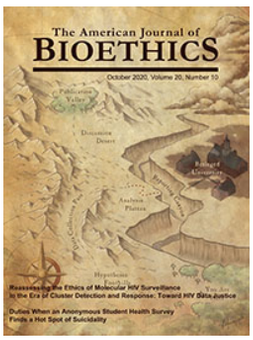

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Reassessing the Ethics of Molecular HIV Surveillance in the Era of Cluster Detection and Response: Toward HIV Data Justice

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ABSTRACT

In the United States, clinical HIV data reported to surveillance systems operated by jurisdictional departments of public health are re-used for epidemiology and prevention. In 2018, all jurisdictions began using HIV genetic sequence data from clinical drug resistance tests to identify people living with HIV in "clusters" of others with genetically similar strains. This is called "molecular HIV surveillance" (MHS). In 2019, "cluster detection and response" (CDR) programs that re-use MHS data became the "fourth pillar" of the national HIV strategy. Public health re-uses of HIV data are done without consent and are a source of concern among stakeholders. This article presents three cases that illuminate bioethical challenges associated with re-uses of clinical HIV data for public health. We focus on evidence-base, risk-benefit ratio, determining directionality of HIV transmission, consent, and ethical re-use. The conclusion offers strategies for "HIV data justice." The essay contributes to a "bioethics of the oppressed."

KEYWORDS

Public health; genetic research; human subjects research; informed consent; health policy; confidentiality & privacy

INTRODUCTION

In the United States, data from HIV surveillance systems operated by state and local departments of public health using guidelines from the Centers for Disease Control and Prevention (CDC) have long been utilized to monitor the HIV/AIDS epidemic (Cohen et al. 2014). Health departments also regularly share HIV surveillance data with researchers. Since 2014, personally-identifiable routine HIV care data reported to surveillance systems—chiefly HIV viral load and CD4-T cell count—have increasingly been used to provide direct prevention services to people living with HIV identified as out of care or as more likely to transmit (CDC 2014, 2018; Project Inform Staff 2012; Sweeney et al. 2013, 2019). In 2018, HIV genetic sequence data generated from antiretroviral drug resistance tests ordered by clinicians for patients living with HIV also began to be used in all CDC-funded surveillance jurisdictions to identify people living with HIV in "clusters" of others with genetically similar strains of the virus (CDC 2017a, 2017b, 2018; Evans and Benbow 2018, 9). HIV genetic sequence data are often called "molecular" HIV data; their use in public health surveillance is thus referred to as "molecular HIV surveillance" (MHS) (CDC 2018; McClelland et al. 2019). In 2019, "cluster detection and response" (CDR) utilizing MHS data was announced as the "fourth pillar" of *Ending the HIV Epidemic: A Plan for America* (Fauci et al. 2019; HHS 2019; Oster 2019). Public health programs that re-use clinical HIV data for prevention aim to advance the goal of reaching universal HIV treatment, following confirmation that antiretroviral treatment is a highly effective way to prevent transmission. This paradigm, called "treatment as prevention" or "test and treat" has become the dominant mode of managing HIV in the U.S. (HHS 2019; Williams et al. 2011).

Re-uses of clinical HIV data for public health surveillance and prevention do not require consent (Fairchild 2003, 615; Lee et al. 2012). Further, there have not been comprehensive efforts to educate people living with HIV that data from routine clinical blood tests ordered by their medical providers are transmitted to departments of public health and systematically re-used (Chung et al. 2019). The increased utilization of MHS data for prevention, often with vulnerable populations, is an increasing source of concern among advocates, researchers, and other stakeholders (Artavia 2019; Center for HIV Law and Policy

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2019; Kempner 2019; McClelland et al. 2019). These practices are poorly-understood and require further analysis. Bioethics offers useful tools for contextualizing and analyzing molecular HIV technologies and their use by public health agencies.

We first explain and historicize MHS and CDR. We then present our theoretical orientation, situating ourselves in critical bioethics and digital bioethics. Our framework prioritizes the bioethical value of justice and contributes to a "bioethics of the oppressed" that centers marginalized groups who are disproportionately impacted by public health interventions (Guta et al. 2018).

We then present three case studies that illuminate known and emerging bioethical and practical challenges associated with uses of molecular HIV data. These cases are drawn from a robust review of literature, including research publications and publicly-available grey literature produced by CDC, state and local governments, and civil society groups (Fourth International Conference on Grey Literature, 1999). The first case is a review of ethical literature about research studies utilizing HIV genetic sequence data. The second case concerns whether HIV phylogenetic analysis—a methodology used to identify groupings or "clusters" of people with genetically similar strains of HIV—can or should be used to determine or infer "directionality of transmission" from one person to another (whether person A transmitted HIV to person B). The third case is a scientific controversy analysis exploring a series of published exchanges between activists and researchers surrounding an MHS study of transgender women and their partners in *The Lancet HIV* (Ragonnet-Cronin et al. 2019).

Each case highlights critical unresolved issues pertaining to the ethics and practice of utilizing molecular HIV data for research and public health. In the conclusion, we offer strategies for stakeholders to undertake reform-oriented conversations. These include suggestions for HIV professionals to consider, such as providing technological affordances to people living with HIV that would allow them to assert some controls over re-uses of their clinical data for public health purposes. These suggestions are framed as starting points in the pursuit of "HIV data justice."

HISTORY AND CONTEXT FOR MHS AND CDR

The use of MHS data by health departments and academic researchers presents complex ethical challenges. Molecular HIV data are primarily generated from blood tests ordered by clinicians during the provision of routine HIV care in order to identify potential antiretroviral drug resistance particular to a person's strain of HIV (Evans and Benbow 2018). In the U.S., results from HIV genetic sequence tests ordered by clinicians are transmitted electronically to HIV surveillance systems by testing laboratories. Data from state and local HIV surveillance systems are the basis for most knowledge about localized HIV/AIDS epidemics and the national epidemic (Cohen et al. 2014).

To understand patterns of HIV transmission, epidemiology has typically relied upon mandatory reporting of new HIV diagnoses, utilizing demographic information, transmission risk factors, and other data (Cohen et al. 2014). MHS employs phylogenetic methods to analyze genetic sequences reported to surveillance systems to determine which individuals in their jurisdiction have strains of HIV that are closely linked at the viral genetic level. This is possible because HIV is highly mutable, and over time, each person's strain becomes increasingly unique (Little et al. 2014). Greater genetic similarity indicates more recent transmission (CDC 2018; Oster 2019). Phylogenetic HIV analysis has been used in multiple ways, such as for retrospective analyses of samples to understand historical transmission patterns, to map rates of antiretroviral resistance, to discern global transmission patterns, and other uses (Crane 2011; Gagnon and Guta 2012; Mehta et al. 2014).

Phylogenetic analysis of MHS data has increasingly been used in prevention. CDC optimistically stated that

> [r]outine use of this systematic method in near real time can automate detection of increases in HIV diagnoses that potentially merit further investigation and help state and local health departments prioritize and target HIV prevention efforts for maximal public health impact (CDC 2018, 8)

High levels of genetic similarity between two or more people's strains of HIV indicate a "cluster" or "transmission network" (CDC 2017a, 2017b, 2018). Software designed to aid in phylogenetic analysis often represents clusters and transmission networks as square or circular "nodes" (each representing a person) connected to each other by lines. Lines, also called "edges," indicate either genetic similarity or another known epidemiological connection, such as data collected during partner services investigations (Kosakovsky Pond et al. 2018; Little et al. 2014). Clusters are identified using traditional methods and molecular HIV data. When clusters that meet specific criteria are identified, health departments must initiate "escalated" responses (CDC 2018, 60–62). Escalated

responses can include seeking assistance from CDC, targeted outreach to individuals and communities, media campaigns, and other efforts. These sources of data, best practices, and technologies form the basis for CDR programs, which are the "fourth pillar" of *Ending the HIV Epidemic: A Plan for America*, released in 2019 (Fauci et al. 2019; HHS 2019).

