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Signature:

Emily Michels

Date

HIV Surveillance, Community Engagement, and Genetic Data Collection Fears: An Ethical Framework for Public Health Intervention

By

Emily Michels
Master of Arts

Bioethics

Arri Eisen, Ph.D.
Advisor

Jessica Sales, Ph.D.
Committee Member

Meg Watson, MPH
Committee Member

Gerard Vong, Ph.D.
Committee Member

Accepted:

Lisa A. Tedesco, Ph.D.
Dean of the James T. Laney School of Graduate Studies

Date

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Emily Michels
B.A., Colorado College, 2011

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Abstract

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By Emily Michels

Data-based surveillance systems have been operationalized in public health for centuries. Recent advancements in genetic sequencing and technology have allowed for more widespread, comprehensive tracking, recognition, and analysis of the spread of disease, however not without pushback. The public health response to the HIV/AIDS epidemic that began in the 1980s ignited fierce debates over privacy, autonomy, stigma, and governmental authority that still persist today. This paper presents an examination of the ethical issues surrounding HIV molecular cluster detection and response, including fears and misunderstandings about viral genomic data collection, the impact of community engagement in the planning and design of interventions, and the tension between clinical and public health ethics approaches. It outlines the power of restorative justice techniques to help mend divisive relationships between agencies and communities through the recognition of previous wrongdoing, as well as the importance of evidence-based dissemination and implementation science techniques.

Building on work from ten frameworks within public health ethics, community engagement, surveillance, and genomic data collection, the culminating final product will be an integrated community-inclusive framework for use by professionals and community members to guide and evaluate the planning, design, and implementation of successful public health interventions. To demonstrate its practical application, examples from HIV public health surveillance are integrated into the framework; a brief discussion of the application to a non-HIV intervention – the recent 2019 novel coronavirus (COVID-19) outbreak – is presented, as well. Intended to call attention to common ethical issues within collaborative project planning and to streamline the evaluation of each stage of intervention design, the success of the presented framework will ultimately be determined by its practical use.

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Glossary of Abbreviations and Terms

ACA	Affordable Care Act
AIDS	Acquired Immunodeficiency Syndrome
AMA	American Medical Association
APA	American Psychological Association
ART	Antiretroviral Therapy
AZT	Azidothymidine (first medical treatment for AIDS)
CAB	Community Advisory Board
CBOs	Community-Based Organizations
CD4	White blood cells, important part of the immune system
CDC	Centers for Disease Control and Prevention
CMO	Context-Mechanism-Outcome
COVID-19	2019 Novel Coronavirus
DHAP	Division of HIV/AIDS Prevention
D&I	Dissemination & Implementation
DNA	Deoxyribonucleic Acid
D2C	Data to Care
DTC	Direct-to-Consumer
FDA	U.S. Food and Drug Administration
GINA	Genetic Information Nondiscrimination Act
HDs	Health Departments
HET	Heterosexuals with increased risk
HICSB	HIV Incidence and Case Surveillance Branch
HIV	Human Immunodeficiency Virus
HIV ME	HIV Molecular Epidemiology
HRSA	Health Resources and Services Administration
ICE	U.S. Immigration and Customs Enforcement
LGBT	Lesbian, Gay, Bisexual, Transgender
MHS	Molecular HIV Surveillance
MMP	Medical Monitoring Project
MSM	Gay, bisexual and other men who have sex with men
NASTAD	National Alliance of State and Territorial AIDS Directors
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NHBS	National HIV Behavioral Surveillance
NHSS	National HIV Surveillance System
NIAID	National Institute of Allergy and Infectious Diseases
NSGC	National Society of Genetic Counselors
PEP	Post-exposure Prophylaxis
PH	Public Health
PHE	Public Health Ethics
PRACTIS	Practical Planning for Implementation and Scale-up
PrEP	Pre-exposure Prophylaxis
PWA	People With AIDS
PWH	People With HIV
PWID	Persons Who Inject Drugs
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
RNA	Ribonucleic Acid
WHO	World Health Organization

Introduction

Public health (PH) agencies lead efforts to protect and promote the health of the population, to control disease, and to educate on general well-being. These organizations must reach challenging goals in the most efficient, cost-effective, and judicious ways, while adhering to the principles of beneficence and non-maleficence, respect for persons, and justice, among other ethical principles. Community trust, which is based in these principles, is essential to the success of public health programs, as protest and avoidance of health resources can cause an intervention to backfire and result in negative or diminished health outcomes. In some cases, like that of Human Immunodeficiency Virus (HIV) surveillance, the backlash comes after the implementation of such a program and acts as a barrier to better health, working against the program's intended goals. Many elements – fear, misunderstanding, loss of autonomy – can inspire these negative opinions of public health and must be addressed in order to develop collaborative and successful public health programs.

This paper focuses on exploring the history of HIV surveillance systems, the fears associated with elements of these systems, and how community engagement is a crucial and necessary part of developing an intervention that respects personal choice as much as possible. The culmination of these insights will be a comprehensive integrated framework that blends recommendations and work from the fields of public health, community engagement, surveillance, and health data collection. This integrated framework is intended to be an analytical tool for both professional and public use, to help evaluate the ethicality and efficiency of HIV molecular cluster detection and response, as well as other similar programs. HIV and the ensuing Acquired Immunodeficiency Syndrome (AIDS) have a complex and problematic history in the United States, which makes public health interventions that much more complicated. The goal of this new tool is be able to assess complex surveillance and response strategies step-by-step, from making sure that the pre-design decision-making process is fair to long-term monitoring of a program once it is in place in a community. Although an intense amount of thought is already being put into evaluating these programs, this tool may help make sure no steps are overlooked, especially relating to the participation of community members and advocates. In addition to demonstrating the utility of this tool for HIV surveillance and response, it will also be briefly discussed within the context of another current outbreak that has inspired similar debates about public health versus individual liberties – 2019 novel coronavirus (COVID-19).

Terminology

Throughout this piece, many terms and acronyms are used to describe people, organizations, and programs within HIV/AIDS and health interventions. Terminology and the purposeful choice of words play a significant role in public health, community engagement work, and ethics. Along with paying attention to each aspect of a program's design and implementation process, being thoughtful about the specific words that are attached is also extremely important. For example, this paper uses the terms "people with HIV" (PWH) and "people with AIDS" (PWA), and purposely does not describe these groups as HIV or AIDS "victims". This word choice is inspired by the Denver Principles, in which activists introduced the more empowering PWA terminology in place of the more passive "victim" language (Agosto-Rosario 2017). Similarly, one of the frameworks discussed later calls attention to semantic differences in how groups of people are described, noticing that "community" is generally self-referring, while "population" stems from outside evaluators (Brunton et al. 2017, 5). There is also the recognition that the term "surveillance" is inherently off-putting and scary, especially for people who are not familiar with how the term is used in the context of public health. Surveillance can invoke a feeling of being watched, a "Big Brother" society in which the government is tracking people for potentially sinister reasons. In public health, however, it simply refers to "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice" (WHO 2020), a more mundane use of the term. Still, it is worthwhile to pay attention to the audience to which one is presenting, to anticipate and be prepared for negative reactions to the term "surveillance", and to perhaps find other words or explanations for these actions that are involved in public health.

Background

In order to understand the complex field of HIV public health surveillance, it is important to recognize the context from which the current state of this work emerged. The history of HIV/AIDS from discovery to the latest medical and prevention technologies demonstrates how quickly public health can adjust to new scenarios and the ethical issues that come with constantly changing policies and methodologies. It would be impossible to create a framework that guides current HIV programs without recognizing what has been tried before, has been rejected by community and/or public health organizations, and what has moved society closer to the common good, through the reduction of HIV transmissions and the treatment of those already diagnosed.

History of HIV/AIDS and Surveillance

The history of HIV and AIDS public health surveillance systems are intimately connected to national and global growth of the disease, advocacy and activism for PWH and PWA, and funding opportunities, or lack thereof. Approaches to learning about and controlling HIV from a public health perspective constantly needed to adapt to developments in medicine and science. With rapidly increasing numbers of affected individuals and worries about disease-based discrimination mounting, these approaches were far from unanimously supported and required tough ethical conversations that eventually led to the divergent opinions on public health surveillance that persist in today's debates.

Initial Response to an Aggressive Disease

Originally appearing in 1981 in clusters of young, gay, and previously healthy men, AIDS first manifested as either a rare lung infection, *Pneumocystis carinii* (CDC 1981), or a rare, aggressive cancer, *Kaposi's sarcoma* (Altman 1981). The presence of both of these diseases in previously healthy patients indicated a rapid weakening of the immune system, which left patients at risk for opportunistic infections. As more news outlets reported cases of Pneumocystis carinii and Kaposi's sarcoma, the term "gay cancer" became the new public moniker for the mystery disease (Wright and Block 2006). This term, although inaccurate in multiple ways, persisted especially in the gay community and the media, along with other terms such as Gay-Related Immune Deficiency (Altman 1982) that perpetuated the incorrect notion that the disease solely affected gay men and set the stage for stigma against PWH that still exists now.

After the discovery of multiple patients with these afflictions, the public health and medical communities need to act quickly. Conferences, specialty clinics, and community-based organizations (CBOs) begin to emerge with little public or private funding behind them – the first dedicated AIDS research and treatment funding would appear in 1983 (Institute of Medicine 1991). As an immediate response to the outbreaks, Centers for Disease Control and Prevention (CDC) develops the "Task Force on Kaposi's Sarcoma and Opportunistic Infections" three days after the first cases are reported, in order to further define the disease and begin tracking its prevalence across the country – the first step toward the eventual development of national HIV surveillance systems (Curran, Harden, and Hannaway 1998). The World Health Organization (WHO) also meets to discuss monitoring AIDS diagnoses, this time on a global scale, and in 1983 they recommend developing AIDS surveillance systems around the world (WHO 1984, 426). By the mid-1980s, multiple industrialized countries, including Australia, Denmark, and Italy, begin name-based reporting of AIDS, aiming to apply the same standards that are used for other infectious diseases and sexually transmitted infections. It is argued that attaching names to case reporting would allow for an accurate picture of the epidemiological threat and for follow-up on cases that might help scientists understand transmission (Bayer and Fairchild 2000, 11). There is little pushback against name-based AIDS reporting, thanks in part to the community's faith in CDC's confidentiality standards that had been proven effective through reporting standards for other diseases. There is even outward support from a major gay physician's group which believes that the reporting will improve the understanding of the disease that is devasting their community (Bayer and Fairchild 2000, 11). Although some other countries feel that this type of reporting is not appropriate, by 1986, all 50 states in the U.S., the District of Columbia (D.C.), and U.S.-dependent areas are utilizing nominal reporting for AIDS cases, with many other countries following suit (DHAP, "Surveillance Systems" 2019).

Meanwhile, frustration grows within affected communities, especially populations of gay men, about the lack of government funding for the study of the epidemic. From demands to be addressed with empowering terms (PWA instead of AIDS victims) to emphasizing their rights to the same full, satisfying lives as people without the disease, PWA become vocal about their need to be actively involved in AIDS decision-making and policy-planning (Agosto-Rosario 2017). To add to the controversy, the development of HIV antibody testing – which allows for the detection of HIV prior to the onset of AIDS – in the mid-1980s leads to the desire of some public health officials to extend name-based case reporting from AIDS to HIV. While supporters state that the same justifications for AIDS reporting should apply to HIV, others note the distinction between reporting the virus versus the disease (Bayer and Fairchild 2000, 12). At-risk communities and advocates call HIV reporting an unjustified violation of privacy since individuals can live with HIV for years without it progressing into AIDS. Public health officials worry that reporting might dissuade people from seeking out testing and counseling. Organizations like the Global Programme on AIDS make statements against name-based HIV reporting, claiming that "HIV [name-based reporting] is a more sensitive issue owing to the potentially harmful social and economic consequences that may arise from breaches of confidentiality" (Bayer and Fairchild 2000, 12); they propose that any HIV surveillance systems avoid the use of personally identifying information whenever possible.

Continued Management of Disease Impacts

With the number of confirmed cases rapidly growing and public health agencies predicting continued increases (CDC 1986, 18), the most substantial AIDS-specific funding is approved – $190 million in 1985 (Shepard 1985). Many organizations and leaders, including the Surgeon General, call for educational and mass media campaigns, as well as voluntary testing (Institute of Medicine 1986, 33). Activist Larry Kramer's organization, ACT UP, pressures lawmakers, drug companies, and religious institutions to protect people with AIDS and HIV and to fight for affordable medical care (Szalavitz 2012). CDC launches a series of public service announcements, *America Responds to AIDS*, alongside AIDS Awareness Month. The campaign aims to reach further than just the previously identified at-risk communities – gay men, racial minorities, and sex workers – in order to reinforce the idea that the disease can affect anyone (U.S. National Library of Medicine 2016). Multiple organizations form to focus on the effects of the disease on specific racial and ethnic populations, and to advocate for members of these communities (HIV.gov 2019). Still, public opinion and confusion about AIDS incites backlash against anyone with the disease regardless of the transmission source (blood transfusion, drug, use, sexual encounter, etc.), with over half of Americans polled supporting a quarantine for AIDS patients (Balzar 1985).

The AIDS-related death of beloved pianist Liberace in 1987 reignites a conversation about privacy and stigma, and whether people with HIV/AIDS are entitled to privacy regarding their diagnoses, in life or in death (Crewdson 1987). From a public health standpoint, notifying previous partners about their risk could encourage them to seek care, and mainstream notification of status could increase general awareness; the stigma associated with the disease, however, could be undesirable even for someone who has passed. Additionally, a report from the Society of Actuaries in 1987 predicts an over-$50 billion AIDS-related cost to insurance companies by 2000, contributing to further discrimination against PWH (AP 1987). Immigration policies prohibiting PWH from entering the U.S. further increase stigma and perpetuate isolationist tactics; these policies are protested at the 1990 AIDS Conference and are ultimately repealed under the Obama administration in 2010 (Center for HIV Law and Policy, "Immigration" 2019).

Persons who inject drug (PWID) with HIV experience the "double stigma" of disease, on top of already-existing discrimination against people who use drugs. Efforts are made to help these populations avoid transmission – the "Godfather of Needle Exchange" David Purchase, for example, starts the first needle exchange in Tacoma, Washington and trades out 13,000 clean needles in the course of five months from his street-side post (Gross 1989). Needle exchanges begin to appear in other major cities amid pushback, sparking a debate about the use of risk-prevention tactics that still continues today (Lopez 2018). Gaining government funding is contentious, but funds are eventually carved out for HIV-specific interventions, including the Ryan White Care Act of 1990, which allots $220.5 million for community-based care and treatments in the first year of the program. This funding has been continuous and now supports accessible HIV care through CBOs, clinical training, and innovative care models (HRSA 2019). FDA approves the first medical treatment for AIDS – azidothymidine (AZT) – in 1987, with multiple other antiretroviral treatments (ART) gaining approval in the early 1990s (NIAID, "Antiretroviral Drug…" 2018). There is still a huge demand, however, for more funding and attention, especially toward research on HIV/AIDS among women and people of color (U.S. National Library of Medicine 2017). CDC announces a shift in their tactics, moving toward a "client-centered" approach that "emphasize[s] increasing the client's perception of risk and developing a personalized risk-reduction plan" (CDC 2006), focusing more on the person and less on the virus.

Policy Changes, Funding, and Monitoring

In the early 1990s, the number of AIDS cases peaks, partially due to an expanded case definition in 1993, but then declines for the first time since its discovery shortly thereafter (CDC 2001). HIV medications are making a positive impact on health, but they also create a worrisome byproduct – drug resistance – the monitoring of which, along with new guidelines for state and local health departments (HDs) to develop surveillance systems, will become an integral part of CDC's national HIV surveillance strategy. CDC draft guidelines in 1998 call for HIV name-based reporting, emphasizing the importance of confidentiality and stating that funding will not be given to states that do not meet expected confidentiality standards. Some HIV/AIDS organizations still oppose the reporting, but other activist and civil liberties groups support it in the name of public health, although some specify that unique identifiers in the place of names would be favorable (Bayer and Fairchild 2000, 13). The U.S. Health Resources and Services Administration (HRSA), which manages the Ryan White CARE program, also supports the development of surveillance systems, with a specific goal to identify and treat populations with unmet needs, "particularly for HIV-infected persons not in care and historically underserved communities and affected subpopulations" (Institute of Medicine, "Overview of…" 2004, 51). The goals of the national surveillance system, set to start in 2000, are to "provide additional data about HIV-infected populations to enhance local, state, and federal efforts to prevent HIV transmission, improve allocation of resources for treatment services, and assist in evaluating the impact of public health interventions" (Fleming et al. 1999, 1).

Toward the end of the 1990's, it becomes even more clear that distinct health inequities are developing – for example, African-Americans make up 43% of new AIDS cases in 1999, even though they comprise 12% of the population (AIDS Policy & Law 1998, 4). These inequities persist in current times, with 42% of new diagnoses in 2018 belonging to African Americans, who comprise 13% of the population (CDC, "HIV and…" 2020). Many minority leaders and advocacy organizations call for emergency funding and Congressional hearings to address the state of HIV/AIDS in their communities (HIV.gov 2019). Advocates establish population-specific HIV/AIDS awareness days and grassroots educational efforts, such as “Get Education, Get Tested, Get Involved, and Get Treated” (amfAR 2014). Efforts to reduce HIV transmission around the world are also increasing in the early 2000s, with attention being paid to the price of pharmaceuticals for countries that cannot produce the drugs themselves (Clinton Foundation 2003) and failed efforts to develop an HIV vaccine (Pollack and Altman 2003).

By 2003, all states except Georgia have confidential HIV case-reporting systems in place; 34 of them utilize the “same confidential name-based reporting of HIV infection as is used for AIDS reporting” (Institute of Medicine, “Public Health…” 2004, 78). Eight states and D.C. use a coded identifier; five use a name-to-code system that strips the case of a name after appropriate state-level follow-up; one reports pediatric cases by name but uses name or code for those thirteen or older; and one allows for case-reporting with or without a name (Institute of Medicine, “Public Health…” 2004, 78). By 2008, all states use confidential name-based reporting, allowing for national-level trend data to begin to be compiled; the data will eventually be released in the first CDC report with estimated data from all 50 states in 2013, and published annually after that (DHAP, “Surveillance Systems” 2019).

The election of President Barack Obama in 2009 brings new awareness and funding opportunities to the fight against HIV/AIDS (amfAR 2008), as well as the reversal of two significant and controversial policies from administrations past. In 2010, the travel ban, which barred PWH who are not U.S. citizens from entering or immigrating to the country for 22 years, is repealed, marking a huge step toward eliminating social stigma and barriers for PWH, but also raising concerns about the potential for diminished testing and diagnosis for foreign-born individuals (Winston and Beckwith 2011, 710). In the same year, the ban on the use of federal funds for services and materials for needle exchanges is modified, as this intervention is proven highly successful for stemming the spread of new HIV (Democratic Policy Committee 2009, 9). The introduction of the Affordable Care Act (ACA) also offers protections for those with chronic illness, such as HIV and related complications; while far from a perfect policy, the ACA allows those with pre-existing conditions to secure health insurance and experience increased financial stability and medical success (Antrim 2019).

Technological Advancements

In order to increase community connection to the rollout of these HIV interventions, CDC begins requiring more state and local-level involvement in the planning of HIV prevention activities, with health departments sharing in the responsibilities of developing and implementing plans. An accompanying CDC report also promises a commitment to "significant community involvement" (CDC 2012, 5). Additionally, CDC recognizes the disconnect between diagnosis and care, noting that out of the 70 percent of people in the United States whose viruses were not under control in 2011, two thirds of them were diagnosed but not in follow-up care (NCHHSTP 2014). The AIDS 2014 Conference releases the recommendation that a "one-size-fits-all" approach to HIV prevention is not suitable, since the populations and geographic regions affected can differ so greatly (International AIDS Society 2014, 7). The term "AIDS" is renamed as "HIV stage 3" in 2013, which simplifies the criteria involved in the case definition of the disease (Selik et al. 2014, 1).

Improvements in treatment, including the development of effective pre-exposure prophylactic medications (PrEP) (NIAID, "Pre-exposure Prophylaxis…" 2018) and prolonged successful use of ART give hope to some people; others lament the new challenges associated with aging as a PWH/PWA (Leland 2013). A 2014 study establishes the lack of sexual transmission when PWH have undetectable viral loads (Cairns 2014). Alongside these medical advancements, government policies loosen some stigmatizing restrictions on HIV-positive individuals. In 2015, the FDA changes their lifetime ban on blood donations from gay, bisexual and other men who have sex with men (MSM) to a deferral of 12 months since last male-to-male sexual contact (American Red Cross 2019) and in the same year, a rule change allows for the recovery and transmission of HIV-positive organs for HIV-positive recipients within clinical research trials (Department of Health and Human Services 2015).

As nominal HIV case reporting has been going on for a number of years, CDC has been able to monitor the trends in HIV diagnoses and outcomes, and report out on the status of the population. Stable trends in the data begin to emerge and, using routine surveillance data, CDC is able to focus prevention efforts more precisely, starting with Data to Care (D2C) programs, which link diagnosed individuals to social and medical care (CDC, "Data to Care" 2020), and later with molecular epidemiology. Although monitoring programs are essential to the process, it is determined that they are no longer sufficient; with discoveries about how to utilize molecular HIV data and phylogenetic networks of HIV strains, action can be taken to track growing clusters of transmissions in order to intervene (Grabowski and Redd 2014, 126). The continuous appearance of clusters around the country from opioid use and sexual encounters, along with initiatives such as the White House "Ending the Epidemic" program (discussed in more detail in the "Immigration Concerns" section), have put this technology in the spotlight both for its potential benefits and for its ethical questions. As with most discoveries and changes in the history of HIV/AIDS and surveillance, there is both support and pushback – striking a balance between risky-but-worthy advancements and community support is the ultimate goal.

CDC HIV Surveillance Programs

CDC's establishment of a national surveillance system (NHSS) inspires the creation of other specific programs to fund state and local health departments to collect certain types of data. These agencies, along with support from other organizations and providers, are responsible for the tracking, reporting, and intervention development involved in these disease response efforts. Below are explanations of NHSS data use and two separate surveillance systems that supplement with medical and behavioral data collection.

NHSS Case Surveillance

This type of surveillance monitoring is predicated on the use of a uniform case definition across all participating jurisdictions. Through the use of a standardized form, jurisdictions report all confirmed HIV and HIV-stage-3 (AIDS) diagnoses to CDC without personally identifying information attached. The data collected at the state or U.S. dependent area level include demographic information, mode of exposure, vital status, and any opportunistic illnesses. By 1986, all 50 states, D.C., and other U.S. dependent areas are using AIDS case reporting; by 2008, all of those jurisdictions have HIV case-reporting, as well. Lab information, including CD4, viral load, and most recently, HIV sequences, are collected as part of case surveillance. Case surveillance provides national and state level data necessary to guide public health actions including resource allocations and analyzing disparities (DHAP, "Surveillance Systems" 2019).

HIV Cluster Detection and Outbreak Response

This program – previously known as molecular HIV surveillance (MHS) and now modernized to have a focus on actionable responses to data analysis – uses molecular data from NHSS. Cluster detection examines viral sequences generated in laboratories, from blood tests collected through a PWH's testing and treatments, and uses them to track the transmission and appearance of similar strains of HIV within groups of people. Once a cluster is deemed "noticeably larger" than the average size, CDC works with state and local health departments to figure out the appropriate resources to reach at-risk individuals and help those who are already diagnosed (DHAP, "Advancing HIV Prevention…" 2019). Cluster detection and the interventions that emerge from it are the main focus of this paper and will be discussed in more detail in "The Science of Cluster Detection."

Medical Monitoring Project (MMP)

The MMP was originally designed in 2005 to survey adult PWH who were receiving medical care for HIV, but has since been expanded (in 2015) to include all adult PWH in the United States and

Puerto Rico. Unlike case surveillance and cluster detection, the MMP relies on contacted individuals' decisions to participate. These 45-minute interviews collect demographic data, behavioral data on substance use and sexual activity, and information on access to care and social services. Using this information, from 23 jurisdictions representing over 70% of HIV cases in the country, CDC is able to derive "national estimates of the clinical and behavioral characteristics of HIV-diagnosed adults" (DHAP, "Surveillance Systems" 2019) that guide policy decisions and aim to improve quality of care.

National HIV Behavioral Surveillance (NHBS)

The NHBS, which began in 2003, follows a specific operational system, managing annual rotating cycles of surveillance between populations of MSM, PWIDs, and heterosexually active persons at increased risk for HIV (HETs) in 20 jurisdictions with high HIV prevalence. MSM are recruited at popular venues during peak attendance times, while PWID and HETs are brought in by peers who have already been contacted to complete the survey; all are asked questions about behavioral risks, testing behaviors (and results), and prevention resources. Like the MMP, the NHBS is a sample survey that requires chosen individuals to actively consent to participation. One of the biggest contributions of this data is from the at-risk populations that "provide an indication of the leading edge of the epidemic" (DHAP, "Surveillance Systems" 2019), in addition to being able to evaluate the impact that HIV response efforts are having on these communities.

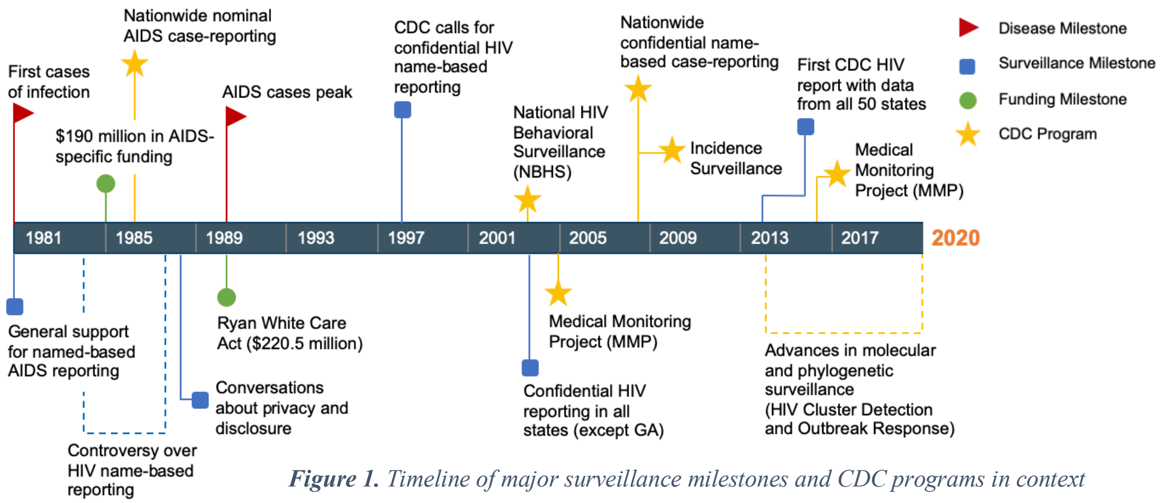

Figure 1. *Timeline of major surveillance milestones and CDC programs in context*

Community Engagement

Community engagement has long been recognized as a useful tool in public health research and interventions, with different goals attached to the inclusion of these community voices (Morgan and Lifshay 2006, 1). Community engagement has transformed over the years, going from a means to mobilize people toward sanitation and immunization in the early 19th century, to involving individuals in the development of disease-fighting strategies in the mid-20th century (Morgan and Lifshay 2006, 2), to community advisory boards (CAB) giving advice on public health interventions now (Strauss et al. 2001, 1938). Still, many believe that community engagement efforts can go further to involve different subgroups of the public and actively incorporate their input, especially within surveillance efforts that do not involve mandatory consent (DHAP, "Meeting Summary…" 2020).

Community engagement is sometimes implemented simply for practical purposes – fulfilling grant requirements, increasing visibility of a project, appeasing concerns – which is useful for researchers, but less beneficial for the community the project is serving (Nyirenda et al. 2019, 3). Community engagement should, however, be recognized for its positive effects on social inequities, which can lead to reduced health disparities and negative social determinants; there is evidence, for example, that participatory empowerment can be associated with increased social capital for groups experiencing social exclusion (O'Mara-Eves et al. 2015, 2). In a 2015 meta-analysis, researchers found that "public health interventions using community engagement strategies for disadvantaged groups are effective in terms of health behaviours, health consequences, health behaviour self-efficacy, and perceived social support" (O'Mara-Eves et al. 2015, 17), concluding that there is evidence that community-influenced interventions have a positive effect on various health and psychosocial measures. Other studies indicate that services tailored to specific communities will result in improved health, and that when individuals are involved with the shaping of services, "the management of their own health and wellbeing would also improve" (De Weger et al. 2018, 2).

Because informed consent is required for research but not practicable or required for public health surveillance, community engagement becomes even more important. In an interesting take on informed consent outside of clinical research or treatment, Cassell and Young use the context of health services research – examining organizational structures within health delivery – in the UK to talk about how informed consent may actually stifle diverse participation in the evaluation of delivery changes and public health surveillance systems. These authors argue that more important than informed consent in these types of studies is consultation with members of the community, clear notification of data use and protections, and transparency about successes and failures of programs (Cassell and Young 2002, 316). Lee, Heilig, and White expand upon the idea of community engagement as a way to balance the lack of informed consent, noting that it is important to gauge when the overriding of autonomy is appropriate based on the potential for improved population health, and how efforts such as community engagement, minimal infringement, and confidentiality standards must be built into a support system for the program (Lee, Heilig, and White 2012, 41). If informed consent is not possible for any number of reasons, community engagement can at least help involve public voices in the decision-making process before the implementation of a program so that the procedures are familiar and representative of the community's needs.

A Need for More Community Engagement

One of the chief complaints about HIV molecular cluster detection and response is the lack of early community participation. For example, when referring to a related program, D2C program, an analysis by Project Inform states that "few community advocates and clinicians were aware that public health officials in some parts of the United States were using reported laboratory data (e.g. viral loads) to find out-of-care individuals, reach out to them, and offer services to relink them to care" when it was already in place (Evans and Gorder 2020). CDC expanded the collection of molecular HIV data in 2018 to all funded jurisdictions and required these jurisdictions to routinely monitory the data to detect emerging clusters (CDC 2019). In response, advocates for PWH raised concerns (Center for HIV Law and Policy, "Is Molecular…" 2019). Founder of the popular PWH blog hub POZ, Sean Strub, has made statements praising the potential benefits of molecular cluster detection, but strongly believes that "before [molecular surveillance is] utilized, the privacy and potential for abuse concerns need to be addressed in partnership with community activists" (Ryan 2018). David Evans of Project Inform is quoted as saying that "meaningful engagement [by the CDC] with the communities most vulnerable to HIV has been sporadic and ineffective or completely absent in many geographic locations already" (Ryan 2018) and expressed skepticism at the idea of it improving in the future.

Advocates and PWH call for further-reaching engagement and decision-making power for community members beyond the usual meeting attendees and committee members (Spieldenner 2019). In a CDC HIV Incidence and Case Surveillance Branch (HICSB) meeting series, participants repeatedly expressed the need for CDC and other public health agencies to reach beyond individuals in the small, actively engaged groups in order to make contact with a wider and more diverse set of concerned residents (HICSB 2019, 6). Aside from reaching the right people, activists also desire meaningful roles within public health efforts, not just to be a token voice or a means to recruiting more community members to participate (Spieldenner 2020). This frustration is a common thread throughout other public health efforts in HIV – when major funding and programmatic initiatives have been introduced, public health agencies have convened to discuss their impact without any community members being involved, leaving advocates to discuss it on their own at conferences and other gatherings (Spieldenner 2019), or with unanswered questions.

