
Lost to Care: An Ethical Expansion of the Public Health Uses of State HIV Registries in the United States

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Abstract

Public Health has not applied traditional public health principles and laws to the control of HIV in the United States. Commentators have labeled this phenomenon as HIV exceptionalism. Given new research demonstrating that HIV treatments can also reduce transmission, some have argued that public health should move away from HIV exceptionalism. This paper describes how exceptionalism has restricted the use of HIV registries primarily to epidemiological monitoring, examines models that have expanded use, and provides an ethical analysis. There is a sound ethical basis to loosen legal restrictions on the public health uses of HIV registries to identify individuals who may be at risk of falling out of care, who are out of care, or who are non-adherent to treatment in order to intervene at the individual level. Slippery slope cautions are also addressed.

1. INTRODUCTION

It has been over 30 years since the first case of Acquired Immune Deficiency Syndrome (AIDS) was reported in the US. Within 2 years after the first AIDS report, scientists identified the cause of the disease as the human immunodeficiency virus (HIV). Since that time, science has made great strides in understanding the disease and in developing new treatments to extend the length and quality of life of those infected [1]. However, the Centers for Disease Control (CDC) estimates that 50,000 -56,000 persons are newly infected with HIV each year [2]. Nearly half of those infected are not engaged in regular HIV care [3].

In July 2010, the Obama administration released a national strategy to address HIV/AIDS. In their introduction to the strategy, the authors caution that “unless we take bold actions...we anticipate a new era of rising infections and even greater challenges in serving people with HIV [4].”

One of those bold actions suggested in the strategy is to “pursue a concerted national effort to get and keep people living with HIV in care [4].” This article discusses the ethical reasons why part of that effort should include an expansion of the public health uses of HIV registries to identify individuals who may be at risk of falling out of care, who are out of care, or who are non-adherent to treatment in order to intervene at the individual level.

Some prominent authors have noted that public health in the US has not applied public health principles, which have been used in the control of other infectious diseases, to HIV [5,6]. Public Health’s neglect to treat HIV like other infectious diseases has been labeled “HIV exceptionalism [5,6].” This neglect is partly due to the political and social history of the disease and that the disease has primarily affected stigmatized populations. Given this, attempts to apply public health principles have been met with real and potential claims of discrimination [6].

Dr. Thomas Frieden, the Director of the Centers for Disease Control (CDC), has called for an end to this exceptionalism and a return to the application of public health principles to address the treatment and spread of HIV [6]. As part of this return, the CDC has called for routine opt-out HIV testing and this has stirred some debate among public health ethicists [7,8]. Additionally, a few have opined about the need to use HIV registry data, including CD4 cell counts and viral loads, to identify individuals lost to care or treatment non-adherent and to intervene [9].

2. REGISTRIES

Public health registries exist for many diseases. Registries were originally conceived as a way for public health to gather data to monitor and understand the magnitude of epidemics [5]. In some cases, reporting to a registry may be

voluntary but for most infectious diseases reporting to a registry is a state or local legally mandated requirement for providers, labs, or others. There is no federal law that restricts the collection, security, and use of the registries. This is reserved for state and local authorities [5].

All US states and territories require doctors and laboratories to report HIV infection with names. However, the reporting of names was not without controversy and most worries and concerns focused around privacy [10]. Many states also require that viral loads and CD4 counts be reported [11].

Treatment as Prevention and the Need to Revisit Registry Use

Public health has a history of direct interventions for other infectious diseases mostly through partner notification, mandated treatment, isolation, and quarantine [5]. However, direct interventions for individuals infected with HIV, with the exception of partner notification and educational efforts, have not been extensively utilized. This could be because of the lack of a curative treatment for HIV and the fact that HIV is primarily sexually transmitted. In the past, the public health duty to use more invasive measures has not been compelling for HIV given that there is no cure and that transmission requires at least two moral actors, outside of forced sex, with individual rights and obligations. Unlike with the transmission of an airborne organism, one is not exposed to HIV by simply being in proximity to an infectious individual, but must instead engage in a specific act. Thus education for these moral actors, infected and not-infected, targeting risky behaviors was the most reasonable approach [12].

