probably save lives and that's why I'm very much in favor of it.[14]

But many AIDS advocacy groups dismissed such assessments. After the CDC's call for the routinization of HIV screening, 33 AIDS-related groups, including the American Foundation for AIDS Research, Gay Men's Health Crisis, the HIV Law Project, Housing Works, and Λ Legal, issued a joint challenge.[15] Although acknowledging that expanded voluntary counseling and testing was "good public health policy," they dismissed the necessity of such reforms:

> An expanded focus on testing without counseling and written informed consent will put people at risk for testing without their prior knowledge or approval—a clear violation of medical ethics and human rights.

One activist claimed,

> This is not informed consent, and it is not even consent, it was an attempt to ram HIV testing down people's throat without their permission.[16]

NEW YORK—NINE YEARS OF CONTENTION

In the face of such opposition, legislators in New York State tried repeatedly from 2006 to 2010 to address the restrictive legal constraints under which HIV testing could occur. In this period, 169 HIV-related bills were introduced to the state legislature, 12 of which explicitly addressed informed consent.[17]

What unfolded was a morally charged debate regarding whether written informed consent impeded what all agreed was crucial: that individuals who were infected but unaware be able to learn their HIV status. The New York State Medical Society, which exemplified one side of this argument, wrote a letter to Assemblywoman Nettie Myerson, a leading proponent of routinizing HIV testing:

> For over 20 years, physicians and other health care personnel have not been allowed to offer HIV testing as part of the standard tests that are offered patients.[18]

Paradoxically, the very exceptionalism that was designed to protect those at risk had stigmatized the test for the disease.

In a New York State Assembly public hearing in 2006,[19] Richard Gottfried—who was the chair of the Assembly's Health Committee and had long-established links to New York's lesbian, gay, bisexual, and transgender community—continued to defend written informed consent while making clear his moral commitment to both privacy and evidence-based practice. He proposed an idea first developed by the Legal Action Center called "mandatory offer," which required an explicit offer of HIV counseling and testing to all patients in health care facilities without regard to risks factors while retaining written informed consent.[20] Paradoxically, this new approach would actually serve to increase the time burdens associated with testing in the clinic. Mandatory offer became the rallying cry of those who believed that the protection of individual rights was not at odds with the public's health. Gay Men's Health Crisis, among the oldest and most established AIDS service organization in New York, declared,

> There is absolutely no scientific evidence that the statutory requirements of written informed consent and counseling pose an actual barrier to testing.[21]

Though activists anchored their opposition in their view of the evidence, what drove the passion to retain written informed consent was a conception of what respect for autonomy and human dignity necessitated. Housing Works, another community-based organization, also denounced the 2006 proposals made by New York City's health commissioner as "One of the greatest threats ever posed in the State of New York to the privacy rights of people living with AIDS and HIV."[22] The Long Island Minority AIDS Coalition asserted that it was "unconscionable" that patients would no longer have the right to written informed consent.[23]

In 2006 the first crack emerged in the previously solid wall of opposition. The availability of powerful HIV-related treatments was central to this change, as was the mission shift among AIDS advocacy organizations toward becoming AIDS services organizations. Harlem United became the first community-based AIDS organization to assert that the prevailing approach to testing was inadequate:

> It is difficult . . . not to view separate written consent as part of a broader practice of testing that is failing us. . . . Although our stance may disturb colleagues, new realities demand new tactics to stop the spread of HIV and further reduce AIDS deaths. We should routinize HIV testing

> in accordance with CDC's new guidelines. . . . [Current] HIV testing policy, amounts to arguing that those most at risk have a civil right to a greater likelihood of spreading HIV infection within their own community or dying sooner of AIDS.[24]

At an organizational level, a striking racial/ethnic divide had begun to emerge within the AIDS advocacy community. Harlem United was joined by the Latino Commission on AIDS and the National Black Leadership Commission on AIDS, which issued a summary of evidence that unequivocally demonstrated that written consent was in fact a barrier to routine HIV testing.[25] Their opponents were largely, although not exclusively, organizations led by gay White men, longtime veterans of AIDS-related battles.