Scientists' opinions of a program and its ethicality may be blurred by the excitement surrounding a new technology that carries the potential for great public health advancement; community members, especially ones who have been affected by "patterns of institutionalized bias" (Holloway 2011, 125) on the other hand, are justifiably self-protective and do not immediately accept new technologies without exploring the risks, perhaps more so than the benefits (Spieldenner 2020). There are examples of agencies and communities coming together collaboratively which result in an increased amount of support for certain aspects of HIV data usage and surveillance practices – New York City was able to develop new public health uses for surveillance data through community discussion; Seattle-King County interviewed PWH and providers about their comfort with follow-up contact from the health department and the majority of responses were positive (Sweeney et al. 2013, 585). These interactions can be successful, but they rely on intensive and long-term discussion, trust, and open-mindedness from both groups. Different approaches to community engagement and standards for public input inclusion will be explored more in depth in the "Community Engagement Frameworks" section.

Conflicting Feelings on Genomics

The field of individual genetic testing has been around for decades, with sequencing and analysis of abnormalities taking off in the mid-20th century (Durmaz et al. 2015, 2). Today, many different types of people consult with genetic counselors to learn about family histories, propensity for certain diseases, and other information that can be gleaned from one's sequence (NSGC 2020). Although there may be some discomfort with the idea of submitting one's genetic information to a lab – worrying, for example, about the potential for discrimination based on health-related results, even though the Genetic Information Nondiscrimination Act of 2008 [GINA] protects against this occurrence (NSGC 2020) – genetic counseling is a widely accepted practice, even with some of its potential ethical issues. The recent boom of at-home genetic testing kits, however, has added a new, commercialized approach to genetic testing and has many people concerned about the privacy of the genetic information being stored in these corporate databases (Regalado 2019).

With over 26 million people having submitted their DNA to the four major testing companies by the beginning of 2019, analysts predict that "the gene troves could hold data on the genetic makeup of more than 100 million people" by 2021 (Regalado 2019). The people who fear these direct-to-consumer (DTC) testing kits, however, seem to overwhelmingly be experts and not the people taking the tests. The fascination with discovering one's ancestry or health proclivities, even though many doctors and genetic counselors warn that the health information can be misleading or of little health benefit (Brodwin 2019), appears to outweigh the worries about private retention of personal data – a stark contrast to the alarm expressed by PWH and community members about government collection of viral genomic data. Admittedly, there is a noticeable difference between generally healthy individuals participating in voluntary DTC testing for entertainment purposes and already-stigmatized PWH having data mandatorily collected – for one, the latter group has a pre-existing condition that opens them up to potential risk from a loss of data confidentiality. It is interesting, however, that there is a general level of comfort with the recreational, less regulated testing of the personal genome – in a study of almost 100 companies, "nearly half lacked even a basic privacy document that governed genetic data" (Brodwin 2019) – but concerns with highly-regulated and protected public health efforts that test viral strain information in order to improve community health (Khoury, Burke, and Thomson 2000, 529).

Americans are becoming more wary of sharing any type of personal data with the government. 75% of people surveyed in 2017 were not comfortable giving up privacy of their internet activities even to thwart terrorism, up from 67% in 2013 (Adler-Bell 2017); in 2015, 93% of Americans agreed on the importance of controlling who receives personal information and 90% wanted to control what data was collected (Geiger 2018). With increased negative attention and policing efforts being paid to immigrant communities (Pierce, Bolter, and Selee 2018) and the number of anti-LGBT hate crimes steadily rising (Hauck 2019), it is understandable why these specific populations of PWH, along with the greater HIV-positive community, might feel fearful of the potential outcomes – real or perceived – of use of their viral genetic information, even if it is not connected to personal genetic material.

The Science of Cluster Detection

CDC currently conducts "HIV Cluster and Outbreak Detection and Response", which uses analysis of public health surveillance data to identify clusters of rapid transmission, in order to focus necessary resources to reduce ongoing transmission (DHAP, "HIV Cluster…" 2020). Cluster detection is not a new technique and has been used for many years to monitor and address growing groups of HIV and other disease diagnoses, and will continue to be used for future outbreaks, such as the recent global COVID-19 pandemic (Yu et al. 2020, 1). The new addition to this technique is the use of molecular analysis, which uses HIV viral sequences to detect rapid transmissions within a network and tailor the response efforts to specific clusters. The process uses viral data that are generated when labs process tests for HIV drug resistance. These tests work to make sure that providers are treating the person's specific strain of HIV with the correct medications; they also provide useful information for tracking the transmission of HIV, allowing for the discovery of transmission clusters that may otherwise have gone undetected (DHAP, "HIV Molecular…" 2019). It is important to note that the data used in cluster detection and response is derived from the virus itself, not the patient's personal DNA.

HIV mutates quickly and if multiple individuals present with similar strains of HIV, it is a sign that the virus is being rapidly transmitted within a population (DHAP, "Advancing HIV Prevention…" 2019). These molecular clusters – "group[s] of sequences for which each sequence is linked, either directly or indirectly (through other sequences), to all other sequences" (DHAP, "HIV Molecular…" 2019) – may be identified by CDC or by state health departments and help to identify transmission clusters and risk networks. These individuals with similar HIV strains may be linked, however the technology does not reveal the directionality of transmission or if the transmission is direct or indirect. **Figure 2** demonstrates the relationship between these groups – "molecular" includes diagnosed patients who have received care and resistance testing; "transmission" includes those who are undiagnosed or whose sequences are not available; and "risk networks" contain those who remain at risk for acquiring the disease (DHAP 2018, 8). By pinpointing these transmission clusters and risk networks, CDC and state health departments are able to target resources (i.e. PrEP, post-exposure prophylaxis [PeP], ART) to the affected areas and intervene in networks where outcomes can be improved.

HIV is a single-stranded retrovirus which attacks the body's immune system by killing off white blood cells called CD4 cells. When the virus enters the human body, it must attach to these cells in order to replicate; using reverse transcriptase enzymes to convert its viral RNA into viral DNA, the virus prepares itself to integrate into the existing DNA of the human's white blood cells. The virus remains dormant in the cell until it is signaled to become active, budding and separating from the CD4 cell, eventually maturing into infectious HIV cells (Avert.org, "The Science…" 2019). As CD4 cell counts diminish, a person's immune system becomes weaker and more susceptible to opportunistic infections. Antiretroviral treatments allow HIV-positive patients to reach viral suppression – a virtually undetectable viral load which carries "effectively no risk of sexually transmitting the virus to an HIV-negative partner" (NIAID Now 2017) – and interfere in different stages of these implantation and replications processes.

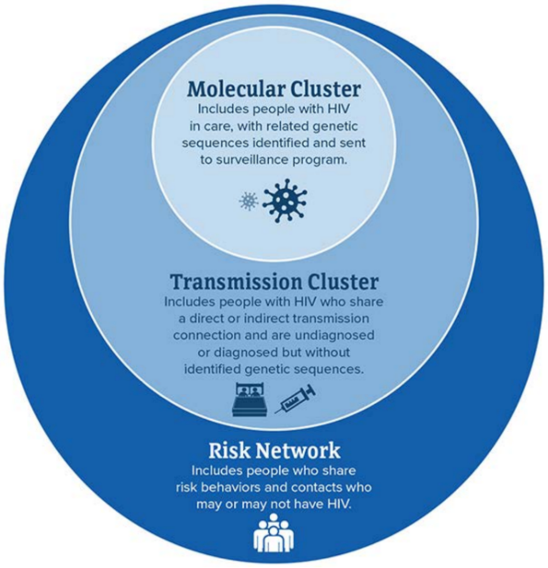

Figure 2. *Relationship between molecular clusters, transmission clusters, and risk networks (DHAP 2018, 8)*

As mentioned above, it is important to emphasize – especially to quell fears from confused members of the public – that the molecular analysis used for this type of surveillance work examines the genetics of the virus (RNA) and not the DNA of the human patient (DHAP, "Advancing HIV Prevention…" 2019). It is not irrelevant, however, that, as a function of how HIV infects a cell, the virus and the person's DNA become intertwined; HIV mutates differently over time in each person it infects (DHAP, "HIV Molecular…" 2019). Although strains of HIV can be categorized into multiple genetically distinct subgroups based on specific sections of the sequence, unique mutations occur within the entire viral genome (Avert.org, "HIV Strains…" 2019). Some community members with knowledge of genomic sequencing could conjecture that the uniqueness of these viral sequences could make them personally identifiable, however there is no current technology that is able to "match" viral and person genomic sequences. There is confusion even within the academic biological community about where DNA stops and the virus begins – various studies estimate that about eight percent of the human genome comes from various types viral RNA that have evolved over millions of years (Zimmer 2017). So, while molecular cluster detection work utilizes the information about each person's strain of HIV and not their own DNA sequence, there may be some dispute about whether it can be said that the virus is entirely separate from the individual.

Data for Non-Public Health Use

People of varying levels of health and science literacy may develop fears and apprehensions due to misunderstandings about the process and intentions of molecular analysis. These fears can be detrimental to the success of public health campaigns, similar to the reappearance of vaccine hesitancy and the subsequent increases of preventable disease (Altman 2019), among other counter-public health movements. Understanding concerns is crucial to reducing fear-based barriers to care. As mentioned in the section above, those with more advanced knowledge of genetics could worry about the ability to derive personal information from one's unique viral sequence. Scientists have been able to find correlations between sequences that may be able to predict general demographic group designations (Anderson et al. 2003), however extracting personal identifiable information on an individual scale does not appear to be a goal or possibility.

For others with a lesser understanding of molecular analysis, fears may be broader and often lumped together with other anxieties about government power or surveillance. Even the reassurance that health departments and CDC are collecting viral genetic sequences and not human DNA may not be enough to alleviate the concerns of others who see HIV data collection and tracking as just another action against already vulnerable populations. And while data collection via public health systems alone makes many people uncomfortable, an even bigger concern is the potential for the data to be requested for non-public health uses, defined by CDC as the "release of data that are either directly or indirectly identifying to the public; to parties involved in civil, criminal, or administrative litigation; to non-public health agencies of the federal, state, or local government; or for commercial uses" (NCHHSTP 2011, 41).

Law Enforcement

Already facing stigmatization and the financial and medical stress that comes with a diagnosis (Spieldenner 2019), PWH and advocates must also deal with the fact that their status could result in criminal charges depending on their actions and their state of residence. As of March 2019, 34 states had "HIV-specific criminal laws and/or sentence enhancements" (Center for HIV Law and Policy, "Map: HIV…" 2019), and 24 states have prosecuted PWH under general, non-HIV specific laws in the past 10 years. Although there are rare cases of intentional transmission, for which people have been sentenced, these laws often seek to punish consensual sexual interactions in which there is no risk of transmission due to viral suppression, further stigmatizing the community and reducing motivation to get tested (Center for HIV Law and Policy 2020).

Additionally, state laws and use of these laws vary. Health department staff have noted that, even if their own state has strong protections for PWH, there is concern about what happens if they identify a cluster that includes individuals residing in a state with more punitive laws and more frequent prosecutions (DHAP, "Virtual Meeting…" 2019, 6). There is a continuum of protection levels against the use of HIV data for non-public health use on which all states fall, from broad discretion of health departments to specific data sharing activities (NASTAD 2018, 3). On the weaker end, some states allow for data release based on the request of law enforcement officers in addition to court orders and subpoenas; stronger state protections refuse all requests other than court orders – most states fall somewhere in the middle. States with the strongest protections do not allow for any type of data release (Killelea 2019).

Prosecutions for HIV typically involve a plaintiff that is aware of their HIV status who "knowingly" exposes others, usually without disclosing their status. For this type of case, prosecuting attorneys might request HIV testing and counseling information to prove knowledge of a diagnosis by a certain date (Killelea 2019). While molecular analysis data would likely not be necessary in exposure cases, there is still some worry that it could be included in a request simply because it is available, and could be seen as another piece of evidence demonstrating transmission, especially when cross-referenced with other data points (HICSB 2019, 5). Additionally, the more useful information for criminal cases would be if molecular cluster detection could determine directionality of transmission, which it currently cannot (Günthard and Kouyos 2018, 1393). Advocates and public health workers alike are not pushing for the development of this technology, since it is seen as involving a disproportionate amount of risk compared to the benefit for public health work (Kempner 2019), however they acknowledge the need to be prepared and educate staff and legal counsel if the technology does eventually develop (HICSB 2019, 3).

It would seem that efforts to modernize or eliminate these laws would be well-supported by advocates, PWH, and public health agencies, who all want to keep this data within the public health system, if it has to be collected at all. Contrary to this belief, there are mixed reactions to the idea of putting a spotlight on these laws and incorporating molecular cluster detection into them. Many advocacy groups and medical experts are working to change state statutes; they cite the advancements in technology and medication that have changed HIV "from a fatal infection into a manageable chronic condition" (Pfleger 2020) as a reason that the laws are outdated. The American Medical Association issued a statement in 2019 calling for a total decriminalization of status non-disclosure, which inspired state law changes in multiple regions (AMA 2019); the American Psychological Association's 2018 revised resolution also called for a repeal or reform of HIV criminalization laws (APA 2018). The Center for HIV Law and Policy states that there is no evidence that these laws decrease transmission rates (Center for HIV Law and Policy 2020), and they have been shown to be harmful and dehumanizing (Sircar 2017). Individuals who have been convicted, served jail time, or been forced to register as sex offenders as a result of aggressive prosecution under criminalization laws have spoken out about the unfairness of the legal system that is in place (Wiltz 2017).

While one might be hard-pressed to find an advocate or PWH who supports criminalization laws, there are some who argue that updating the laws might bring unintended consequences. One suggestion that has been proposed by the pro-modernization group is to change the language to focus on transmission as opposed to exposure, effectively removing cases that do not involve a new transmission. Skeptics point out, however, that this change may increase the demand for molecular HIV data or other medical data, potentially increasing law enforcement requests for data (HICSB 2019, 5). They also worry about the incorporation of language protecting those who are virally suppressed; although major strides have been made in allowing people to be undetectable and untransmittable, these changes might increase socioeconomic and racial inequalities, as lower income and minority groups often have reduced access to care and viral suppression (Heslin et al. 2005, 283). Addressing these laws and potential changes to better protect both individuals and their data is a highly nuanced issue and should progress with care. Regardless of the result, agencies that control data should work with legal counsel to understand protections and release policies, and be transparent with communities about the real risks of legal use of data (Killelea 2019).

PWID face a different, complex battle, as their behaviors inherently involve illegal actions and require additional consideration of the relationship between law enforcement and prevention efforts. It has been suggested, however, that teamwork between public health and law enforcement in certain aspects of HIV efforts might have positive results. For example, working with police to encourage direction toward evidence-based needle and syringe programs or methadone clinics instead of immediate arrest could help reduce new infections for PWID (Crofts and Patterson 2016, 3). In other countries, police attend sensitivity and nondiscrimination training to understand the needs of PWH, to reduce HIV vulnerability for sex workers, and to reduce violence against communities of MSM (Crofts and Patterson 2016, 4). While the United States might not be implementing these collaborations yet, it is hopeful that partnership for certain aspects of HIV prevention could one day be fruitful if carried out carefully and with meaningful community input.

Immigration Concerns

Another concern for PWH is the potential for data use by non-public government health agencies, specifically Immigration and Customs Enforcement (ICE). Undocumented populations have a higher uninsured rate than lawfully present immigrants and citizens – 45% of the nonelderly population compared to 23% and 8%, respectively (Artiga and Diaz 2019, 1) – and utilize health care less than others, accounting for 1.4% of total U.S. medical expenditures in 2018 (Rapaport 2018). There are already multiple barriers in place that keep undocumented people from seeking health care. The fact that many of these individuals believe, incorrectly, that health departments are readily sharing data with immigration agencies increases their apprehension (HICSB 2019, 6), and advocates continually ask for information on how often this data-sharing actually occurs. Organizations like the National Alliance of State and Territorial AIDS Directors (NASTAD), have expressed that they have no knowledge of any HIV data requests from ICE and re-emphasize that immigration status information is not a collected data point (Killelea 2019), but also recognized that even unfounded fears can have limiting effects on health care (HICSB 2019, 6).

Recent federal announcements and rule changes are also exacerbating immigrant communities' discomfort with the idea of government surveillance. The "Ending the HIV Epidemic" White House initiative plans to focus on specific areas of the country with high diagnosis rates, increasing funding for resources and calling for community involvement to be a large part of the process (HIV.gov 2020). To many, this program seems like welcome support for the important cause of lowering new HIV diagnoses; for undocumented immigrants and other communities that already feel unfairly targeted, this initiative is an "aggressive surveillance system that targets the most marginalized people living with HIV" (Spieldenner 2019). This initiative may also have the effect of shifting focus from useful social services and community recognition to treatment-heavy approaches. One activist blogger writes: "I am worried that our voices and needs as people living with HIV are reduced to treatment adherence. What about treatment access? Harm reduction and mental health services? Poverty reduction and affordable housing initiatives? Eliminating HIV criminalization laws? Support for immigrants? Sexual and reproductive health and rights?" (Spieldenner 2019). If an initiative is quantitatively driven like "Ending the Epidemic", which calls for 75% and 90% reductions in new HIV cases by 2025 and 2030, respectively (HIV.gov 2020), it risks minimizing the importance of these other social factors and forgoes an opportunity to address deeper structural issues.

The newly approved federal "public charge" rule, which determines an immigrant's admissibility to the country based on their likelihood to become a public charge and utilize benefits (DHS 2020), may also be detrimental to this population's level of comfort receiving health care services, especially when the services result in government data collection. Although the public charge rule does not have HIV-specific language, it indirectly targets HIV-positive immigrants through their use of health services (most forms of Medicaid) and through other programs like housing (Housing Opportunities for People with AIDS) (Spieldenner 2018). In this way, the public charge rule is yet another barrier to access for this community, compounded by the fears that the government will use any HIV data that is collected against them. Other anecdotal cases – a Honduran father being separated from his three daughters and deported because of his HIV status, testimonies from the chief of Customs and Border Control explaining a policy for family separation based on parental HIV status, which has since been walked back but not shut down (King 2019) – are perpetuating fear and anger, as well.

Advocates have continually called for evaluative data from public health agencies on how the HIV data they collect is used and who accesses it in order to help quantify the risk of non-public health uses (HICSB 2019, 3). The use of molecular HIV data analysis is a relatively new addition to the process of HIV surveillance, so quantifiable results are limited based on how many outbreak responses occur, but CDC staff have acknowledged that the dissemination of this type of information will be important as it becomes available (HICSB 2019, 9). CDC has released some quantifiable results from cluster detection – for example in 2018, they noted that they had identified 60 transmission clusters and rates of transmission 11 times larger than the general population's rate, which could help them start to understand the disproportionate rise in new cases among certain demographics (Ryan 2018). The root of the desire for these quantifiable and transparent results is to be able to better evaluate the balance of risks and benefits for communities, which advocates do not feel they can accurately do with the currently available information.

Restorative Justice

Restorative justice, or the more broad "restorative practice," is typically associated with criminal justice and the act of engaging those who have been harmed, those who have acted wrongly, and the surrounding communities within the context of crime and law. This movement, which works to "institutionalize peaceful approaches to harm, problem-solving and violations of legal and human rights" (Boyes-Watson 2020) also has a place within public health, especially for programs that are public-facing and that have potential social, emotional, or physical risks. Restorative practice offers the opportunity for those who feel they have experienced harm to heal from the damage and move forward; it also gives a space to those who have been the cause of the harm to make amends. Through this collaborative practice, the two or more parties can experience each other's perspectives and can hopefully grow into a more productive and safe relationship in the future (Centre for Justice & Reconciliation 2020). In the case of HIV surveillance, public health agencies, PWH, and advocacy groups should consider using the principles of restorative justice to heal their sometimes divisive relationships and work toward more successful and collaborative public health programs in the future.

Bridging the Disconnects in Perspectives

HIV molecular cluster detection and outbreak response work has thus far not been widely embraced by communities, especially those that it directly and indirectly affects. Public health often relies on a utilitarian ethical approach, calculating which options produce the most benefit for the most people (Buchanan 2008, 17) and sometimes necessitates giving priority to efficacy and efficiency over principles of respect for persons and liberty. The legal and ethical mandate to protect the public's health often conflicts with individual ideals of autonomy and consent, and agencies have the added barrier of working with populations that may lack trust in government already (Rainie and Perrin 2019). Community groups, on the other hand, trend toward an ethics of care, focusing on the importance of personal relationships, but prioritizing individual and small-group needs over the population as a whole (Reamer 2016). This approach promotes care and helping as opposed to non-harming, and acknowledges the power of actual experience versus abstract ideals. The use of multidisciplinary teams in public health, consisting of representatives from each of these ideologies, would likely be useful in order to bridge this disconnect, creating a less divided sense of authority and control through the understanding of other perspectives.

The four pillars of restorative justice – inclusion, encounter, making amends, and reintegration – are perhaps a good starting point for realigning community and public health goals (Centre for Justice & Reconciliation 2020). Ultimately both groups desire respect and improved health outcomes, however the groups' perspectives on how to approach these goals likely differ. Public health experts have the experience and academic knowledge to recognize the potential health benefits of a program like HIV cluster detection and response, working with public health partners to develop what they view as an effective and successful program. From a community perspective, the experiential knowledge that advocates and PWH possess is just as valuable, since it dictates the true needs of a population and what individuals will utilize and appreciate. The combination of these two knowledge bases has the potential to result in effective and culturally sensitive public health efforts, but the collaboration is often foiled by a lack of recognition of the wide range of viewpoints involved, perhaps due to fear, misunderstanding, or harbored feelings of discomfort.

Within any field of work, contentious groups participate in conversations that have the potential to be productive, but can often devolved into anger and frustration, leading to more frustration and less progress. One non-profit executive director states that "while expressing anger is important, it's seldom as effective as sharing a great idea" (Lee 2017). Communities and public servants need spaces to express their frustrations, but part of addressing what makes people angry is figuring out how to rectify the situation within the context of a whole network of people. Even when someone is expressing anger, it is important to listen to what they are saying, to acknowledge that there is truth to their feelings, and to work to fix the problem together. Then, when the feuding parties have come to recognize the value in each other's involvement and that differing opinions need not clash, the resources that each group brings can be utilized for the same cause (Lee 2017). Some restorative justice thinkers compare this reconciliation practice to tertiary prevention, "introduced after the problem has occurred, with the intention of avoiding reoccurrence" (Wachtel 2016, 1), later bolstered with more general restorative practices that act as primary prevention before the next problem might occur.

Recognition of Wrongdoing and Rebuilding Trust

As discussed earlier, one of the main conflict points in HIV cluster detection and response is the fact that community engagement was not prioritized early on in the planning of the initiative and that decisions were made on behalf of the affected communities; this aspect will serve as an example of one harm that could be addressed through the restorative justice approach. Inherent to the first step of restorative justice – inclusion – is the need to have all relevant parties be a part of the discussion. Although in the case of cluster detection and response, inclusion would be addressed retroactively addressed, engaging all interested parties from now on is a vital first step toward healing. While active conversations between the groups are one option, information-sharing, and use of personal narrative are some other options that allow people to connect. The next step, encountering, typically involves a facilitated meetup between parties, but can also utilize some of the techniques listed above – it aims to elicit emotional responses, understanding of each other's perspectives, and a basis for future resolution (Centre for Justice & Reconciliation 2020). While representatives from public health agencies may not feel it is appropriate to show intense emotional reactions, it is important for them to be genuinely empathetic and sincere about what the community members and advocates share with them.

Making amends is perhaps the most important step to restoring any sort of trusting and productive collaboration between public health agencies and communities that feel harmed. This step is comprised of apology, changed behavior, generosity, and restitution (Centre for Justice & Reconciliation 2020); all are important, however the first two aspects are especially relevant to the relationship between communities and agencies, as there is much future work on which these groups will need to collaborate. Apologizing for harms may allow for some hurt to heal – although permanent damage that cannot be changed by a retroactive admission of wrongdoing may still persist – and may reinforce that a change of behavior will be legitimate. The last step of restorative justice is often geared more toward victims who have been blamed for their own harms and isolated as a result, but the concepts can be adapted to the tense relationships between agencies and community members. When programs are developed and implemented without the input of those affected, some may be dissuaded from future participation in community engagement activities and from feeling comfortable interacting with the program itself. Reintegration loops back to the inclusion principle, in that community members need to be welcomed back into the public health process and given support in order for meaningful collaboration to be an option (Centre for Justice & Reconciliation 2020).

It must be recognized that there can be a legal or political aspect to a public health agency's work that may complicate the process of admitting wrongdoing or harm. Since agencies such as CDC are government institutions, there is a bureaucratic process for almost everything and many public statements need to be approved through multiple levels of organization, including legal teams, before being released (Institute of Medicine 2002, 101). It also means that they cannot advocate for or against specific legislation, so they would not be able use legislative activism to demonstrate collaboration with the community. Although admitting wrongdoing and apologizing are appropriate for restorative justice and reconciliation, agencies must guard against lawsuits, loss of trust from supporters, and causing increased distress. In medical malpractice, for example, there is evidence that admitting to a medical error is better for the patient and their family, as well as the provider. The risk of bad evaluations, termination from a position, or the psychological burden of verbalizing one's harmful acts, however, is a deterrent for many providers to go through with the admission process (Detsky, Baerlocher, and Wu 2013, 448). The risk of bad press, a loss of funding, and reprimands from governmental authority figures are the parallels within public health that might cause hesitation, even if the process can result in better long-term outcomes. Even if an agency has a well-thought-out plan to involve community in the planning of future projects, the same level of success and mutual trust will likely not be reached unless there is a healing process for all parties and a recognition of faults.

Dissemination and Implementation Science

Dissemination and implementation science (D&I) is a part of translational science that works to test an innovation in a clinical or practice setting. Especially within a well-developed field like public health, D&I plays an important role in recognizing barriers to program implementation and making sure that the evidence-based information gathered from the program is received by all who need and want to access it. Defined as "a growing field of study that examines the process by which scientific evidence is adopted, implemented, and sustained in typical community or clinical settings" (Estabrooks et al. 2018, 1), the theories behind D&I have been used since the 1930s and help determine appropriate ways of implementing an intervention. It calls for multidisciplinary teams comprised of organizational representatives, affected individuals, and social scientists to work together to conduct research to "demonstrat[e] local impact while concurrently contributing to generalizable knowledge on how best to move evidence into practice" (Estabrooks et al. 2018, 1).

Throughout HIV molecular cluster detection and response efforts, advocates and PWH have requested quantitative results from cluster detection work and information about how the data are used – this information is just now being disseminated, so there is no program-level data. There have also been barriers to comprehensive community support of these programs that have the potential for negative health outcomes that move in the opposite direction of CDC and public health goals. Whether dissemination and implementation are studied together or separate, they contribute to the study of public health and are used in HIV/AIDS efforts such as the "Framework for Operations and Implementation Research of the Global Fund to Fight AIDS, Tuberculosis and Malaria" and the "William J Clinton Foundation Center for Strategic HIV Operations Research" (Schackman 2010, 1).

D&I science can help professionals and public participants better understand how to design a public health intervention – specifically one within HIV and other highly stigmatized infectious diseases – and elements of this approach can augment a framework that evaluates and monitors these types of programs.

Dissemination vs. Implementation

The "D" of D&I refers to dissemination science, which works to "identify mechanisms and approaches to package and convey the evidence-based information necessary to improve public health and clinical care services" (Schackman 2010, 2). The demand for accessible resources and results from HIV cluster detection work demonstrates the need to study best practices for the distribution of these types of materials. While academic papers and conference presentations are helpful for the scientific and professional communities, they do not address a key target audience – those who will be affected and those who advocate on the community's behalf. In order to support an increase in evidence-based interventions in public health and regain community trust, there need to be "more creative and rigorous dissemination efforts" (University of Colorado 2020). While dissemination is crucial and aims to spread knowledge derived from scientific and health-based programs, it is typically not sufficient just to study dissemination on its own (Schackman 2010, 2).

The other half of the approach, implementation, focuses on identifying barriers to the realization of an intervention and, in public health, studies strategic ways that interventions can be integrated into both community and clinical settings with the goal of improving health outcomes (Burnham et al. 2019, 2). Implementation science attempts to make evidence-based interventions the easiest option for clinicians or public health agencies to choose, seamlessly incorporating them into common practices and replacing inefficient alternatives (Burnham et al. 2019, 1). Scalability and sustainability are two hallmark measures that implementation science attempts to quantify, making sure to identify approaches that will be applicable to both small and large target audiences and will be able to be maintained for a reasonable amount of time even if funding sources are cut off (Estabrooks et al. 2018, 5). Although they share common goals of determining successful approaches and the reasoning behind them, both dissemination and implementation sciences differ from the earlier stages of translational science – evaluation and monitoring – in that they "broaden the scope of monitoring and evaluation activities to understand the etiology of gaps between expected results and observed outcomes" (Schackman 2010, 2).

Overcoming Barriers Through D&I Methods

Much of the literature on dissemination and implementation science in health relates to clinical studies and the importance of helping providers integrate research-based programs into their practice; the same practices, however, are applicable to public health interventions. D&I science is extremely framework-driven, with different types of models developed for various scenarios. For example, the PRACTIS (Practical Planning for Implementation and Scale-up) and RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) models are process-driven and outcome-driven approaches, respectively. PRACTIS utilizes a step-by-step approach to "speed the adoption, implementation, and maintenance of evidence-based interventions in clinical or community settings" (Estabrooks et al. 2018, 2) – characterizing the setting, engaging stakeholders, identifying barriers or facilitators, and finding solutions to the barriers. This model is similar to the integrated framework that will be developed throughout this paper in that it walks the user through sequence stages of a project, using if-then questions to explore impediments to the successful implementation of an intervention (Estabrooks et al. 2018, 3). RE-AIM, on the other hand, focuses on outcomes, asking the evaluator to "balance the focus on internal and external validity to improve the translation of public health interventions to practice" (Estabrooks et al. 2018, 3). Using these internal and external validations, such as cost, quality, and consistency of an implementation process, and health outcomes for the effected populations, researchers or public health agents can estimate how successful a program will be.

Examples of the use of D&I science in the field of HIV intervention can help demonstrate its potential impact. In one study of mother-to-child HIV transmission in Africa, providers noticed that each step on a "coverage cascade" was an opportunity for an intervention, whether it be offering an HIV test or making sure that all the necessary information was included in the medical chart. By identifying the barriers to these interventional steps and designing methods to overcome them, better outcomes were seen in many of the steps of the coverage cascade (Schackman 2010, 3). In another clinical-setting study, researchers noticed an increase in antiretroviral treatment from 50% to 83% after the launch of "a program to disseminate and implement findings of an acquired immunodeficiency syndrome clinical trial" (Burnham et al. 2019, 5). In a more community-focused scenario, barriers to the successful implementation of needle exchanges were studied through D&I and it was discovered that multiple factors – fear of policing, social and cultural structures, different target rates for different populations, etc. – contribute to some of the apprehension of people to utilize these resources. By identifying the barriers, policymakers and scientists can start to formulate a plan to address them. Within HIV cluster response work, D&I can help pinpoint the barriers to implementation and key gaps in resources, helping to identify the approaches that will best address them. Especially if paired with some of the aforementioned restorative justice practices, this approach can lead to more cooperation between agencies and communities, and more effective public health interventions.

Bioethics vs. Public Health Ethics

When one thinks of bioethics and public health ethics (PHE), the assumption is often that they are almost entirely at odds. While bioethics and clinical ethics promote autonomous choice, informed consent, and individual health, public health maintains that certain circumstances call for coercion, mandatory reporting, and a focus on the good of others even if it comes with personal risk. In HIV surveillance and response efforts, especially in the early years of the disease, finding a balance between these perspectives was hard, as new diagnoses and transmissions were growing exponentially, alongside fears of privacy and autonomy loss. The COVID-19 outbreak, for example, demonstrates the type of situation in which national and state mandates (closing of non-essential establishments, travel restrictions, shelter-in-place orders, etc.) have superseded individual freedoms in the name of community health (Al Jazeera 2020). There are clear differences between the HIV and COVID-19 situations, but both scenarios invite conversation about the individual versus the common good and the extent to which government and the public clash.