Balancing concerns over privacy, stigma, and discrimination, some states created and still have laws which limit the use of registries to epidemiological purposes and do not allow them to be used for individual interventions [5]. However, laws and surveillance practices created early in the epidemic should be revisited now that the medical and public health context has changed. These laws and practices were developed and put in place at a time when treatment options were not plentiful and privacy risks, along with traditional notions of how registries should be used, ethically trumped other clinical and public health concerns.

Today the situation is different. Recent research demonstrates that HIV antiretroviral treatment may reduce an individual's viral load, and at least at a community level, a reduction in viral load reduces transmission [13, 14]. In

other words, treatment has become a means of not only extending the lives of people living with HIV but it may also help decrease the incidence of disease. In short, treatment of those infected with HIV has become another tool to protect the health of those not already infected.

In light of these developments, administrative and legal restrictions on the use of HIV surveillance registries should be reconsidered. Given that treatment has utility as a tool to manage HIV spread, public health entities in states that require the reporting of CD4 counts and viral loads possess knowledge that could be used to reduce HIV transmission. Public health departments could use this information to determine if a person infected with HIV is possibly out of care or non-adherent to treatment. If the person has not had a viral load or CD4 count reported when expected, that individual may be out of care, or if a person's viral load dramatically increases, he or she may be out of care or non-adherent. Out of care and non-adherence are not the only explanations for lack of reporting or increases in viral load, but public health entities have enough information to inquire further and determine if out of care and non-adherence are indeed the reasons and if the person is engaging in behaviors that put others at risk of infection.

3. MODELS AND COMMUNITY RESPONSES

3.1. Model 1

One state, Louisiana, has used its HIV registry to alert physicians that a patient may be HIV positive and not receiving care. In a pilot, this notification alone resulted in approximately 75% of those identified returning to care [9].

The project is a collaborative one between the Louisiana State University Hospital System--the state's largest provider of HIV care--and the state's public health department. There are no laws forbidding the use of the registry for this purpose and there was purportedly intensive community engagement before implementation [15].

As demonstrated in the Louisiana example, a simple physician notification may have a tremendous impact on returning to care. However, it is also reasonable to assume that this one intervention would not work for everyone since 25% apparently for some reason did not return to care and it is unclear if the 75% who returned stayed in care and remained adherent to treatment.

Many reasons have been given for non-adherence and dropping out of care including the quality of the patient-

provider relationship, drug side effects, neuropsychological impairment, substance use, lack of social support, psychological distress, patient self-efficacy, treatment convenience, literacy, stigma, economic factors and structural impediments [16]. On the other hand, some interventions have been shown to effectively contribute to reengagement in care and assist in maintaining adherence [17-20]. Although effective, a simple physician notification may not be enough to address this complexity.

3.2. Model II

Prompted by the national HIV strategy and by being a county with one of the highest incidence and prevalence of HIV in the country, the staff of the Florida Department of Health in Broward County (“the department”) proposed a more intensive approach which has been in stages of development, though its future is unclear (I formerly served as the Communicable Disease Director there and what follows in the Model II section is based upon personal experience and observations).

In this model, the health department would contact the physician of an individual identified through the registry as out of care or possibly non-adherent. Additionally, the individual would be contacted by a trained Disease Intervention Specialist (DIS). The DIS would offer the individual enrollment in a treatment adherence program which could include a myriad of services such as peer navigation, text message reminders, education, assistance with pill boxes, support groups, and voluntary modified directly observed therapy. These services would be free of cost.

Like Louisiana, Florida does not have a legal prohibition against the registry being used in this manner. However, unlike Louisiana, the community context and institutional relationships are very different. In Broward county, the relationship between the department and the community has been a contentious one over the past few years, not one of engagement. Despite this, there has not been a lot of vocal criticism from the HIV impacted community regarding the ethics of expanding the use of the registry and its use in an adherence program.