While surveillance for infectious diseases is a longstanding practice, MHS and CDR programs repurpose HIV surveillance data for direct prevention in entirely new ways. These interventions have largely been enabled by the digitization and linkage of U.S. clinical, research, and public health data infrastructures, and have been rolled out and scaled up with atypical rapidity (Evans and Benbow 2018, 3; Oster 2019). The opening up of HIV surveillance data—which were formerly used only for epidemiological purposes—for direct public health prevention aimed at individuals constitutes the most significant transformation in uses of HIV data in the U.S. since the epidemic began (Fairchild and Bayer 2011; Sweeney et al. 2013, 2019). This trajectory follows a growing tendency in U.S. biomedicine to make different classes of health data infrastructures interoperable with one another, involving the linkage of clinical, research, and public health datasets (ONC 2015, 2019). New uses of MHS data pose risks and dilemmas that disproportionately impact marginalized communities and raise concerns that exceed those posed by older forms of HIV data utilization for public health (Mutenherwa et al. 2019).

People living with HIV currently have no mechanisms to refuse participation in programs in which their clinical data are re-used for public health purposes (Wertheim et al. 2019). This is true even of very advanced re-uses of personally-identifiable HIV surveillance data for direct prevention, such as uses of HIV genetic sequence data in escalated CDR (CDC 2018). Guta et al. (2016) have expressed concerns about the impacts of new forms of HIV surveillance in which traditional epidemiological data, combined with the integration of biomarkers such as viral load, are used to reach out to the most vulnerable people living with and affected by HIV. These concerns are shared by many activists, researchers, and policy advocates (Center for HIV Law and Policy 2019; Chung et al. 2019; Kempner 2019; McClelland et al. 2019). However, others actors in this milieu (including activists) are far more optimistic (see Evans and Benbow 2018).

New forms of surveillance have a tendency to be positioned as necessary and inevitable (Monahan and Wall 2002), and the appeal of "knowing" local HIV epidemics orchestrates much of the HIV response (ONAP 2015). The assumption is that by knowing how epidemics happen in their local contexts in close to "real-time" (Little et al. 2014), public health actors can better work toward treating people living with HIV and preventing new infections. Optimism over the power of new technologies tends to foreclose the possibility of sensitively understanding the new practices that accompany their application (Chun 2011; Timmermans and Berg 2003). MHS and CDR are not just deployments of technologies to solve a public health problem. They are assemblages of longstanding and novel practices that involve complicated sociotechnical processes and embedded assumptions. The work of MHS and CDR carries deep implications for data practices, for HIV care and prevention, and for the role of bioethics in milieus where marginalized populations are disproportionately targeted for enhanced public health action. MHS and CDR programs call for new applications of critical bioethics in public health.

THEORETICAL FRAMING: FROM "CRITICAL BIOETHICS" TO "BIOETHICS OF THE OPPRESSED"

This article contributes to critical bioethics (see Hedgecoe 2004, 2010). Critical bioethics draws on core insights from fields such as Science and Technology Studies, social theory, critical theory, and Medical Sociology and Anthropology to advance critiques of current and emergent practices in biomedicine and health where the benefits to society and to the individuals and communities targeted by interventions are unclear or potentially harmful. Critical bioethics is opposed to an approach that would seek to provide ethical justification for new interventions or simply to describe known challenges (Hedgecoe 2004, 121–122). Positioned thusly, critical bioethics strives not to function as a kind of handmaiden to health actors and institutions that are often highly invested in new approaches. Rather, critical bioethics functions as an intentional counterweight to forms of optimism that often accompany the implementation of novel technologies in the practice of healthcare, public health, and biomedical research (Hedgecoe 2010, 166, 180).

Re-uses of clinical HIV data in public health constitute an area where futures are being imagined and remade, often motivated by rhetorically powerful discourses such as the "End of AIDS" or, more recently, "Ending the HIV Epidemic" (HHS 2019; see also

Ribes and Polk 2015). Amidst such high levels of enthusiasm, the critical bioethicist has an important role to play as a thoughtful counterbalance to temper optimism and to generate new conversations (see Guta et al. 2018).

We take cues from the people living with HIV/AIDS movement regarding the value of coalition-building across differences of interest and positionality and the "Meaningful Involvement of People Living with HIV/AIDS" (AIDS United 2018; Bordowitz 1987; People with AIDS Advisory Committee 1983). Specifically, we center the ways that people living with HIV are turned into multiple different kinds of clinical, research, and public health "data subjects" by actors and institutions across domains of clinical and public health practice. Public health re-uses of individuals' clinical HIV data are usually done without consent, and with the express aim of using data to act upon individual people and communities living with HIV to control or modify their behavior and bring them into various regimes of compliance (on "data subjects" and coercive state power, see Cheney-Lippold 2017, 157; on the subjectivities of people living with HIV and various forms of compliance, see also Deleuze 1992; Gagnon and Guta 2012; Lloyd 2018; see Race 2009, 107–137).

Thus, as part of the project of building a critical bioethics that privileges the situated positions of people and communities living with and affected by HIV, we model an approach that Guta et al. (2018) call a "bioethics of the oppressed" (on "building up," see Law 2004). A bioethics of the oppressed centers "vulnerable and marginalized communities … whose social location and health behaviors [bring] them into conflict with medicine, public health, and the law" (Guta et al. 2018, 62). New HIV surveillance and prevention technologies such as CDR arguably create new forms of *de facto* criminalization, particularly for people who cannot fulfill the biopolitical requirements of new HIV treatment as prevention paradigms (Center for HIV Law and Policy 2017; Cormier McSwiggin 2017).

We thus also advance Benjamin's (2016) call for a "justice-based bioethics" that de-privileges categories of biomedical subjectivity, such as being virally "undetectable," that are currently valorized and to which people living with HIV have unequal access—often because of issues related to racial and economic inequality, substance use, virologic composition that prevents individuals from becoming virally suppressed, and myriad barriers to remaining in medical care (Cormier McSwiggin 2017; Lloyd 2018). New prevention strategies such as CDR aim to remedy these and other HIV-related inequalities by surveilling and controlling people living with HIV more intensely, rather than by addressing the root causes of inequalities that lead to disparate health outcomes (for similar critiques, see Ehlers and Krupar 2017). In addition to mobilizing resources aimed at retaining people in care, programs such as CDR also have the potential to exacerbate, rather than ameliorate, varied HIV-related injustices.

We also agree with digital bioethicists that "in the rapidly changing context of emerging health care technologies, the role and focus of the ethicist need to be revisited" (Jongsma et al. 2018; see also, Klugman et al. 2018a, 2018b, W6–W7). Therefore, building on the notion of "data justice," we suggest "HIV data justice" as a method and "a form of critique, a framework for shifting the entry-point and debate … in a way that foregrounds social justice concerns and ongoing historical struggles against inequality, oppression, and domination" (on data justice, see Dencik et al. 2019, 876). Data justice provides a way of conceptualizing how forms of resistance to and critical engagement with biomedical and public health institutions can reformulate data practices to the benefit of oppressed groups. HIV data justice draws on the collective resources of the HIV/AIDS movement to build new alliances aimed at providing affected individuals and communities with greater control over how their data are utilized in the healthcare system, with the paired aim of providing them with greater access to better services on terms of their own choosing.

CASE 1: THE ETHICS OF MOLECULAR HIV RESEARCH AND SURVEILLANCE

Ethical papers about analyses of HIV genetic sequence data have usually focused on research ethics, such as when and how researchers must seek institutional review board (IRB) approval for accessing and conducting analysis on HIV data (Coltart et al. 2018; Mutenherwa et al. 2019). However, the conduct of routine surveillance by public health institutions does not require ethical oversight in the same way that research does (Fairchild 2003; Lee et al. 2012). The distinction between public health surveillance and research ethics are often blurred, notwithstanding attempts to clarify this "grey area" (Sherman and Campione-Piccardo 2007). This grey area is apparent in current MHS practices.