In individual medicine, unless patients actively reject their autonomy in favor of paternalistic treatment from a provider, the expectation is that they are the stewards of their own care; by contrast, in PHE, the government assumes a paternalistic role over individuals unless the individual opts not to interact with health care or other societal systems, in which case legal power and compulsion can still be used to control their actions. There is a spectrum of acceptance of this divide – some accept the separation of bioethics and PHE, acknowledging that the fields simply utilize different policies and principles (Bayer and Fairchild 2004, 488); others argue that the fields should merge, with public health ethics adopting the principles of bioethics and shedding its propensity toward paternalism to embrace individual rights (Flanigan 2013, 170). Still others see a space for overlap and collaboration between the subjects (Callahan and Jennings 2002, 169).

The field of bioethics started gaining traction in the 1960s and 70s, growing out of the call for the correction of problematic human subject research and technological advancements in medicine (Callahan and Jennings 2002, 169). Research ethics and a desire for the dismissal of paternalism in medicine came together to form a new individual and autonomy-focused movement, leaving population health and its seemingly opposite priorities on the outside of mainstream conversation (Bayer and Fairchild 2004, 474). While some public health issues, such as the emergence of

HIV/AIDS, briefly reignited attention to public health, it was not until the 1990s and 2000s that systematic outlines of public health ethics and calls for formal education on the topic began to emerge (Callahan and Jennings 2002, 176). Increasing health policy concerns such as cost-savings and preventive measures bolstered public health advocacy and legislation (Callahan and Jennings 2002, 169), but the "epistemological obstacle…between the individualistic orientation of bioethics and the population and societal focus of public health" (Bayer and Fairchild 2004, 475) still remained. As PHE and bioethics have moved forward, the idea of identifying opportunities for rewarding partnerships have inspired "those in the field of public health…to welcome the growing interest among their colleagues in bioethics" (Callahan and Jennings 2002, 170).

Viewpoint 1: Separation of Bioethics and Public Health Ethics

Bayer and Fairchild's "The Genesis of Public Health Ethics" represents those that feel that, although bioethics and public health ethics can coexist and slightly overlap, they will never be able to fully understand each other. They state that the goal of public health is to protect the common good and that goal "necessitate[s] limits on the choices of individuals on grounds of communal protection" (Bayer and Fairchild 2004, 488). They discuss Mill's harm principle, which sets a standard for assessing governments' liberty-limiting activities – a standard that they claim involves moral judgment and differing perspectives, which therefore negates the ability to use the same standards for PHE as clinical ethics. The authors do not intend this statement to dismiss the importance of individual rights or even to encourage unnecessarily restrictive measures, even though they do recognize that human rights law and other legislative systems do permit limiting liberty if there is recognized and substantial risk (Bayer and Fairchild 2004, 489). The nexus of bioethics and PHE for Bayer and Fairchild is the efforts made to use the least restrictive and noncoercive methods whenever possible; the reason the fields cannot be entirely aligned is that public health can justify "far more extensive limitations on privacy…and on liberty" (Bayer and Fairchild 2004, 490) than would be accepted in classic bioethics. For example, in situations in which the potential for risk is unclear but the costs of inaction would be detrimental, PHE recognizes that autonomy and liberty-limiting actions may be acceptable, even though they may feel stifling and that the same actions might not be necessary for the treatment of an individual, as opposed to a society, at risk (Bayer and Fairchild 2004, 490). Bayer and Fairchild promote the idea of transparency in order to help make paternalism in public health more palatable, but they stand by the idea that PHE will never be built on the same basic principles or values as bioethics (Bayer and Fairchild 2004, 492).

Viewpoint 2: Merging Bioethics and Public Health Ethics

At the other end of the spectrum lie writers like Jessica Flanigan, who, in her paper "Public Bioethics", calls for PHE to abandon its acceptance of paternalism in favor of bioethics' fervent views against it. Instead of working to find common ground, at least on the topic of coercive public health policies, PHE should change its priorities to be the same as bioethics'. Flanigan argues that the same reasoning that rejects paternalism for individuals can be used to reject it in public health – that there is "no moral difference between public and private health choices" (Flanigan 2013, 170) and therefore an individual's right to choose their health actions should be protected in both cases. Flanigan lists multiple reasons why informed, autonomous decision-making is superior, from trusting patient-provider relationships and personal responsibility for health, to citizens owning their bodies and having the right to make even self-harming decisions (Flanigan 2013, 172). The acceptance of paternalism in PHE, she states, fosters learned helplessness and indicates that there is a difference between an individual as a consumer and as a patient, a distinction she does not believe should exist (Flanigan 2013, 173). Perhaps the most distinct difference between public health and medicine, fields which she attempts to equate in terms of patient rights, is the effect one's decisions can have on others' health.

Flanigan touches on the argument that paternalistic coercion can be justified in cases where the policies would protect others, but then rebuts this line of thinking by saying that "even if it is permissible to violate the rights of a few to protect people… it does not follow that it is permissible to violate the rights of some to protect a population from harming themselves" (Flanigan 2013, 177). The author's argument seems mostly to pertain to self-regarding individual actions, such as requirements for seatbelts or smoking bans, and not policies that, for example, aim to suppress the spread of disease. Perhaps since more is understood about HIV and personal actions that can be taken to avoid transmission nowadays, personal autonomy could be relied upon slightly more heavily, however this approach would still not address the need for surveillance data. For a scenario like the current COVID-19 spread, this emphasis on personal choice has proven ineffective, as some have shirked the responsibility for others' and their own wellbeing, ignoring recommendations for social distancing and necessitating government mandates instead (Pinsker 2020). Still, Flanigan represents one subset of thinkers that do not believe that bioethics and PHE can find overlap and compromise, since they disagree on one of the staple ethical principles.

Viewpoint 3: Compromising Between Bioethics and Public Health Ethics

In their article "Ethics and Public Health: Forging a Strong Relationship", Callahan and Jennings advocate for a middle ground between these two fields that have historically clashed (Callahan and Jennings 2002, 169). While much of the article is dedicated to explaining the importance of the creation of a code of ethics for the field of public health itself, the authors also discuss the possibilities for alliance between ethicists who rely on classical bioethical principles and public health agents who seek to provide better health for those they serve, though guided by different values. Callahan and Jennings suggest that bioethics and PHE can grow collaboratively, resulting in the recognition and analysis of issues in public health and the expansion of bioethics (Callahan and Jennings 2002, 170). The authors note that, for situations as complex as those dealt with in public health and bioethics, one type of ethical analysis will not be able to answer every questions, and as such, they introduce four different types that vary based on the "point of view and needs from which it originates" (Callahan and Jennings 2002, 172). The most inclusive and adaptive of the ethical analysis methods they highlight is "critical ethics", which combines historical perspectives, social values and trends, and evaluation of systemic and institutional structures to evaluate an issue. This approach is human rights-oriented and calls for public citizens to be a part of the discourse. Although the tension between freedom from governmental interference and the need to serve the common good still exists, this method of analysis incorporates both perspectives.

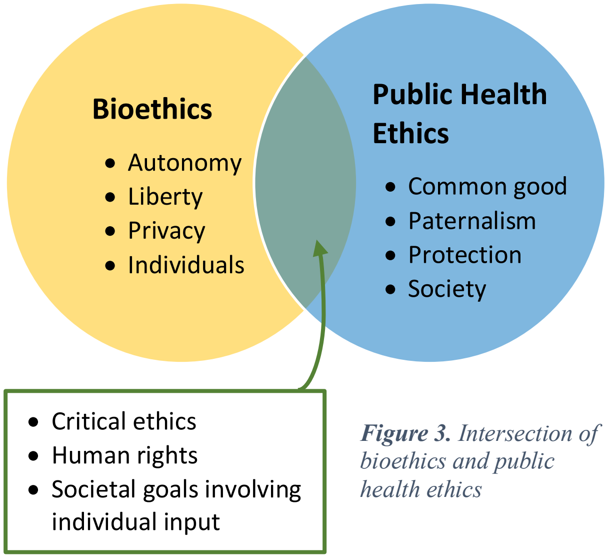

Figure 3. *Intersection of bioethics and public health ethics*

Differing Perspectives on HIV/AIDS Response

Callahan and Jennings, among many other authors, use the response to the HIV/AIDS epidemic to demonstrate how bioethics and PHE can, in fact, work together in appropriate contexts. Approaches to the epidemic with a rights-based agenda were "occasioning some important struggles about the relationship between individual and society and seeking better ways to balance community health needs and individual rights" (Callahan and Jennings 2002, 170). Jonathan Mann's international human rights framework offers another way to incorporate both perspectives (Patterson and London 2002, 965). HIV/AIDS offered public health officials a chance to stray from the conventional expectations of epidemic treatment. There was a pledge to treat this issue differently than issues in the past, supported by the idea that "no public health policy that violated the rights of individuals could be effective in controlling the spread of HIV" (Bayer and Fairchild 2004, 478). There was even consensus between public health agencies and community-based advocates that HIV reporting was dangerous for people's freedom and privacy, and was a barrier to individuals seeking testing and treatment. As treatment options improved, however, this partnership began to weaken and the public health benefits of name-based reporting began to take precedence over individual privacy once again (Bayer and Fairchild 2004, 481).

Current HIV surveillance analysis, testing, and treatment technologies have advanced even further since then, and many advocates who resonate with bioethical principles are once again at odds with agencies promoting traditional PHE values. Public health surveillance does not require informed consent and does not have an opt-out option for patients whose data has already been collected, which strikes some as coercive and may dissuade them from seeking initial or further care. The reliance on community consent for some public health actions is an attempt to quell some concerns about lack of individual consent (Lee, Heilig, and White 2012, 40), but is not accepted by some outspoken advocates. Lee, Heilig, and White compare public health to the typical patient-provider relationship but on a larger scale, with agencies as providers and populations as patients. It is the provider's goal to weigh options to find what is best for the patient, however in PHE, governmental powers allow for more paternalism than in clinical ethics (Lee, Heilig, and White 2012, 41). In order to maintain effective HIV surveillance and prevention programs, it is important to recognize the differences in bioethics and PHE, and work to include both perspectives in the design, implementation, and evaluation of these programs.

Utilitarianism vs. Social Justice Perspective

There are two major schools of thought within public health work that tend to be portrayed as opposites: utilitarianism and social justice. Utilitarianism relies on quantifiable outcomes of attempts to balance harms and benefits – a cost-benefit calculation. Pure utilitarianism argues that the maximum benefit for the most people is the best and most ethical option to choose, and is sometimes complicated by the difficult task of calculating long term cause and effect (Buchanan 2008, 17). David Buchanan gives the example of social marketing in public health to demonstrate how utilitarianism embraces focusing on the end goal. For example, in order to reach the goal of better health and health care cost savings, it would be justified to run campaigns that utilize scare tactics that evoke "base emotional reactions…and bypass rational thought processes" (Buchanan 2008, 17) to convince people not to smoke. Forgoing the potential ethical problems with using this type of messaging, utilitarian thinkers focus on whether the campaign will result in the intended outcomes.

Although the measurement-based utilitarianism may make sense to some, many others identify more with an equity, or social justice, view. The goals in this school of thought are more qualitative than quantitative, aiming to "promot[e] population health and reduc[e] inequalities" (MacKay 2017, e414). These thinkers believe that public health exists to improve and maintain the health of society, which heavily involves addressing disparities and focusing efforts on disadvantaged groups. The social justice perspective also takes into account modifiers of health, not just as a means to calculate an outcome (as in utilitarianism), but as an important part of health improvement and empowerment. Health and other social determinant disadvantages cause "varieties of unfreedom" (Sen 1999, 15), potentially limiting people's capacity to live their most fulling lives. The social justice perspective recognizes that throughout the process of bettering health, individuals should also become empowered and learn from the process, as opposed to just focusing on the ultimate goal.

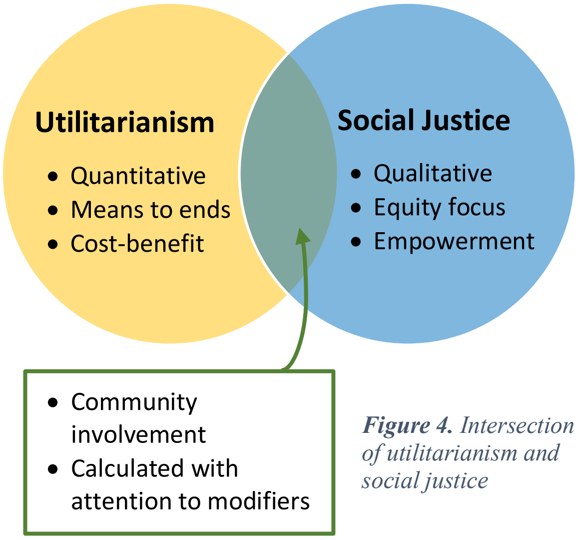

Figure 4. *Intersection of utilitarianism and social justice*

Finding a balance between these two schools of thought is not easy. Public health has historically been associated with utilitarianism, is often necessary during disastrous emergencies, mass spread of disease, and scarcity of resources (MacKay 2017, e414). Many public health efforts do also involve a social justice focus, however it may be difficult to advocate, for example, for changes to government systems when the agency is intrinsically attached to government. A sole focus on the numerical cost-benefit analysis of health actions will likely not serve individuals nearly as well as a process in which they can feel involved and responsible for their own health; there is, however, great value in recognizing what actions will maximize societal protection and flourishing. Some thinkers propose the use of behavioral economics to encourage people to make autonomous, healthy choices on their own by making the healthy choice the easiest one (Volpp and Asch 2017, 271). Just like the need for balance between bioethical and PHE values, there is a need for compromise between utilitarianism and social justice.

Integrated Ethical Framework

A framework is quite simply a “basic conceptual structure” (Merriam-Webster 2020); ethical frameworks are structures based on various ethical theories, as well as practical knowledge, that help to guide decision-making in many fields of study and industry (Bonde and Firenze 2013). Ethical frameworks allow for consistency in the evaluation of situations and aid in ensuring that actions are well-thought out through the use of evidence and rational thinking. Particularly for multifaceted and complex issues, a framework is useful not only for the people developing the solutions, but for the people affected by the issue, as well. Frameworks encourage transparency, allowing the public and others within an organization to trace back the reasoning that justifies decisions that are made. Although different people involved in a project may personally prioritize different values, the use of a framework may help foster compromise and help individuals realize what values are appropriate for the task at hand. The ultimate goal of this project is to create a useable analytical tool in the form of an integrated framework, through which HIV cluster detection and response, and similar public health programs, can be designed, implemented, and assessed. While many frameworks exist that address individual aspects of HIV cluster response work that make it complex – public health ethics, community engagement, surveillance, and genomic/health data use – it is important to be able to evaluate all of these foundations of the work together. The context in which these frameworks operate is also important to discuss, recognizing the influence of both public health ethics and bioethics, and the different schools of thought under which frameworks are developed.

In order to develop this type of analytical tool, multiple frameworks within each of the aforementioned aspects were identified, from which elements were chosen to include in the final structure. The selection of these frameworks was largely subjective and is simply a representation of the types of frameworks that exist in that space. By no means is the selection of principles derived from these pieces exhaustive and other additions or edits to the collection are be welcome , especially from those who attempt to use the tool. The process by which these principles were chosen involved the review of the chosen frameworks' suggested principles and main ideas, recognition of overlap between frameworks, and the narrowing down of those principles into one set that represents a strong, novel ethical framework. **Figure 5** demonstrates an abstract of this process; **Figure 7** later in the chapter demonstrates this process with the actual details from the chosen articles.

The final integrated framework is proposed as a useful and practical instrument for public health agencies and communities. As it is comprised of principles from four main fields of study – public health ethics, community engagement, surveillance, and genomic/health data use – it is modular and can be adapted to different types of public health intervention, not only HIV cluster detection and response. The public health and community engagement pieces have both been determined to be necessary for any application of this framework, however it is possible for one to utilize this tool for programs that do not involve genomic data, surveillance, or both as fundamentally. By removing or altering the genomic and/or surveillance questions and examples from the final framework, one can use the tool to evaluate a wider subset of public health programs. The final integrated framework appears at the end of this chapter, along with examples of how to use the tool in conjunction with D&I and restorative justice. In addition, there will be a brief discussion of the application of this type of analytical tool for non-HIV situations, specifically the recent COVID-19 outbreak.

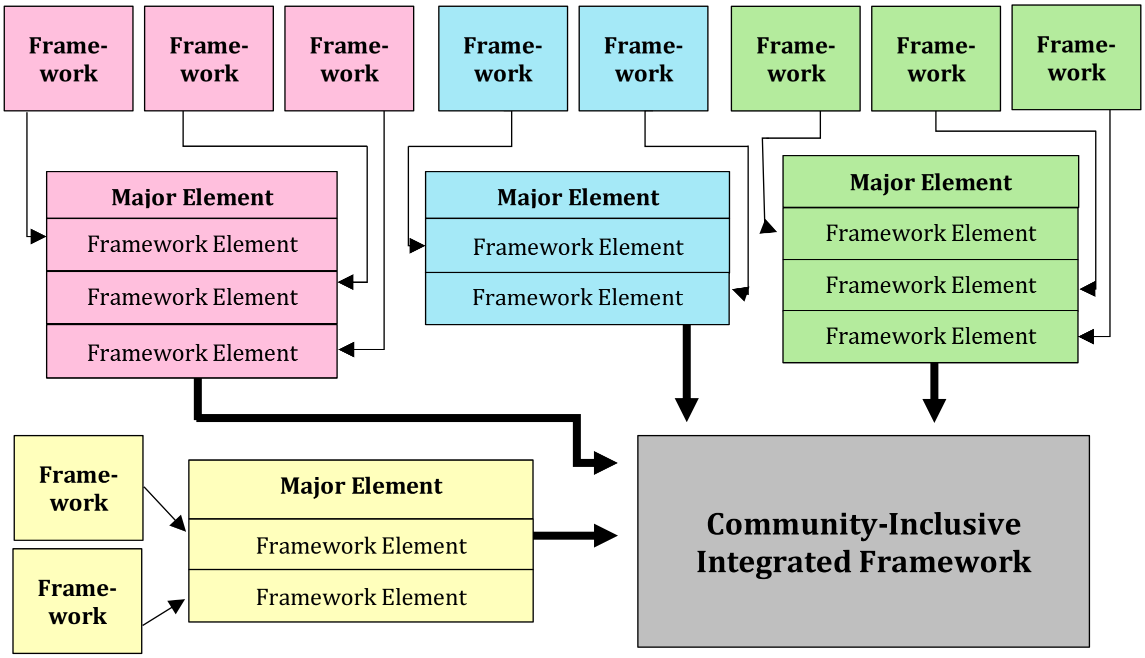

Figure 5. Representation of framework element flowchart for development of final synthesized framework

Public Health Ethics Frameworks

As discussed in earlier, bioethics and PHE tend to be seen as divergent fields, mainly due to their differing emphasis on individual autonomy versus paternalism, although there is a movement to intertwine the fields more closely. The task for public health is to develop an evaluation system that takes into account the ultimate goals of improved societal health, while incorporating citizens' concerns about their rights and autonomy. Public health ethics is faced with the additional challenge of developing an "approach specific enough to provide clear guidance yet sufficiently flexible and encompassing to adapt to global contexts" (Ortmann et al. 2016, 3).

Nowadays, many frameworks exist within the scope of PHE that can help guide interventions, educational programs, and other activities working toward the ultimate goal of overall better health.

These frameworks take different approaches to evaluating the ethical issues involved in a public health program – analytical tools, questionnaires, decision-making aides – and are aimed toward different audiences, typically professional or agency-level (Have et al. 2010, 3). Within the scope of this project, three public health ethics frameworks – two classically-cited (Kass; Childress et al.) and one more recently developed (Marckmann et al.) – have been identified. All are aimed at evaluating interventions specifically, but differ in their approaches to the evaluation. Kass presents an evaluative tool that is conceptual in nature, but allows for the practical application of a questionnaire, Childress et al. propose a more theoretical framework for assessing programs, and Marckmann et al. place a special emphasis on the importance of being able to apply the structure to concrete issues. By choosing aspects of each of these frameworks, a comprehensive set of guidelines for ethical public health interventions can emerge and become the first prong of the final integrated framework.

Nancy E. Kass – "An Ethics Framework for Public Health", 2001

The strength of Nancy E. Kass' public health ethics framework lies in the simple analytical tool she develops in the form of a questionnaire (Kass 2001, 1777). Using six straightforward questions, one can use the framework to evaluate the efficacy of a program and the balance of burdens on and benefits to the community. Importantly, she recognizes that a public health intervention should serve a further-reaching purpose than just the direct objectives of the activities themselves. She uses the example of an HIV screening program, saying that it "should have as its ultimate goal fewer incident cases of HIV, not simply that a certain proportion of individuals will agree to be tested" (Kass 2001, 1777). This emphasis on an ultimate reduction of morbidity or mortality is especially crucial to keep in mind when evaluating programs with multiple steps between intervention and end goal. The six questions posed in Kass' framework are as follows:

(1) *"What are the public health goals of the proposed program?"* This question is used to address the aforementioned further-reaching goals of a program. Kass urges public health officials to think of

how a program will work toward the ultimate goal of a reduction in morbidity or mortality, and not just to focus on the immediate objectives of the program itself. The relationship between each step of the program and future programs is also important – a research study should, of course, aim to gather findings that contribute to the field, but those findings must also be implementable in a way that will be meaningful for the improvement of health status. Kass states that there may be additional outcomes from the work – for example, increased education on the issue or coalition-building – but that those are still incidental, and not the final goal of the program. Even if the project does not have a direct impact on the final public health goal, the implementors should be able to envision how it can complement other programs that will have impact. If a program will not contribute to the greater goal of improved health status, the program should not be pursued, at least not under the label of "public health". (Kass 2001, 1778)

(2) *"How effective is the program in achieving its stated goals?"* The evaluation of the effectiveness of a program is similar to the evaluation of the goals in that the program will not be viable if its ultimate goals cannot be reached. Kass warns against falling into the assumption that methods relate to outcomes of a program and states that "it is when our assumptions seem most intuitively obvious that we are at greatest risk of neglecting to determine to what extent they are supported by real evidence" (Kass 2001, 1778). Perhaps the better question is about the determination of how much data can justify the implementation of a program, taking into consideration the fact that these interventions are more often imposed upon communities rather than sought out by them. The general rule, Kass posits, is that programs with greater risks or burdens must demonstrate stronger evidence of successful goal-achievement, and that the implementing agency must be the one to provide the proof (Kass 2001, 1779).

(3) *"What are the known or potential burdens of the program?"* This third question tackles many of the classic ethical principles – privacy and confidentiality, liberty and autonomy, and justice,

specifically. The recognition that individuals have different levels of sensitivity to privacy is key; some people may be comfortable with more data sharing than others, especially dependent upon the outcomes or benefits they potentially could experience. The risk of a breach of confidentiality, however, is generally regarded as harmful, regardless of one's comfort level and especially when dealing with disease data and stigmatized conditions. Agencies must be aware of the risks of contact tracing, as well, since individuals who are identified do not have a choice in whether they are identified or not, and therefore lose some aspect of their liberty. Other risks to liberty include the coercive nature of regulations that penalize noncompliance and the inherent suggestion that "certain ways of being…are universally valued" (Kass 2001, 1779), which can manifest as paternalism in educational and other public health interventions. Risks to justice rely on a subtle balance – if programs only target certain populations, it can be an unfair burden on those communities; if, however, there is a justification for the targeted approach, it may ease the ethical concerns. It is also important to consider the potential outcomes of targeted approaches if the same population is consistently featured in educational materials or public service announcements, as the featured community can become unfairly associated with a certain condition and feel stigma more intensely (Kass 2001, 1780).

(4) *"Can burdens be minimized? Are there alternative approaches?"* Question four takes the burdens identified in question three and asks if there are ways for the program to avoid or lessen the negative impacts that may be felt. If there are multiple approaches to an intervention and one reveals itself to be the least intrusive or risk-laden without significantly hampering the objectives of the program, Kass' system would deem moving forward with the other options unethical. When participation in a program is not optional, efforts should be made to respect individuals as much as possible through transparency and education – although the person cannot opt out, their burden may be minimized by at least being adequately informed (Kass 2001, 1780).

(5) *"Is the program implemented fairly?"* This question takes an intense look at distributive justice, asking whether a population is being targeted without justification, or if a community might experience disproportionate burdens from the program. Kass notes that "equal" distribution of resources is not necessarily the goal; in order for a program to pass this question, it must not base its distribution of resources on assumptions or arbitrary decisions, making sure to balance the felt burdens with the potential benefits (Kass 2001, 1781).

(6) *"How can the benefits and burdens of a program be fairly balanced?"* The concluding question in Kass' analytical tool asks if the potential benefits ultimately outweigh, or at least justify, the potential risks. Just as people's views of liberty and privacy are subjective, opinions on how burdensome a program feels can greatly differ. The framework places emphasis on the importance of procedural justice – society determining, through democratic process, which public health functions the government should sustain – and the discussion of why the chosen program is the best option, even when measured against other less intrusive methods. Noteworthy is the recognition that some burdens are inescapable, and that measures should be taken to give minority opinions an avenue for expression to ensure that the will of the majority is not simply imposed. Although there may be dissenters discovered through procedural justice, their presence is not enough to render a program unethical or non-pursuable; if, however, a particular subgroup wholly disagrees with the program, it must be looked into further (Kass 2001, 1781).

Review of the Framework

The format of Kass' questionnaire makes it ideal as a basis for the ethical analysis of public health interventions. Not overly complex, the tool allows public health agents to analyze a program from its inception – from goals to implementation. The questions address basic ethical principles, practical considerations, and the inevitabilities of public health work. This framework is somewhat understandable for the public, rather than just a professional audience, as community members can use these questions to assess a program once it is in place, however the public rarely has all the information necessary to weigh the benefits and burdens beforehand. These questions rely heavily on determinations made by public health agencies, even though it recognizes the variability that can be introduced by community opinion. This tool does include a question about whether there was any planning input outside of the public health professional sphere – it notes that there may be dissent or discomfort expressed in response to the implementation, and that "the involvement of communities will help identify the public health threats divergent groups face" (Kass 2001, 1782), but without including questions about community involvement in the actual analytical tool, it misses a key opportunity for public health officials to acknowledge the necessity for engagement. In combination with a more community-focused approach to evaluating public health actions, this tool can be strong, but it needs to look further outside of the agency perspective.

Table 1. *Kass, 2001*

List of Ethical Principles	
Kass, 2001	
(1) What are the public health goals of the proposed program? (2) How effective is the program in achieving its stated goals? (3) What are the known or potential burdens of the program? (4) Can burdens be minimized? Are there alternative approaches? (5) Is the program implemented fairly? (6) How can the benefits and burdens of a program be fairly balanced?	
Review of the Framework	
Pros (+)	Cons (–)
• Simple, straightforward tool format • Some mentioned of community input	• Agency-focused and directed • No direct questions about engagement

James F. Childress, et al. – "Public Health Ethics: Mapping the Terrain", 2002

James Childress and his colleagues present a framework that relies heavily on a discussion of moral principles in public health and how people developing interventions must take them into consideration during planning and implementation. Although not a fully-developed evaluative tool, the framework presents a list of moral considerations, as well as two main "practical questions" to be addressed. The authors write that "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" (Childress et al. 2002, 170) and discussion public justification in detail. Childress et al. use the example of an HIV screening program, as well – in this case to demonstrate the difference between "imposing" and "expressing" community, and the ethical issues associated with the matrix of voluntary/non-voluntary and universal/selective actions.

There is a large amount of overlap in the moral considerations that are featured in Childress et al. and Kass. Both frameworks emphasize privacy and confidentiality, distributive and procedural justice, and autonomy and liberty, among other principles; both also recognize that interventions must have the ultimate goal of reducing morbidity and mortality in society. Childress et al. take a different approach to their practical questions, however, posing two questions about the general process of PHE evaluation as opposed to the evaluation of specific programs. The authors ask how moral considerations can be transformed into concrete and specific guidelines, and what steps can be taken to resolve clashes between principles, concluding that determining the scope of a principle is crucial and that a rigid system of prioritization of values will not work, as context must be taken into account for each scenario (Childress et al. 2002, 172).

The framework presents five "justificatory conditions" – determinations of whether public health goals and projects can defensibly supersede individual rights and values – which are similar to Kass' analytical questions, albeit less detailed. First, "effectiveness" (1) asks if there is a high probability of an outcome that protects public health. Paired with the second condition, "proportionality" (2), these questions are similar to the "goals" and "effectiveness" questions in Kass and aim to ensure that the balance between risks and benefits trends toward benefits. "Necessity" (3) and "least infringement" (4) conditions also work in tandem, questioning whether a project needs to be carried out in certain ways or at all, similar to Kass' questions about minimizing and avoiding burdens. Necessity focuses on the prioritization of approaches that are "less morally troubling" (Childress et al. 2002, 173) and places the onus on the people supporting a more troubling approach to prove its necessity. Least infringement gauges whether these projects are overstepping in any way and what less invasive alternatives could result in similarly positive health effects (Childress et al. 2002, 173).

The fifth justificatory condition, "public justification" (5) and the larger umbrella of "public accountability" under which it falls, centers around the need for transparency, communication, and trust throughout the process of a public health intervention, between agencies and the public. The authors write that when a program is thought to have potential negative consequences, "public heath agents… have a responsibility, in our judgment, to explain and justify that infringement, whenever possible, to the relevant parties, including those affected by the infringement" (Childress et al. 2002, 173). Engendering trust and treating citizens with respect is a key part of the process of developing an intervention. Not only should risks and benefits be outlined and explained to the community, but there should be active input from the potentially-affected parties in the creation of the policies. A truly fair process, according to the article, involves transparent reasoning behind the decision to pursue a program, evidence that the reasonable listener would find relevant, and a procedure for stakeholder challenges to result in revisions or appeals of a policy. At the very least, information should be sought from and disclosed to the community in a transparent manner to ensure some level of accountability to the public (Childress et al. 2002, 174).

The HIV screening example given in Childress et al. serves to recognize the ethical issues that arise between voluntary versus mandatory actions, and how the universality, or lack thereof, of a public health intervention can cause moral discomfort. The authors explain that mandatory and selective programs are typically based in efficiency and utility – standards geared more toward public health goals – while voluntary and universal programs value liberty, privacy, and justice – more commonly in line with advocate and community priorities. The authors introduce the ideas of “imposing” and “expressing” community, stressing that expression is typically the most justifiable option, if all other factors remain the same. Imposing, as the name indicates, involves coercion and mandates in order to move a public health program forward; expressing, alternatively, values community trust and solidarity, provides support, and protects the public’s interest as much as possible (Childress et al. 2002, 174). Even still, there is no distinct rule to govern which voluntary, mandatory, universal, or selective programs are ethically sound and necessary. It must also be recognized that these discussions are within the context of a screening or testing scenario, and that other types of public health interventions might necessitate an approach that does not fit within the ethical ideal of community expression proposed in this framework.

Review of the Framework

Childress et al. approach PHE from a mainly philosophical perspective, as opposed to developing a practical evaluative tool, however they touch on many important questions to ask of the system as a whole. The authors direct their attention to many of the same ethical principles as Kass, recognizing the delicate balances between individual freedoms, protections, and the teleological goal of the improving public health. The strength of this framework lies in the intense focus on community involvement, trust-building, and transparency through the process of actualizing an intervention. Childress et al. make the reader acutely aware that public health without the input of those affected by the policies will never be as ethical as one with it, even if it fits all of the other justificatory conditions. They acknowledge that this inclusive nature does not necessarily mean that individual rights will be protected at all costs, but that in order for citizens to be treated as respected equals, they should at least be made aware of those risks and have a say in trying to minimize them. Content-wise, this framework is very useful, however it falls short as an actual tool for the evaluation and assessment of public health ventures. In order for these ideas to be utilized by public health agents and community members, they must be translated into something more tangible than the theoretical questions and explanations posed in this framework.