The decision to use the registry to intervene and to develop a new adherence program coincided with the department’s decision to no longer be a federally Ryan White funded HIV primary care provider. In the 1980’s, the department was the county’s first HIV primary care provider. At that time, few

would provide such services to the HIV infected population, so public health stepped in to fill the gap. Over the years, several new providers entered the field and became Ryan White HIV care providers. This meant that the department now had to compete with these providers for patients and dollars. The department’s costs were very high compared with other providers and additional funds consistently had to be used to supplement Ryan White reimbursements. Thus, the department decided to no longer compete with other agencies and to shift the additional non-Ryan White funds used to supplement clinical services to a focus on linkage and adherence including this new program. The Broward community loudly objected to the clinic closure and any controversies surrounding use of the registry were diminished by or intertwined with the closure clamor.

Prior to the clinic closure, the relationship between the department and the HIV affected community was already a strained one. The department made the closure decision a few years after the appointment of a new county health officer who the community thought often made decisions without community input and who saw the community more as an antagonistic force. Many of the more vocal HIV affected community leaders signed a letter publically calling for her resignation which did not occur. This rift grew wider when the department decided to close the clinic and did not engage the community before making this decision. The closure came as a shock and surprise making the new program and use of the registry a concern secondary to the clinic closure.

Notwithstanding, the new program and use of the registry were still met with some skepticism. The main publicly aired concern was that if the new program were started, the department may abandon it whenever it saw fit without community engagement. Although this may have been more of a roundabout criticism of the clinic closure than of the use of the registry and the new program, it seemed to be the greatest ethical concern.

After the closure of the HIV primary care clinic, the department did bring in neutral consultants to engage the community in a series of HIV prevention think tanks and invited both providers and community members. This was prompted by CDC funding increases which included planning funds. In these think tanks, the department raised the use of the registry but it was met with little objection. This because it was wrapped and normalized within discussions about other HIV prevention services and approaches and not put forth specifically as its own

initiative. Indeed, some community members also proposed combining the registry data with other data sources that could then be shared in aggregate back to the community.

The main initial resistance to the use of the registry, however, was internal. Florida's public health structure is one in which the county health departments are part of the state department of health and do not function independently. The HIV registry is housed in the state offices in Tallahassee, Florida. The state office raised issues of privacy about how the data would be handled. Privacy concerns were addressed through developing policies and procedures for how the data would be transferred, housed, accessed, and disclosed. After these concerns were addressed, the state office reluctantly agreed to share the data with the local health department for these purposes. The final reluctance appeared to be a fear of losing control once the data left the state office, but once each concern was addressed, the data begin to be received by the local health department.

Nevertheless, developing the program has and continues to run into many barriers. First, there are technical difficulties and quality issues with using the data especially if it is to be combined with other data sources. Second, unlike in Louisiana where there was apparently one major HIV primary care provider, in Broward, there are multiple providers. Some, but far from all, of these providers do not object to being notified about individuals who may be out of care but resist cooperating with the department in providing the additional services to help maintain adherence. Some view the services as a potential interference in the doctor/patient relationship while others maintain that their practices already have high retention. Third, there are some concerns that the department will want to take more coercive action if the patient refuses the services offered and/or still does not engage in care. Lastly, out of frustration with all the above, the department may have lost its will to implement the program in full, and if so, this may further the community's view that the department lacks the commitment to follow through.

3.3 The National Discussion

San Francisco's Project Inform convened a think tank to discuss using HIV surveillance data to improve HIV care linkage and retention. The think tank included members from a variety of organizations across the country including public health departments, advocacy organizations, providers, and universities. In its report, the unease of the

situation reads through. The group made a very cautionary approval to move forward with engaging stakeholders to consider using surveillance data for linkage and retention stating that the benefits potentially outweigh the risks. The report notes that some in the group were fundamentally opposed citing issues of privacy, stigmatization, and the potential of more harsh measures for those found to be out of care [15].