Despite being nationally rolled out as the "fourth pillar" of *Ending the HIV Epidemic* (Fauci et al. 2019),

there is little high-ranking evidence demonstrating the benefit or efficacy of MHS and CDR (see Burns et al. 2011 on levels of evidence, and Rychetnik et al. 2002). Mehta et al. (2019) pointed out that no controlled trials or prospective empirical observations have been conducted with MHS, and all currently published studies have been uncontrolled observational studies. In stating this we note that there are important critiques of evidence-based medicine, particularly regarding how evidence is not simply implemented, but rather is *made* through the contingencies of implementation (Rhodes and Lancaster 2019). Importantly, expert stakeholders who conducted molecular HIV research studies (Mutenherwa et al. 2019, 68) could not categorically state whether these studies offered a favorable risk-benefit ratio for participants, an important condition of ethical research (Buchanan and Miller 2006).

If individual consent was to take place, expert stakeholders were unsure of how to communicate the benefits of MHS to both individuals and communities (Mutenherwa et al. 2019, 66). Some participants in Schairer et al.'s (2017) study, including HIV professionals and people living with and affected by HIV, were confident of some benefits. However, researchers also noted that "both support for and concerns about this approach may be based on flawed understandings of molecular epidemiology" (Schairer et al. 2017, 133). These studies reveal that expert stakeholders are unsure of the benefit to participants in molecular HIV studies (Mutenherwa et al. 2019), and that obtaining individual consent would be difficult due to the challenge of ensuring that participants would understand what they are consenting to. This also partly reflects the lack of clarity regarding individual and community benefit of molecular HIV studies (Schairer et al. 2017).

The utilization of phylogenetic analyses of HIV genetic sequence data in criminal proceedings where HIV transmission is alleged is a recognized problem (Barré-Sinoussi et al. 2018; Galletly et al. 2019; UNAIDS 2013). A key issue in criminal contexts is whether phylogenetic analysis can be utilized to discern directionality of transmission (i.e. to prove that person A transmitted HIV to person B). A consensus across the ethical literature is that HIV phylogenetic analysis cannot be used to infer directionality (Coltart et al. 2018; Mutenherwa et al. 2019). However, as we explore in case two, some practitioners argue that directionality can be inferred. Similarly, Mutenherwa et al.'s (2019) participants were concerned about MHS being used to identify "high HIV transmitters" and marginalized subpopulations. As we explore in case three, this has occurred, and some researchers encourage the use of phylogenetic software for "[f]inding likely transmitters in a large population cohort" (Wymant et al. 2018, 728). From an ethical and methodological perspective, the distinction between whether directionality *cannot* or *should not* be inferred using molecular data is not clear.

The potential for MHS to lead to new forms of re-identification is a concern, particularly because MHS relies on demographic, behavioral, and other data in addition to HIV genetic sequence data to make any meaningful public health intervention (Mehta et al. 2019). Mehta et al. (2019) therefore argued that great care needs to be taken in presenting such data, even in an aggregated form, in geographically concentrated analyses. In their article about HIV phylogenetics in public health, Brooks and Sandstrom (2013) cited human genomics researchers who were able to re-identify individuals through a combination of publicly available genetic ancestry data with metadata and internet searchable information (Gymrek et al. 2013). Re-identification of research participants in data-sets continues to be an ongoing risk (Rocher et al. 2019). We note that annotated HIV genetic sequence data for the known HIV genome are publicly available from the Los Alamos National Laboratory HIV databases, the main reference dataset used in MHS (LANL 2019). Further, as described in case two, multiple open source software tools exist for analyzing and visualizing HIV genetic sequence data and other viral genetic datasets using phylogenetic methods (e.g. Kosakovsky Pond et al. 2018). In sum, the increasing availability of both identifiable and de-identified HIV genetic sequence data to practitioners, along with other issues regarding potential re-identification, raise multiple known and emergent concerns that require further study.

Coltart et al. (2018) stated that a key ethical principle is that study participants and patients should be able to consent to the use of their samples for phylogenetic analysis. In the absence of such consent, they stipulated that waivers of consent must be obtained from IRBs. University researchers did obtain individuals' informed consent in the San Diego Primary Infection Cohort study, which collected and analyzed HIV genetic sequence data on new cases of HIV in San Diego starting in 1996 (Little et al. 2014, 2). However, we have not found any molecular HIV studies that utilized surveillance data provided by health departments in which authors state that individual consent was sought.

This is consistent with current practices, which exempt nearly all uses of HIV surveillance data from consent requirements (Evans and Benbow 2018; Lee et al. 2012). There is currently no mechanism in the U.S. for people with HIV to opt-out of surveillance, to withdraw their data, or to request that their data not be used in certain ways. These are key elements of voluntary participation in research, but are not currently applicable to uses of molecular HIV data by public health agencies (Mutenherwa et al. 2019). In the absence of informed consent, Mehta et al. (2019) and CDC technical guidance suggest that community engagement should take place as part of the rollout of MHS and CDR (CDC 2017a 35, 43; CDC 2018, 50–52). As CDR initiatives move ahead, health departments are required to "inform community stakeholders about cluster response efforts and to garner community feedback, support, and potential collaboration in the process" (Galletly et al. 2019). However, no mechanisms of refusal exist.

In sum, the ethical literature to date has focused mostly on the *research* context of MHS. CDR is an emerging extension of molecular HIV technologies into direct prevention. The current focus on obtaining a waiver of consent from IRBs for re-uses of HIV surveillance data obfuscates the ethical problem of how HIV surveillance systems collect molecular data in the first instance: from routine clinical tests ordered by clinicians for patients living with HIV. At present, the U.S. public health infrastructure fails to recognize the emergent rights of individuals to have some control over how their electronic health information is collected, stored, and used, particularly when those data are sensitive (ONC 2015, 25). A balance between individual rights and protecting the public is a core mandate of public health (Buchanan and Miller 2006). Along with others (e.g. Artavia 2019; Center for HIV Law and Policy 2019), we suggest that this mandate is out of balance in the current U.S. approach to MHS and CDR. Furthermore, the routine conduct of MHS and CDR has been scaled up as a national policy without respect to standard benchmarks of evidence (Fauci et al. 2019). It is therefore not clear what public health benefit they afford.

CASE 2: DETERMINING DIRECTIONALITY OF TRANSMISSION

A key claim made by molecular HIV practitioners is that the directionality of HIV transmission between two people cannot be inferred using molecular HIV data "alone" (e.g. CDC 2018 8, 86; Oster et al. 2018). This is because close genetic relationships between two cases do not exclude the possibility of additional unidentified individuals in the transmission network (CDC 2017a, 8–11; Evans and Benbow 2018, 2–4, 9, 13–14; Oster 2019).

There is some level of expert consensus on specific conditions for determining legal proof of directionality in criminal cases (Barré-Sinoussi et al. 2018; UNAIDS 2013, 31–34). However, as we examine in case three, opinions vary about the public health value of discerning directionality. Advocates, researchers, and civil society organizations have flagged this as a concern (e.g. Kempner 2019; McClelland et al. 2019; UNAIDS 2013). This is true not only because of HIV criminalization laws, but also because many public health agencies possess and utilize mechanisms to place controls on the behavior of people living with HIV who are deemed a "health threat to others," "high risk," "recalcitrant," and/or who are suspected of having exposed another person to HIV (Hoppe 2018, 68–98; NSW Health 2019; Proctor 2019).

Determining whether there is ever public health value in ascertaining directionality of HIV transmission is outside the scope of this essay and should be the subject of future inquiries. Here, we focus on the claim that "phylogenetic analysis alone cannot prove beyond reasonable doubt that one person infected another" (Barré-Sinoussi et al. 2018; see also UNAIDS 2013). We show the assertion that "molecular surveillance data alone" (Oster et al. 2018) cannot be used to determine directionality to be spurious, and problematic in at least two senses.