Table 2. *Childress et al., 2002*

List of Ethical Principles				
Childress et al., 2002				
(1) Effectiveness	(2) Proportionality	(3) Necessity	(4) Least Infringement	(5) Public Justification
Review of the Framework				
Pros (+) • Strong focus on community engagement • Use of a practical example • Questions the system as a whole		Cons (–) • Theoretical, philosophical • Abstract, not a fully usable analytical tool		

Georg Marckmann, et al. – "Putting Public Health Ethics Into Practice: A Systematic Framework", 2015

Marckmann et al. present their framework over a decade after Kass and Childress et al. publish, but they still state that PHE is a relatively new field and that there has yet to be a framework developed that is practice-oriented and based on a methodological approach to choosing and applying ethical norms. The authors recognize that many other attempts have been made, even recognizing the Childress et al. article as a framework that comes close to achieving this goal, but note that this new approach is *systematic*, which differentiates it from its predecessors. The strength in Marckmann et al.'s structure is that each step is extremely intentional; it is designed such that there are no gaps in the logic behind the inclusion of each element, and if there is confusion, one can trace a choice back to the original evidence and reasoning. The authors self-referentially explain the systematic development and evaluation of the framework itself before explaining how to use the framework to systematically evaluate other programs.

Marckmann et al. explain that a systematic process must be present throughout the development and application of a framework, noting that each change or deviation must be explicitly justified. They go on to explain the benefits of this detail-oriented process, stating that it is less likely that one will miss an important ethical consideration, that both public health professionals and affected individuals can evaluate whether the correct issues have been considered, and that the process itself can be a teaching device to further the ethical knowledge of students and professionals. This framework relies on a coherentist model of justification, as, it notes, biomedical ethics does with its four main principles of beneficence, nonmaleficence, respect for persons, and justice. As opposed to consequentialist or deontological methods which allow for considerable variation in ethical analyses of a situation, the coherentist model relies on morals that people hold in their everyday lives as a basis that can then be revised or altered once they are considered for inclusion in the framework. The authors use this "reflective equilibrium" that results to choose the ethical norms that they include in the subsequent framework (Marckmann et al. 2015, 2).

Marckmann et al. insist that two factors are fundamental for a successful framework: 1) a basis in explicit ethical justification for moral claims, and 2) practical guidance for those involved in public health, reached through a methodological process of relating ethical principles to programs and policies. The authors achieve these two requirements by developing a set of five ethical criteria, seven procedural conditions, and a six-step methodological approach to implementation (Marckmann et al. 2015, 2). The first two ethical criteria – "expected health benefits for the population" (1) and "potential harms and burdens" (2) – are evaluated through similar factors, namely measuring the scope, magnitude, and likelihood of expected endpoints, assessing the evidence for these measures, and comparing them to alternative approaches. Both of these criteria, similarly to Kass' questions about goals and balancing and Childress et al.'s effectiveness and proportionality considerations, aim to ensure that the program results in a net-benefit outcome rather than net-risk. As for net-neutral alternatives, the authors do not seem to accept these as the most ethically acceptable, saying that the "intervention-specific, health-related benefit should be higher than the potential benefits of alternative interventions, thereby providing an *additional* benefit for the target population" (Marckmann et al. 2015, 3). In terms of exploration of burdens, they stress the importance of exploring not only direct but also indirect burdens that populations might experience. Marckmann et al.'s fifth criterion – "expected effectiveness" (5) – has a similar purpose to the above considerations in determining the balance of benefit and risk, but examines *efficiency* as opposed to effectiveness. Whereas the first two criteria refer to sociological and health-related outcomes, the fifth criterion questions the cost-benefit ratio in terms of public resources in a bid to determine which programs are ethical *and* practically feasible (Marckmann et al. 2015, 4).

The remaining normative criteria – impact on autonomy (3) and impact on equity (4) – assess how individuals experience the programs in question and the distribution of the program's effects, both positive and negative. The authors write that a crucial part of respecting autonomy includes attempting to "improve the health literacy and competence of the target population" (Marckmann et al. 2015, 4), which can be achieved in one part through the dissemination of accessible information and materials. This information should recount a description of the intervention, including potential benefits and risks, and should be made available at appropriate skill-levels, through multiple channels for the most universal access possible. Also important is the idea that informed consent and voluntary participation are the most respectful to autonomy; the authors do, however, recognize that this is not possible in every intervention and explain that "if individual informed consent to participation is not possible… there should be a democratically legitimate public decision process about the implementation of the PH intervention" (Marckmann et al. 2015, 4). When an intervention involves coercion or manipulative actions, special justification is necessary for choosing these approaches over alternatives; within this justification, it is not necessarily sufficient to demonstrate that a less restrictive approach would cause a potential health benefit to be sacrificed. This criterion echoes some of the sentiments in Kass' "minimized or avoided" question and Childress et al.'s "necessity" and "least infringement", but goes further in that it suggests positive actions such as the focus on health literacy that may offset some of the negative effects of the loss of autonomy and choice (Marckmann et al. 2015, 4).

Marckmann et al.'s discussion of the impact on equity is akin to Kass' question of fair implementation, questioning the distribution of benefits and risks, and taking it further to analyze the impact on health disparities and the needs for compensation. This framework reiterates the importance of access, emphasizing that the intervention needs to be available for anyone who may benefit. Targeted interventions require special attention; the article states that interventions should seek to reduce existing health disparities, however if the program is aimed at a certain population, the planners must be cognizant of the possibility of increased or continued stigmatization stemming from the population-specific efforts. Another concept unique to this framework is the topic of compensation for those burdened on behalf of others' health – the authors give the example of someone who is placed under quarantine being entitled to psychological support after the experience. These two impact criteria address some aspects of community engagement within public health programs that have not been addressed in the previous two frameworks (Marckmann et al. 2015, 4).

In order for these norms to be utilized correctly, the authors lay out seven conditions under which they believe a fair decision process can be carried out. These conditions are straightforward and allow for the assessment of interventions by public health officials and affected populations in a systematic and regulated environment. Marckmann et al. also state that, although not their primary intention, this fair decision process can and should be utilized for political decision-making (Marckmann et al. 2015, 6). The framework calls for the following conditions in order to "'[hold] decision makers accountable for the reasonableness' of their decisions" (Marckmann et al. 2015, 4):

- *Transparency:* The decision-making process and the underlying ethical norms should be public and clear.
- *Consistency:* The equal treatment of various communities stems from the application of the same criteria across different interventions.

- *Justification:* Decision-making should be supported by relevant reasoning and systematically selected criteria.
- *Participation:* Those who may be affected by the intervention should be entitled to give input on the development and implementation of the program.
- *Managing conflicts of interest:* Existing conflicts of interest between stakeholders should be minimized as much as possible.
- *Openness for revision:* Programs should not be inflexible to change; should certain aspects be found to have been neglected or new evidence arise, there should be an openness to alteration.
- *Regulation:* The implementation of and adherence to this fair decision process should be guaranteed through legal or voluntary regulation.

The final step of this detailed, methodological approach to PHE is the six-step guide for the "ethical evaluation of a given PH intervention in the different phases of its development, implementation, and evaluation" (Marckmann et al. 2015, 5). These steps, again, are straightforward and some may seem obvious, but when analyzing the ethics of a program, it is not uncommon for some aspects to be overlooked. The first step is to give a thorough description of the intervention, identifying alternative approaches and acknowledging the context in which it will take place. Next, the evaluators are to review the ethical criteria being used to assess the intervention, clarifying the practical relevance of each and questioning whether any of the criteria need to be further defined, and reaching as much consensus on points of disagreement as possible. They then use the established criteria to scrutinize the intervention. Steps four and five examine the findings – an overall evaluation of the program is developed from the individual criterion appraisals, and conflicts between norms with their assigned weights are explicitly laid out and either justified or revised. From this synthesis, recommendations are created that strongly or weakly advocate or discourage the implementation of the program; these recommendations should include ways to maximize positive effects and minimize social, health, and resource costs. The final phase of this practical evaluation is to follow up with the intervention after it is executed. Monitoring should be done to determine the adequacy of the ethical evaluation, if new issues have appeared, whether the given recommendations are being followed, and if they are “effective in assuring an ethically appropriate execution of the PH program” (Marckmann et al. 2015, 6).

Review of the Framework

Marckmann et al.’s framework is extremely logical and procedural – it takes the reader through the entire process of utilizing their framework, from the development of the structure itself to the guidance for utilization. The article introduces concepts that are untouched in the other classic frameworks, recognizing the need to evaluate health disparities, practical resources, and reparation for those who suffer the burdens of public health. Although they do state that the framework can be used by affected populations to evaluate the ethicality of an intervention, the authors do not go into nearly as much depth as Childress et al. on the importance of accountability to the public. Some of the same concepts – accessible information, community input in planning and implementation, and transparency – are present in the Marckmann et al. framework, but the “justification” they speak of is more of a systematic demonstration of evidence and reasoning than one based in ethics. Nevertheless, this guidance contains useful elements that can help public health agents and community members think logically through the effects of an intervention and use these tools to identify and revise points of conflict.

Table 3. *Marckmann et al., 2015*

List of Ethical Principles	
Marckmann et al., 2015	
(1) What are the expected health benefits of the intervention for the target population? (2) What are the potential burdens and harms of the intervention? (3) How does the intervention affect the autonomy of the individuals in the target population? (4) Impact on equity: how are benefits and burden distributed? (5) Expected efficiency: what are the costs and opportunity costs of the intervention?	
Review of the Framework	
Pros (+)	Cons (–)
• Systematic and logic-based • Intended to be used by a wide audience • Offers practical steps toward implementation	• Limited community justification principles • Long, potentially overcomplicated

These three frameworks approach the idea of public health ethical evaluation very differently, but there is a significant amount of overlap in the ethical principles they identify as important. **Table 4** demonstrates the alignment of each framework's ethical norm choices. By combining elements of these analytical, philosophical, and practical methods, it is possible to create a strong and modern PHE framework that acknowledges the necessity for community involvement in the development of interventions and clear guidelines for both public health agents and the community to use to break down complex ethical issues.

Table 4. *Alignment of ethical norms in identified public health frameworks*

Kass	Childress et al.	Marckmann et al.
(1) What are the program's goals?	(1) Effectiveness (2) Proportionality	(1) What are the expected health benefits of the intervention for the target population?
(2) How effective is the program?	(1) Effectiveness (2) Proportionality	––
(3) What is the potential burden?	––	(2) What are the potential burdens and harms of the intervention?
(4) Can the burden be minimized or avoided?	(3) Necessity (4) Least Infringement	(3) How does the intervention affect the autonomy of the individuals in the target population?

Kass	Childress et al.	Marckmann et al.
(5) Is the program implemented fairly?	––	(4) Impact on equity: how are benefits and burdens distributed?
(6) How do we balance the burdens and benefits?	(2) Proportionality	(2) What are the potential burdens and harms of the intervention?
––	(5) Public Justification	––
––	––	(5) Expected efficiency: what are the costs and opportunity costs of the intervention?

Community Engagement Frameworks

Despite the evidence of the importance of community engagement and the loud demands for its implementation, there is still no conclusive, universal framework upon which public health interventions base their engagement efforts. Systemic and practical barriers to achieving meaningful community engagement still exist and though researchers have attempted to study the underlying mechanisms of community engagement, there is limited information of what influences the outcomes of these efforts (De Weger et al. 2018, 2). Some authors believe that the availability of different approaches to engagement is beneficial and that engagement should be tailored to the specific intervention and/or community; others have developed a set of guidelines to evaluate community engagement efforts that should be generally applicable to the majority of scenarios. In order to demonstrate these differing approaches, two articles have been identified – the former approach, a framework developed out of a systematic review of community engagement literature (Brunton et al.), and the latter approach, guidelines stemming from a Rapid Realist Review of barriers and enablers (De Weger et al.). Elements from both of these documents will be included in the final integrated framework.

Brunton et al. – "Narratives of community engagement: a systematic review-derived conceptual framework for public health interventions", 2017

Brunton et al.'s article takes the approach of evaluating hundreds of articles in a systematic review to develop guidelines for community engagement and to outline potential models for effective engagement based on the literature. Before explaining the methodology behind their systematic review, the authors note that there is "inconsistency in the terms used to describe [community engagement], the meanings ascribed to it, and the rationales underpinning the stated 'need' for it" (Brunton et al. 2017, 2) and that their study aims to answer questions about the variety of approaches to community engagement, as well as mechanisms through which the public is brought into the conversation.

An important part of the coding and characterization that these authors completed is the attention given to the definitions and terms used throughout the studies, specifically the terms used to describe the affected groups (community versus population) and the types of health needs (felt, expressed, comparative, or normative). Community can manifest from various shared characteristics; a group may share an identifier (e.g. age or ethnicity), an experience (e.g. graduating college), or socioeconomic and geographic similarities. Regardless of the trait that binds them, the authors find that the groups are more likely to self-identify as a "community", whereas outsiders more often describe the group as "population". While the words may seem interchangeable (and they are often used as such), Brunton et al. call attention to the "semantic differences in how communities were perceived" (Brunton et al. 2017, 5). This discovery is an indication that usually culturally-sensitive terminology might help bridge some of the gap between agencies and the public.

The other important definition refers to the health need being addressed through an intervention; this article breaks health needs into four types that vary by the way that the need is revealed. When communities identify the need, it is "felt", and represents the most autonomous classification – the authors note that throughout the studies they survey, only 25% of them involved felt needs being addressed (Brunton et al. 2017, 6). “Expressed” need is one step removed, coming from observations of the community’s use of services, and “comparative” need one step further, using a similar community’s service use patterns to predict the need of the original group. The most imposing definition of need is “normative”, typically determined by experts and agents outside of the community through the comparison of the community’s service use and living conditions to social standards. In advocacy work, this difference is often expressed in the separation of grassroots and grasstops advocacy – the former involves work directly with individuals being affected, learning their concerns and including them in the efforts; the latter focuses more on reaching out to experts, politicians, and agencies to fight for causes that may or may not have been generated from direct conversation with the affected group. When combined, the community-level approach and the agency-level approach can be very effective (Fuld 2017).

The framework then introduces the various concepts that recur throughout the papers, grouping them together into subcategories. One category, for example, asks how much the community is involved with the design and delivery of the intervention, outlining a hierarchical spectrum of engagement from “receiving information” to “control”. The authors find that some studies had community engagement “embedded” in their plan, meaning that they intended to involve public input from the start, whereas others did not predetermine that engagement would be involved (Brunton et al. 2017, 7). Agents are motivated to include community engagement in a planning effort for multiple reasons, including ethical and democratic values, leveraging resources, and to strengthen political alliances (Brunton et al. 2017, 6). Brunton et al. also analyze the impacts of engagement, finding that there are direct (those who are actively engaged in the activities) and indirect beneficiaries (the larger community, those who administer the activities, researchers, governments, etc.). For those who do directly engage, there are many motivations, including economic incentives, improved health literacy and other skills, a sense of altruism, and wanting to benefit one’s community. They do also recognize that there can be harms that result from community engagement including disillusionment with the process, attrition and loss of motivation, and cost overrun (Brunton et al. 2017, 8).

In addition to the overlap in concepts and approaches to community engagement, the authors highlight an important contextual pattern that appears throughout the papers – the attribution of utilitarianism or social justice perspectives (discussed in "Utilitarianism vs. Social Justice Perspective"). In utilitarianism, community engagement is a tool that can either improve or worsen the measurable outcomes and its inclusion will be decided depending on its impact. Because engagement methods are seen as one piece of the process, interventions created with this perspective may be formulated before any community involvement, inspired by an expert-identified need, with community members becoming involved in the priority setting and delivery of the program instead of the design (Brunton et al. 2017, 8). The social justice perspective is quite the opposite, purporting that community engagement should not just be a means to an end, but an interactive process that benefits the community further than just the outcomes of the intervention. These approaches, with motives to empower community members, affect systemic structures, and hold agency-level actors accountable, are based on felt needs. Also referred to as "community development" efforts, this type of engagement "respects community-defined priorities, recognizes community assets as well as problems, gives priority to capacity-building and is a key mechanism for enabling effective community participation and empowerment" (Brunton et al. 2017, 9). In some social justice models, it is believed that any community engagement efforts without some delegation of power to the individuals is not true participation and is instead a form of "tokenism" where community voices are allowed and heard but there is no sense that their opinions will actually be taken into account (Arnstein 1969, 217).

Brunton et al. emphasize that, since authors are writing motivated by these separate schools of thought, there will be varying definitions and uses of the term "community engagement" throughout the literature, muddying the understanding of the term and "[allowing] it to be analysed as a political symbol capable of being simultaneously employed by a variety of actors to advance conflicting goals” (Brunton et al. 2017, 9). Amongst these differing uses of the term there exist papers that call for a bridging of the two main school of thought – community engagement that empowers the people but also works towards quantifiable goals. Those who attempt to use both perspectives say that structural issues, over which individuals have little control, are the root cause of poorer health in disadvantaged communities, so a transfer of power to the individual would both empower the person and also be effective in addressing health concerns. Others call attention to the importance of changing intermediate social outcomes to improve health effectively – a change that can only be made through the ceding of some power to the individuals themselves, with full community control yielding the highest gains (Brunton et al. 2017, 9).

The framework concludes with three proposed models of community engagement, in increasing order of community input. The first, the “classic” peer or lay-led intervention, does not involve community members in the design of the program and focuses on “communicative and implementation competence rather than empowerment” (Brunton et al. 2017, 10). This method falls into the utilitarian perspective and tackles a comparative or normative need. Engagement activities led by laypeople instead of professionals are thought to be more empathetic and accessible, and have been shown to be most cost-effective; those who administer the activities also benefit significantly. The second model, involving varying degrees of collaboration between community and health services, is a hybrid between utilitarianism and social justice views, exhibiting a range of involvement from community members. The spectrum of involvement – information exchange, consultation, co-production, and control – “focus[es] on community empowerment becoming more explicit and having greater priority to the right of the continuum where community development approaches are located” (Brunton et al. 2017, 10). The health need is still typically identified externally, but some actions are taken to gain community input about what the group may need or prefer. The third and most social justice-focused model is empowerment-based interventions, in which community-identified felt needs are addressed and the affected group participates in the planning of the program. In these approaches, empowerment is the goal of engagement but also acts as a mediator, since empowerment is thought to have other positive effects for communities and individuals (Brunton et al. 2017, 10).

Review of the Framework

Brunton et al. develop a conceptual framework that offers different approaches depending on the public health context, instead of formulating one succinct set of guidelines. The authors state that their takeaway from the literature is to "encourage a fit-for-purpose approach to designing community engagement interventions because they embrace diversity and promote thinking about dimensions of difference across health definitions, motivations, participation models, conditions, actions, and impacts" (Brunton et al. 2017, 10). Instead of attempting to decipher a universal definition and approach to community engagement, the authors suggest breaking down engagement interventions into their key characteristics and underlying models in order to figure out what actions work best for different types of scenarios. The strength of Brunton et al.'s framework is its adaptability to many types of public health programs – and other areas such as education, environmental work, and policing – and its derivation from evidence-based literature. It brings to light definitional differences in community engagement terminology, as well recognizing patterns within the literature that show many approaches to engagement. As it is a conceptual framework, one of its downfalls is that it does not offer a usable analytic tool for evaluating engagement efforts, instead giving users categories into which they can try to fit their actions. The framework would be more useful, especially for community members, with sample questions or elements for each category that serve at least as a basis for assessment.

Table 5. *Brunton et al., 2017*

Main Ideas	
Brunton et al., 2017	
Definitions: • Community = internal definition of a subgroup • Population = external definition of a subgroup • Felt need = identified by the community • Expressed need = observed from community use of services • Comparative need = based on observations of similar groups • Normative need = based on a comparison of community’s service use to social standards	Intervention Models: (1) Peer or lay-led intervention (2) Varying degrees of collaboration (3) Empower-based intervention
Review of the Framework	
Pros (+) • Adaptable to many types of intervention • Introduces practical engagement models • Emphasis on terminology and perspectives • Derived from evidence-based literature	Cons (–) • Not a usable analytical tool format • Not standardized or concrete • Would benefit from examples or sample questions as a basis for assessment

De Weger et al. – “Achieving successful community engagement: a rapid realist review”, 2018

De Weger et al.’s approach to creating a framework for meaningful community engagement is similar to Brunton et al.’s in that it reviews the existing body of literature and distills the information into subcategories of similarities. The outcomes of these two reviews differ, however, in that De Weger et al. decide to create a distinct set of guidelines that direct the development of community engagement interventions instead of providing a variety of possible and loosely defined approaches. Within these action-oriented guidelines there is room for variation depending on the program being assessed, but the principles are strict in demanding that the organization take specific, meaningful actions. They stress the importance not only of involve community members, but of ensuring a mutually beneficial experience for the professionals and citizens involved so that engagement efforts are actually acted upon instead of implemented and then pushed aside by frustrated professionals. De Weger et al. state that there have been previous studies that examine why community engagement interventions do not result in meaningful participation – which is a key element in understanding engagement as a whole – but that these studies do not take the next step to provide information on how to create successful engagement procedures that defy these barriers, which is what these authors aim to provide.

In order to achieve this goal, De Weger et al. set out to create action-guided principles by examining the mechanisms and contextual factors affecting them. The mechanisms – motivations or triggers for individuals to join or refrain from engagement activities – are often expressed as "cognitive, emotional or behavioural responses to intervention resources and strategies" (De Weger et al. 2018, 4). Context refers to the systemic structures and cultural norms in place for the community in which the intervention will take place. Using a context-mechanism-outcome (CMO) model, the authors can tell the story of what factors affected the ultimate results of community engagement efforts, allowing them to report out the positive or negative influences and seek patterns that eventually become their guiding principles (De Weger et al. 2018, 4). They note, for example, that if constraining contextual factors – populations with deteriorating health, groups that have low levels of readiness to participate, etc. – are acknowledged, there is still the chance for fruitful community engagement, but if they are ignored, there is a high likelihood of the community resisting the efforts (De Weger et al. 2018, 6). The authors also utilize a panel of experts in health care, inequities, and public health, as well as citizens and advocates to give input on the principles and gather suggestions for steps toward successful community engagement (De Weger et al. 2018, 2). The action-guided principles the authors develop are as follows:

(1) *Ensure staff provide supportive and facilitative leadership to citizens based on transparency.* To begin, the authors explain that all work should be done with a basis of transparency. There is a fine balance to strike as a professional administering a community engagement intervention – the literature dictates that participants need support and encouragement from the agency-level actors, but not so much instruction that it feels controlling or restraining. Professionals should make sure that everyone is clear on their roles and the expectations of the activities from the

start. The panel suggests that there be a professional whose purpose is to be the community contact throughout the project in order to demonstrate consistency (De Weger et al. 2018, 6).

(2) *Foster a safe and trusting environment enabling citizens to provide input.* In addition to providing support, it is important to deliver "safe spaces" for both professionals and community members to share their ideas and opinions. Cultural, practical, or readiness barriers can often keep community members from participating or speaking up, so extra steps should be taken, especially for classically marginalized groups, to ensure these barriers are reduced (De Weger et al. 2018, 6). It is also important to recognize that communities will not always share the same views or be comprised of similar demographics – different forums should be provided for different subgroups if it will allow for more candid discussions, and spaces should be created to facilitate mediation between varying opinions (De Weger et al. 2018, 10).

(3) *Ensure citizens' early involvement.* As with the previous guidelines, starting off the intervention correctly is key. The authors found that involving the public as soon as possible is important to building trust and participation early, although they note that it is also important to talk to the community about when they think it is appropriate to be called in (De Weger et al. 2018, 10). The panel also noted that sometimes it is hard to make forward progress if there are no concrete objectives already, so professionals should make sure that there is something meaningful to discuss when they bring in community members, as well as helping individuals turn their abstract ideas into tangible work plans (De Weger et al. 2018, 13). Learning these community-identified needs early in the planning process allows agencies to make sure their objectives can align as closely as possible with community desires. If affected groups are not brought into the process early – for example, if they are called upon once agencies have already determined goals and allocated resources – the individuals can feel tokenized, useless, disempowered, and unmotivated to continue engaging (De Weger et al. 2018, 12).

(4) *Share decision-making and governance control with citizens.* Once community members have been integrated, it is imperative that they take active roles and are given some level of control. Agencies should encourage participants to take on leadership roles and should help direct them toward where they can give their input – many community members lack information about which agencies to approach with suggestions, which acts as a barrier to their participation. De Weger et al. reveal that organizations often invite community members to contribute but then refuse to cede any control, even taking steps to assert their power by dominating the conversation, discussing bureaucratic and complex processes, or cancelling meetings with last-minute notice. The authors suggest, instead, that allowing communities to choose their own representatives and shape the roles they play in the discussion are ways for individuals to feel more equal (De Weger et al. 2018, 13).

(5) *Acknowledge and address citizens' experiences of power imbalances between citizens and professionals.* Similar to the principle (4), De Weger et al. emphasize the impact of recognizing the power disparities between professionals and community members, and how this authority gap has affected community members' lives and experiences of community engagement. Acknowledging the fact that organizations have a propensity to favor professional-led and designed interventions can help work toward shared power and responsibility, especially if professionals and the public treat each other as respected equals. One issue that the authors identified from some studies is the contradictory expectations that agency-level workers have of citizens, which contributes to the "us vs. them" narrative; for example, one study reported that agency-level experts felt that citizens should "[have] professional-level skills, while at the same time being a 'genuine' citizen in the local area" (De Weger et al. 2018, 13).

(6) *Invest in citizens who feel they lack the skills and confidence to engage.* Professionals and agencies can contribute to the empowerment and equal representation of community members by

offering educational opportunities. By increasing health literacy and leadership skills, individuals can feel more prepared and confident during engagement activities and can go on to facilitate peer-led learning opportunities of their own. The panel suggests creating a “buddy system” whereby community members who are typically more involved or easily reached can use their pre-existing relationships to involve less involved individuals and empower their voices. One constraining contextual factor is the lack of strong, trusting relationships between agencies and community members or community liaisons – the authors note that it is crucial to start developing these relationships early on, even before a planned intervention, so that engaging and reaching out citizens is not as much of a struggle (De Weger et al. 2018, 14).

(7) *Create quick and tangible wins.* The need for instant gratification is engrained in human psychology – the “pleasure principle” drives people to want to fulfill their needs and desires (Patel 2014). While in some cases people are encouraged to fight the need for immediate fulfillment, the authors suggest that these “quick wins” can be very helpful for community engagement. Especially for groups that have had negative or no-result community engagement experiences previously, positive results early on can help maintain motivation and inspire others to join the experience. De Weger et al. report that without these wins, citizens may feel discouraged and disempowered, leading to attrition or lack of future participation. The panel, however, counters these findings by saying that it is sometimes challenging to keep individuals engaged once they have experienced the instant successes, but that consistent notification of how community input is used and to what parts of a project it contributes may help in retaining participation (De Weger et al. 2018, 14).

(8) *Take into account both citizens’ and organisations’ motivations.* De Weger et al. state that motivations should be transparent and respected. Agencies should encourage citizens to participate in projects that support their own interests – a personal connection can increase

> loyalty and motivation to a project and reduce the number of community members dropping out of activities. Organizations must be transparent about their motivations and problems that the programs are encountering so that trust is built and individuals do not feel disempowered; if this type of sharing occurs, long-term collaborative relationships can flourish. It is also noted that programs with a more local focus – even down to the neighborhood level – may have more fervent involvement than those with a wider focus, so promoting projects to the right groups can make a difference in meaningful participation (De Weger et al. 2018, 15).

De Weger et al. present a streamlined set of practical guidelines for implementing community engagement practices that empower communities and result in meaningful input for agencies. The most common pattern that the authors identified was the need to acknowledge and confront power imbalances, working toward "organisational processes [that] are adapted to ensure they are inclusive, accessible and supportive of citizens" (De Weger et al. 2018, 15). Paired with initial efforts to build relationships and early involvement of community, this recognition should ease some of the tension between agencies and individuals. What may put further strain on these relationships, however, are funding and resource concerns from organizations, and feelings of inequality and trepidation from the public. The authors also write that there is a distinct lack of studies that address how disadvantaged and marginalized groups participate in community engagement, which is a space for investigation in the field (De Weger et al. 2018, 16).

Review of the Framework

Although this framework presents a set of principles that are easy to apply to real-world projects, it is aimed primarily at professionals and not community members. The public could benefit from an accompanying version of the framework that addresses what they can do and expect in order to create successful and respectful engagement environments for themselves. It is beneficial and commendable, however, that the authors involved community members and representatives to give feedback and perspective on the proposed principles. Overall, the piece is a useable analytical tool with an effective underlying procedure (CMO configuration) that will be useful in the formation of the final integrated framework.

Table 6. *De Weger et al., 2018*

List of Action-Guided Principles

De Weger et al., 2018

(1) Ensure staff provide supportive and facilitative leadership to citizens based on transparency.
(2) Foster a safe and trusting environment enabling citizens to provide input.
(3) Ensure citizens' early involvement.
(4) Share decision-making and governance control with citizens.
(5) Acknowledge and address citizens' experiences of power imbalances between citizens and professionals.
(6) Invest in citizens who feel they lack the skills and confidence to engage.
(7) Create quick and tangible wins.
(8) Take into account both citizens' and organisations' motivations.

Review of the Framework

Pros (+)	Cons (–)
• Concrete, actionable tasks • Practical, statement based guidelines • Guidelines shaped by community input	• Very agency-focused • Would benefit from an accompanying community-focused set of guidelines

Surveillance Frameworks

Surveillance has been a crucial part of public health efforts for a long time and continues to evolve with the technology that supports it. However surveillance – although useful for monitoring, estimating populations' health status, and targeting resources – is not without its ethical concerns. The implementation and use of surveillance systems consist of three parts: development, data collection and analysis, and data use, each comprised of ethically-charged sub-steps within them (Petrini and Ricciardi 2015, 270). The field of public health surveillance exemplifies the tension between bioethics and PHE, as surveillance techniques often seem to minimize the importance of autonomy, consent, and privacy. It is possible, however, to recognize that although the practical approaches may differ, the goals of achieving better health and the value of "respect for persons" is an underlying principle in both fields (Petrini 2012, 1).

In order to employ public health surveillance effectively while minimizing individual rights violations, structures and guidelines need to be put in place to address these issues. One author writes that "often, the devil is in the complex detail of how surveillance occurs and not on the broad principle of whether surveillance should occur" (Pounder 2008, 14). The WHO names "the common good, solidarity, accountability, trust and balancing of individual rights with collective interests" (WHO 2017) as the guiding principles for surveillance ethics, and produced a comprehensive set of guidelines for ethical public health surveillance. Other research groups have taken on this challenge, as well, and have created more succinct, digestible frameworks – often containing significant overlap with the WHO recommendations – to recognize and address the complex issues of tracking, data sharing, and lack of consent, among others. Three such articles have been identified to represent surveillance frameworks that take different approaches – one with a special focus placed on conditions that justify lack of informed consent (Klingler et al.); the next, a set of principles assessing practical privacy protection in surveillance policy (Pounder); and last, eleven principles to guide the assessment of surveillance programs based on the grouping of ethical issues (Désy, Filiatrault, and Laporte).