One of those harsh measures mentioned in the report is criminal prosecution for sexual behaviors [15]. I have criticized elsewhere public health's involvement in criminal approaches given the difference in the functions of public health versus criminal law [21]. However, based upon treatment as prevention and working within a public health framework, the focus for more invasive measures could shift away from a focus solely on sexual behaviors and move on to strategies dealing with the consequences of medication non-adherence. Public health authorities already guard large amounts of information about individuals engaging in behaviors that could put them at risk of prosecution under criminal statutes in many states, and yet most public health authorities maintain this information in confidence with few cases occurring where information about these behaviors is given to prosecutorial authorities. Where such a risk exists, it could be alleviated by tightening restrictions on sharing this information. What treatment as prevention does, however, is move the focus away from the possibly criminalized behavior to a medical behavior not subject to criminal intervention.

Put simply, this shift pushes the discussion into an area of well-established public health interventions, and into a behavior that though complex, is not nearly as loaded psychologically, socially, and politically as sexuality. Following established public health practices for some other infectious diseases, the result could be suggestions to implement court ordered treatment should an individual refuse treatment or care while continuing to engage in risky behaviors.

4. RECENT HISTORIC COMPARISON: UNLINKED ANONYMOUS TESTING

This is not the first time that changes in clinical and public health needs have prompted an ethical change in surveillance practices. In the late 1980s, unlinked anonymous testing (UAT) was an accepted CDC surveillance activity. UAT involved screening blood for HIV. The blood was originally collected for other reasons, not for HIV testing, and

identifiers were removed from the blood samples. Individuals whose blood tested positive for HIV were not notified, and since this was considered a public health activity, no consent or ethics oversight was thought to be required. As more and better quality therapeutic approaches were developed and tested, there became a greater need for individuals to know their HIV status. This need caused an international ethics controversy when researchers found that zidovudine therapy for a pregnant woman could greatly decrease perinatal transmission. Pressure grew to unblind the results of UAT in order to notify women of their status and to abandon UAT altogether as a surveillance method [22]. Eventually there was “a clear consensus that both the principle of consent and the right of the individual to have access to information critical to their well-being and to their capacity to access treatment that might be locally available render UAT—an approach to surveillance that makes neither possible—all but moribund [22].”

There are similarities between the change in UAT as a surveillance method and expanding the use of HIV registries for direct intervention. As a response to the discovery of new clinical and public health benefits, both involve an expansion in the purpose of surveillance registries beyond gathering data to monitor and understanding the magnitude of epidemics. Both also involve the ethics of public health withholding accessible information when the information could be used to benefit the infected individual and others.

Each case to some degree also involves privacy concerns. For UAT, like with most anonymous testing, keeping the HIV status unlinked protects against risks to privacy. Restrictions on a registry’s use also better protects the privacy of the individual. I should note, however, the main argument given by public health for maintaining UAT was not based upon privacy concerns but more upon improving the quality of data for monitoring the epidemic [22].

Lastly, both abandoning UAT and expanding the use of HIV registries could prompt more ethical questions about the potential use of more invasive public health actions should the individual not seek or accept treatment.

On the other hand, there are some differences to consider. In the UAT case, advocates for changing the status quo argued that the change was necessary to enhance the autonomy of the individual by giving the individual more information upon which to make treatment decisions. In the case of using the HIV registry to identify those lost to care, however, the intent is more paternalistic. The purpose is to determine if

the individual is not in treatment and to share the information with providers, not with the infected individual, in order to intervene both for the individual’s own health and to protect the health of others. Given this paternalistic aspect, the push to use the registry is more likely to come from public health than it is from others advocating for greater autonomy and likely to be met with greater skepticism.