Firstly, HIV genetic sequence data almost never exist in the absence of other data. The only way that molecular HIV data could exist in this way—"alone"—would be if the genetic sequences were stripped of all other associated data and metadata. This level of de-identification extends far beyond best practices (Office of Civil Rights, 2012). Further, the success of CDR depends on connecting identifiable, names-based HIV surveillance and public health data to HIV genetic sequence data (CDC 2018, 6–11). Discussions of what can be done using "sequence data alone" (e.g. Evans and Benbow 2018, 9, 13; Grande et al. 2019, 150) are thus disconnected from the reality of public health and research practice. Therefore, discussions of what can be done with HIV genetic sequence data "alone" should be avoided.

Secondly, some of the same authors who argue that molecular HIV data "alone" cannot be used to infer directionality have acknowledged or endorsed the use of HIV genetic sequence data in combination with

other data to infer directionality (see Grabowskiet al. 2018, 186; Little et al. 2014, 4; Mehta et al. 2019, 222; Oster et al. 2018, 1658). Some researchers have developed phylogenetic methods specifically to discern directionality (Rose et al. 2019; Wymant et al. 2018).

Thus, the claim that molecular HIV data will not be used to determine the directionality of transmission has been rightly called into question (see Kempner 2019; McClelland et al. 2019). Advocates have also expressed concerns that phylogenetic methods may evolve to a point where directionality can be determined using molecular data (Kempner 2019). CDC scientists leading CDR efforts also note that phylogenetic data could be (mis)interpreted to make determinations about directionality (Oster 2019). Recent history suggests that these concerns are warranted.

Several leading molecular HIV researchers have implied or stated outright that directionality of transmission can be determined using molecular data. Wymant et al. (2018) built "PHYLOSCANNER: A set of methods implemented as a software package" to do this (720). PHYLOSCANNER performs seven sequential analytical operations on pathogenic genetic datasets, including HIV, with the seventh step being the "[i]dentification of transmission events from ancestral host-state reconstructions" (720). Coltart et al. (2018) cited PHYLOSCANNER as an appropriate tool for "inferring, with a degree of uncertainty, the direction of transmission within clusters" (e657). Little et al. (2014) utilized HIV genetic sequence data from the San Diego Primary Infection Cohort study to make determinations about directionality between specific individuals. Little et al. (2014) wrote that, using a phylogenetic analysis tool called HyPhy, "It was possible to discern the direction of the putative HIV-1 transmission in 332 of the 540 connections (61.5%) by comparing the sampling date of the secondary partner and the [Estimated Date of Infection] for the putative initial (i.e., transmitting) partner" (4).

Further, indicators of directionality have been built into data visualization tools used to model molecular HIV transmission networks. These include the HyPhy and HIV-TRACE software packages (Kosakovsky Pond et al. 2018; Little et al. 2014). Kosakovsky Pond et al. (2018) released HIV-TRACE as an open source tool. HIV-TRACE has been utilized for transmission network modeling by researchers, CDC, and health departments (CDC 2017a, 52–59). HIV-TRACE is also the basis for "Secure HIV-TRACE," browser-based software developed by CDC for health departments to facilitate CDR (CDC 2018 15–16, 54; Oster 2019). Indicators of directionality in these and other software packages lend themselves to misinterpretation.

One of the visual characteristics of the transmission network diagrams that HIV-TRACE produces are arrows or "directed edges" linking nodes in the network. Kosakovsky Pond et al. (2018) included a transmission network diagram with several arrows between two individuals that are disconnected from any other connections in the network. Directed edges which flow unidirectionally from one node to another without additional links strongly imply directionality, whether or not the designers intended this. Thus, it is unsurprising that such arrows have been interpreted by molecular HIV researchers as indicating that transmission has occurred. Grabowski et al. (2018) wrote that in "transmission network" diagrams, "[a] directed edge (arrow) drawn between nodes indicates that the pathogen was transmitted" (186).

Further, Oster et al. (2018) suggested that HIV genetic sequence data can be included among other data used to make claims about possible transmission "…when strong epidemiologic evidence supports a direct transmission event" (1658) and flag this as a concern. Mehta et al. (2019, 222) argued that molecular data in combination with traditional sources of public health data can be used to suggest directionality.

These statements are troubling, because they show that certain practitioners believe that it is possible to use existing methods and instruments to identify probable transmission events. Conflicting statements by experts about the ability to determine directionality suggest that, even if best practices and technical guidance insist that HIV genetic sequence data ("alone") cannot be used to determine directionality, these data will likely be used in this way in some instances, as they have in criminal cases and public health responses (McClelland et al. 2019; UNAIDS 2013). Misalignments on the question of determining directionality among experts raises a parallel set of concerns about how health department personnel or others not trained in phylogenetic analysis may interpret these data or employ available tools.

CASE 3: CONTROVERSY SURROUNDING MHS AND TRANSGENDER WOMEN IN *THE LANCET HIV*

On February 11th, 2019, *The Lancet HIV* published "HIV transmission networks among transgender women in Los Angeles County, USA: a phylogenetic analysis of surveillance data" (Ragonnet-Cronin et al.

2019). The study was conducted by a group including three university-based HIV researchers and three employees of the Los Angeles County Department of Public Health (LADPH). The study utilized HIV-TRACE to analyze de-identified surveillance data provided by LADPH. Ragonnet-Cronin et al. (2019) secured approval from both the University of California, San Diego and LADPH IRBs, but were not required to secure consent from subjects because the data were public health surveillance data (Wertheim et al. 2019).

Ragonnet-Cronin et al. (2019) suggested that MHS could aid in the identification of more transgender women living with HIV in Los Angeles County, and that molecular data could shape interventions aimed at transgender women and their cisgender male sexual partners. This followed observations that transgender women living with HIV in Los Angeles County (1) were more likely to be in an HIV cluster than any other group, (2) were likely to have strains of HIV that were genetically linked to other transgender women, and (3) were more likely to be linked to "cisgender men who did not identify as men who have sex with men."

The article was covered by the HIV press and generated expressions of concern (Kempner 2019). Critical responses also included a published correspondence in *The Lancet HIV* from a group of activists, researchers, and people living with HIV (Chung et al. 2019). *The Lancet HIV* also published a reply to Chung et al. (2019) by the three university-affiliated original study authors (Wertheim et la. 2019), and an appreciative commentary of the study from two other HIV phylogenetic researchers (Gräf and Herbeck 2019). We explore this episode as a scientific controversy (Latour 2005, 21–25).

In their correspondence critiquing Ragonnet-Cronin et al. (2019), Chung et al. (2019) expressed generalized skepticism about MHS, and raised four specific concerns about the study: (1) that MHS "risks reducing people living with HIV to vectors of disease," (2) that the transgender women involved in the study likely did not "consent to their health data being used in this manner," (3) that "the study results" are "already known to transgender women and other experts working on the ground," specifically the fact "that [transgender women's] sexual networks are different from men who have sex with men," and (4) that Ragonnet-Cronin et al. (2019) "overlooked" "the myriad of reasons why transgender women may be out of reach of public health authorities (e.g. discrimination from health-care workers, by choice, fears of criminalization)."

In their response to Chung et al. (2019), Wertheim et al. (2019) wrote that "[s]urveillance for numerous infectious agents, including HIV, is done ethically and without consent. The public good of HIV surveillance justifies this approach." The authors employed the category of "surveillance" to justify not seeking subjects' informed consent for reuses of HIV surveillance data for research, citing Lee et al. (2012). Wertheim et al. (2019) were correct in saying that the reporting of infectious agents to health departments without patient consent, and the analysis of these data, is a longstanding practice.