Klingler et al. – "Ethical issues in public health surveillance: a systematic qualitative review", 2017

Klingler et al. have two missions to fulfill with their article: to carry out a systematic qualitative review that fills a gap in the field of surveillance ethics research, and to help inform the aforementioned WHO guidelines, which were released a few months after this review's publish date. The authors make it clear that this piece only serves to report out a "comprehensive overview of ethical issues in public health surveillance" (Klingler et al. 2017, 2) and not evaluate the ideas that are mentioned, however they hope that the descriptions provided can help agents be more conscious of possible issues when they design and implement surveillance programs in the future. Through a methodical search and narrowing process, Klingler et al. identify 83 articles to analyze, looking for unique ethical issues – of which they find 86 – to group into categories based on each "phase of the surveillance life-cycle" (Klingler et al. 2017, 4). In addition to the four categories they distinguish, the authors identify conditions that the various articles state may justify a lack of informed consent in public health surveillance activities.

The first category of issues stem from background conditions, specifically the choice of framework used and the risk of unfulfilled pre-conditions for a successful surveillance program. These include lacking guidance or having a misguided framework that does not address ethical issues appropriately (e.g. using clinical ethics standards rather than PHE), research barriers (e.g. outdated technology, lack of interdisciplinary input), and not having strong enough evidence to support a proposed surveillance method. Errors made in this early step of the planning process can lead a team to make oversights or leave important ethical issues unaddressed (Klingler et al. 2017, 6). Next, numerous design and implementation issues are called into question. These fall into four subcategories: choosing a type of surveillance system, designing that chosen system, implementation and facilitation risks, and issues specific to a certain type of intervention. The first subcategory deals with issues such as issues with priority setting – tackling emerging health threats versus existing ones, efficiency versus thoroughness, and extensive data collection versus limited data collection to ensure minimum infringement and privacy risk, for example (Klingler et al. 2017, 6). The second tackles the risks of making poor choices – choosing surveillance over other uses for funding and resources, helping developed areas or those in need, not including community members in the process, and putting unsustainable or unethical systems in place (Klingler et al. 2017, 6). Once the system is designed, implementation issues arise, mainly relating to legal and ethical complications, barriers to success, and unfair distribution of burdens from the intervention. The last set of issues are specific to the type of intervention – they mention genetic testing, real-time surveillance, and vaccine safety programs in the midst of a pandemic – and refer mostly to misdirected focus and prioritization (Klingler et al. 2017, 7).

The "data collection and analysis" section, too, falls into four subcategories: protection of autonomy and privacy, inadequate outcomes and findings from the data, insufficient consideration of vulnerable subgroups, and intervention-specific issues. Informed consent is a major focus of the autonomy issues – finding a balance between gathering informed consent while still achieving public health goals and risks associated with misinformation about how one's data is used. Intentional and unintentional privacy and confidentiality breaches also play a part, with concerns about data being obtained by illegitimate authorities or technology malfunctions revealing confidential information. The authors identify concerns about collecting manipulated or incorrect data, not being able to complete a thorough enough analysis, and health professionals displaying distrust of the system and therefore withholding important information (Klingler et al. 2017, 7). Issues with vulnerable populations are related to inadequate representation of various racial, socioeconomic, and citizenship status groups in the data, as well as the risk of increasing stigma from targeted interventions. Lastly, the authors acknowledge issues with verbal data collection and anonymous and unlinked blood sampling – the former involves risks of emotional distress or unreliable data collection; the latter recognizes the inability to perform follow up for unidentified individuals (Klingler et al. 2017, 8).

Finally, once the data has been collected and analyzed, concerns about data reporting and use are important. Similar to the risks of violating autonomy and privacy, there are worries about the insufficient protection of privacy and confidentiality when disseminating data. These concerns, again, look at the unintentional or intentional breaches of data sets, including the selling of data to commercial agents, retraceable data, and incorrectly trained agents handling data. The authors also bring up the tensions between sharing data with as few people as possible and the gains that can be achieved through input from outside actors. The next group of identified issues pertain to the risks to the freedom of individuals who are determined to be "unhealthy". Half of these problems relate to coercive or punitive interventions that contribute to the health of others or the individual; the other half relate to psychosocial or physical harms the person might experience, including health care access and economic issues, stigma or discrimination, and mental distress.

The final piece of the data use section recognizes the harms that can come from the collection of data that goes unused or unsatisfactorily used. Some of these concerns are politically charged, including the misrepresentation of data for political gain, regulations forbidding data-sharing across agencies, and public health goals being overlooked due to other political interests. Others talk about how information might not be disseminated in a timely manner or in full, and that there can be miscommunications about the level of alarm the public should experience (Klingler et al. 2017, 8). Although it is not discussed in the article, it is important note that public health agencies have both a governmental and ethical duty to use data for the betterment of public health. It is often proposed that the collection of data without accompanying analysis and dissemination of findings is riskier for the affected individuals, since they only experience the potential risks of data collection and not the potential benefits of health-improving findings.

Klingler et al. place specific emphasis on the exploration of conditions found in the literature for the justification of foregoing informed consent in the name of public health. They group the 20 conditions identified into eight categories, the first five of which align with Childress et al.'s justificatory conditions and include some similarly coded requirements. Klingler et al.'s effectiveness (1) condition requires that collected data is actually put to use, while necessity (2) talks about infeasible and bias-inducing informed consent procedures and the lack of other options. The least infringement (3) condition brings up the possibility of opting out, making sure that affected individuals receive relevant information about surveillance, and that the minimum amount of data necessary is collected. Proportionality (4) contains the most robust set of standards, including minimal or minimized risks associated with collection, implementation of informed consent requiring abundant resources or setting an unwanted precedent for other surveillance activities, and probable and substantial benefits gained, or harms avoided, through the activities (Klingler et al. 2017, 9).

While Childress et al. spend a lot of time explaining the public justification and engagement (5) section of their framework, Klingler et al. identify but one element: that the community or affected groups were a part of the decision to forgo informed consent, ostensibly giving community consent up front. The first of the three additional categories that Klingler et al. include is vulnerability (6), in which they describe collecting data in order to protect children's health and purposely not collecting data from children; although the examples drawn from the literature only reference minors, it can likely be extrapolated that other vulnerable populations should be given special considerations, as well, depending on the use for the surveillance data. Legitimacy (7) tackles some of these issues by recognizing the importance of "only legitimate entities trusted by the public" (Klingler et al. 2017, 9) being able to collect data. Lastly, the authors note that surveillance is meant to prevent health risks for others, not only the people undergoing the surveillance, in a category entitled "harm principles/unreasonable exercise requirement" (Klingler et al. 2017, 9).

Review of the Framework

Klingler et al. offer a useful look into many of the ethical issues that one can encounter throughout the brainstorming, planning, implementation, and analysis of a surveillance program. Their categorizations help bring to light the multiple ways in which surveillance can be useful but problematic, which is, in itself, a useful practice for anyone putting together a surveillance system. Unfortunately, this set of guidelines does not talk about community input much, which may indicate that there is a lack of surveillance literature that studies the impact of community input. It is not entirely surprising, however, that there is less community engagement mentioned in programs that are implemented or carried out unbeknownst to those being affected. While this article is more of a collection of commonly experienced issues throughout the literature than a formulated framework, it offers a comprehensive basis from which other frameworks can develop.

Table 7. *Klingler et al., 2017*

Main Ideas		
Klingler et al., 2017		
Surveillance Life-Cycle Issues: • Background issues • Issues in system design and implementation • Issues in data collection, analysis and storage • Issues in data reporting, sharing and using for action	Lack of Informed Consent: (1) Effectiveness (2) Necessity (3) Least infringement (4) Proportionality (5) Public justification / engagement	(6) Vulnerability (7) Legitimacy (8) Harm principles / unreasonable exercise requirement
Review of the Framework		
Pros (+) • Systematic, logical approach • Dissemination & implementation focus • Attention paid to informed consent issues	Cons (–) • Not a useable analytical tool • Lack of community engagement focus • Just an overview, not evaluative	

Pounder – "Nine principles for assessing whether privacy is protected in a surveillance society", 2008

Pounder's framework is broken up into two parts – one criticizing the existing regulatory system for not protecting privacy strongly enough, and the other proposing nine new principles by which surveillance should be evaluated. It is important to note that Pounder writes within the context of the UK Parliamentary system, and as such, many of his critiques and suggestions pertain specifically to the way the UK government can reform their practices. That being said, the content of his suggestions are applicable in the contexts of other government if some of the regulatory terminology is generalized (i.e. "regulator" is intended to mean the "information commissioner" in most cases, but can be replaced with any professional who oversees a surveillance program; the author talks about Parliament and Ministers, but these terms can be translated to refer to agency professionals and government officials). In addition, this framework discusses surveillance – or "dataveillance", since "personal data processed as a result of a surveillance activity, any sharing of personal data and any revelation of identity information are all considered to be a surveillance activity” (Pounder 2008, 11) – as a whole, not public health surveillance. However, many of the principles still apply, recognizing the fact that other forms of surveillance may benefit private interests more than public health interests. The focus of this framework is different from those previously outlined, as Pounder’s recommendations refer mainly to policies and regulations about surveillance, as opposed to the interventions themselves. A systematic approach such as this one is important to include in order to demonstrate that ethical evaluation of surveillance work need not only apply to the programs, but to the regulation and supervision of them, as well.

To start, Pounder explains the protections built into surveillance laws. He mentions that a downfall of surveillance policies is the fact that there are many different policies that handle privacy protections – although this may sound like a positive aspect of surveillance policy, it means that if individuals feel that surveillance has harmed them, there is a confusing, divergent route to redress. If analysis of proposed surveillance legislation is lacking, the process of seeking retribution for harm may fall to the courts or complex bureaucratic complaint systems; as legal fees can be expensive, and lower health and legal literacy renders complex systems less accessible, this route to compensation pits individuals against the government in an unfair battle (Pounder 2008, 9). There is also the problem of conflicts of interest within the supervisory structure of surveillance projects, since regulators report to the “Minister who has a political interest in the success of the surveillance” (Pounder 2008, 2). Within the United States system, these conflicts can manifest in the form of agencies with predetermined agendas – even though the goal of the agenda is to improve public health and provide advocates with information on the disease burden – which can cause aspects of a program to be overlooked in favor of “successfully” carrying out the surveillance, or can take the form of pressure from outside organizations.

Pounder also emphasizes the lack of scrutiny that exists within the system he is critiquing, noting that committees have unsuccessfully called for the inclusion of a human rights assessment to be included with legislation in order to evaluate the impact on individuals. He also recognizes the need for the explicit statement of how the data is to be used in the primary legislation proposing it (Pounder 2008, 8). He recognizes that "function creep" – the phenomenon of surveillance systems broadening their purposes to exceed the initial goals once they are installed – is also an element that risks the privacy of individuals, especially if data is able to be shared across different databases and cross-referenced to further identify the individual (Pounder 2008, 4). Retention and sharing of data after surveillance has occurred may also negate some of the protective effects that have been built into the legislation that initially approved the surveillance (Pounder 2008, 5). Because of all of these shortcomings, Pounder proposes nine principles to guide stronger legislative and regulatory privacy protections. He stresses that they are not legislative principles, but instead "a means of exploring possible deficiencies in information law governance" (Pounder 2008, 1).

(1) *The justification principle.* Similar to many of the justification principles mentioned in other frameworks, this principle states that in order for a program or piece of legislation to be approved, it must be demonstrated that the surveillance action is in response to a social need and can deliver measurable outcomes. Pounder recommends that "to gain public confidence, information about surveillance policy (e.g. justifications, complaints procedures) should be proactively made available by the public authority performing the surveillance" (Pounder 2008, 12). Throughout the framework, it is recognized that certain pieces of information may contain confidential information and may not be able to be released to the public, but that a governing body should figure out how to redact the necessary information while still providing as much relevant information as possible (Pounder 2008, 13).

(2) *The approval principle.* In this principle, Pounder calls for all surveillance programs to be "thoroughly scrutinised by a fully informed [agency]" (Pounder 2008, 13) to ensure that they are lawful and appropriate. He also writes that community input, or "public debate", should be a part

of the analysis of the surveillance program when applicable – again recognizing that some aspects might be claimed to be confidential. This process of evaluation of a program prior to approval is thought to be able to identify alternative methods that could be used; if the alternatives are determined to be less appropriate, it further justifies the surveillance being evaluated (Pounder 2008, 13). The article notes that special attention will need to be paid to certain types of surveillance and how these programs interact with other initiatives, especially programs involving children or the collection of genetic information (Pounder 2008, 14).

(3) *The separation principle.* Pounder states in this principle that procedures approving surveillance activities should be separate from the policies that govern the actual surveillance. Although this principle is slightly vague on the surface, the idea behind it is to combat the conflict of interest issue mentioned earlier. This principle diminishes the risk that politicians or agency leaders will overlook ethical issues in favor of the success of a surveillance program; by keeping these policies separate, there can be two levels of control and assessment (Pounder 2008, 14).

(4) *The adherence principle.* This principle addresses the practical side of surveillance evaluation and implementation – it dictates that surveillance staff should be well-trained and obey predetermined procedures, that the training and procedures have been professionally assessed, and that wrongdoing is identified and punished accordingly through a consistent oversight mechanism (Pounder 2008, 15). The author raises the important point that this principle is very important for the individual – if a member of the public feels wronged or experiences an issue with a surveillance action, they must be able to have faith in the system and the relevant agent or agency that their problem can be explored and hopefully resolved (Pounder 2008, 16).

(5) *The reporting principle.* The reporting principle is also administrative however this time it pertains to the documentation and record-keeping associated with surveillance programs. Pounder calls for standards about which records are retained in order to be transparent and

accountable to the regulators, the public, and the government. This principle does not refer to the personal data from individuals that is collected through surveillance efforts; instead, it references administrative records that demonstrate that a surveillance program was carried out according to regulations and procedures (Pounder 2008, 16). Pounder writes that these records are important both for evaluating the cost-efficiency and effectiveness of the programs, as well as for the public to feel confident that there are records of the activities, especially if they need to reference them in complaints or in suggestions for policy changes during periods of public input (Pounder 2008, 17).

(6) *The independent supervision principle.* Similar to the separation principle, this guideline proposes that supervision of a surveillance program should be independent of the government. Again, this suggestion aims to combat the dismissal of concerns by those invested in a program's success, and wants to ensure that there is an actor "with particular responsibility to protect the public" (Pounder 2008, 18). The person supervising the program would be able to bring attention to issues before they become public or are brought to the courts, suggesting policy changes that can help avoid potential harm (Pounder 2008, 17).

(7) *The privacy principle.* Principle seven looks out for individuals, stating that they have an inherent right to privacy of their personal data and that they need a simple and accessible means of objecting to the processing of their data in certain situations. This principle also acts to "encourage a public authority not to exceed its powers" (Pounder 2008, 18). Pounder gives suggested text for an addition to the existing data protection laws: "personal data shall not be processed in a way that does not respect the private and family life or correspondence of data subjects" (Pounder 2008, 19). He also notes that if there is trust in the system, there should be no need for complaints to be made by the public. This trust can be enhanced, for example, by providing clear notice of how personal data will be used, since it is hard for individuals to feel as

though they can protect themselves if they do not know whether or how their data are being used (Pounder 2008, 20).

(8) *The compensation principle.* Although it does not specify the type or amount of compensation that one should receive, this principle serves to remind actors within surveillance systems that harms resulting from these programs should be recognized and given remedy. Although financial compensation clearly does not correct social, emotional, or physical harms, it can offer some sort of recourse for an individual (Pounder 2008, 20).

(9) *The unacceptability principle.* This principle acts as a "bottom line" for the preceding principles. If the eight other guidelines cannot be followed, the three options are to stop the program entirely, take measures to bring the program into compliance with the guidelines, or to gain special exception by a Parliamentary (or agency, or governmental) committee to continue with the surveillance. This last option is vague about why or how a program would be granted exception, however Pounder states that the "public interest generated by the Regulator's report would oblige Parliament or a Committee to consider the surveillance issue in detail" (Pounder 2008, 21).

Review of the Framework

Overall, Pounder's principles help to guide the policy and regulatory side of surveillance, recognizing aspects of this work that need to be addressed even before the conception of the project. Although he writes in the context of the UK parliamentary system, the ideas behind the principles can be translated to the U.S. agency and government structure. The focus of this framework is clearly directed toward professionals both in the agencies that design surveillance systems and those who serve in the government, but he does pay attention to the importance of individual rights in some of the principles. This framework is not accessible or useful for community members and some further work on aspects such as public debate and community-driven policy suggestions would be welcome. Though vague in some parts, the suggested principles offer a strong basis for evaluating surveillance from the policy perspective and acknowledging that human rights and individual protections should be deeply ingrained in the development of surveillance legislation, instead of an afterthought.

Table 8. *Pounder, 2008*

List of Ethical Principles

Pounder, 2008

(1) Justification	(4) Adherence	(7) Privacy
(2) Approval	(5) Reporting	(8) Compensation
(3) Separation	(6) Independent Supervision	(9) Unacceptability

Review of the Framework

Pros (+)	Cons (–)
• Regulatory and legislative focus	• Framed specifically for UK (although adaptable)
• Addresses important policy steps	• Professional-focused, not layperson-friendly
• Human rights and individual protections focus	

Désy, Filiatrault, and Laporte – “A Tool for Ethical Analysis of Public Health Surveillance Plans”, 2012

Désy, Filiatrault, and Laporte’s public health surveillance analytical tool is simple but effective, calling out eleven ethical dimensions by which surveillance programs should be evaluated and designed. Many of the principles are familiar from other frameworks, however the authors introduce some new elements and also emphasize subtle differences between terms that may have seemed interchangeable in other articles. The article first explains each dimension separately and then translates those dimensions into ethical questions grouped by plan element in a practical tool for evaluation. The authors also provide sample issues for each question in order to demonstrate how the questions might be answered. This tool is designed to make it easier for public health ethics committees to analyze the complex surveillance plans they receive, but can also be used by researchers or anyone “concerned more with ethical issues in public health – and more specifically, in surveillance” (Désy, Filiatrault, and Laporte 2012, 53). As the framework is a part of a larger text on population and public health ethics, the authors also pose discussion questions at the end of their article asking what else could be added to make the framework more comprehensive or practical.

The first two principles, proportionality (1) and usefulness (2), mimic other frameworks in calling for a surveillance program to make sure its issues are balanced out by its public health benefits and that potential health improvements will result from the actions. Much of the time the major benefit and justification for surveillance is that it informs public health activities, but the authors note that this measure is hard to quantify and that as "the number of subjects of surveillance and surveillance indicators continues to grow, [it] makes the problem of proportionality ever greater" (Désy, Filiatrault, and Laporte 2012, 53). Transparency (3) is also mentioned in other frameworks, but the main focus of Désy, Filiatrault, and Laporte's principle is that the purposes and objectives of a program must be explicit from the start. They also emphasize that research, monitoring, and surveillance are different, even though they are all working toward better public health, and that the boundaries between these actions should be made clear (Désy, Filiatrault, and Laporte 2012, 54).

The authors use their fourth and fifth principles to make an important distinction concerning affected populations and how they are treated. They contrast the ideas of representativeness (4) and equity (5), the former referring to the need to depict subgroups in surveillance programs accurately and equitably, and the latter recognizing the need to pay special attention to groups who may experience higher burdens of disease. While representativeness strives to make sure that a program fairly pays attention to each group and the health needs that are determined to be important to them, equity aims to make sure that resources are distributed in a manner that gives each subgroup an equal chance at improvement. Along the same lines of representing communities accurately, the participation (6) principle addresses the need for multiple sources of input, including partners and the public. This framework is rather skeptical about community engagement, however, noting that the "advantages of having the public or certain sub-groups within the public participate seem less clear" (Désy, Filiatrault, and Laporte 2012, 54) than the benefits of having partners give input on data use. The authors admit that some of the benefits of community engagement can be the recognition of health concerns that are important to those people and assessing if the surveillance indicators have potentially negative impacts on stigma and discrimination (Désy, Filiatrault, and Laporte 2012, 54).

Similar to Pounder, the authors discuss the ideas of surveillance operating independently, the negative outcomes that can come from cross-referencing data sets, and privacy rights. The independence (7) dimension of this framework states that a surveillance plan must stay true to its original intentions and not skew from them because of outside, specifically financial, pressures (Désy, Filiatrault, and Laporte 2012, 54). Stigmatization (8) addresses the need to pay attention to the cross-referencing of surveillance indicators and other demographic information in case data can be re-identified and cause individuals to be discriminated against based on the revealed information. This risk is much higher for data sets containing demographic information for smaller subgroups or less populous geographic locations. The privacy (9) principle also confronts this issue of re-identification, emphasizing that privacy is the "fundamental concern of surveillance authorities" (Désy, Filiatrault, and Laporte 2012, 55) and that care must be taken to ensure that data is not traceable back to any level – individual, household, or community. The authors also single out informed consent (10) as an important dimension, although less-so to demonstrate the complexities of its absence in many surveillance programs and more to talk about the challenges of gaining consent for secondary uses of data, which they note is more applicable when comorbidity or multimorbidity is being explored (Désy, Filiatrault, and Laporte 2012, 55).

The last of Désy, Filiatrault, and Laporte's ethical dimensions is understandability (11). This principle revolves around the idea of accessibility – the authors state that the data and findings from surveillance should be publicized in a way that people can understand "because of course it is with the public's health that these data deal" (Désy, Filiatrault, and Laporte 2012, 55). This idea of accessibility and practicality carries over into the way that they format and develop their own framework. Presented as a simple table of "plan element", "standard ethical question", and "example of a problem", they turn these eleven dimensions into applicable and typical scenarios that arise in the evaluations of surveillance programs. The authors identify five categories of plan elements: plan purposes, subjects and indicators, cross-referencing, data management, and dissemination.

Review of the Framework

The authors recognize that the questions and examples they pose are not comprehensive of all of the nuances of surveillance work, however they do manage to address many of the common issues, upon which researchers or evaluators can expand in order to find answers to their plan-specific inquiries. The explanations of the ethical dimensions are high-level and simple, but they offer insight into some new concepts that have not been stated in other frameworks. The user-friendly format of the tool and the fact that the authors manage to translate the more abstract or theoretical ethical dimensions into tangible questions makes this framework a strong model for future, more expanded frameworks.

Table 9. *Désy, Filiatrault, and Laporte, 2012*

List of Ethical Principles

Désy, Filiatrault, and Laporte, 2012

(1) Proportionality
(2) Usefulness
(3) Transparency
(4) Representativeness
(5) Equity
(6) Participation
(7) Independence
(8) Stigmatization
(9) Privacy
(10) Informed Consent
(11) Understandability

Review of the Framework

Pros (+)	Cons (−)
• Approachable, usable tool format	• High-level, very simplistic explanations
• Translation of principles into tangible examples	• Professional-focused, although intended for all
• Open to further input from others	

Genomic and Health Data Collection Frameworks

As discussed in the "The Science of Cluster Detection" section, recent developments in genomic research and analysis have opened up opportunities for public health programs to closely track the spread of disease and to concentrate prevention and treatment responses. Along with these successes in science, of course, come ethical considerations and concerns from those affected by the work and those carrying it out. Although numerous documents explore the ethical issues of genetic data collection and testing, they tend to be within the context of personal genomics or research; there are far fewer developed frameworks for addressing the issue of viral genomics within public health surveillance, which does not have the same consent requirements. Even in the frameworks previously discussed, informed consent and patient notification are emphasized and touted as an important part of public health efforts. Mary Warnock reframes the idea of informed consent, saying that instead of calling simply for consent, "we, as individuals and society, demand from the research process… that it should not exploit us" (Cassell and Young 2002, 315). Although, again, the requirements for informed consent within research and surveillance are different, there is similar community discomfort with the idea of exploitation in both realms. There is still pushback from people who do not feel comfortable with the idea of unconsented tracking and collection of stigmatizing information, even for the benefit of public health, especially when genetic information, even viral genetics, is involved.

While informed consent is a distinct part of the ethical discussion around genetic data collection, many other elements – notably privacy, confidentiality, and data use – also factor into the success or failure of creating an ethically sound program. In order to explore these issues further, two articles have been identified that take different approaches to evaluating the ethical and acceptable use of health data. Xafis et al. focus their framework on the use and sharing of "big data" in health, developing two sets of principles – one substantive and one procedural – to aid in the evaluation of ethical data use concerns. Although this framework does not expressly concern genomic data, its suggestions can be extrapolated to any type of sensitive data set. In opposition to the more generic framework that Xafis et al present, Schairer et al. explore the very specific world of HIV molecular epidemiology (HIV ME) – closely related to cluster detection and response – through interviews with a diverse set of individuals on their feelings about the use of HIV ME data. These two recently published articles offer insight into the ethical considerations needed when working with delicate data sets within the context of modern technology.

Xafis et al. – "An Ethics Framework for Big Data in Health and Research", 2019

Xafis et al. offer a robust examination of the ethical issues within the burgeoning field of big data in health. Their multi-part framework – consisting of various definitions, three major ethical themes, nine substantive principles, seven procedural principles, and six-step process for resolving ethical issues – demonstrates that big data, while a useful tool for health activities, takes extensive care and thought to use correctly. Big data – defined by the authors through the characteristics of volume (number of persons whose data is collected and the level of detail of the data), variety (the assortment of data sources and forms), and velocity (the speed of data transfer and analysis) – is increasingly expanding outside of the "traditional" fields in which it usually operates (Xafis et al. 2019, 228). This article specifically discusses the expansion of big data into the health and research fields. Although it does not specifically reference public health efforts, the article defines health as "systems or fields whose primary aim is the maintenance or restoration of our physical and mental condition and wellbeing" (Xafis et al. 2019, 229) and research as "systematic investigation with the intention of generating or contributing to generalisable knowledge" (Xafis et al. 2019, 230), both of which certainly overlap with the intentions of public health and surveillance work.

One big change for data storage and protection is the existence of large online databases; this technology is useful but also contributes to the risk of hacking and misuse. Xafis et al. note that anonymization and de-identification of data may not be as successful anymore since there is a variety of data collected and cross-referencing can weaken the protections put in place. The authors write that "disclosure risks can only ever be completely eliminated if data is not shared at all" (Xafis et al. 2019, 232), which is an unlikely scenario. They also mention secondary consent and the difficulty of either re-consenting a participant for different data uses or initially informing them of all possible data uses; Xafis et al. suggest alternative methods of protecting individuals that are still ethically sound (Xafis et al. 2019, 233). Even if the genomic data being collected as a part of public health surveillance systems may not generally be thought of as “big data”, it will likely reach that categorization in the near future, or at least share many of the same privacy and ethical concerns that these larger data sets do. By being prepared for the management of these data sets, researchers and health officials can utilize the data to achieve cost savings, more efficient health care delivery, and improved access to necessary resources for communities (Xafis et al. 2019, 229).

The authors of this framework call attention to three ethical threads that run through all of their suggestions – respect for persons, social license, and vulnerability-power dynamics. Respect for persons, they argue, relies heavily on communication, with a failure to communicate demonstrating a lack of respect. For this reason, it is crucial that “reliable and digestible information on big data in health and research underlies any meaningful interaction that professionals, communities, and governments may hope to establish with publics” (Xafis et al. 2019, 235). Not only should information be provided, but so should the space for conversation where the public can share their concerns or expectations about data collection and use. Importantly, Xafis et al. write that these interactions should not just be carried out for due diligence or to appease the public, but instead should be rooted in genuine interest with the intent to incorporate suggestions from participants. Social license – broad social acceptance or approval based on perceived legitimacy of actions – is intimately related to respect for persons (Xafis et al. 2019, 236). The authors comment that making assumptions about the acceptability of using health data with or without consent is not respectful and should not be done; instead, open communication about expectations, large-scale and local, should be utilized (Xafis et al. 2019, 237).

Vulnerabilities and the power dynamics that cause them are also an important piece of the big data ethics discussion, as all people have inherent vulnerabilities that can be magnified in certain scenarios. Within the context of big data, anyone who has had data collected is susceptible to the risk of its misuse, and unwanted intervention from government bodies or agencies; regulations and built-in protections are intended to diminish these risks but are not always successful (Xafis et al. 2019, 238). Vulnerability is multidimensional and finding a correction for all risks is difficult, as an action may reduce one risk while adding to another. If these vulnerabilities are overwhelming and cannot be balanced correctly, "there will be a need to decide whether the research is justified, given the nature and scale of the harms and wrongs faced by the data subjects" (Xafis et al. 2019, 239). Similar to the ideas of proportionality or justification previously discussed, vulnerabilities should be expected but not outweigh the benefits of the research or data collection.

The authors identify three specific vulnerability-related issues in big data: the big data divide, group harms, and co-governance. The big data divide is about balancing the benefits derived from data collection versus the contribution of data. This gap continues to widen, especially with the growth of information-sharing online; the more robust an online profile one develops, the more data exists and can be used without the individual having total control or knowledge about how it is being used and by whom (Xafis et al. 2019, 240). The phenomenon of group harm refers to the damage a community experiences from data misuse. It is possible for groups to be harmed while individuals remain safe – communities may be coerced to participate in research or be stigmatized based on a discovery made while individuals are not specifically negatively affected. Some sets of guidelines do warn against escalating the study of group harms to treating whole groups as vulnerable, however, as there can be distinct differences within a subgroup that require more specific attention (Xafis et al. 2019, 241).

Xafis et al. present the idea of governments intervening to protect at-risk populations from exploitation from biotech companies or other data users in order to foster co-governance of the data. This setup, however, is reliant on a strong level of trust in the government, which is not necessarily present in many countries, and can potentially turn into governmental appropriation of citizen's rights to their own data (Xafis et al. 2019, 242). Co-governance, a system in which all stakeholders have a large amount of input on how their data is processed and used, is a good option for enhancing protections, however true co-governance may be more of a theoretical possibility than a practical one. Since it is unrealistic to be able to gather and honor input from each individual on how their data can be used, the next best solution is to have a representative for each subgroup. Still, representatives can be problematic since it is unknown how they would be determined and how they would promote differing opinions within the community (Xafis et al. 2019, 243).

The sixteen principles determined to be most important for big data in health and research, along with the six-step process for evaluation, are relatively straightforward and reflective of other ethical principles that have been identified in many of the other identified frameworks. The difference in this piece, aside from the big data-specific examples given, is the division of the principles into substantive and procedural; the format is reminiscent of Marckmann et al.'s PHE framework, which proposes a methodological approach with ethical principles, procedural criteria, and a multi-step process for applying the determined values. It should be noted that Xafis et al.'s principles are listed in alphabetical order in the framework, as opposed to in a step-wise or priority-based order – the authors go on to explain in their step-by-step evaluation process that weighing the values against each other will be context-based and up to those carrying out the assessment (Xafis et al. 2019, 247). Xafis et al.'s substantive principles are as follows:

- *Harm minimization:* Similar to burden and risk reduction principles, harm minimization pays attention to lessening both real and perceived harms.
- *Integrity:* A characteristic of a program or actor, integrity refers to "acting in accordance with personal and/or accepted scientific and professional values and commitments" (Xafis et al. 2019, 245).
- *Justice:* Respectful treatment of groups and people, including care given to equity issues and fair distribution of risk and reward.

- *Liberty/autonomy:* Liberty refers to external pressures and the freedom not to be coerced by these powers; autonomy is more internal, focusing on self-determination and choice.
- *Privacy/confidentiality:* Privacy is related to one's control over access to information and the freedom from potential harms that could come from the misuse of that data; it is intertwined with autonomy. Confidentiality concerns the commitment to protect and keep safe information that is given in trust.
- *Proportionality:* A familiar concept within these frameworks, proportionality is about balancing positives and negatives; in this framework, it is phrased as ensuring that the means are necessary relative to the ends.
- *Public benefit:* This dimension may be hard to measure since the individual elements (wellbeing, cohesion, human rights, etc.) involved must be evaluated differently, however the ultimate goal is to recognize the overall good that society experiences from a big data project.
- *Solidarity:* The solidarity principle is about the commitment between people with "recognised morally relevant sameness or similarity" (Xafis et al. 2019, 245) to share the risks and rewards for the ultimate good of a group, however local or broad.
- *Stewardship:* Stewardship involves taking care of something or someone and guiding it through a process. In this case, one helps move toward improvement and away from risk through caring guidance by protecting the data and promoting its value (Xafis et al. 2019, 245).