As the legislative battle unfolded from 2006 to 2010, the divide between what most AIDS activist groups held as morally necessary and empirically unambiguous and the views of the public health and medical communities continued to widen. The New York State Association of County Health Officials in 2007[26] and the American College of Obstetricians and Gynecologists in 2008[27] joined the Medical Society of the State of New York to call for an end to the exceptionalism surrounding the state's HIV testing. In 2007, the deeply divided state-appointed AIDS Advisory Council voted five to three to support a resolution stating, "The requirement for written informed consent for HIV testing in medical settings should be removed."[28]

Despite the certitude with which opponents of written consent described the evidence, the bulk of the AIDS advocacy community continued to maintain that written informed consent did not impede testing. In 2007, a joint statement of the American Civil Liberties Union Law Project and Lambda Legal asserted that a conflict between increased testing and strict consent was "fictional."[29] In 2008, a Gay Men's Health Crisis commissioned review of the literature asserted,

> Some have cited written consent as a barrier to testing. . . . Such claims have proven baseless and have not been empirically documented in any major peer reviewed academic journal.[30]

CHANGE COMES TO NEW YORK

After decades of debate, in 2010 the New York State legislature voted overwhelmingly to modify the state's legal framework for HIV testing; the assembly voted 97 to 0, the senate 42 to 10. The result was a carefully crafted compromise. The statute required a mandatory offering of testing to people aged 13 to 64 years in hospitals, emergency departments, and primary care settings. Rapid HIV testing could be conducted using oral consent except in jails and prisons. Consent for testing could be integrated into general consent as long as a specific part of the form provided the clear option to decline the HIV test. It is of singular importance that once consent had been given it was to be considered durable and could be terminated only when a patient explicitly sought to withdraw it.[31]

Although this statute finally permitted New York State to move forward, the long-fought controversy was not over. Patrick McGovern, the chief executive officer of Harlem United, declared in 2010,

> New York's' debate on HIV testing . . . has been passionate and sometimes contentious . . . while this legislation falls short on a true opt out approach, the required offer of HIV testing in all primary care settings foretells an end to the current practice of segregated and stigmatized HIV testing.[32]

Gay Men's Health Crisis, by contrast, underscored that it had protected written informed consent under challenging political circumstances:

> For years we have held up the standard of written informed consent as a marker for acceptable legislation to expand HIV testing. Although GMHC [Gay Men's Health Crisis] has compromised on some long standing principles to support this bill we still strongly believe in the value of written informed consent. This legislation contains as many adequate safeguards to informed consent as the current environment in the legislature will allow.[33]

The compromise of 2010 was clearly only a first step for those committed to ending written informed consent. In 2012, the state health department issued a report that concluded that to increase testing uptake the state might "consider additional steps to streamline and fully routinize the offer of HIV testing."[34] One possibility would be to accept the CDC's recommendation for routine HIV screening without specific consent but with an option for patients to decline to be tested. Indicative of the importance of the evidence derived from clinical experience, the AIDS Institute concluded, "Written consent was consistently identified as a barrier to implementing the 2010 law."[35]

Reflecting on his own shift, Dan O'Connell, director of the AIDS Institute, stressed that "developments in science," the massing of evidence at both state and national levels, had compelled him to rethink policy. For O'Connell, the deeply held values of his opponents had become an expression of an evidence-resistant rigidity:

> For a long time advocates were not grappling with the need to protect people's health and get the care they need. It took a long time for the community to catch up.

It was in this context that Gottfried was noted as having said how much of an outlier New York State had become: "For God's sake it's just us and Nebraska."[36]

In 2014, the AIDS Institute forcefully moved to end written informed consent through a provision included (some critics would say buried) in the governor's 2014–2015 executive budget. The more stringent written requirements were retained only in the potentially coercive context of correctional settings. The changed testing regulations were packaged with other measures of great importance to AIDS activists: creating a 30% salary rent cap for HIV-infected people and facilitating the sharing of clinical data among health care providers to promote "linkage and retention in care."[37] Commenting on the milestone, O'Connell stated,

> Eliminating most written consent for HIV testing in New York heralds the end of an era in the decade's long fight against the epidemic.[38]

That New York took this step was unsurprising, but that the ultimate elimination of written informed consent occurred without a public battle was stunning. The advocates, who for years described written consent as a pillar of an effective, rights-informed approach to public health and who feared that the elimination of such consent would allow coercion and mandatory testing, were silent.

Assemblyman Gottfried, a veteran of the testing wars, noted his surprise that he "had not heard a peep" from advocates on the proposed testing provisions in the governor's budget. His office therefore contacted the leaders of New York's advocacy community:

> What we heard back was that nobody had a problem with the change. . . . I didn't receive a single e-mail or phone call. [There was] almost a wall to wall of unbroken silence.[39]