However, in limiting their understanding of "HIV surveillance" to "data collection, analysis, and interpretation," Wertheim et al. (2019) did not account for the most significant transformation in U.S. HIV surveillance data in the last decade. Specifically, they did not address the fact that HIV surveillance data are no longer only used for "data collection, analysis, and interpretation," but also for direct prevention (CDC 2014, 2017b, 2018; Evans and Benbow 2018, 9; Sweeney et al. 2013, 2019).

Wertheim et al. (2019) indicated that Ragonnet-Cronin et al. (2019) were working with de-identified surveillance data provided by LADPH. This seems to preclude the use of the study data for any purposes other than "analysis, and interpretation" (Wertheim et al. 2019). However, in making this assertion, it should be noted that the de-identified data that were employed in the study also exist as identifiable HIV surveillance data held by LADPH, and that LADPH is now required to utilize these data in enhanced CDR (CDC 2018).

Employing CDC technical guidance (CDC 2018), LADPH personnel could simply replicate the analysis presented in Ragonnet-Cronin et al. (2019) using identifiable HIV surveillance data. These data could then be used to inform CDR interventions. This form of analysis and utilization is now mandated and at the core of CDR strategies laid out in CDC guidance (CDC 2017a, 2017b, 2018).

The use of methods employed by Ragonnet-Cronin et al. (2019) by LADPH to identify transmission networks and then to target interventions at individuals in them through CDR is, in fact, what Ragonnet-Cronin et al. (2019) recommended. They wrote that "Molecular epidemiology could be used to prioritize these genetically linked non-transgender women for partner elicitation interviews by public health investigators" (7). Wertheim et al. (2019) framed

Ragonnet-Cronin et al. (2019) as presenting an analysis of de-identified HIV surveillance data. However, the original study went beyond this, recommending that the methods used be repurposed by LADPH in CDR.

The recommendation to employ Ragonnet-Cronin et al.'s (2019) analysis to inform direct prevention was affirmed by Gräf and Herbeck (2019) in their appreciative commentary on the study. However, Gräf and Herbeck (2019) went further, lamenting that Ragonnet-Cronin et al. (2019) did not attempt to infer directionality of transmission as one of several "drawbacks" of the study. Gräf and Herbeck (2019) stated that using HIV genetic sequence data to discern directionality via "[s]ource attribution methods" could be a useful strategy to inform direct prevention. They wrote that

> questions remain: who is transmitting HIV to transgender women? Who are transgender women transmitting the virus to? Are transgender women more often sources or recipients of HIV transmission? … assumptions about the directionality of transmission are not tested by the cluster identification method used in [Ragonnet-Cronin et al. (2019)], which does not identify putative sources and recipients of transmission in each linked pair of sequences. Source attribution methods might be useful for such questions, providing details about viral transmission dynamics among distinct subpopulations.

In sum, Gräf and Herbeck (2019) used Ragonnet-Cronin et al. (2019)'s findings to argue for the public health value of using HIV genetic sequence data and existing tools to infer directionality.

Following the correspondence in *The Lancet HIV*, two of the critics of the study published open letters in *POZ Magazine* expressing their dissatisfaction with the reply by the researchers (Spieldenner and Wesley 2019). More recently, in a protest at the 2019 U.S. Conference on AIDS, a group of activists that included at least one coauthor of Chung et al. (2019) listed molecular surveillance and CDR among their grievances (Artavia 2019).

The increased implementation of CDR using HIV surveillance data presents researchers who work with de-identified HIV surveillance data with ethical burdens that have not been robustly explored (Mutenherwa et al. 2019). Researchers who work with de-identified HIV surveillance data for publications must now account for the fact that the de-identified data they have access to not only exists in identifiable form at the health department that shared it with them, but also that the methods researchers employ to analyze de-identified data can be replicated by health department personnel to inform mandated CDR efforts (CDC 2018).

CONCLUSION: TOWARD HIV DATA JUSTICE

The concerns we have delineated can help guide future conversations among a diverse set of stakeholders interested in developing new best practices governing uses of HIV data. In this conclusion, we mobilize information from the preceding cases and the framework of HIV data justice to suggest some tools and methods for reforming MHS, CDR, and other re-uses of clinical HIV data for public health.

The nature of U.S. HIV data dramatically changed in the 2010s, chiefly through surveillance systems' collection of routine clinical laboratory data and the systematic re-use of these data in direct public health prevention. However, the public health reporting and consent frameworks governing the use of these data have not kept pace with the strategies and technologies used to administer programs. Centering the voices of individuals and communities most affected by these programs should be a priority moving ahead.

Articulating the benefits of MHS and CDR to individual people—not only for "communities" or "the public"—is necessary for continued justification of these interventions. Re-linking or engaging individuals in HIV medical care is certainly a transformative potential individual benefit of public health action related to HIV. However, escalated CDR responses involve the mobilization of many public health resources into vulnerable communities (CDC 2018). These programs raise concerns about confidentiality and exposure that may outweigh individual benefits. Stakeholders such as CDC could fund controlled trials or prospective empirical research on the benefits of CDR to individuals (Mehta et al. 2019), thus generating higher quality evidence (Burns et al. 2011; Rychetnik et al. 2002) about the effectiveness, unintended consequences, and ethical implementation of these interventions. Solutions oriented toward HIV data justice ought to be rooted in a strong evidence-base, and this evidence should be generated *before* the wide-scale deployment of new interventions.

Providing mechanisms for people living with HIV to assert controls over some re-uses of their data would aid in promoting shared decision-making (Hargraves et al. 2016) and trust between public health, individuals, and clinicians. The introduction of affordances for "informed refusal" (Benjamin 2016) or of "dynamic consent" platforms that connect electronic health records to public health data

infrastructures could contribute to HIV data justice (Williams et al. 2015). Indeed, the lack of a mechanism for people living with HIV to refuse any re-uses of their public health data fosters distrust from people with HIV toward public health (Chung et al. 2019). An opt-out system with robust public education was suggested by Tsai and Junod (2018) as a reasonable solution to similar ethical problems posed by the use of health insurance data for research in Taiwan. Any effort that supports an increase of individuals' rights over their data would be welcome.

However, we share Guta et al.'s (2018) observation that new forms of oppression posed by technological advancements cannot be overcome with the assurance of individual consent. Nor, do we think, can the simple addition of informed refusal or dynamic consent mechanisms to health data systems solve the complex problems we have discussed here. Stakeholders ought to also consider and develop entirely new forms of consent control and shared decision-making to shape other areas of practice in an era of increasingly digitized health where data move more easily between the domains of clinical medicine, biomedical research, and public health. These are new bioethical and design imperatives for the era of digital health.

Stakeholders should reassess the risks to privacy and confidentiality when sharing MHS data with researchers. Since HIV surveillance data are no longer only used for "data collection, analysis, and interpretation" (Wertheim et al. 2019), but also for direct prevention (CDC 2014, 2018), and because every HIV genetic sequence is unique to the individual, the use of de-identified MHS data poses a range of unexamined ethical problems (Mutenherwa et al. 2019). This potentially includes new risks of re-identification using nominally de-identified data. There is a growing literature on new risks of re-identification from re-uses of health data, and emerging alternative health data governance models that could inform stakeholder dialogues (e.g. Mòdol 2019).

Both CDC and advocates who are critical of MHS promote community engagement (CDC 2018, 50–52; Chung et al. 2019; Galletly et al. 2019; Spieldenner 2019). However, what constitutes successful community engagement is widely variable depending on context and perspective. Despite this, meaningful community engagement will be essential as CDR becomes common, and must play a role in fostering HIV data justice. However, if undertaken indelicately, uses of molecular HIV data and the framing of community engagement initiatives could assist in fulfilling problematic narratives regarding risk and blame (Douglas 1992), which are a long-standing feature of HIV discourse (Tomso 2017). McClelland et al. (2019) and participants in Mutenherwa et al.'s (2019) study expressed concerns about molecular HIV epidemiology being used to "single out" marginalized groups, mischaracterizing them as "dangerous" rather than as materially dispossessed and/or unable to access services for structural reasons. Resisting the reproduction of harmful narratives that further marginalize those who are already precariously positioned ought to be central in building up HIV data justice. There are rich resources in bioethics and the history of HIV/AIDS that can inform this work (see for example, Crimp 1987; Nie, Gilbertson et al. 2016; Nie, Rennie, et al. 2016; Race 2009, 138–190, 2016). Affected communities should be empowered with collective mechanisms to assert some authority over CDR in their jurisdictions and afforded opportunities for both informed consent and/or refusal.