The issues surrounding consent are also different. In the UAT case, the individual never voluntarily sought HIV testing. The blood was collected for other reasons and then tested without his or her knowledge and consent. In finding those lost to care, the individual may have sought, accepted, and/or consented to HIV testing and may have been informed of his or her status and that identifying information would be reported to public health authorities as required by law. However, that does not mean that he or she consented to uses or disclosures.

In sum, although a change in clinical care and public health knowledge challenge the ethical underpinnings of both UAT and the use of HIV registries, the ethical analysis may not be identical. Though in both cases the clinical and public health benefits are fairly analogous, using the registry in lost to care requires an analysis that justifies taking a paternalistic action (expanding the use and disclosures of private information collected pursuant to law) instead of taking an action to expand autonomy (no longer withholding knowledge of HIV infection and testing blood without consent). This difference could make consensus harder to reach.

5. ETHICAL CONSIDERATIONS

It is settled in the United States legal system and in secular medical ethics that a competent adult has autonomy and can refuse medical treatments, and according to medical ethicists, the patient’s autonomy may conflict with a provider’s duty of beneficence (i.e. doing good over harm for this individual) raising the issue of paternalism [23]. Unlike the provider of medical care, however, who is concerned primarily, albeit not exclusively, for the patient in his or her office, public health is charged with protecting and promoting the public’s health. Public health “involves interactions and relationships among many professionals and members of the community as well as agencies of government in the development, implementation and assessment of interventions [24].”

Direct interventions by public health authorities in infectious diseases serve a prevention function at the community level

and this function inherently contains some degree of paternalism both for the infected or exposed individual and the non-infected public. For example, public health has implemented direct interventions for tuberculosis and other curable sexually transmitted infections including notifying others exposed, providing free treatment, directly observing treatment, and in some cases, as with tuberculosis, isolation and court ordered treatment—i.e. usurping autonomy-- in order to prevent new infections. Given public health's broad authority, expanding the use of HIV registries could raise slippery slope concerns which will be addressed below.

An HIV registry contains data about individuals collected without direct use consent, an allowable limitation on the rights of the individual. Though sharing this information with the individual's physician of record is an expansion of the limits of the original infringement on autonomy, beneficence and justice are also important considerations [5].

Beneficence requires that the act do more good than it does harm. As discussed, the additional harm of expanding the use of the HIV registry is primarily a risk of further loss of privacy in notifying the patient's physician when the physician may not be aware of the patient's status. As with the sharing or storage of any medical information, there is also a risk of inadvertent disclosure to the wrong person or a breach, but public health authorities have more strict confidentiality and security protocols in place for registries than most medical facilities have in place for medical records. Nevertheless, that risk does exist and should be addressed in confidentiality and security protocols and procedures.

However, there are also substantial benefits. First, using the registry to alert physicians about patients in the registry will benefit those populations with a higher burden of HIV infection. Second, this use of the registry can potentially give infected individuals and their physicians more choices, not less, while preventing new infections in the community [9]. Lastly, these choices and benefits are even greater if public health justly allocates resources to provide services as proposed by the Florida Department of Health in Broward County to assist the individual and physician in keeping the patient in care and adherent to treatment.

It could be argued that this intense focus on those already infected would create a moral hazard. For example, HIV negative individuals could perceive less risk and thus discontinue protective behaviors leaving the burden to prevent transmission being placed solely upon those living

with HIV. On the other hand, it could also be argued that slowing the epidemic itself could create such a moral hazard. Although public health has focused most prevention resources toward, and placed a substantial burden upon, HIV negative individuals to avoid infection, as noted earlier new HIV infections continue to rise. This means that despite great risk, individuals are still becoming infected. There is no suggestion here to discontinue current public health practices with HIV negative individuals. Though moral hazard is a theoretical possibility and should be monitored, it should not prevent public health from focusing resources on those who are HIV infected while not decreasing interventions targeting those who are HIV negative and engage in risky behaviors.