The above set of principles contain overlapping ideas with other frameworks but also introduce new concepts, such as integrity, solidarity, and stewardship. They can be easily molded to fit the context of molecular sequence data collection, as well as other public health uses. These principles are more theoretical and "should be realised through the outcome of a decision" (Xafis et al. 2019, 244) – here, the authors mean that these substantive values actually develop with assistance from the use of procedural values in order to create a program that can embody the substantive ideals.

These supporting procedural principles, which are especially helpful when substantive principles conflict, are as follows:

- *Accountability:* Holding decision-makers responsible for the consequences of those decisions, and being able to judge and assess actions involved.
- *Consistency:* Within the comparison of different situations, applying the same standards of evaluation if all else remains the same. Consistency is a crucial part of displaying fairness and dependability within a system.
- *Engagement:* Meaningful participation from all stakeholders that goes beyond simple education and dissemination of information; it should be demonstrated that input from stakeholders has had an influence on the development or design of the program.
- *Reasonableness:* Operating under widely accepted values that are determined to be applicable and rational.
- *Reflexivity:* Self-reflection and recognition of limitations and uncertainties within the development of a system. This self-awareness includes managing biases and conflicts of interest, organizational goals, and creating policies that work toward systemic change while being open to revision.
- *Transparency:* Willingness to receive public scrutiny on decisions and actions, which helps demonstrate respect and truthfulness.
- *Trustworthiness:* Derived from transparency, consistency, and other previously mentioned procedural principles, it is the characteristic of being deserving of trust and confidence; applicable to individuals, organizations, groups, and things (data, etc.) (Xafis et al. 2019, 246).

Xafis et al. conclude their framework by introducing a practical process for utilizing the principles, which is designed to help think through conflicts in the importance of values and justification of actions (Xafis et al. 2019, 234). First, one must identify the ethical issue. Next, the relevant substantive and relevant principles must be chosen – these principles can be picked from the aforementioned sixteen, or others can be identified. Potential actions to combat the issue are then considered, followed by a weighing of the "relative ethical merit" (Xafis et al. 2019, 247) of these actions based on the previously selected values and context of the situation. Once an option is designated to be the most optimal, the evaluators must examine if any personal or professional biases or interests have influenced their decision – if they do find that there has been undue influence, they must be open to revisiting the decisions made earlier in the assessment. After deliberation and finalization, the results and reasoning should be made available and clear to all stakeholders (Xafis et al. 2019, 247). This process is geared toward people who are responsible for big data decisions – researchers, data scientists, policy makers – but the authors also state that anyone who is interested in the ethics of big data, whether professionals or lay-people, can benefit (Xafis et al. 2019, 233).

Review of the Framework

The discussion of ethical issues in big data in this framework allow the reader to see how previously discussed ethical principles can be applied to the growing field of database management and data sharing. The authors introduce important new concepts like self-reflection and recognition not only of real, but perceived harms. Through the use of their six-step application process and list of relevant principles, those who need to evaluate data collection-based programs can easily identify what aspects of a project are most important and how the actions they take can result in positive or negative outcomes. Although the multiple steps presented in this framework make it less straightforward than other approaches, the practical applicability of this tool, as well as the novel principles, are worthy of inclusion in the integrated framework.

Table 10. *Xafis et al., 2019*

List of Ethical Principles			
Xafis et al., 2019			
Substantive Principles:		Procedural Principles:	
• Harm minimization • Integrity • Justice • Liberty/autonomy • Privacy/confidentiality	• Proportionality • Public benefit • Solidarity • Stewardship	• Accountability • Consistency • Engagement • Reasonableness	• Reflexivity • Transparency • Trustworthiness
Review of the Framework			
Pros (+)		Cons (–)	
• Address ethical issues in technology • Discusses vulnerability in depth		• Overwhelming multistep process • Not specific to public health, but applicable	

Schairer et al. – "Trust and Expectations of Researchers and Public Health Departments for the Use of HIV Molecular Epidemiology", 2019

Schairer et al.'s article does not present a systematic framework but instead reports out the results from individual interviews with a diverse group of medical professionals, public health workers, PWH, and at-risk individuals (Schairer et al. 2019, 2). This piece specifically focuses on HIV ME, which inspires very similar ethical questions as cluster detection and response. Using three hypothetical scenarios to describe the collection, sharing, and response to viral genomic data for research or public health efforts, the authors expose results about the trust, or lack of trust, that interviewees have in this type of work. The authors make it clear that since they have only gathered input from 40 people, the study is far from exhaustive, but instead that it represents a range of opinions that exist (Schairer et al. 2019, 4). The main takeaways from the study are not surprising – that people expect extreme care to be taken with this type of data, that transparency is important to maintaining trust, and that vulnerability should be addressed in order to lower barriers to interaction with the health care system. Some of the more intriguing results, however, come from answers about individuals' trust in research ventures versus public health surveillance. Although no distinct principles or procedures are presented in this article, the findings can lend themselves to the development of important questions in the final synthesized framework.

Scenarios 1a and 1b exist in the research context – in 1a, "John" is HIV-positive and joins a study in which researchers find out that he is part of an HIV network with other individuals who are acting in ways that permit transmission the virus; in 1b, John is a university student and the outbreak is at least partially on campus. The line of questioning for these scenarios asks participants what they expect researchers to do with the public health-related findings (Schairer et al. 2019, 3). In scenario 2, Steve lives in a society where HIV cluster detection and response programs are in place. He receives an HIV diagnosis and, instead of being invited to participate in the research study, is told that his data will be sent to the health department as a part of routine public health surveillance efforts. The participants are asked what they think public health agencies will do with the data and their level of comfort with these actions (Schairer et al. 2019, 4). Main discussion points for the three scenarios emerge – informed consent, responsibilities to notify or intervene, and general trust or mistrust of the actors – and further exemplify the divergent feelings of participants about research and public health.

The authors report that informed consent is generally assumed in the research context, but not in the public health context, although there is strong call for it in the latter (Schairer et al. 2019, 10). For scenarios 1a and 1b, informed consent concerns have to do with further research and notification. Participants stress that the uses of the data past the initial study should be included in the informed consent up front, whether those plans are for further inquiry or results that the subject will receive. Some participants mention the need to inform study members that they may find out information that can be emotionally troubling and offer for them not to be informed of the results if they wish (Schairer et al. 2019, 5). For scenario 2, the group was divided on their acceptance of the lack of informed consent in some public health activities; some recognize that it was not a requirement, others call for it to be the norm, as it is in research. One suggestion is for the presentation of options within a consenting process, the ability to approve certain uses of personal data but deny others. Regardless, some participants note that, once they were alerted to the data collection, they would warn others and potentially discourage them from seeking the same services because of the lack of informed consent (Schairer et al. 2019, 8). There is no discussion or recognition of the challenges that make informed consent in public health surveillance impractical, such as the inability to collect fully representative data, data that is biased toward those who have a certain level of trust in medical and government systems, and inaccurate funding distribution based on these under-representative data sets.

The responses regarding expectations for data use in research and public health demonstrate a difference in confidence depending on the data collection purposes. For the research scenarios, most interviewees expressed comfort with researchers sharing data for notification purposes or for further investigation. Many indicated they would expect researchers to inform public health agencies, university health services, or individuals about their results. Only a few participants spoke about discomfort with institutional reporting based on research results, citing the possibility for stigmatization or fears of legal consequences through criminalization laws. One respondent expressed a rare but interesting opinion that instead of actively intervening or notifying, care and information should be provided when patients seek it out (Schairer et al. 2019, 6). By contrast, answers about data use in the public health context reflected some extreme expectations including individual targeting for intervention or notification of transmission networks, as well as more mundane procedures like supporting Partner Services or influencing policy changes. An oddly cavalier suggestion from an HIV-positive participant recommended the data be used to indicate status on one's driver's license or other IDs; a different, more concerned interviewee worried about attempts to identify "patient zero" (Schairer et al. 2019, 6).

Touched upon within the dialogue of participants' expectations for data use, the discussion of trust levels in research versus public health expands upon the reasons for the difference in comfort in the two contexts. Participants seem to trust researchers to notify of disease threats responsibly and not risk confidentiality breaches; confidence in public health agencies was more split. Participants who expressed comfort with data handling in public health tended to be professionals, perhaps attributed to their familiarity with existing protections, practices, and institutional structures (Schairer et al. 2019, 7). Those who were less trusting, mostly lay-people, communicated a general discomfort with government agencies – uncertainty that they can prevent data misuse, lack of discretion, general confusion about what aspects of public health government actually oversees – exacerbated by technology and the potential for unapproved online sharing of information (Schairer et al. 2019, 7). This division exemplifies one of the main challenges of public health surveillance; if the programs rely on informed consent, the data has the potential to be misrepresentative because less-trusting individuals would be hesitant to consent to data collection, making it appear that they have lower rates of disease. In addition, participants recognized the potential negative consequences of mistrust in public health, mainly that people might avoid or continue to avoid seeking care out of fear of privacy loss or external ownership of their genetic information (Schairer et al. 2019, 8). Interviewees expressed that partaking in stigmatized behaviors already comes with anxiety and that the potential to be constantly surveilled made the feeling of vulnerability even worse (Schairer et al. 2019, 7).

The great divide between feelings of trust in research and fear of public health have definite implications for how public health may attempt to gain favor in the public eye. Perhaps because informed consent is seen as an oversight mechanism or perhaps because public health is linked to authoritative governmental power, participants generally felt that researchers work toward the public good more so than public health agents. Although informed consent or options for partial consent seem to be the desired change within public health, the authors discuss how it is not a way to fix all of the trust issues, since HIV ME networks contain information about more than just the individual that would be consenting. Again, the opportunity to discuss the impracticability of informed consent for public health surveillance is missed within these interviews. The authors do, however, interpret the call for informed consent to be a "desire for public health surveillance to incorporate more opportunities for communication, notification, and choice" (Schairer et al. 2019, 9). Schairer et al. do validate fears regarding re-identification and the potential for criminalization, recognizing that public health relies on "the willingness of individuals to engage with health care and public health institutions" (Schairer et al. 2019, 2) and that agencies should be careful not to create further barriers to this participation. They also suggest community engagement and the consultation of expert panels to help create a more trusting arena for this type of work.

Review of the Framework

Many of the views presented in this article seem to express more comfort with HIV ME data collection for research or public health purposes than is typical from outspoken advocates, for example those featured in The Legacy Project's "Without Our Consent" webinars (Legacy Project 2019) or representatives from the Positive Women's Network (Kempner 2019). Benefits of this article are that it utilizes a diverse group of participants to generate qualitative data, and that it delves into some of the differences between research and public health efforts. There are some missed opportunities for education and discussion but, nevertheless, findings from these interviews highlight a range of opinions that exist amongst professionals and laypeople. These interviews can offer useful insight into how to evaluate and update genomic data collection programs in public health in the future to gain more public trust and confidence.

Table 11. *Schairer et al., 2019*

Main Ideas		
Schairer et al., 2019		
Informed Consent: - Assumed in research, not in public health contexts - Offer a sense of trust and oversight - All potential data uses should be included in initial consent - Suggestion for partial consent or opt-outs in public health	Data Usage: - Research: further investigation and notification - Public health: individual intervention and tracking - Concerns about re-identification, stigmatization - Desire to know how data will be used up front	Research vs. Public Health: - Researchers seen as working toward the public good - Researchers expected to notify but not intervene - Public health is tied to government authority - Lack of confidence in public health to protect data

Review of the Framework	
Pros (+)	Cons (–)
- Diverse group generating qualitative data	- Not a useable analytical tool
- Focus on ethics of informed consent	- Some missed opportunities for discussion
- Discussion of public health versus research	- Small group, not necessarily representative

Community-Inclusive Integrated Framework

The intention of this in-depth framework analysis was to produce a targeted, integrated ethical framework that can guide the design, implementation, and data processing involved with public health interventions, specifically those that include surveillance efforts and/or genomic data collection. By creating a framework that includes elements from all four genres of work – public health, community engagement, surveillance, and genomic/health data collection – it allows agencies, advocates, and community members to evaluate programs that may have a great effect on the targeted population, whether negative or positive. Like almost all of the frameworks outlined above, the integrated framework does ask many questions that agency professionals are most equipped to answer – for example, questions about the cost-effectiveness of a program or regulatory requirements in public health – but this tool is designed with the intention that any lay-person, specifically those affected by the implementation of a surveillance program, can answer the majority of the questions from their perspective. In this way, the tool is a means not only to evaluate an existing program or activity, but also to compare the evaluations of different groups to find points where they agree and disagree. It is vital to the creation of a community-supported and co-designed public health program, and the creation of future programs, to be able to find these nexus points and see the effects of public health intervention from multiple perspectives. In fact, use of the ethical framework can itself be a community engagement activity if professionals and lay-people compare their opinions at each stage in the process and only move on to the next step once consensus is reached and all parties feel comfortable with the project status.

In order to organize and narrow down the ethical principles, findings, and suggestions within the ten chosen frameworks, a methodology for selecting elements had to be devised. As stated earlier, the selection of the frameworks was subjective; the same can be said about the selection of the elements to be included in the final tool. However, the process of selecting these elements did follow a methodology, laid out in the flowchart in **Figure 7**, which allowed for the uniform evaluation of each set of principles. As visualized in the flowchart, the first step was to identify the *major elements* deemed to be most important from each framework. It should be noted that the inclusion of a major element does not necessarily mean it will be placed into the final analytical tool verbatim; it may simply act as the inspiration for ethical questions that appear in the final framework. Those elements that will be altered in some way are marked with an asterisk notation.

Once the major elements were identified, the individual principles (*sub-elements*) within the major elements were evaluated and chosen for their relevance and importance. Part of this process involved the creation of a list of all sub-elements that were presented in the ten frameworks – this full list can be viewed in **Appendix A**. From this extensive list, the sub-elements under consideration were compiled into a smaller, more selective list, attached in **Appendix B**. This table breaks the components down into “format”, “normative principles and concepts”, and “procedures and application” to explain the structure of the tool, ethical ideas to be included, and practical evaluative steps to be used, respectively. The sub-elements within this table were broken down further by theme – effectiveness, justification, autonomy, etc. – in order to identify and diminish overlap between principles, and to make sure that all necessary subjects were addressed. Although the concepts will not be grouped by these themes in the final framework, it was a useful step to view the commonalities between frameworks and recognize the weight that should be given to certain themes. After completing this tapering process, the sub-elements were then translated into questions to be included in the final framework, to be accompanied by examples of positive and negative answers with which an evaluator could respond.

In order to illustrate this multi-step process, it is helpful to walk through an example of the how a framework becomes integrated into the final tool; for this example, Pounder's framework will act as the example (**Figure 6**). Beginning with the whole framework, the *major elements* of importance are selected: nine ethical principles, focus on regulation and legislation. From there, *sub-elements* are chosen: justification, approval, separation, adherence, reporting, independent supervision, and privacy; compensation and unacceptability are not selected. These principles are now translated into questions, for example: the principle of "reporting" turns into "Is there a system in place to keep records of the program's actions and costs?"; "justification", along with other justification principles, contributes to the question "Has the reasoning behind the program and relevant evidence been shared with the community?" .

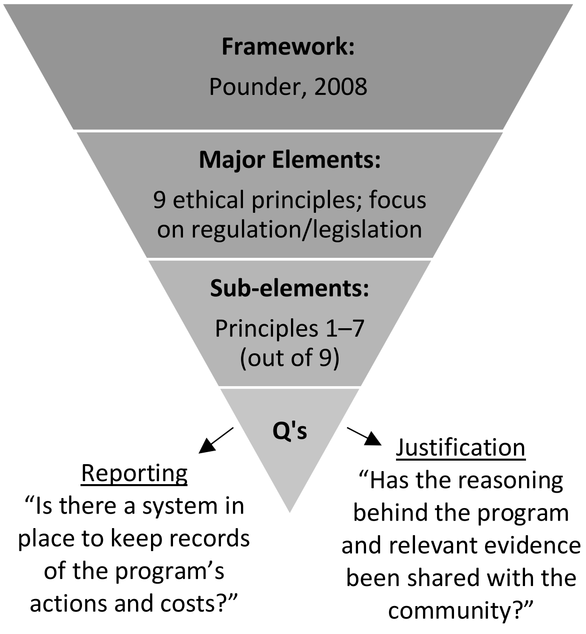

__Figure 6.__ Example of framework element selection process

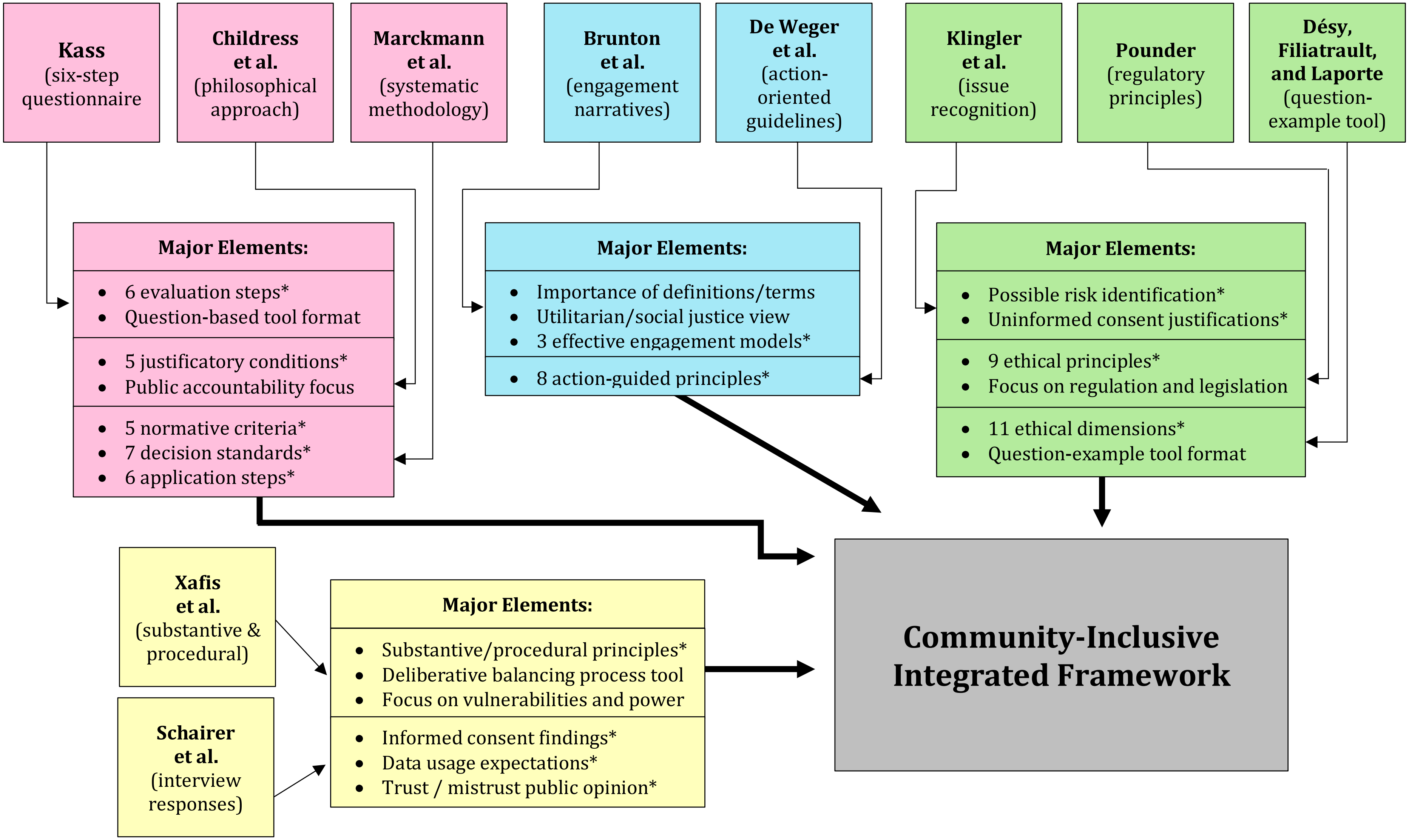

Figure 7. *Framework element flowchart for development of final synthesized framework*

*This flowchart demonstrates the process of selecting elements from each of the identified frameworks in order to create the final integrated framework. Public health frameworks are in pink (upper left), community engagement in blue (upper middle), surveillance in green (upper right), and genomic data collection in yellow (lower left). The * notation indicates that the element will be incorporated into the final framework after being altered or combined with other elements. If desired, the framework can be applied to interventions without the genetic or surveillance components by removing issues and questions associated with the yellow and/or frameworks, respectively.*

Applying the Finalized Integrated Framework

The final integrated framework (**Table 12**) is a combination of major and sub-elements from the chosen original frameworks, feedback from communities and advocates given during public health outreach efforts and community-driven meetings, and findings from research conducted on the impacts of fear, community engagement, and restorative implementation processes. The framework is written as questions with accompanying positive and negative response examples (in this case, related to HIV public health surveillance); it is intended to make common ethical issues within public health interventions accessible and understandable for a wide audience. Unlike some of the original frameworks that were critiqued for being too agency-focused and inaccessible for those outside of the public health profession, this framework is written in plain language, shies away from epidemiological lingo, and asks short yes or no questions that then inspire further discussion.

While some questions are still inherently easier for professionals to answer, the presence of these questions within the tool can alert community members to these aspects of planning and implementation, even if they cannot answer the questions themselves. The framework purposely does not direct the questions at any specific audience, making it easier for a more diverse set of evaluators to utilize the tool. For this analytical tool to be most useful, it has been divided into sections based on different steps in the process of a public health intervention, from before an intervention is considered to after it has been operating for a period of time. These steps are chronological and cannot in most cases be considered out of order; evaluators should use this analytical tool for each stage in order to determine if it is acceptable to move on to the next stage.

Table 12. *HIV molecular cluster detection-specific application of novel framework*

	Ethical Question	Positive Example	Negative Example
Establish a Fair Decision-Making Process	Has a diverse group of professionals and laypeople been invited?	There are representatives from agencies, communities, and advocacy organizations involved; public events have also been planned.	Public health agency staff will be evaluating the program. The public may be included later in the process.
	Is the evaluation tool and process transparent?	The ethical framework is available on the agency website and we will respond to questions about it from the public.	We will publish the resulting recommendations, but the tool will not be available outside the agency.
	Is the same evaluative process being used for all similar scenarios?	We will utilize the same framework, with slightly modifications for relevancy, to evaluate all similar programs.	Scenarios will be evaluated how agency professionals see fit.
	Is there recognition of personal influences and openness to revising policies if there are conflicts?	We recognize that participants bring different perspectives to the conversation and we are happy to revisit parts of a program that are questionable.	This evaluation is being conducted to meet a requirement. It is unlikely that we will change the policy after this evaluation.
	Have past wrongdoings or tensions been addressed? Is work being done to mend tensions between groups?	We have come together with community members and discussed some faults of previous programs and actions, using restorative justice techniques. The discussions felt open and well-received, and will continue.	Although there may have been issues with previous projects, we want to leave those in the past and focus on new efforts.
Identify Goals and Needs	What are the public health goals of the proposed program?	To use data to target testing and treatment resources and help eliminate new HIV transmissions.	To gather data about HIV transmission frequency.
	Have these goals been stated clearly to everyone involved?	The goals were presented at the first public meeting and all chosen actions are being checked against them as we move forward.	The goals we have decided for this program may change as we move forward, so we are not presenting them until later in the project.
	How was the health need identified?	Community members and advocates identified a felt need for more testing resources after	Researchers relied on statistics about high rates of HIV in Hispanic MSM and decided to intervene here.

	Ethical Question	Positive Example	Negative Example
		multiple people in the community were diagnosed in succession.	
Identify Goals and Needs	Will the program benefit those whose data are being collected, others, or both?	The program has major benefits for others that have not yet been diagnosed or infected, however those who are already HIV+ can see beneficial results, as well.	The program benefits the individuals whose data is collected. It may eventually benefit others.
	Is there any outside pressure from financial or other interests?	No, the interventions are managed and funded by CDC and the data is to be used by molecular cluster detection partners only.	There is political pressure for this intervention to succeed and higher-up administrators will be monitoring the quantifiable results.
Regulation / Administration	Has there been opportunity for public debate? Have stakeholders outside of the leading agency evaluated the plans?	Local health departments and advocacy organizations have also evaluated the plan, and there have been two public meetings about the concept, which has resulted in revisions.	Funding recipients are required to implement the program without piloting and providing input.
	Are the staff well-versed in the procedures and protection measures involved?	The public health agency has provided state and local health departments with training materials and support, and regional representatives will monitor the program and visit to provide guidance.	Local health department staff will run the project and decide how to train their staff.
	Is there a system in place to keep records of the program's actions and costs?	All participating agencies will keep detailed notes of their actions and the costs associated. CDC will retain these records, and records of their own activities.	Individual staff will take notes as needed and provide estimates of the costs of the intervention.
Program Design	What are the expected health benefits of the intervention for the target population?	The ultimate goal of the project is to improve the health of PWH and at-risk individuals, and prevent any further transmissions. In order to reach this goal, the shorter term goal is to identify at-risk groups in order to focus resources and education.	The expected benefits are new testing sites and increased access to PrEP and PeP.

	Ethical Question	Positive Example	Negative Example
Program Design	Is this approach necessary? Are there any alternative approaches that are less infringing?	For HIV public health surveillance, the data being collected already exists, so there is no extra infringement, and, as discussed, informed consent is not implementable. We do, however, recognize that some amount of emotional burden is being placed on affected communities, so in order to balance the feeling of infringement as much as possible, we will offer support and transparent communication.	This approach provides the most useful information for the intervention to move forward, so other approaches were not explored. There may be other approaches that are less intrusive, but they were not considered.
	Is there an informed consent process? If not, how is this justified?	Informed consent is not required for public health surveillance, and it is widely accepted that the inclusion of consent would greatly hinder the collection of useful data. However, communities were consulted and educated about the details of the program early and continuously.	There is no legal requirement for informed consent. The inclusion of a consent process would make data collection and use much more difficult and cumbersome for agencies.
	Has the reasoning behind the program and relevant evidence been shared with the community? Is the process transparent and clearly explained?	In a series of public meetings, we have explained how the data collection and response works and how it can help. We have welcomed people to contact us with further questions.	Flyers were shared with existing partners who are leaders of local agencies and CBOs. It will be their responsibility to distribute and clarify information.
	Have community members, activists, and representatives been involved in the design of this program? Since when?	We work with a community advisory board (CAB) made up of members with diverse opinions. They meet on their own and then with the agency to give input on how the program is developing. This board was formed before any concrete decisions about the program were made.	We reached out to a few community representatives that have been involved in previous engagement activities for input. We will hold a few meetings once the program is in place to make sure it is going well.

	Ethical Question	Positive Example	Negative Example
Program Design	Do public participants share decision-making power? Has the team acknowledged the power imbalances between citizens and professionals?	The CAB reviews each major element of the program that is designed, and gets to vote on whether they believe the benefits are worth the risk for their community. We have discussed ways in which the agency sits in a position of authority and what we can do to make the community members feel appreciated, heard, and respected.	The community representatives give feedback on the program, but the agency has the ultimate deciding power on what moves forward. We believe it is understood that there is an uneven power dynamic and that we will do our best to accommodate public input.
	Are there clear examples of where community input has been included? Have they experienced tangible wins?	The CAB has impacted the design of this program greatly. For example, they suggested reaching out to leaders in the community to act as trusted liaisons to help spread correct information about HIV data collection, which we now do.	Those community members that have participated have given a lot of input that we will consider and possibly incorporate. They will experience wins when they see the results of the work.
	Has the team recognized and attempted to diminish any stigma-inducing aspects of the program?	The CAB ran a peer-led workshop for the public to help the health department to develop non-stigmatizing language for communications about HIV clusters and our planned response.	We will make sure to avoid stigmatizing actions as much as possible, but it is important to recognize and make people aware that certain groups are more at-risk for HIV transmission, so some groups may be targeted more than others.
	What are the known or potential burdens of the program? How can the benefits and burdens of a program be fairly balanced?	Burdens may vary across populations and across geographic areas. Some states frequently prosecute PWH while others have stronger built-in protections. We will work with jurisdictions to identify and minimize harms to their populations.	While there are rare instances of prosecution or confidentiality breaches, most of the burdens highlighted by advocates and community members are perceived and potentially exaggerated. We will work to minimize the true harms.
	How does the intervention affect the autonomy of the individuals in the target population?	We recognize that people feel their autonomy is being infringed upon by the data collection and use. Although it is not possible to include informed consent or an opt-out, since this reporting is mandatory, we will educate people about how and why their data is being used and include community members in the decision-making process as much as possible.	Unfortunately, this program cannot include aspects like informed consent and therefore people feel as though their right to autonomy is being ignored. Public health often involves programs that work toward the common good and have to sacrifice some level of individual autonomy.

	Ethical Question	Positive Example	Negative Example
Program Implementation	Is it clear what type of data being collected?	As a part of the public events and education materials, there is high-level information on the difference between viral and human DNA, which attempts to clarify that personal identifiable information is not being collected and how that minimizes risks. We are also educating people to the fact that these data are already generated as a part of routine care.	The public health agency website has information about how cluster detection works and what is collected. Due to low health/science literacy, it may not be possible to clarify the DNA versus RNA confusion any further.
	What intervention model does the program follow?	While this intervention relies heavily on the actions of medical and public health professionals, it also utilizes lay-led activities (e.g. community leaders spreading accurate information at public events) and empowerment activities, especially through participation in the CAB and public feedback sessions.	This intervention is primarily run by the professionals involved. Occasionally we may call upon some people to facilitate peer-led activities in order to appear more "empathetic" to their concerns.
	Is the program implemented fairly? Are resources being targeted equitably?	As the data is collecting during routine care, we will only be able to work with the information we have from those whose data are within the system already. We will use these cluster data sets to determine where and to whom to direct the appropriate resources based on need and community feedback, attempting to provide resources that will make improved health more equitable and attainable.	All individuals whose data is reported by the lab will be entered into the system. As the data is de-identified at the national level, all data points will be treated equally.
	Have barriers/ facilitators to implementation been identified?	Through work with local organizations and individuals, we identified the barriers as the need for a knowledgeable staff, community education, and centralized, accessible locations for resource sites. Key, trusted community leaders are facilitators to implementation.	The main barrier is community distrust, however the program will be implemented regardless of community acceptance.

	Ethical Question	Positive Example	Negative Example
Program Implementation	Have community members continued to be involved in this phase of program development?	We continue to consult with our CAB and rely on them to relay feedback from others in the affected communities. We also continue to hold public meetings to engage the community as a whole.	Community representatives are called in when necessary or when significant complaints have been made.
	Are processes in place to engage groups with limited opportunities to participate?	Involved community members have been trained to educate others on the program and to help encourage engagement. We will also offer opportunities for people to learn and express concerns or comments through webinars and phone calls at alternate times to accommodate different schedules.	Anyone who wants to participate is welcome. Resources and time will not be spent seeking out more community participants.
	Will the program be implemented in such a way that people will know about its existence?	We do not want this program to act as a barrier for people seeking health care, so we hope to be able to educate people about the program in a controlled and accurate manner instead of them finding out potential misinformation through word-of-mouth. The public events and educational materials are examples of how we are "announcing" the program.	The program will not be officially announced because providers have indicated that they fear people will avoid care if they know their data will be collected through that interaction. Once people find out about the program, we can educate and do damage control.
	Is the necessary infrastructure in place for the program to succeed?	We have worked with HDs to make sure they have adequate staff to carry out the extra work associated with the program. Our national agency will provide financial, technical, and ethics support.	HDs will adapt their organizational structures to be able to handle the extra work. They may need to hire more staff.
Data Management	Is data being collected from protected groups (e.g. minors)?	It is possible that minors' data will be collected and tracked through this program if their blood samples are processed. These individuals' data will be treated with the same protections as everyone else, however there will be different precautions taken if any individual contact needs to be made later on (e.g. Partner Services).	It is possible that minors' data will be collected and tracked through this program if their blood samples are processed. The data will not be included in cluster detection and response efforts in order to avoid complications for protected classes.