Regarding directionality of transmission, the question of whether molecular HIV data *can* be used to infer whether one person infected another person with HIV misses the mark. HIV genetic sequence data *have been and are* used to infer directionality by some researchers (e.g. Little et al. 2014; Wymant et al. 2018) and in courts (Galletly et al. 2019; McClelland et al. 2019; UNAIDS 2013), and some researchers endorse or encourage this practice (e.g. Gräf and Herbeck 2019; Mehta et al. 2019). It is better to argue that molecular HIV data *should not* be used to infer directionality. Stakeholders should develop more rigorous arguments for why this is by, for example, starting from the premise that there is likely little demonstrable public health value in determining directionality, owing to HIV stigma and criminalization (Hoppe 2018; McClelland et al. 2019).

A bioethics of the oppressed ought to take a capacious view of oppression, treating sexual marginality and other forms of individual or group deviance seriously as sources of stigma, marginalization, and subaltern status. There are subcultures of people who eroticize seroconversion, both in fantasy and in fact (Dean 2009; Klein 2014; Orne 2017, 49–50, 145–149). Additionally, many people from groups who are more likely to become HIV-positive are understandably ambivalent about the possibility of their own seroconversion (Halperin 2007; Sheon and Crosby 2004). For some of these individuals—who possess stigmatized and misunderstood sexual subjectivities—confirmation that they became infected with HIV from a particular person can be a validating affirmation of identity and even of communal belonging (Dean 2009; Klein 2014). Some people living with HIV refuse, delay, or interrupt

treatment on a variety of bases, and for periods that vary (Persson et al. 2016). Others cannot sustain viral suppression even when taking antiretroviral therapies (Kiweewa et al. 2019). In the era of treatment as prevention, these groups are being pushed further to the margins of respectability in HIV discourse (Cormier McSwiggin 2017; Lloyd 2018); they should be included in HIV data justice-oriented conversations.

HIV-related marginalization also means that extra care must be taken by practitioners to ensure not only that HIV data are properly managed, but also that individual and collective rights, personhood, and autonomy are respected during every stage of program implementation. These considerations ought to include emergent rights, such as the right of persons to assert controls over the exchange of their sensitive electronic health information (ONC 2015, 25; 2019, 7426, 7528). All stakeholders—including in jurisdictions other than the U.S.—should engage in active dialogue about the ethics and practice of MHS and CDR, with the aim of reforming and improving these programs.

ETHICAL APPROVAL

IRB approval was not required as there were no human subjects for this study, and all data relate to public documents or published material.

DISCLOSURE STATEMENT

No potential conflict of interest was reported by the author(s).

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REFERENCES

AIDS United. 2018. Meaningful involvement of people with HIV/AIDS (MIPA): 'Nothing about us without us.' https://www.aidsunited.org/resources/meaningful-involvement-of-people-with-hivaids-mipa?docid=78.

Artavia, D. 2019. Watch activists storm the stage at USCA, protesting neglect from CDC. HIV Plus Magazine, September 5, 2019. https://www.hivplusmag.com/treatment/2019/9/05/activists-storm-stage-hiv-conference-citing-neglect-cdc.

Barré-Sinoussi, F., S. S. Abdool Karim, J. Albert, et al. 2018. Expert consensus statement on the science of HIV in the context of criminal law. *Journal of the International AIDS Society* 21(7): e25161.

Benjamin, R. 2016. Informed refusal: Toward a justice-based bioethics. *Science, Technology, and Human Values* 41(6): 967–990.

Bordowitz, G. 1987. Picture a coalition. In *AIDS: Cultural analysis/cultural activism*, ed. Douglas Crimp, 1st MIT Press ed., 182–196. Cambridge, Mass: MIT Press.

Brooks, J. I., and P. A. Sandstrom. 2013. The power and pitfalls of HIV phylogenetics in public health. *Canada Journal of Public Health* 104(4): e348–e350.

Buchanan, D. R., and F. G. Miller. 2006. A public health perspective on research ethics. *Journal of Medical Ethics* 32 (12):729–733.

Burns, P. B., R. J. Rohrich, and K. C. Chung. 2011. The levels of evidence and their role in evidence-based medicine. *Plastic and Reconstructive Surgery* 128(1): 305–310.

Centers for Disease Control and Prevention (CDC). 2014. "Data to Care: Using HIV Surveillance Data to Support the HIV Care Continuum (the 'Data to Care Toolkit')." Atlanta, GA. https://effectiveinterventions.cdc.gov/docs/default-source/data-to-care-d2c/pdf-of-important-considerations.pdf.

Centers for Disease Control and Prevention (CDC). 2017a. *National HIV surveillance system technical guidance – detecting, investigating and responding to HIV transmission clusters.* Atlanta, GA: Centers for Disease Control and Prevention (unpublished technical guidance).

Centers for Disease Control and Prevention (CDC). 2017b. Integrated HIV surveillance and prevention programs for health departments – CDC-RFA-PS18-1802. CDC. https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/cdc-hiv-ps18-1802-nofo.pdf.

Centers for Disease Control and Prevention (CDC). 2018. *"Detecting and responding to HIV transmission clusters: A guide for health departments.* Atlanta, GA: Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-AttachmentE-Detecting-Investigating-and-Responding-to-HIV-Transmission-Clusters.pdf.

Center for HIV Law and Policy (CHLP). 2017. Consensus Statement on HIV "Treatment as Prevention" in Criminal Law Reform (2017). The Center for HIV Law and Policy. https://www.hivtaspcrimlaw.org/the-consensus-statement.

Center for HIV Law and Policy (CHLP). 2019. HIV molecular surveillance worth the risks? Fact sheet. http://www.hivlawandpolicy.org/resources/hiv-molecular-surveillance-worth-risk-center-hiv-law-and-policy-september-2019.

Cheney-Lippold, J. 2017. *We are data: Algorithms and the making of our digital selves*. New York: New York University Press.

Chun, W. H. K. 2011. *Programmed visions: Software and memory*. Cambridge, MA: MIT Press.

Chung, C., N. Khanna, B. Cardell, et al. 2019. Consent and criminalisation concerns over phylogenetic analysis of surveillance data. *The Lancet, HIV* 6(7): e420.

Cohen, S. M., K. M. Gray, M. C. Bañez Ocfemia, A. S. Johnson, and H. Irene Hall. 2014. The status of the National HIV surveillance system, United States, 2013. *Public Health Reports* 129(4): 335–341.

Coltart, C. E. M., A. Hoppe, M. Parker, et al. 2018. Ethical considerations in global HIV phylogenetic research. *The Lancet, HIV* 5(11): e656.

Cormier McSwiggin, C. 2017. Moral adherence: HIV treatment, undetectability, and stigmatized viral loads among Haitians in South Florida. *Medical Anthropology* 36(8): 714–728.

Crane, J. T. 2011. Viral cartographies: Mapping the molecular politics of global HIV. *BioSocieties* 6(2): 142–166.

Crimp, D. 1987. How to have promiscuity in an epidemic. *October* 43: 237–271.

Dean, T. 2009. *Unlimited intimacy: Reflections on the subculture of barebacking*. Chicago; London: The University of Chicago press.

Deleuze, G. 1992. Postscript on the societies of control. October 59: 3–7.

