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PERSPECTIVES

Achieving Greater Transparency Regarding Molecular HIV Surveillance: A Proposal to Move Beyond the Status Quo

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Molecular HIV surveillance is used to in effort to enhance HIV prevention efforts by identifying emerging clusters of rapid HIV transmission. In the United States, it relies upon data from antiretroviral resistance testing done in the context of clinical care. However, information about the public health uses of these data are not always disclosed to patients at the time of testing, which raises ethical concerns. Building upon accumulating data about this practice, a multidisciplinary group argues that there is a need to increase transparency of the practice through active disclosure.

Keywords. consent; disclosure; molecular HIV surveillance; transparency; trust.

Molecular HIV surveillance (MHS) uses data from antiretroviral resistance testing (ARVRT) in effort to enhance HIV prevention efforts by identifying emerging clusters of rapid HIV transmission. Although ARVRT is often conducted during treatment initiation for people with HIV to inform clinical decisions, MHS is a public health activity [1].

Approximately 120 conditions are notifiable by the National Notifiable Diseases Surveillance System, including infectious diseases, foodborne outbreaks, and noninfectious conditions of interest [2]. However, HIV data arguably differ from those related to other reportable conditions, due in part to their potential use for HIV criminalization and stigma. Unlike many other reportable conditions, HIV exposure and the condition itself are criminalized in some jurisdictions [3–5]. There are also factors about HIV making MHS fundamentally different from molecular surveillance of other pathogens. For instance, HIV disproportionately impacts marginalized communities who experience social villainization, heightened stigma, and overpolicing [6, 7]. Furthermore, HIV transmissions often occur through stigmatized activities such as sex and injection drug use.

Concerns regarding the public health uses of ARVRT data are intensified by the routine absence of disclosure and consent for this data sharing [8]. Worries about privacy and autonomy have in turn led to calls for increased transparency about this process [1, 9]. In 2022, the Presidential Advisory Council on HIV/AIDS recommended obtaining informed consent for the use of health data for MHS [10]. However, public health practitioners have raised objections to obtaining consent, citing concerns about feasibility and potential reductions of the amount of public health data that might then be available to fuel robust MHS [11].

As part of the Study of Stakeholder Attitudes towards HIV Molecular Epidemiology (SESAME), a large project designed to gather empirical data to inform deliberations about the ethical, legal, and social risks of HIV molecular epidemiology, we convened a multidisciplinary group of clinicians, community members, ethicists, public health practitioners, and scientists to address the competing tensions related to disclosure regarding MHS. The discussion is summarized here.

SPECTRUM OF DISCLOSURE REGARDING MHS

There is a spectrum of possible disclosure for MHS (Figure 1).

Status Quo and Passive Disclosure Options

The most significant ethical objections to the status quo are that most individuals are unaware that the genetic sequence data of their HIV virus will be shared with public health departments. This compromises personal autonomy and the individual's right to make an informed choice about testing. In addition, if individuals subsequently learn their HIV virus was subjected to genetic sequencing, their trust in the health care

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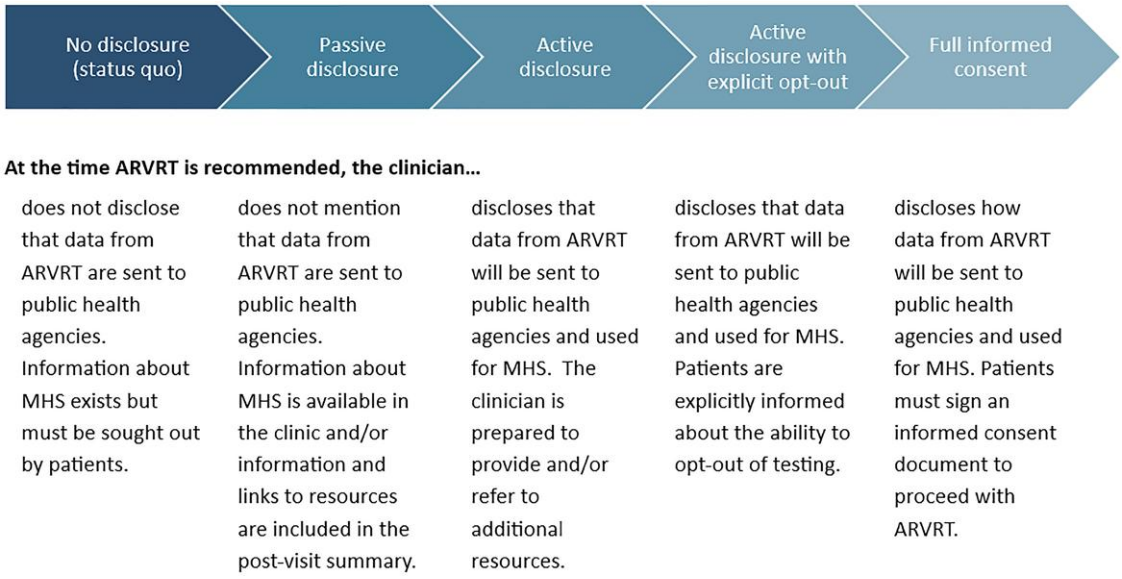

Figure 1. Spectrum of potential disclosure for HIV-molecular HIV surveillance.

and public health systems might be eroded.

With *passive disclosure*—where information is available as posters, handouts, or websites—there is increased likelihood individuals would know what happens to their ARVRT results before undergoing testing. Although passive disclosure begins to address concerns about violating decision-making autonomy, it does not ensure understanding of MHS and its associated data-sharing practices. Moreover, the responsibility falls on the individual who may have only recently learned they have HIV to seek out or consume the information that may understandably seem less immediate than making decisions about engaging in care.