	Ethical Question	Positive Example	Negative Example
Data Management	Is there a balance of risk and benefit between those giving data and those collecting it?	Although there are real and perceived risks associated with the data collection and processing, there are many safeguards in place, and we believe that everyone involved will benefit. Those collecting the data will not receive any benefits from this program (financial or otherwise) other than being able to contribute to the better health of communities.	The data collected through this program will greatly help public health agencies understand the spread of disease throughout a community. We do not believe that there is great risk for those giving the data, but they also do not benefit much from the submissions.
	What entities are allowed access to this data? Is the data being used for any non-public health purposes?	The intention of this program is to collect data for use by public health agencies for public health uses only. On the rare occasion that the data is requested for a non-PH use, the request will be carefully evaluated under established criteria, and data will only be released based on the applicable state law. It is possible that PH agencies may need to partner with academic organizations to evaluate patterns in the data, however the least possible information will be released, and data will remain de-identified.	This data is intended for public health use. States vary in their data release requirements, so we will leave it up to our legal counsel to figure out the necessary steps or if data release will be required.
	Has clear notice of how the data will be used been given to the affected groups?	Through community leaders, public events, and educational materials, we have described in accessible language the reasons for collecting the data and how it will be used and protected.	The public health agency's website has information on data use. It is geared toward people with a basic understanding of molecular epidemiology, however it could be used by those less versed.
	Will all of the data be utilized?	All data collected through this surveillance program will be input into the system and utilized to detect transmissions and target resources. As the data is already being collected as a part of routine care, it would be unethical not to put it to use for public benefit if it can help.	We will collect as much data as possible so that we can study many aspects of the issue. Some data may ultimately not be utilized.

	Ethical Question	Positive Example	Negative Example
Data Management	Is the data being protected against re-identification? Against intentional or unintentional data breaches?	Data protection standards are in place at the national level and all participating agencies, and states will only receive funding if they comply with confidentiality standards. Staff has been trained on data security procedures and only authorized staff will have data access.	All participating agencies have servers to store the data that have been cleared by national standards.
	Are there risk-assessment resources available for program partners?	Materials have been developed to help health departments determine risks and benefits associated with cluster detection-related actions. For example, if there is a data request from researchers, these materials can help evaluate the public health benefits and risks.	Health department staff can determine for themselves whether they think there are risks or benefits associated with certain data-sharing actions.
Dissemination of Findings	Are results/findings from this program disseminated in a timely manner? Are they widely accessible?	The results will be reported in accessible language and we will partner with HDs to make sure that advocates and community members receive concrete examples of the program's successes and failures as soon as we complete the analysis.	The results will be distributed within the agency and to other government agencies. They will be available to the public and advocates by request but not widely distributed.
	Do the results communicate an appropriate level of alarm? Are the results quantifiable and clear?	We will be careful to convey an appropriate level of urgency without spreading fear in whatever we distribute. We will make sure to include quantifiable statistics in the results we report and to be able to reference other scenarios as examples of benefits and risks.	We will report out statistics that are necessary to demonstrate quantifiable successes of the program or major health risks; it is unpredictable what the community's reaction to these statistics may be.
	Is the disseminated information careful not to perpetuate stigma or stereotypes?	Special care will be given to ensure that the disseminated information portrays all subgroups in a fair and equitable way, regardless of patterns found in the data. Even if certain subgroups require more information or attention in the materials, we will be careful to be sensitive to the potential for group and individual harm.	The results and subsequent materials may include information that aligns with existing stereotypes. It is important for the public to know that some groups are more at-risk than others.

	Ethical Question	Positive Example	Negative Example
Monitoring and Review	How cost and resource-effective is the program?	This program identified multiple clusters and a large number of at-risk individuals. Testing and treatment options were introduced in specific areas and the high utilization rates may indicate a reduction in new transmissions, removing some future burden from the health care system.	Due to the minimal community involvement in the program, many individuals did not feel comfortable and therefore avoided seeking care. Because of this barrier, some people did not receive treatment and may therefore have more complex health profiles in the future, leading to higher costs to the system.
	Has the community seen better health outcomes?	It appears that many individuals who were at-risk have sought out preventative care, and many PWH who were not in treatment now are. Further analysis will be done to assess the long-term outcomes.	Our focus is mainly on the data collection itself, therefore we cannot assess whether there are better health outcomes, although the data collection may be able to fuel future interventions.
	Are the newly implemented resources still being utilized?	A public health representative will keep monitoring to ensure that resources remain necessary and appropriate. Currently, they are highly utilized.	We expect the state and local health departments to reach out if the resources are no longer useful for their communities.
	Is the program still operating ethically? Is there consistent monitoring of the program?	The regional representative carries out scheduled checks of staff and agency policies to ensure they are respecting the community and program design. The representative also holds public events with advocacy organizations to receive feedback from the community.	Once the program is in place, we expect it to continue to operate ethically. We will check in if we receive complaints from community members or HDs.

The reader will notice that there is no specific section of the analytical tool dedicated to community engagement, even though its benefits and importance have been emphasized throughout the discussion. Although it is important to draw attention to the need for other voices to be heard during the planning and implementation process, separating out community engagement efforts was deemed to be counterintuitive to that cause. Instead, community engagement-related questions are integrated into the rest of the sections, demonstrating that public input is integral to each step and diminishing the sense that community engagement can be "completed" as a step unto itself.

The framework contains specific questions which aim to address important checkpoints along the design, implementation, and monitoring process, however it is not all-inclusive and evaluators using the tool are welcome to tailor or augment the list of questions to apply more closely to their given area of work. The examples serve as a starting point for evaluators that may not understand the scope of the question or who may have trouble relating the question to their own situations. Groups utilizing the tool are also welcomed to develop their own applicable examples, especially if the tool will be used as an educational tool for public health workers or community members.

Incorporating Restorative Justice and D&I Science

In order for this analytical tool to be used to its fullest potential, bridging the divide between agencies and communities to create ethical, relevant, and multi-perspective intervention programs, it must be actualized in real, collaborative settings. To explore how the use of this tool within a communal forum might work, it is useful to return to the previously discussed restorative justice and D&I science techniques, and how they may aid in the development of community-vetted and scientifically effective interventions. Continuing to use HIV public health surveillance as the context for this work, the following is a hypothetical narrative exploration of two scenarios in which the tool could be helpful .

Scenario 1: In the case of a small, centralized outbreak of new HIV diagnoses, which has been identified by local health department cluster detection teams and concerned providers, it is decided in conjunction with state health departments and CDC that the number of new transmissions likely warrants interventional response. The CDC reminds the leading jurisdictions about the integrated framework tool and encourages them to take the steps seriously in order to respect the community's needs throughout their pursuit of better health. The local health department reaches out to advocacy groups and community members who have previously participated in health department meetings to help gather a group of individuals interested in giving input. The HD is met with some hesitation, as the agency and community have conflicted on issues in the past, but agrees to recruit meeting participants. Before any discussion occurs about the outbreak or potential interventions, a health department representative states that the HD acknowledges the tensions that have existed between the two groups and recognizes that a lack of inclusion, respect, and open-mindedness from the HD has contributed to these issues. She offers community members time to express their frustrations and recommendations on how this design and implementation process can be more conducive to meaningful engagement and community comfort. There is also a strong emphasis placed on transparency throughout the process and on open communication about implementation and monitoring.

Here, questions from the "Establishing a Fair Decision-Making Process" section of the tool and restorative justice techniques have facilitated the creation of a forum in which all participants feel respected and are comfortable to speak candidly. The importance placed on communication and transparency indicates that the agency will work toward the prompt dissemination of necessary materials and findings, and the consideration of frustrations may help identify certain barriers to implementation. This positive start to the process will hopefully lead to a more collaborative and community-driven intervention plan and to a mended relationship between health department and community.

Scenario 2: The same local health department has been working with a group of community members who expressed interest in representing the population, and they have finally developed an intervention plan that suits the public health needs. The community is still uncomfortable with some elements of the plan, however there have been constant communication and education efforts from both agency-level staff and peers that have allowed the community to become more comfortable with and knowledgeable about the need for cluster detection and response. In order to implement the program, barriers and facilitators must be identified. While public health staff can explore the technical and financial barriers, community members can help bring to light local nuances, for example explaining the neighborhood compositions of the town to figure out the best geographical placement of testing sites. The use of these suggestions allow for community members to experience quick wins and see the tangible results of their participation. They will experience similar victories during the evaluation of the dissemination of results, being able to provide feedback from the public on accessible and useful materials, as well as what information is desired. Advocates will also play an important role in the dissemination of findings, as they can help protect against stigma and make sure that communications are sending messages about the correct level of alarm. It will be important for all participants to be open to hearing continuous feedback throughout the process and to widen their perspectives in order to understand the fears and frustrations that others are experiencing.

During this step of the process, D&I science is at the forefront and the questions within "Program Implementation" and "Dissemination of Findings" will aid in the evaluation. Collaborative efforts will add a new set of knowledge to the planning efforts and should be rewarded with the respectful and legitimate consideration of community suggestions. Restorative justice techniques, specifically the inclusion and encountering steps, will be important to maintain throughout the process. There is an expected learning curve to adapt to the use of D&I and restorative justice in the development of public health interventions, however the potential for trusting and productive agency-community relationships and logical exploration of implementation barriers will likely be beneficial long-term.

Non-HIV Public Health Surveillance Application of the Framework: COVID-19

Many people have been quick to note the similarities between the rapidly growing pandemic of COVID-19 and the devasting course that HIV/AIDS has taken since the 1980s. Between the difficulty of implementing protection measures, mistrust in government actions and leaders, and the impact of the use of certain stigmatizing language, the diseases inspire many of the same concerns. In addition, the battle between individual liberties (i.e. being able to go to work and socialize) and government protections (i.e. "shelter-in-place" and the closing of non-essential businesses) has been passionately reignited. One distinct contrast between the diseases, journalist Mark Schoofs notes, is that COVID-19 can affect anyone very easily, which he frames as a positive aspect (Schoofs 2020). While COVID-19 carries a different type of judgement – racial prejudices and assumptions of irresponsible behaviors (Tavernise and Oppel Jr. 2020) – it does not have the same stigmatizing and othering effect that HIV does; COVID-19 demonstrates how connected we all truly are. This connectedness is unfortunately a major cause of the virus' prolific spread, however it does invite the opportunity to utilize cluster detection and response efforts to attempt to understand transmission and intervention.

The low frequency of COVID-19 testing and data – 313.6 tests per million people administered in the U.S. so far (Ortiz-Ospina and Hasell 2020) – limit the extent to which cluster detection and response can be carried out. Currently, CDC is developing standards for data collection and support for persons under investigation, working alongside state and local health departments (Relief Central 2020). There are, however, groups studying clusters of COVID-19, not through viral genomics, but through case reporting and symptom recognition (Cai et al. 2020; Sisson, Warth, and Winkley 2020). The same idea of identifying a connected social contact network applies – although without the fears associated with government collection of biological data – which allows public health workers to anticipate diagnoses and act proactively by recommending quarantine and testing. Others are looking into the use of artificial intelligence and machine learning to cross-reference existing data with other data sets such as biometric authentications from airports (Hamade 2020), which will likely inspire other concerns over data privacy and surveillance, even if it is helpful for containing disease. Once more data is available and the potential for molecular cluster detection and response increases, it will allow public health agencies to more intentionally track the virus' spread and origins.

The integrated framework presented in this paper offers guidance and standardization for the evaluation of existing and future COVID-19 cluster detection and response efforts. The declaration of a national emergency in the U.S., among other countries, has shifted response efforts toward paternalistic government protections and away from personal autonomy, but a wave of pushback against these socially-limiting regulations may soon arrive (Schoofs 2020). If this pandemic persists for an extended amount of time, interventions will begin to face similar challenges to those of HIV surveillance, with calls for data privacy, informed consent for collection, and treatment options. The case of informed consent will be particularly relatable to HIV surveillance, in that nationally representative data would likely be impossible to gather if informed consent was required for COVID-19 data collection. While there is currently a surge of community togetherness in response to COVID-19 (Salonikas 2020), people are protective of their individual rights – especially when it comes to data – and may not be comfortable with the idea of the government tracking their diagnoses. If there were to be an opt-out or an informed consent process, it is likely that the amount of usable and unbiased data collected would be diminished, just as it would be for HIV surveillance. Some content, including the accompanying examples, within the framework would need to be altered in order to be applicable and appropriate for use on COVID-19 responses, however the developed tool can operate as a useful basis for the development and ethical evaluation of these new data collection and response efforts.

Conclusion

The field of public health is extremely well-established, and surveillance programs have been a cornerstone of efforts to improve and protect the general health and well-being of the population for centuries. New uses of surveillance data to focus public health response, however, inspire new challenges, community pushback, and ethical roadblocks to overcome. Cluster detection and response in HIV, and now in COVID-19, have the potential to protect many people who are at risk and to direct resources toward those who have already been diagnosed; the results from some of the first cluster outbreaks to be identified in HIV demonstrate these possible successes. Without the support and buy-in from community members, though, these programs risk losing trust among community members, potentially leading to poorer health outcomes. The disconnect between the desire for informed consent to be a part of the public health surveillance process and the lack of understanding that it would significantly diminish the usefulness and representativeness of the data creates tension between communities and agencies. The perceptions of coercion and fear may act as a barrier to individuals seeking health care services – the opposite of what these interventions seek to accomplish – while professional staff may become frustrated with the public's inability to recognize the ethical and epidemiological importance of collecting fully representative data and using to it promote health.

Compromise can be found through meaningful collaboration between these groups and acknowledgement of myopic viewpoints that may have caused damage to the other stakeholders involved. By using a combination of restorative justice techniques and D&I science to cooperatively design and implement these interventions with affected communities, there is major potential not only to design a better and more appropriate intervention, but to heal the damaged relationship between professionals and the public. Coupled with outreach, education, and transparency, it is possible that some fears associated with the idea of public health surveillance can be overturned, as well. Although there will likely never be full support from everyone for HIV cluster detection and response, or other public health interventions, recognizing past wrongdoing and working to understanding the perspectives of all groups involved may help ease some of the tensions and result in more successful, effective, and ethical interventions..

References

Adler-Bell, Sam. “Is America Ready to Abandon Fear-Based Surveillance Policy?” The Century Foundation, April 5, 2017. *https://tcf.org/content/commentary/america-ready-abandon-fear-based-surveillance-policy/*.

Agosto-Rosario, Moisés. “Living the Denver Principles.” NMAC, May 31, 2017. *http://www.nmac.org/living-denver-principles/*.

AIDS Policy & Law. “Black Caucus Seeks Emergency Attention for HIV Epidemic.” AIDS Policy & Law 13, no. 10 (May 29, 1998): 4–5.

Al Jazeera. “Emergencies, Closures: How Are US States Handling Coronavirus?” Al Jazeera, March 19, 2020. https://www.aljazeera.com/news/2020/03/emergencies-closures-states-handling-coronavirus-200317213356419.html.

Altman, Lawrence K. “New Homosexual Disorder Worries Health Officials.” The New York Times, May 11, 1982, sec. Science. *https://www.nytimes.com/1982/05/11/science/new-homosexual-disorder-worries-health-officials.html*.

Altman, Lawrence K. “Rare Cancer Seen in 41 Homosexuals.” The New York Times, July 3, 1981, sec. U.S. *https://www.nytimes.com/1981/07/03/us/rare-cancer-seen-in-41-homosexuals.html*.

Altman, MJ. “Reluctance to Vaccinate Named a Top Global Health Threat in 2019.” United Nations Foundation, January 22, 2019. *https://unfoundation.org/blog/post/anti-vaxxers-named-top-global-health-threat-in-2019/*.

American Medical Association (AMA). “AMA Adopts New Public Health Policies to Improve Health of Nation.” American Medical Association, June 13, 2019. *https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-public-health-policies-improve-health-nation-3*.

American Psychological Association (APA). “APA Resolution on Opposing HIV Criminalization.” American Psychological Association, 2018. http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2009.828.

American Red Cross LGBTQ+ Team Member Resource Group. “LGBTQ+ Donors.” American Red Cross, 2019. *https://www.redcrossblood.org/donate-blood/how-to-donate/eligibility-requirements/lgbtq-donors.html*.

amfAR. “National Black HIV/AIDS Awareness Day: Get Educated, Get Tested, Get Involved, and Get Treated.” amfAR: National Black HIV/AIDS Awareness Day, February 6, 2014. *https://www.amfar.org/national-black-hiv-aids-awareness-day/*.

amfAR. “New President, a New Era in HIV/AIDS Policy.” amfAR, November 14, 2008. *https://www.amfar.org/content.aspx?id=4642*.

Anderson, Jon P., Gerald H. Learn, Allen G. Rodrigo, Xi He, Yang Wang, Hillard Weinstock, Marcia L. Kalish, Kenneth E. Robbins, Leroy Hood, and James I. Mullins. “Predicting Demographic Group Structures Based on DNA Sequence Data.” *Molecular Biology and Evolution* 20, no. 7 (July 1, 2003): 1168–80. https://doi.org/10.1093/molbev/msg128.

Antrim, Aislinn. “Study: ACA Improved Insurance Coverage for People Both Cancer, HIV.” Pharmacy Times, November 13, 2019. *https://www.pharmacytimes.com/news/study-affordable-care-act-improved-insurance-coverage-for-people-both-cancer-hiv*.

AP. "Insurers' Study Sees AIDS Cost Of $50 Billion." The New York Times, August 5, 1987, sec. U.S. *https://www.nytimes.com/1987/08/05/us/insurers-study-sees-aids-cost-of-50-billion.html*.

Arnstein, Sherry R. "A Ladder Of Citizen Participation." Journal of the American Institute of Planners 35, no. 4 (July 1, 1969): 216–24. *https://doi.org/10.1080/01944366908977225*.

Artiga, Samantha, and Maria Diaz. "Health Coverage and Care of Undocumented Immigrants." Kaiser Family Foundation, July 2019. *http://files.kff.org/attachment/Issue-Brief-Health-Coverage-and-Care-of-Undocumented-Immigrants*.

Avert.org. "HIV Strains and Types." Avert, February 26, 2019. https://www.avert.org/professionals/hiv-science/types-strains.

Avert.org. "The Science of HIV and AIDS - Overview." Avert, October 10, 2019. *https://www.avert.org/professionals/hiv-science/overview*.

Balzar, John. "The Times Poll : Tough New Government Action on AIDS Backed." Los Angeles Times, December 19, 1985. *https://www.latimes.com/archives/la-xpm-1985-12-19-mn-30337-story.html*.

Bayer, Ronald, and Amy L. Fairchild. "The Genesis of Public Health Ethics." Bioethics 18, no. 6 (November 2004): 473–92. *https://doi.org/10.1111/j.1467-8519.2004.00412.x*.

Bayer, Ronald, and Amy Fairchild. "The Role of Name-Based Notification in Public Health and HIV Surveillance." UNAIDS: Joint United Nations Programme on HIV/AIDS, July 2000, 1–52.

Bonde, Sheila, and Paul Firenze. "A Framework for Making Ethical Decisions." Brown University Science and Technology Studies, May 2013. *https://www.brown.edu/academics/science-and-technology-studies/framework-making-ethical-decisions*.

Boyes-Watson, Carolyn. "What Is Restorative Justice?" Suffolk University, Center for Restorative Justice. Accessed 2020. *https://www.suffolk.edu/cas/centers-institutes/center-for-restorative-justice/what-is-restorative-justice*.

Brodwin, Erin. "Genetic Testing Is the Future of Healthcare, but Many Experts Say Companies like 23andMe Are Doing More Harm than Good." Business Insider, January 12, 2019. *https://www.businessinsider.com/future-healthcare-dna-genetic-testing-23andme-2018-12*.

Brunton, Ginny, James Thomas, Alison O'Mara-Eves, Farah Jamal, Sandy Oliver, and Josephine Kavanagh. "Narratives of Community Engagement: A Systematic Review-Derived Conceptual Framework for Public Health Interventions." BMC Public Health 17, no. 1 (December 11, 2017): 944. *https://doi.org/10.1186/s12889-017-4958-4*.

Buchanan, David R. "Autonomy, Paternalism, and Justice: Ethical Priorities in Public Health." American Journal of Public Health 98, no. 1 (January 2008): 15–21. *https://doi.org/10.2105/AJPH.2007.110361*.

Burnham, Jason P., Elvin Geng, Chinmayi Venkatram, Graham A. Colditz, and Virginia R. McKay. "Putting the Dissemination and Implementation in Infectious Diseases." Clinical Infectious Diseases ciz1011 (October 14, 2019): 1–8. *https://doi.org/10.1093/cid/ciz1011*.

Cai, Jing, Wenjie Sun, Jianping Huang, Michelle Gamber, Jing Wu, and Guiqing He. "Indirect Virus Transmission in Cluster of COVID-19 Cases, Wenzhou, China, 2020." *Emerging Infectious Diseases* 26, no. 6 (June 2020). https://doi.org/10.3201/eid2606.200412.

Cairns, Gus. “Treatment as Prevention.” HIVandHepatitis.com, March 4, 2014. *http://www.hivandhepatitis.com/hiv-prevention/hiv-test-treat/4553-croi-2014-no-one-with-undetectable-viral-load-transmits-hiv-in-partner-study*.

Callahan, Daniel, and Bruce Jennings. “Ethics and Public Health: Forging a Strong Relationship.” American Journal of Public Health 92, no. 2 (February 2002): 169–76. *https://doi.org/10.2105/ajph.92.2.169*.

Cassell, J., and A. Young. “Why We Should Not Seek Individual Informed Consent for Participation in Health Services Research.” Journal of Medical Ethics 28, no. 5 (October 1, 2002): 313–17. *https://doi.org/10.1136/jme.28.5.313*.

Center for HIV Law and Policy, The. “Criminal Law.” The Center for HIV Law and Policy. Accessed 2020. *http://www.hivlawandpolicy.org/issues/criminal-law*.

Center for HIV Law and Policy, The. “Immigration.” The Center for HIV Law and Policy. Accessed 2019. *https://www.hivlawandpolicy.org/issues/immigration*.

Center for HIV Law and Policy, The. “Is Molecular HIV Surveillance Worth the Risk?” The Center for HIV Law and Policy, 2019. *http://www.hivlawandpolicy.org/sites/default/files/CHLP%20Molecular%20Surveillance%20Final.pdf*.

Center for HIV Law and Policy, The. “Map: HIV Criminalization in the United States, The Center for HIV Law and Policy (2018).” The Center for HIV Law and Policy, March 1, 2019. *https://www.hivlawandpolicy.org/resources/map-hiv-criminalization-united-states-center-hiv-law-and-policy-2018*.

Centers for Disease Control and Prevention (CDC). “Data to Care.” Centers for Disease Control and Prevention, Effective Interventions, January 2, 2020. https://www.cdc.gov/hiv/effective-interventions/respond/data-to-care/index.html.

Centers for Disease Control and Prevention (CDC). “Evolution of HIV/AIDS Prevention Programs --- United States, 1981--2006.” *Morbidity and Mortality Report Weekly* 55, no. 21 (June 2, 2006): 597–603.

Centers for Disease Control and Prevention (CDC). “Funding Opportunity Announcement (FOA) PS18-1802: Integrated Human Immunodeficiency Virus (HIV) Surveillance and Prevention Programs for Health Departments.” Centers for Disease Control and Prevention, HIV Funding and Budget, April 11, 2019. *https://www.cdc.gov/hiv/funding/announcements/ps18-1802/index.html*.

Centers for Disease Control and Prevention (CDC). “HIV and African Americans.” Centers for Disease Control and Prevention, HIV Public Health Partners, January 30, 2020. *https://www.cdc.gov/hiv/group/racialethnic/africanamericans/index.html*.

Centers for Disease Control and Prevention (CDC). “HIV and AIDS --- United States, 1981--2000.” Morbidity and Mortality Report Weekly 50, no. 21 (June 1, 2001): 430–34.

Centers for Disease Control and Prevention (CDC). “HIV Planning Guidance.” Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, July 2012. *https://www.cdc.gov/hiv/pdf/p/cdc-hiv-planning-guidance.pdf*.

Centers for Disease Control and Prevention (CDC). “Pneumocystis Pneumonia --- Los Angeles.” Morbidity and Mortality Report Weekly 30, no. 21 (June 5, 1981): 1–3.

Centers for Disease Control and Prevention (CDC). “Update: Acquired Immunodeficiency Syndrome – Unites States.” Morbidity and Mortality Report Weekly 35, no. 2 (January 17, 1986): 17–20.

Centre for Justice & Reconciliation. “Lesson 1: What Is Restorative Justice?” Restorative Justice. Accessed 2020. *http://restorativejustice.org/restorative-justice/about-restorative-justice/tutorial-intro-to-restorative-justice/lesson-1-what-is-restorative-justice/*.

Childress, James F., Ruth R. Faden, Ruth D. Gaare, Lawrence O. Gostin, Jeffrey Kahn, Richard J. Bonnie, Nancy E. Kass, Anna C. Mastroianni, Jonathan D. Moreno, and Phillip Nieburg. “Public Health Ethics: Mapping the Terrain.” The Journal of Law, Medicine & Ethics 30, no. 2 (2002): 170–78. *https://doi.org/10.1111/j.1748-720X.2002.tb00384.x*.

Clinton Foundation. “Press Release: Agreement on Major Reduction in Price of AIDS Drugs.” Clinton Foundation, October 23, 3AD. *https://www.clintonfoundation.org/main/news-and-media/press-releases-and-statements/press-release-agreement-on-major-reduction-in-price-of-aids-drugs.html*.

Crewdson, John. “Liberace’s Death Raises Privacy Questions.” The Chicago Tribune, February 15, 1987. *https://www.chicagotribune.com/news/ct-xpm-1987-02-15-8701120256-story.html*.

Crofts, Nick, and David Patterson. “Police Must Join the Fast Track to End AIDS by 2030.” Journal of the International AIDS Society: Police, Law Enforcement and HIV 19 (July 18, 2016): 2–6. *https://doi.org/10.7448/IAS.19.4.21153*.

Curran, James. In Their Own Words. Interview by Victoria Harden and Caroline Hannaway, May 19, 1998. *https://history.nih.gov/nihinownwords/docs/curran1_01.html*.

De Weger, E., N. Van Vooren, K. G. Luijkx, C. A. Baan, and H. W. Drewes. “Achieving Successful Community Engagement: A Rapid Realist Review.” *BMC Health Services Research* 18, no. 1 (2018). https://doi.org/10.1186/s12913-018-3090-1.

Democratic Policy Committee. “The Conference Report to Accompany H.R. 3288: The Consolidated Appropriations Act, 2010.” DPC.senate.gov, December 11, 9AD. *https://www.dpc.senate.gov/dpcdoc.cfm?doc_name=lb-111-1-156*.

Department of Health and Human Services. “Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act.” Federal Register, May 8, 2015. *https://www.federalregister.gov/documents/2015/05/08/2015-11048/organ-procurement-and-transplantation-implementation-of-the-hiv-organ-policy-equity-act*.

Department of Homeland Security (DHS). “DHS Implements Inadmissibility on Public Charge Grounds Final Rule.” Department of Homeland Security, February 24, 2020. *https://www.dhs.gov/news/2020/02/24/dhs-implements-inadmissibility-public-charge-grounds-final-rule*.

Désy, Michel, France Filiatrault, and Isabelle Laporte. “A Tool for Ethical Analysis of Public Health Surveillance Plans.” In Population and Public Health Ethics: Cases from Research, Policy, and Practice, 52–57. Toronto, Ontario: University of Toronto Joint Centre for Bioethics, 2012. *http://jcb.utoronto.ca/publications/documents/Population-and-Public-Health-Ethics-Casebook-ENGLISH.pdf*.

Detsky, Allan S, Mark O Baerlocher, and Albert W Wu. “Admitting Mistakes: Ethics Says Yes, Instinct Says No.” CMAJ : Canadian Medical Association Journal 185, no. 5 (March 19, 2013): 448. *https://doi.org/10.1503/cmaj.121187*.

Division of HIV/AIDS Prevention (DHAP), CDC. “Advancing HIV Prevention through Cluster Detection and Response,” February 2019. *https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-advancing-HIV-prevention-through-cluster-detection.pdf*.

Division of HIV/AIDS Prevention (DHAP), CDC. “Detecting and Responding to HIV Transmission Clusters - a Guide for Health Departments.” Centers for Disease Control and Prevention, June 2018, 1–132.

Division of HIV/AIDS Prevention (DHAP), CDC. “HIV Cluster and Outbreak Detection and Response.” Centers for Disease Control and Prevention, HIV Public Health Partners, February 5, 2020. *https://www.cdc.gov/hiv/programresources/guidance/cluster-outbreak/index.html*.

Division of HIV/AIDS Prevention (DHAP), CDC. “HIV Molecular Surveillance: Questions and Answers.” Centers for Disease Control and Prevention, HIV Public Health Partners, October 31, 2019. *https://www.cdc.gov/hiv/programresources/guidance/molecular-cluster-identification/qa.html*.

Division of HIV/AIDS Prevention (DHAP), CDC. “Meeting Summary: Responsible Use of HIV Cluster Data for Public Health Action: Amplifying Benefits, Minimizing Harms.” Centers for Disease Control and Prevention, HIV Public Health Partners, February 5, 2020. *https://www.cdc.gov/hiv/programresources/guidance/cluster-outbreak/responsible-use.html*.

Division of HIV/AIDS Prevention (DHAP), CDC. “Surveillance Systems.” Centers for Disease Control and Prevention, HIV Public Health Partners, October 30, 2019. *https://www.cdc.gov/hiv/statistics/surveillance/systems/index.html*.

Division of HIV/AIDS Prevention (DHAP), CDC. “Virtual Meeting Series Summary – Responsible Use of HIV Cluster Data for Public Health Action: Amplifying Benefits, Minimizing Harms.” Centers for Disease Control and Prevention, December 11, 2019.

Durmaz, Asude Alpman, Emin Karaca, Urszula Demkow, Gokce Toruner, Jacqueline Schoumans, and Ozgur Cogulu. “Evolution of Genetic Techniques: Past, Present, and Beyond.” BioMed Research International 2015 (March 22, 2015): 1–7. *https://doi.org/10.1155/2015/461524*.

Estabrooks, Paul A., Ross C. Brownson, and Nicolaas P. Pronk. “Dissemination and Implementation Science for Public Health Professionals: An Overview and Call to Action.” Preventing Chronic Disease 15, no. E62 (December 2018). *https://doi.org/10.5888/pcd15.180525*.

Evans, David, and Dana Van Gorder. “~~MHS~~ Molecular HIV Surveillance(?) And Community Engagement: Project Inform.” Accessed 2020.

Flanigan, Jessica. “Public Bioethics.” Public Health Ethics 6, no. 2 (July 15, 2013): 170–84. *https://doi.org/10.1093/phe/pht022*.

Fleming, Patricia L., John W. Ward, Robert S. Janssen, Kevin M. De Cock, Ronald O. Valdiserri, and Helene D. Gayle. “Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome.” Morbidity and Mortality Report Weekly 48, no. RR13 (October 10, 1999): 1–28.