Dencik, L., A. Hintz, J. Redden, and E. Treré. 2019. Exploring data justice: Conceptions, applications and directions. *Information, Communication and Society* 22(7): 873–881.

Department of Health and Human Services. 2019. Ending the HIV epidemic: A plan for America. https://www.hhs.gov/sites/default/files/ending-the-hiv-epidemic-fact-sheet.pdf.

Douglas, M. 1992. *Risk and blame: Essays in cultural theory*. London; New York: Routledge.

Ehlers, N., and S. Krupar. 2017. When treating patients like criminals makes sense. Medical hot spotting, race, and debt. In *Subprime health: Debt and race in U.S. medicine*, ed. Nadine Ehlers and Leslie R. Hinkson, 31–54. Minneapolis: University of Minnesota Press.

Evans, D., and N. D. Benbow. 2018. *Ethical considerations for a public health response using molecular HIV surveillance data*. Chicago, IL: Project Inform and Northwestern University. https://www.projectinform.org/surveillance2017/.

Fairchild, A. L. 2003. Dealing with Humpty Dumpty: Research, practice, and the ethics of public health surveillance. *The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics* 31(4): 615–623.

Fairchild, A. L., and R. Bayer. 2011. HIV surveillance, public health, and clinical medicine-will the walls come tumbling down? *The New England Journal of Medicine* 365(8): 685–687.

Fauci, A. S., R. R. Redfield, G. Sigounas, M. D. Weahkee, and B. P. Giroir. 2019. Ending the HIV epidemic: A plan for the United States. *Journal of American Medical Association* 321(9):844–845.

Fourth International Conference on Grey Literature. 1999. What is Grey Literature? The New York Academy of Medicine. http://www.greylit.org/about.

Gagnon, M., and A. Guta. 2012. Mapping HIV community viral load: Space, power and the government of bodies. *Critical Public Health* 22(4): 471–483.

Galletly, C. L., N. Benbow, A. Killelea, Z. Lazzarini, and R. Edwards. 2019. Considerations for modernized criminal HIV laws and assessment of legal protections against release of identified HIV surveillance data for law enforcement. *American Journal of Public Health* 109(11): 1576–1579.

Grabowski, M. K., J. T. Herbeck, and A. F. Y. Poon. 2018. Genetic cluster analysis for HIV prevention. *Current HIV/AIDS Reports* 15(2): 182–189.

Gräf, T., and J. T. Herbeck. 2019. Genetic clusters and transmission in transgender women. *The Lancet, HIV* 6(3): e143.

Grande, K. M., C. L. Schumann, M. Cheryl Bañez Ocfemia, J. M. Vergeront, J. O. Wertheim, and A. M. Oster. 2019. Transmission patterns in a low HIV-morbidity state – Wisconsin, 2014–2017. *MMWR. Morbidity and Mortality Weekly Report* 68(6): 149–152.

Guta, A., J. Voronka, and M. Gagnon. 2018. Resisting the digital medicine panopticon: Toward a bioethics of the oppressed. *The American Journal of Bioethics* 18(9): 62–64.

Guta, A., S. J. Murray, and M. Gagnon. 2016. HIV, viral suppression and new technologies of surveillance and control. *Body & Society* 22(2): 82–107.

Gymrek, M., A. L. McGuire, D. Golan, E. Halperin, and Y. Erlich. 2013. Identifying personal genomes by surname inference. *Science* 339(6117): 321–324.

Halperin, D. M. 2007. *What do gay men want?: An essay on sex, risk, and subjectivity*. Ann Arbor, MI: University of Michigan Press.

Hargraves, I., A. LeBlanc, N. D. Shah, and V. M. Montori. 2016. Shared decision making: The need for patient-clinician conversation, not just information. *Health Affairs (Project Hope)* 35(4): 627–629.

Hedgecoe, A. 2010. Bioethics and the reinforcement of socio-technical expectations. *Social Studies of Science* 40(2): 163–186.

Hedgecoe, A. M. 2004. Critical bioethics: Beyond the social science critique of applied ethics. *Bioethics* 18(2): 120–143.

Hoppe, T. 2018. *Punishing Disease: HIV and the Criminalization of Sickness*. Oakland, California: University of California Press.

Jongsma, K. R., A. L. Bredenoord, and F. Lucivero. 2018. Digital medicine: An opportunity to revisit the role of bioethicists. *The American Journal of Bioethics* 18(9): 69–70.

Kempner, M. 2019. New study triggers concerns over use of molecular HIV surveillance. The body pro: The complete HIV/AIDS resource, March 4, 2019. http://www.thebody-pro.com/content/81639/concerns-over-use-of-molecular-hiv-surveillance.html.

Kiweewa, F., A. Esber, E. Musingye, et al. 2019. HIV virologic failure and its predictors among HIV-infected adults on antiretroviral therapy in the African cohort study, edited by Luis Menéndez-Arias. *PLoS One* 14(2): e0211344.

Klein, H. 2014. Generationing, stealthing, and gift giving: The intentional transmission of HIV by HIV-positive men to their HIV-negative sex partners. *Health Psychology Research* 2(3): 1582.

Klugman, C. M., L. B. Dunn, J. Schwartz, and I. Glenn Cohen. 2018a. The ethics of smart pills and self-acting devices: Autonomy, truth-telling, and trust at the dawn of digital medicine. *The American Journal of Bioethics* 18(9): 38–47.

Klugman, C. M., L. B. Dunn, J. Schwartz, and I. Glenn Cohen. 2018b. Response to open peer commentaries on

the ethics of smart pills and self-acting devices: Autonomy, truth-telling, and trust at the dawn of digital medicine. *The American Journal of Bioethics* 18(10): W4–W7.

Kosakovsky Pond, S. L., S. Weaver, A. J. Leigh Brown, and J. O. Wertheim. 2018. HIV-TRACE (TRAnsmission Cluster Engine): A tool for large scale molecular epidemiology of HIV-1 and other rapidly evolving pathogens., edited by Beth Shapiro. *Molecular Biology and Evolution* 35(7): 1812–1819.

LANL HIV Sequence Database. (n.d). Los Alamos National Laboratory (LANL) HIV sequence database. https://www.hiv.lanl.gov/content/sequence/HIV/mainpage.html.

Latour, B. 2005. *Reassembling the Social: An introduction to actor-network-theory*. Oxford: Oxford University Press.

Law, J. 2004. *After method: Mess in social science research.* London, New York: Routledge.

Lee, L. M., C. M. Heilig, and A. White. 2012. Ethical justification for conducting public health surveillance without patient consent. *American Journal of Public Health* 102(1): 38–44.

Little, S. J., S. L. Kosakovsky Pond, C. M. Anderson, et al. 2014. Using HIV networks to inform real time prevention interventions, edited by Paul Richard Harrigan. *PLOS One* 9(6): e98443.

Lloyd, K. C. 2018. Centring 'being undetectable' as the new face of HIV: Transforming subjectivities via the discursive practices of HIV treatment as prevention. *BioSocieties* 13(2): 470–493.

McClelland, A., A. Guta, and M. Gagnon. 2019. The rise of molecular HIV surveillance: Implications on consent and criminalization. *Critical Public Health* :1–7. https://www.tandfonline.com/doi/full/10.1080/09581596.2019.1582755.

Mehta, S. R., C. Schairer, and S. Little. 2019. Ethical issues in HIV phylogenetics and molecular epidemiology. *Current Opinion in HIV and AIDS* 14(3): 221–226.

Mehta, S. R., S. A. Vinterbo, and S. J. Little. 2014. Ensuring privacy in the study of pathogen genetics. *The Lancet Infectious Diseases* 14(8): 773–777.

Mòdol, J. R. 2019. Citizens' cooperation in the reuse of their personal data: The case of data cooperatives in healthcare. In *Collaboration in the Digital Age*, ed. Kai Riemer, Stefan Schellhammer, and Michaela Meinert, 159–185. Cham: Springer International Publishing.