In large measure, the silence that Gottfried encountered reflected a shift in priorities within the advocacy community to pressing, above all else, for programs and policies to expand care for HIV-infected persons. Committed to ending AIDS in New York State, AIDS advocates now viewed collaboration with the AIDS Institute as of central importance. Most striking in this regard was Housing Works's shift after years of publicly resisting the CDC's 2006 recommendations and not joining Harlem Untied, the Latino Commission on AIDS, and the Black Leadership Commission on AIDS in their earlier calls for change. Charles King, the executive director of Housing Works, noted that treatment availability was a "game changer." To make the promise of the end of AIDS real, it was essential to bring people into care. This was not, he underscored, a political tradeoff to win the support of the AIDS Institute for the new radical goal; abandoning a long-held policy perspective was not easy. Deeply rooted ideas do not yield without organizational strain. With clear reference to those who had refused to shift, he said, "We have an emotional attachment to ideas. No one wants to admit they had been wrong." Speaking of himself he continued "I get a twinge. . . . We are on the opposite side of an issue than we were years ago."[40]

Ten weeks after this policy shift, Governor Andrew Cuomo clarified what the new targets were: reduce new HIV infections in New York from 3000 to 750 by 2020 and reduce the rate at which HIV-infected persons progressed to AIDS by 50%. These combined efforts would cause the prevalence of AIDS in New York State to decrease for the first time since the start of the epidemic.[41]

But what of those who had not publicly embraced an end to written informed consent but who chose not to engage in further debate? For some, the prospect of battling the AIDS Institute with whom it would be necessary to develop programmatic efforts over the next years seems strategically counterproductive. But much more was at stake.

Corrine Carrie of the New York Civil Liberties Union acknowledged that it was increasingly difficult to argue that written informed consent did not impede HIV testing and that instead they should frame the argument with protecting people's right to choose to be tested. In 2009, she had already noted, "It's gotten to the point where only lawyers and sophisticated advocates understand these arguments."[42] Because of the shifting institutional realities of the AIDS advocacy community in New York, that constituency was shrinking. "Lawyers funding [has been] decimated," said Catherine Hanssens, who had for years been among the most vocal opponents of limiting consent-related protections in HIV testing.[43] Simultaneously, the HIV Law Project, which had played such a prominent role in earlier battles, had been absorbed by Housing Works. Housing Works now supported eliminating written consent, while focusing energy on providing treatment and ancillary services to those in need.

It was in this political context that an urgent online discussion among those who still supported written informed consent took place. None thought a renewed battle could have a meaningful impact, "the horse was out of the barn." Tracy Gardner of the Legal Action Center spoke candidly of being "worn out, sick of the fight."[44] For each organization that might lead the battle, however futile, a strategic decision had to be made. Hanssens said,

> When you are thinly funded, thinly staffed you have to make choices. . . . We have lost the battle in the context of HIV testing.[45]

For Carrie, a new battle

> would not be a wise investment. . . . [We must ask] which threat is most serious? Where are we likely to win?[46]

With no one willing to assume leadership of a renewed battle, a collective decision was made to abandon what had been a defining issue for the HIV advocacy community. By deed if not by word, the struggle to preserve written informed consent had come to an end. With an obvious need to view this outcome in its broader contemporary context and to maintain a sense that the struggle had not been in vain, it was possible for some to say that the legacy of advocates' work was alive even though written informed consent was over.

CONCLUSIONS

There is a rich literature on the history of science-related controversies that seeks to explain how they emerge, persist over time, and are resolved.[47] That literature shows that only part of the story is told by narratives that frame the end of such conflicts as the result of the triumph of evidence in the face of uncertainty or because of the emergence of new evidence.[48] The careful examination of scientific controversies suggests that, whatever the role of evidence, more is involved: that epistemic, political, and social factors are virtually always at play. How evidence is understood and indeed disagreement about what should count as evidence must be examined in historical context.

The controversy over written informed consent did not end because the evidence had at last become definitive. A similarly fraught and linked debate occurred on pretest and posttest counseling for HIV. There was also a protracted struggle[49] for evidence and ethics, but the persistence of those arguing for counseling differed greatly from those arguing for written consent. Important funding streams had long underwritten support for such efforts, and a virtual army of counselors were employed across the nation with an institutional commitment to maintaining their role—and employment. Institutional resistance helps to explain the politics of de-implementation, but the written consent story was very different. There was no army of workers whose professional identities depended on testing, and the numbers of individuals who found the issue of written consent to be morally compelling had dramatically declined. Written informed consent could no longer marshal the numbers to resist change.

At an individual level, the controversy ended because of the exhaustion of those who, under different circumstances, might have persisted. New York was left behind, and so were local activists, who knew that their allies across the nation had also conceded. A bandwagon-like process had occurred.[50] Those involved in HIV advocacy, care, and policy had come to agree on a new paradigm for testing. On a political level, AIDS advocates had concluded that because of the social and funding context they should adjust their agendas to best serve those they were committed to. In doing so, they made it clear that despite its central role in the formative years of the AIDS epidemic, both locally and nationally, written informed consent for HIV testing was no longer a priority, no longer worth the fight. AJPH

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