The theoretical argument for withholding information about sharing of ARVRT results with health departments is the belief that such disclosure might serve as a deterrent to ARVRT potentially leading to adverse clinical and public health consequences. First, in the absence of ARVRT data, there remains a low, but real, risk that individuals may be prescribed a treatment regimen that is suboptimal, potentially leading to virologic failure and the emergence of additional resistance mutations. This could negatively impact the health of both the individual and their sex or needle sharing partners who may be at heightened risk of acquiring HIV. Second, reducing the number of people who undergo ARVRT might result in insufficient data for public health surveillance. Third, there are practical barriers to clinician disclosure about data sharing, such as limited time during clinical encounters and lack of familiarity with the specific mechanisms of data sharing with public health authorities.

Opt-out and Informed Consent Options

Voluntary, autonomous decision-making is the gold standard for ethical medical practice and research [12] and is generally operationalized with either an explicit opt-out or informed consent process. *Opt-out* processes involve informing someone that a procedure will be performed unless they specifically decline it. The amount of information provided may be somewhat limited. Opt-out processes are often done when procedures are of minimal risk or are similar to other routine clinical procedures [13]. However, despite the sensitivity of HIV testing data, consistent with Centers for Disease Control and Prevention guidance, in many contexts an opt-out process for routine HIV screening can be appropriate [14].

Informed consent is more elaborate than opt-out processes and typically involves detailed disclosure about a procedure, its benefits, harms, and alternatives, followed by asking the individual to affirm their agreement to it, often in writing. High-quality informed consent usually requires a substantial time investment of patients and clinicians.

Active Disclosure

Active disclosure involves providing a concise, standardized explanation that normalizes MHS within broader public health reporting. Proactively informing patients prepares them for potential future contact from public health departments, possibly improving cooperation with epidemiologic investigations. As such, it addresses normative concerns about the status quo and *passive disclosure* options. Figure 2 includes a sample script that clinicians might use. It is intended to be flexible; clinicians can modify it, while ensuring the inclusion of the main talking points.

The empirical work conducted by SESAME provides preliminary evidence that the practical concerns about active

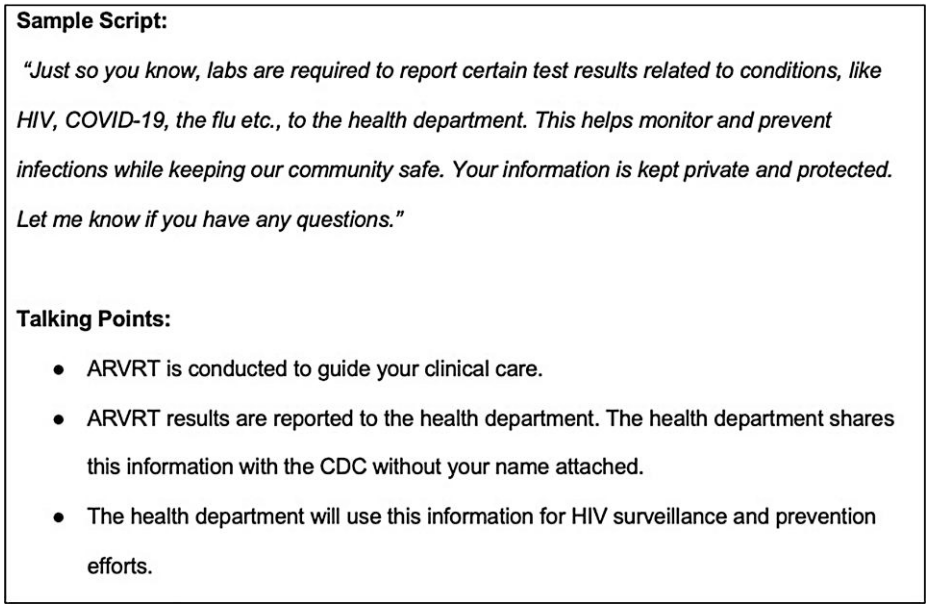

Figure 2. Standardized messaging for active disclosure.

disclosure may be overstated. Specifically, in a pilot survey of clinician perspectives on MHS, respondents endorsed an ethical obligation to disclose to patients that their ARVRT results would be shared with health departments, and they were receptive to taking on the responsibility for this disclosure [15]. In a large vignette study of people with or at greater risk of HIV, respondents were less likely to undergo ARVRT if their clinicians did not disclose this information and they found out about it after the fact [16]. This suggests that the absence of transparency could, in fact, reduce testing and erode trust.

CALL TO ACTION

Effective use of MHS to actively intervene in HIV transmission networks requires community trust and relationships with individuals identified as part of these networks. Enhancing transparency through active disclosure is an ethically sound approach that has the potential to not only improve the effectiveness of MHS, but also to mitigate broader harms tied to medical mistrust and systemic inequities in healthcare. To effectively implement active disclosure, efforts should be taken to ensure that clinicians ordering ARVRT are aware of not only public health reporting of these data, but also their use in MHS, which may not currently be the case [15]. In addition, there is a need to develop guidance for clinicians to use during interactions with patients as well as approachable and accessible educational materials explaining the benefits and risks of MHS. Such guidelines and materials should be developed in collaboration with clinicians who treat people with HIV, people with HIV, advocates, and representatives from public health departments to ensure they are community-informed, context-sensitive, accurate, and trustworthy. Finally, empirical work should be conducted to provide a more definitive answer to the question of what impact active disclosure has on testing and trust in public health, both specifically for MHS and more broadly.

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