Monahan, T., and T. Wall. 2002. Somatic surveillance: Corporeal control through information networks. *Surveillance & Society* 4(3): 154–173.

Mutenherwa, F., D. R. Wassenaar, and T. de Oliveira. 2019. Experts' perspectives on key ethical issues associated with HIV phylogenetics as applied in HIV transmission dynamics research. *Journal of Empirical Research on Human Research Ethics* 14(1): 61–77.

Nie, J.-B., A. Gilbertson, M. de Roubaix, et al. 2016. Healing without waging war: Beyond military metaphors in medicine and HIV cure research. *The American Journal of Bioethics* 16(10): 3–11.

Nie, J.-B., S. Rennie, A. Gilbertson, and J. D. Tucker. 2016. No more militaristic and violent language in medicine: Response to open peer commentaries on "healing without waging war: beyond military metaphors in medicine and HIV cure research." *The American Journal of Bioethics* 16(12): W9–11.

NSW Health. 2019. Policy directive – management of people with HIV who risk infecting others. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2019_004.pdf.

Office of Civil Rights (OCR), U.S. Department of Health and Human Services (HHS). 2012. *Guidance regarding methods for de-identification of protected health information in accordance with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule.* Washington, DC: HHS Office of Civil Rights.

Office of the National Coordinator for Health Information Technology (ONC). 2015. *Federal health IT strategic plan, 2015–2020.* Washington, D.C.: Office of the Secretary, United States Department of Health and Human Services. https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

Office of the National Coordinator for Health Information Technology (ONC). 2019. *Notice of proposed rulemaking: 21st Century Cures Act: Interoperability, information blocking, and the ONC health IT certification program.* Washington, DC: Federal Register.

ONAP – White House Office of National AIDS Policy. 2015. The national HIV/AIDS strategy for the United States: Updated to 2020. The White House. https://files.hiv.gov/s3fs-public/nhas-update.pdf

Orne, J. 2017. *Boystown: Sex & community in Chicago*. Chicago; London: The University of Chicago Press.

Oster, A. 2019. Hugging phylogenetic trees: Use of molecular analysis for public health intervention. CROI, March 6. http://www.croiwebcasts.org/console/player/41159?mediaType=slideVideo&&crd_fl=0&ssmsrq=1561626503541&ctms=5000&csmsrq=6446.

Oster, A. M., A. M. France, and J. Mermin. 2018. Molecular epidemiology and the transformation of HIV prevention. *Journal of American Medical Association* 319(16): 1657–1658.

People with AIDS Advisory Committee. 1983. The Denver principles. http://www.actupny.org/documents/denver_principles.pdf.

Persson, A., C. E. Newman, L. Mao, and J. de Wit. 2016. On the margins of pharmaceutical citizenship: Not taking HIV medication in the "treatment revolution" era. *Medical Anthropology Quarterly* 30(3): 359–377.

Proctor, J. 2019. Vancouver police search for subject of unprecedented HIV-medication order. CBC, June 6, 2019. https://www.cbc.ca/news/canada/british-columbia/hiv-order-missing-david-hynd-1.5165751.

Project Inform Staff. 2012. *Using surveillance and other data to improve HIV care linkage and retention*. San Francisco, CA: Project Inform.

Race, K. 2009. *Pleasure consuming medicine: The queer politics of drugs*. Durham, NC: Duke University Press.

Ragonnet-Cronin, M., Y. W. Hu, S. R. Morris, Z. Sheng, K. Poortinga, and J. O. Wertheim. 2019. HIV transmission networks among transgender women in Los Angeles County, CA, USA: A phylogenetic analysis of surveillance data. *The Lancet HIV* 6(3): e164.

Rhodes, T., and K. Lancaster. 2019. Evidence-making interventions in health: A conceptual framing. *Social Science & Medicine* 238: 112488.

Ribes, D., and J. B. Polk. 2015. Organizing for ontological change: The kernel of an AIDS research infrastructure. *Social Studies of Science* 45(2): 214–241.

Rocher, L., J. M. Hendrickx, and Y.-A. de Montjoye. 2019. Estimating the success of re-identifications in incomplete datasets using generative models. *Nature Communications* 10(1): 1–9. https://www.nature.com/articles/s41467-019-10933-3.pdf

Rose, R., M. Hall, A. D. Redd, et al. 2019. Phylogenetic methods inconsistently predict the direction of HIV transmission among heterosexual pairs in the HPTN 052 cohort. *The Journal of Infectious Diseases* 220(9): 1406–1413.

Rychetnik, L., M. Frommer, P. Hawe, and A. Shiell. 2002. Criteria for evaluating evidence on public health interventions. *Journal of Epidemiology and Community Health* 56(2): 119–127.

Schairer, C., S. R. Mehta, S. A. Vinterbo, M. Hoenigl, M. Kalichman, and S. Little. 2017. Perceptions of molecular epidemiology studies of HIV among stakeholders. *Journal of Public Health Research* 6(3): 992.

Sheon, N., and G. M. Crosby. 2004. Ambivalent tales of HIV disclosure in San Francisco. *Social Science and Medicine* 58(11): 2105–2118.

Sherman, G., and J. Campione-Piccardo. 2007. Distinguishing surveillance from research. *Critical Public Health* 17(4): 279–287.

Spieldenner, A. & Wesley, S. (2019, August 2). Drama in the correspondence section of the Lancet. *POZ*. https://www.poz.com/blog/lancet-correspondence-section-drama.

Sweeney, P., E. A. DiNenno, S. A. Flores, S. Dooley, R. L. Shouse, S. Muckleroy, and A. D. Margolis. 2019. HIV data to care—using public health data to improve HIV care and prevention. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 82: S1–S5.

Sweeney, P., L. I. Gardner, K. Buchacz, P. M. Garland, M. J. Mugavero, J. T. Bosshart, R. L. Shouse, and J. Bertolli. 2013. Shifting the paradigm: using HIV surveillance data as a foundation for improving HIV care and preventing HIV infection: Using HIV surveillance data to improve care and prevent infection. *The Milbank Quarterly* 91(3): 558–603.

Timmermans, S., and M. Berg. 2003. The practice of medical technology. *Sociology of Health & Illness* 25(3): 97–114.

Tomso, G. 2017. HIV monsters: Gay men, criminal law, and the new political economy of HIV. In *The War on Sex*, ed. David M. Halperin and Trevor Hoppe, 353–377. Durham, [North Carolina]; London: Duke University Press.

Tsai, F.-J., and V. Junod. 2018. Medical research using governments' health claims databases: with or without patients' consent? *Journal of Public Health* 40(4): 871–877.

UNAIDS. 2013. Guidance note – ending overly broad criminalization of HIV non-disclosure, exposure and transmission: Critical scientific, medical and legal considerations. https://www.unaids.org/sites/default/files/media_asset/20130530_Guidance_Ending_Criminalisation_0.pdf.

Wertheim, J. O., S. Morris, and M. Ragonnet-Cronin. 2019. Consent and criminalisation concerns over phylogenetic analysis of surveillance data – Authors' reply. *The Lancet HIV* 6(7): e420.

Williams, B., R. Wood, V. Dukay, et al. 2011. Treatment as prevention: Preparing the way. *Journal of the International AIDS Society* 14(Suppl 1): S6.

Williams, H., K. Spencer, C. Sanders, D. Lund, E. A. Whitley, J. Kaye, and W. G. Dixon. 2015. Dynamic consent: A possible solution to improve patient confidence and trust in how electronic patient records are used in medical research. *JMIR Medical Informatics* 3(1): e3.

Wymant, C. M Hall, O. Ratmann, STOP-HCV Consortium, 2018. The Maela Pneumococcal Collaboration, and The BEEHIVE Collaboration, et al. 2018. PHYLOSCANNER: Inferring transmission from within- and between-host pathogen genetic diversity. *Molecular Biology Evolution* 35(3): 719–733.