6. SLIPPERY SLOPE

What if the individual refuses these additional interventions? Are the community concerns about more coercive interventions valid? In other words, is this really a choice or will public health authorities want to then take further actions to protect the public's health and move to find or create legal means to infringe upon the legal right of the individual to refuse treatment?

The public health authority has the ability to determine not only who is out of care but can also assess who is and who is not engaging in risky behaviors through DIS interviews or other sexually transmitted disease registries. While this may reduce potential unwarranted burdens being placed upon those who may refuse care but do not perform behaviors that put others at risk, it also poses an ethical issue for the public health authority. Take the case of an individual who is determined from the registry to be lost to care or non-adherent and is known to continue to practice high risk behaviors and continuously refuses any intervention to assist in reengaging in care or to improve adherence. Would public health authorities be justified to take other actions including court ordered treatment, case management, or confinement/isolation as done in some states for tuberculosis?

This would clearly be a much heavier infringement upon an individual's autonomy and would require further ethical justification. Childress et al. have suggested 5 conditions that justify when public health interventions may infringe on individual autonomy. They are (1) effectiveness, (2) proportionality, (3) necessity, (4) least infringement, and (5) public justification [24].

6.1 Effectiveness

Effectiveness means that the infringement on a right or moral consideration should in actuality effectively protect the public's health. Mandated services could effectively protect the public's health by keeping the individual under treatment and or confinement as is done with tuberculosis.

6.2 Proportionality

It is not clear, however, that such an approach would be proportional. To be proportional the public health benefits should be greater than the infringement. There is a distinction here between tuberculosis and HIV. An individual with infectious tuberculosis can in most cases become non-infectious in a short period of time with treatment (around 2 weeks) and then continue to complete treatment in 6 months or up to 2 years for resistant tuberculosis [25]. However, an HIV infected individual has to remain in treatment for life to keep his or her viral load in check, and even if the individual is in treatment for life, this may not prevent the development of resistance or other medical complications. A life time of mandated treatment or confinement may not be proportional to the public health benefits of the treatment.

Instead of lifetime treatment or confinement, treatment or confinement could be mandated until viral loads are reduced to a certain level, but this may reduce the effectiveness of the strategy as there is no guarantee of adherence once mandated treatment is completed. There may also be medical reasons beyond adherence why the viral load is not lowering [26].

6.3 Necessity

Necessity is also problematic. If it is assumed that many will accept voluntary assistance if it were offered to them to re-engage in care or assistance with treatment adherence, it is unclear that mandating treatment is necessary to have a major impact on HIV incidence in a community. It is unrealistic for public health to believe it can eliminate HIV [27]. Thus a voluntary program as set forth above could possibly reduce transmission in a community to a level that has an acceptable and significant public health impact. Furthermore, a reduction in a given individual's viral load is not a 100% guarantee that the individual will not be able to infect another person if he or she continues to engage in certain behaviors.

6.4 Least Infringement and Public Justification

In addition to an intervention being effective, proportional and necessary, public health should use the least restrictive

intervention necessary to protect the public's health.

Voluntary treatment and/or case management would clearly be a lesser infringement than mandatory or court ordered services and confinement.

Given all of the above, before pursuing mandated treatment, case management or confinement, public health would need to offer a public justification for any such approach, with sound reasons and evidence for why this would be necessary, proportional, and the least restrictive means. However, slippery slope concerns should not deter public health authority pursuits similar to those of the state of Louisiana and the Florida Department of Health in Broward County. The use of the registry to intervene in both cases rests upon sound ethical principles.

7. CONCLUSION

State and local health departments should use HIV registries to identify potential individuals who may be lost to care or non-adherent to treatment and intervene. There is an ethical imperative for public health to do so. If resources are available in high incidence and prevalence communities, voluntary programs for services to assist the patient to stay engaged in care and adherent should be offered. It is unclear if mandatory treatment, case management, or confinement would be necessary, proportional, and the least restrictive means, but concerns over a slippery slope should not deter a broader use of HIV registries as put forth in this article provided there is extensive community engagement.

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