Fuld, Joe. “Grassroots vs. Grasstops Advocacy | The Campaign Workshop.” The Campaign Workshop, May 12, 2017. *https://www.thecampaignworkshop.com/grassroots-vs-grasstops-advocacy*.

Geiger, AW. “How Americans Have Viewed Surveillance and Privacy since Snowden Leaks.” Pew Research Center, June 4, 2018. *https://www.pewresearch.org/fact-tank/2018/06/04/how-americans-have-viewed-government-surveillance-and-privacy-since-snowden-leaks/*.

Grabowski, Mary K., and Andrew D. Redd. “Molecular Tools for Studying HIV Transmission in Sexual Networks.” Current Opinion in HIV and AIDS 9, no. 2 (March 2014): 126–33. *https://doi.org/10.1097/COH.0000000000000040*.

Gross, Jane. "Needle Exchange for Addicts Wins Foothold Against AIDS in Tacoma." The New York Times, January 23, 1989, sec. U.S. *https://www.nytimes.com/1989/01/23/us/needle-exchange-for-addicts-wins-foothold-against-aids-in-tacoma.html*.

Günthard, Huldrych F., and Roger Kouyos. "Can Directionality of HIV Transmission Be Predicted by Next-Generation Sequencing Data?" The Journal of Infectious Diseases 220, no. 9 (December 24, 2018): 1393–95. *https://doi.org/10.1093/infdis/jiy737*.

Hamade, Mohamad Ali. "COVID-19: How to Fight Disease Outbreaks with Data." World Economic Forum, March 19, 2020. https://www.weforum.org/agenda/2020/03/covid-19-how-to-fight-disease-outbreaks-with-data/.

Hauck, Grace. "Anti-Gay Hate Crimes on the Rise, FBI Says, and They Likely Undercount." USA Today, June 28, 2019. *https://www.usatoday.com/story/news/2019/06/28/anti-gay-hate-crimes-rise-fbi-says-and-they-likely-undercount/1582614001/*.

Have, Marieke ten, Inez D. de Beaufort, Johan P. Mackenbach, and Agnes van der Heide. "An Overview of Ethical Frameworks in Public Health: Can They Be Supportive in the Evaluation of Programs to Prevent Overweight?" BMC Public Health 10, no. 638 (October 22, 2010): 1–11. *https://doi.org/10.1186/1471-2458-10-638*.

Health Resources & Services Administration (HRSA). "About the Ryan White HIV/AIDS Program." HRSA: Ryan White & Global HIV/AIDS Programs, February 2019. *https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program*.

Heslin, Kevin C, Ronald M Andersen, Susan L Ettner, and William E Cunningham. "Racial and Ethnic Disparities in Access to Physicians with HIV-Related Expertise." Journal of General Internal Medicine 20, no. 3 (March 2005): 283–89. *https://doi.org/10.1111/j.1525-1497.2005.40109.x*.

HIV.gov. "A Timeline of HIV and AIDS." HIV.gov. Accessed 2019. *https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline*.

HIV.gov. "What Is 'Ending the HIV Epidemic: A Plan for America'?" HIV.gov, February 26, 2020. *https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview*.

Holloway, Karla F. C. "'Vulnerable' Populations: Medicine, Race, and Presumptions of Identity." AMA Journal of Ethics 13, no. 2 (July 1, 2011): 124–27. *https://doi.org/10.1001/virtualmentor.2011.13.2.msoc1-1102.*

Institute of Medicine, National Academy of Sciences. Confronting AIDS: Directions for Public Health, Health Care, and Research. National Academy Press, 1986. *https://doi.org/10.17226/938*.

Institute of Medicine (US) Committee on Assuring the Health of the Public in the 21st Century. "The Governmental Public Health Infrastructure." In The Future of the Public's Health in the 21st Century, 96–177. Washington (DC): National Academies Press (US), 2002. https://www.ncbi.nlm.nih.gov/books/NBK221231/.

Institute of Medicine (US) Committee on the Ryan White CARE Act. "Overview of the HIV/AIDS Epidemic and the Ryan White CARE Act." In Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act, 41–72. National Academies Press (US), 2004. *https://www.ncbi.nlm.nih.gov/books/NBK216136/*.

Institute of Medicine (US) Committee on the Ryan White CARE Act: Data for Resource Allocation, Planning, and Evaluation. "Public Health and HIV/AIDS Surveillance." In Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act, 73–86. National Academies Press (US), 2004. *https://www.ncbi.nlm.nih.gov/books/NBK216140/*.

Institute of Medicine (US) Committee to Study the AIDS Research Program of the National Institutes of Health. Supporting the NIH AIDS Research Program. National Academies Press (US), 1991. *https://www.ncbi.nlm.nih.gov/books/NBK234085/*.

International AIDS Society. "Conference Summary Report." AIDS 2014: 20th International AIDS Conference. Melbourne, Australia: International AIDS Society (IAS), 2014. *https://www.iasociety.org/Web/WebContent/File/AIDS2014_Summary_Report_Dec2014.pdf*.

Kass, Nancy E. "An Ethics Framework for Public Health." American Journal of Public Health 91, no. 11 (November 2001): 1776–82. *https://doi.org/10.2105/ajph.91.11.1776*.

Kempner, Martha. "CDC Explains and Defends Molecular Surveillance System." TheBodyPro, March 18, 2019. *https://www.thebodypro.com/article/cdc-explains-defends-molecular-surveillance-system*.

Khoury, Muin J., Wylie Burke, and Elizabeth J. Thomson, eds. Genetics and Public Health in the 21st Century: Using Genetic Information to Improve Health and Prevent Disease. Oxford Monographs on Medical Genetics. Oxford, New York: Oxford University Press, 2000.

Killelea, Amy. "Health Department HIV Data Release for Law Enforcement." Virtual Meeting Presentation presented at the Responsible Use of HIV Cluster Data for Public Health Action: Amplifying Benefits, Minimizing Harms (Virtual Meeting 2 of 3), Atlanta, GA, February 28, 2019.

King, Mark S. "HIV Groups Bash HIV Separation as Border Policy Gets Walked Back." My Fabulous Disease (blog), July 27, 2019. *https://marksking.com/my-fabulous-disease/hiv-groups-bash-hiv-separation-as-border-policy-gets-walked-back/*.

Klingler, Corinna, Diego Steven Silva, Christopher Schuermann, Andreas Alois Reis, Abha Saxena, and Daniel Strech. "Ethical Issues in Public Health Surveillance: A Systematic Qualitative Review." BMC Public Health 17, no. 1 (April 4, 2017): 1–13. *https://doi.org/10.1186/s12889-017-4200-4*.

Lee, Lisa M., Charles M. Heilig, and Angela White. "Ethical Justification for Conducting Public Health Surveillance Without Patient Consent." *American Journal of Public Health* 102, no. 1 (January 2012): 38–44. https://doi.org/10.2105/AJPH.2011.300297.

Lee, Myung J. "Bridging the Disconnect Between the People and Their Governments." Voices of the Governing Institute, April 11, 2017. *https://www.governing.com/gov-institute/voices/col-cities-citizens-elected-officials-impact-volunteering.html*.

Legacy Project, The. "Without Our Consent: Centering People Living with HIV in HIV Genetic Sequencing." Webinar, Fred Hutch Institute HIV/AIDS Network Coordination, March 27, 2019. https://www.facebook.com/HANCLegacyProject/videos/2129826247054379/.

Leland, John. "'People Think It's Over.'" The New York Times, June 1, 2013, sec. New York. *https://www.nytimes.com/2013/06/02/nyregion/spared-death-aging-people-with-hiv-struggle-to-live.html*.

Lopez, German. "Needle Exchanges Have Been Proved to Work against Opioid Addiction. They're Banned in 15 States." Vox, June 22, 2018. *https://www.vox.com/science-and-health/2018/6/22/17493030/needle-exchanges-ban-state-map*.

MacKay, Kathryn. "Utility and Justice in Public Health." Journal of Public Health 40, no. 3 (September 2018): e413–18. *https://doi.org/10.1093/pubmed/fdx169*.

Marckmann, Georg, Harald Schmidt, Neema Sofaer, and Daniel Strech. "Putting Public Health Ethics into Practice: A Systematic Framework." Frontiers in Public Health 3, no. 23 (February 6, 2015). *https://doi.org/10.3389/fpubh.2015.00023*.

Merriam-Webster. "Definition of FRAMEWORK." Merriam-Webster Dictionary, 2020. *https://www.merriam-webster.com/dictionary/framework*.

Morgan, Mary Anne, and Jennifer Lifshay. "Community Engagement in Public Health." Contra Costa Health Services, March 2006. *https://cchealth.org/public-health/pdf/community_engagement_in_ph.pdf*.

NASTAD. "HIV Data Privacy and Confidentiality: Legal & Ethical Considerations for Health Department Data Sharing." NASTAD, June 2018. *https://www.nastad.org/resource/hiv-data-privacy-and-confidentiality*.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action." U.S. Department of Health and Human Services, 2011. *https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf*.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). "Only 3 in 10 Americans with HIV Have Virus in Check." Centers for Disease Control and Prevention, November 25, 2014. *https://www.cdc.gov/media/releases/2014/p1125-HIV-testing.html*.

National Institute of Allergy and Infectious Diseases (NIAID). "Antiretroviral Drug Discovery and Development." NIH: National Institute of Allergy and Infectious Diseases, November 26, 2018. *https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development*.

National Institute of Allergy and Infectious Diseases (NIAID). "Pre-Exposure Prophylaxis (PrEP) to Reduce HIV Risk." NIH: National Institute of Allergy and Infectious Diseases, October 16, 2018. *https://www.niaid.nih.gov/diseases-conditions/pre-exposure-prophylaxis-prep*.

National Society of Genetic Counselors (NSGC). "NSGC > Genetic Counseling > About Genetic Counseling." About Genetic Counselors. Accessed 2020. *http://aboutgeneticcounselors.com/Genetic-Counseling*.

NIAID Now. "10 Things to Know About HIV Suppression." NIH: National Institute of Allergy and Infectious Diseases, November 14, 2017. *https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression*.

Nyirenda, Deborah, Kate Gooding, Rodrick Sambakunsi, Linley Seyama, Joseph Mfutso-Bengo, Lucinda Manda Taylor, Stephen B. Gordon, and Michael Parker. "Strengthening Ethical Community Engagement in Contemporary Malawi." Wellcome Open Research 3, no. 115 (March 18, 2019). *https://doi.org/10.12688/wellcomeopenres.14793.2*.

O'Mara-Eves, Alison, Ginny Brunton, Sandy Oliver, Josephine Kavanagh, Farah Jamal, and James Thomas. "The Effectiveness of Community Engagement in Public Health Interventions for Disadvantaged Groups: A Meta-Analysis." BMC Public Health 15, no. 129 (February 12, 2015). *https://doi.org/10.1186/s12889-015-1352-y*.

Ortiz-Ospina, Esteban, and Joe Hasell. "How Many Tests for COVID-19 Are Being Performed around the World?" Our World in Data, March 20, 2020. https://ourworldindata.org/covid-testing.

Ortmann, Leonard W., Drue H. Barrett, Carla Saenz, Ruth Gaare Bernheim, Angus Dawson, Jo A. Valentine, and Andreas Reis. "Public Health Ethics: Global Cases, Practice, and Context." In Public Health Ethics: Cases Spanning the Globe, edited by Drue H. Barrett, Leonard W. Ortmann, Angus Dawson, Carla Saenz, Andreas Reis, and Gail Bolan, 3–35. Cham (CH): Springer, 2016. *http://www.ncbi.nlm.nih.gov/books/NBK435780/*.

Patel, Neil. "The Psychology of Instant Gratification and How It Will Revolutionize Your Marketing Approach." Entrepreneur, June 24, 2014. *https://www.entrepreneur.com/article/235088*.

Patterson, David, and Leslie London. "International Law, Human Rights and HIV/AIDS." Bulletin of the World Health Organization 80, no. 12 (2002): 964–69.

Petrini, Carlo, and Gualtiero Ricciardi. "Ethical Issues in Public Health Surveillance: Drawing Inspiration from Ethical Frameworks." Annali Dell'Istituto Superiore Di Sanità 51, no. 4 (2015): 270–76. *https://doi.org/10.4415/ANN_15_04_05*.

Petrini, Carlo. "Person: Centre Both of Clinical Ethics and of Public Health Ethics." Annali Dell'Istituto Superiore Di Sanità 48, no. 1 (2012): 1–4. *https://doi.org/10.4415/ANN_12_01_01*.

Pfleger, Paige. "Some Push To Change State Laws That Require HIV Disclosure To Sexual Partners." NPR, January 22, 2020. *https://www.npr.org/2020/01/22/797359483/some-push-to-change-state-laws-that-require-hiv-disclosure-to-sexual-partners*.

Pierce, Sarah, Jessica Bolter, and Andrew Selee. "U.S. Immigration Policy under Trump: Deep Changes and Lasting Impacts." Migration Policy Institute, July 2018. *https://www.migrationpolicy.org/research/us-immigration-policy-trump-deep-changes-impacts*.

Pinsker, Joe. "The People Ignoring Social Distancing." The Atlantic, March 17, 2020. https://www.theatlantic.com/family/archive/2020/03/coronavirus-social-distancing-socializing-bars-restaurants/608164/.

Pollack, Andrew, and Lawrence K. Altman. "Large Trial Finds AIDS Vaccine Fails to Stop Infection." The New York Times, February 24, 3AD. *https://www.nytimes.com/2003/02/24/us/large-trial-finds-aids-vaccine-fails-to-stop-infection.html*.

Pounder, C. N. M. "Nine Principles for Assessing Whether Privacy Is Protected in a Surveillance Society." Identity in the Information Society 1, no. 1 (December 18, 2008): 1–22. *https://doi.org/10.1007/s12394-008-0002-2*.

Rainie, Lee, and Andrew Perrin. "Key Findings about Americans' Declining Trust in Government and Each Other." Pew Research Center, July 22, 2019. *https://www.pewresearch.org/fact-tank/2019/07/22/key-findings-about-americans-declining-trust-in-government-and-each-other/*.

Rapaport, Lisa. "Immigrants Use Less Healthcare than People Born in U.S." Reuters, September 13, 2018. *https://www.reuters.com/article/us-health-costs-immigration-idUSKCN1LT3BW*.

Reamer, Frederic G. "The Ethics of Care." Social Work Today, September 2016. *https://www.socialworktoday.com/news/eoe_0916.shtml*.

Regalado, Antonio. "More than 26 Million People Have Taken an At-Home Ancestry Test." MIT Technology Review, February 11, 2019. *https://www.technologyreview.com/s/612880/more-than-26-million-people-have-taken-an-at-home-ancestry-test/*.

Relief Central. "Reporting Coronavirus Disease (COVID-19) in the United States." Relief Central, March 21, 2020. https://relief.unboundmedicine.com/relief/.//view/Coronavirus-Guidelines/2355002/all/Reporting_COVID_19_in_the_United_States?refer=true.

Ryan, Benjamin. "Will the Genetic Analysis–Based HIV Surveillance Safeguard Privacy?" POZ, August 13, 2018. *https://www.poz.com/article/will-genetic-analysisbased-hiv-surveillance-safeguard-privacy*.

Salonikas, Christina. “Community Coming Together To Feed Each Other During COVID-19 Pandemic.” 13 WHO TV, March 19, 2020. https://whotv.com/news/community-coming-together-to-feed-each-other-during-covid-19-pandemic/.

Schackman, Bruce R. “Implementation Science for the Prevention and Treatment of HIV/AIDS.” Journal of Acquired Immune Deficiency Syndromes (1999) 55, no. Suppl 1 (December 1, 2010): S27–31. *https://doi.org/10.1097/QAI.0b013e3181f9c1da*.

Schairer, Cynthia E., Sanjay R. Mehta, Staal A. Vinterbo, Martin Hoenigl, Michael Kalichman, and Susan J. Little. “Trust and Expectations of Researchers and Public Health Departments for the Use of HIV Molecular Epidemiology.” AJOB Empirical Bioethics 10, no. 3 (May 3, 2019): 201–13. *https://doi.org/10.1080/23294515.2019.1601648*.

Schoofs, Mark. “I Lived Through The AIDS Epidemic. Here’s How To Live Through The Coronavirus.” BuzzFeed News, March 20, 2020. https://www.buzzfeednews.com/article/markschoofs/how-to-survive-yet-another-plague.

Selik, Richard M, Eve D Mokotoff, Bernard Branson, S. Michele Owen, Suzanne Whitmore, and H. Irene Hall. “Revised Surveillance Case Definition for HIV Infection — United States, 2014.” Morbidity and Mortality Report Weekly 63, no. RR03 (April 11, 2014): 1–10.

Sen, Amartya. Development as Freedom. Oxford University Press, 1999.

Shepard, Robert. “House Approves Millions for AIDS Research.” UPI, October 3, 1985. *https://www.upi.com/Archives/1985/10/03/House-approves-millions-for-AIDS-research/5541497160000/*.

Sircar, Neiloy. “HIV Criminalization Laws and the Right to Health.” *Health and Human Rights Journal*, August 18, 2017. https://www.hhrjournal.org/2017/08/hiv-criminalization-laws-and-the-right-to-health/.

Sisson, Paul, Gary Warth, and Lyndsay Winkley. “Two COVID Clusters Spotted among First 55 San Diego County Cases.” San Diego Union-Tribune, March 17, 2020. https://www.sandiegouniontribune.com/news/health/story/2020-03-17/one-of-two-coronavirus-clusters-in-san-diego-county-touched-the-crssd-concert.

Spieldenner, Andrew. “Ending the Epidemic: What Happens to Us?” POZ, September 9, 2019. *https://www.poz.com/blog/ending-epidemic-happens-us*.

Spieldenner, Andrew. “The Public Charge Rule, Immigration and the HIV Community: Connecting the Dots.” POZ, October 1, 2018. *https://www.poz.com/blog/public-charge-rule-immigration-hiv-community-connecting-dots*.

Spieldenner, Andrew. “Who Counts? Some Thoughts on HIV Surveillance.” POZ, February 26, 2020. *https://www.poz.com/blog/counts*.

Strauss, Ronald P., Sohini Sengupta, Sandra Crouse Quinn, Jean Goeppinger, Cora Spaulding, Susan M. Kegeles, and Greg Millett. “The Role of Community Advisory Boards: Involving Communities in the Informed Consent Process.” American Journal of Public Health 91, no. 12 (December 2001): 1938–43. https://doi.org/10.2105/ajph.91.12.1938.

Sweeney, Patricia, Lytt I Gardner, Kate Buchacz, Pamela Morse Garland, Michael J Mugavero, Jeffrey T Bosshart, R Luke Shouse, and Jeanne Bertolli. “Shifting the Paradigm: Using HIV Surveillance Data as a Foundation for Improving HIV Care and Preventing HIV Infection.” The Milbank Quarterly 91, no. 3 (September 2013): 558–603. *https://doi.org/10.1111/milq.12018*.

Szalavitz, Maia. “How to Survive a Plague: Q&A with Act-Up’s Peter Staley on Effective Activism.” Time, September 27, 2012. *http://healthland.time.com/2012/09/27/how-to-survive-a-plague-qa-with-act-ups-peter-staley-on-effective-activism/*.

Tavernise, Sabrina, and Richard A. Oppel Jr. “Spit On, Yelled At, Attacked: Chinese-Americans Fear for Their Safety.” *The New York Times*, March 23, 2020, sec. U.S. https://www.nytimes.com/2020/03/23/us/chinese-coronavirus-racist-attacks.html.

University of Colorado. “About Dissemination and Implementation Science.” Dissemination and Implementation Science. Accessed 2020. *http://www.ucdenver.edu/academics/colleges/medicalschool/programs/crisp/about/Pages/About-Dissemination-and-Implementation-Science.aspx*.

U.S. National Library of Medicine. “Digital Gallery - America Responds to AIDS- Surviving and Thriving - NLM Exhibition Program.” NIH: U.S. National Library of Medicine, July 29, 2016. *https://www.nlm.nih.gov/exhibition/survivingandthriving/digitalgallery/america-responds-to-AIDS.html*.

U.S. National Library of Medicine. “Exhibition - Fight Back, Fight AIDS -Surviving and Thriving - NLM Exhibition Program.” NIH: U.S. National Library of Medicine, June 1, 2017. *https://www.nlm.nih.gov/exhibition/survivingandthriving/exhibition-fight-back-fight-aids.html*.

Volpp, K. G., and D. A. Asch. “Make the Healthy Choice the Easy Choice: Using Behavioral Economics to Advance a Culture of Health.” *QJM: Monthly Journal of the Association of Physicians* 110, no. 5 (May 1, 2017): 271–75. https://doi.org/10.1093/qjmed/hcw190.

Wachtel, Ted. “Defining Restorative.” International Institute for Restorative Practices, 2016, 1–12.

Wiltz, Teresa. “HIV Crime Laws: Historical Relics or Public Safety Measures?” Pew Trusts, September 6, 2017. *http://pew.org/2gE1UVd*.

Winston, Susanna E., and Curt G. Beckwith. “The Impact of Removing the Immigration Ban on HIV-Infected Persons.” AIDS Patient Care and STDs 25, no. 12 (December 2011): 709–11. *https://doi.org/10.1089/apc.2011.0121*.

World Health Organization (WHO). “Acquired Immunodeficiency Syndrome — an Assessment of the Present Situation in the World: Memorandum from a WHO Meeting.” Bulletin of the World Health Organization 62, no. 3 (1984): 419–32.

World Health Organization (WHO). “Public Health Surveillance.” World Health Organization: Health Topics. World Health Organization. Accessed March 5, 2020. *http://www.who.int/topics/public_health_surveillance/en/*.

World Health Organization (WHO). “Q&A: Ethics in Public Health Surveillance.” WHO, June 2017. *http://www.who.int/features/qa/surveillance-ethics/en/*.

Wright, Joe, and Melissa Block. “Remembering the Early Days of ‘Gay Cancer.’” All Things Considered. National Public Radio, May 8, 2006. *https://www.npr.org/templates/story/story.php?storyId=5391495*.

Xafis, Vicki, G. Owen Schaefer, Markus K. Labude, Iain Brassington, Angela Ballantyne, Hannah Yeefen Lim, Wendy Lipworth, et al. “An Ethics Framework for Big Data in Health and Research.” Asian Bioethics Review 11 (October 1, 2019): 227–54. *https://doi.org/10.1007/s41649-019-00099-x*.

Yu, Ping, Jiang Zhu, Zhengdong Zhang, and Yingjun Han. “A Familial Cluster of Infection Associated With the 2019 Novel Coronavirus Indicating Possible Person-to-Person Transmission During the Incubation

Period." *The Journal of Infectious Diseases*, no. Brief Report (February 18, 2020): 1–5. https://doi.org/10.1093/infdis/jiaa077.

Zimmer, Carl. "Ancient Viruses Are Buried in Your DNA." The New York Times, October 4, 2017, sec. Science. *https://www.nytimes.com/2017/10/04/science/ancient-viruses-dna-genome.html*.

Appendix A – List of all ethical principles and concepts from all frameworks

List of All Ethical Principles and Concepts			
Public health, community engagement, surveillance, and genomic data collection frameworks			
Kass, 2001	**Ethical Questions:** • What are the public health goals of the proposed program? • How effective is the program in achieving its stated goals? • What are the known or potential burdens of the program?	• Can burdens be minimized? Are there alternative approaches? • Is the program implemented fairly? • How can the benefits and burdens of a program be fairly balanced?	
Childress et al., 2002	**Justificatory Conditions:** • Effectiveness • Proportionality • Necessity • Least Infringement • Public Justification		
Marckmann et al., 2015	**Normative Criteria:** • What are the expected health benefits of the intervention for the target population? • What are the potential burdens and harms of the intervention? • How does the intervention affect the autonomy of the individuals in the target population? • Impact on equity: how are benefits and burden distributed? • Expected efficiency: what are the costs and opportunity costs of the intervention?	**Fair Decision-Process:** • Transparency • Consistency • Justification • Participation • Managing conflicts of interest • Openness for revision • Regulation	**Methodological Approach:** • Description of the public health intervention • Specification and modification of the normative criteria • Evaluation of the public health intervention using the specified criteria • Synthesis: overall evaluation of the public health intervention • Generating recommendations • Monitoring

List of All Ethical Principles and Concepts

Public health, community engagement, surveillance, and genomic data collection frameworks

Brunton et al., 2017	**Group Definitions:** • Community = internal definition of a subgroup • Population = external definition of a subgroup	**Need Definitions:** • Felt need = identified by the community • Expressed need = observed from community use of services • Comparative need = based on observations of similar groups • Normative need = based on a comparison of community's service use to social standards	**Intervention Models:** • Peer or lay-led intervention • Varying degrees of collaboration • Empowerment-based intervention
De Weger et al., 2018	**Action-Guided Principles** • Ensure staff provide supportive and facilitative leadership to citizens based on transparency. • Foster a safe and trusting environment enabling citizens to provide input. • Ensure citizens' early involvement. • Share decision-making and governance control with citizens.	• Acknowledge and address citizens' experiences of power imbalances between citizens and professionals. • Invest in citizens who feel they lack the skills and confidence to engage. • Create quick and tangible wins. • Take into account both citizens' and organisations' motivations.	
Klinger et al., 2017	**Surveillance Life-Cycle Issues:** • Background issues • Issues in system design and implementation • Issues in data collection, analysis and storage • Issues in data reporting, sharing and using for action	**Lack of Informed Consent:** • Effectiveness • Necessity • Least infringement • Proportionality • Public justification / engagement • Vulnerability • Legitimacy • Harm principles / unreasonable exercise requirement	

List of All Ethical Principles and Concepts

Public health, community engagement, surveillance, and genomic data collection frameworks

Pounder, 2008	**Ethical Principles** • Justification • Approval • Separation	• Adherence • Reporting • Independent Supervision	• Privacy • Compensation • Unacceptability
Désy, Filiatrault, & Laporte, 2012	**Ethical Principles** • Proportionality • Usefulness • Transparency • Representativeness	• Equity • Participation • Independence • Stigmatization	• Privacy • Informed Consent • Understandability
Xafis et al., 2019	**Substantive Principles:** • Harm minimization • Integrity • Justice • Liberty/autonomy • Privacy/confidentiality • Proportionality • Public benefit • Solidarity • Stewardship	**Procedural Principles:** • Accountability • Consistency • Engagement • Reasonableness • Reflexivity • Transparency • Trustworthiness	**Deliberative Balancing Process:** • Identify and clearly articulate the presumptive ethical issue or problem at hand • Identify the relevant (substantive and procedural) values pertinent to the issue or problem • Identify potential actions that could be taken in response • In light of the values and context, weigh up the relative ethical merit of the different options • Select the option that has the strongest ethical weight attached to it and reflect on how your personal or the group's position and interests have influenced the decision • Communicate the decision transparently to all stakeholders
Schairer et al., 2019	**Informed Consent:** • Assumed in research, not in public health contexts • Offer a sense of trust and oversight • All potential data uses should be included in initial consent • Suggestion for partial consent or opt-outs in public health	**Data Usage:** • Research: further investigation and notification • Public health: individual intervention and tracking • Concerns about re-identification, stigmatization • Desire to know how data will be used up front	**Research vs. Public Health:** • Researchers seen as working toward the public good • Researchers expected to notify but not intervene • Public health is tied to government authority • Lack of confidence in public health to protect data

Appendix B – Framework sub-elements selected for final framework, by theme, with sources

	Framework Element	Source	Theme
Format	Question–example analytical tool	Kass, 2001 Marckmann et al., 2015 Désy, Filiatrault, and Laporte, 2012	N/A
	Normative principles and concepts	Kass, 2001 Childress et al., 2002 Marckmann et al., 2015 De Weger et al., 2018 Klingler et al., 2017 Pounder, 2008 Désy, Filiatrault, and Laporte, 2012 Xafis et al., 2019	N/A
	Procedural principles and application process	Marckmann et al., 2015 Xafis et al., 2019	N/A
Normative Principles and Concepts	What are the public health goals of the proposed program?	Kass, 2001	Goals / Health needs
	Take into account both citizens' and organisations' motivations.	De Weger et al., 2018	
	Public benefit	Xafis et al., 2019	
	Managing conflicts of interest	Marckmann et al., 2015	Outside influence
	Definitions of need	Brunton et al., 2017	
	Separation	Pounder, 2008	
	Independent supervision		
	Independence	Désy, Filiatrault, and Laporte, 2012	
	How effective is the program in achieving its stated goals?	Kass, 2001	Effectiveness / Outcomes
	Effectiveness	Childress et al., 2002	
	What are the expected health benefits of the intervention for the target population?	Marckmann et al., 2015	
	Expected efficiency: what are the costs and opportunity costs of the intervention?		
	Effectiveness	Klingler et al., 2017	
	Usefulness	Désy, Filiatrault, and Laporte, 2012	
	Necessity	Childress et al., 2002	Justification / Necessity
	Least infringement		
	Public justification		
	Definitions of need	Brunton et al., 2017	
	Necessity	Klingler et al., 2017	
	Least infringement		
	Public justification / engagement		
	Justification	Pounder, 2008	

	Framework Element	Source	Theme
Normative Principles and Concepts	What are the known or potential burdens of the program?	Kass, 2001	Proportionality
	Can burdens be minimized? Are there alternative approaches?		
	How can the benefits and burdens of a program be fairly balanced?		
	Proportionality	Childress et al., 2002	
	What are the potential burdens and harms of the intervention?	Marckmann et al., 2015	
	Proportionality	Klingler et al., 2017	
	Issues in system design and implementation		
	Proportionality	Désy, Filiatrault, and Laporte, 2012	
	Harm minimization	Xafis et al., 2019	
	Proportionality		
	Is the program implemented fairly?	Kass, 2001	Justice / Equity
	Acknowledge and address citizens' experiences of power imbalances between citizens and professionals.	De Weger et al., 2018	
	Vulnerability	Klingler et al., 2017	
	Harm principles / unreasonable exercise requirement		
	Representativeness	Désy, Filiatrault, and Laporte, 2012	
	Equity		
	Stigmatization		
	Justice	Xafis et al., 2019	
	Big data divide / Group harms		
	How does the intervention affect the autonomy of the individuals in the target population?	Marckmann et al., 2015	Autonomy / Individual Rights
	Liberty/autonomy	Xafis et al., 2019	
	Legitimacy	Klingler et al., 2017	Privacy / Data Use / Consent
	Issues in data collection, analysis and storage		
	Issues in data reporting, sharing and using for action		
	Privacy	Pounder, 2008	
	Privacy	Désy, Filiatrault, and Laporte, 2012	
	Informed consent		
	Privacy/confidentiality	Xafis et al., 2019	
	Informed consent discussion	Schairer et al., 2019	
	Data usage discussion		
	Transparency	Marckmann et al., 2015	Transparency
	Transparency	Désy, Filiatrault, and Laporte, 2012	
	Transparency	Xafis et al., 2019	
	Informed consent discussion	Schairer et al., 2019	
	Data usage discussion		

	Framework Element	Source	Theme
Normative Principles and Concepts	Approval	Pounder, 2008	Regulatory
	Adherence		
	Reporting		
	Participation	Marckmann et al., 2105	Community Engagement
	Definitions of need	Brunton et al., 2017	
	Peer or lay-led intervention		
	Varying degrees of collaboration		
	Empowerment-based intervention		
	Ensure staff provide supportive and facilitative leadership to citizens based on transparency.	De Weger et al., 2018	
	Foster a safe and trusting environment enabling citizens to provide input.		
	Ensure citizens' early involvement.		
	Share decision-making and governance control with citizens.		
	Acknowledge and address citizens' experiences of power imbalances between citizens and professionals.		
	Invest in citizens who feel they lack the skills and confidence to engage.		
	Create quick and tangible wins.		
	Take into account both citizens' and organisations' motivations.		
	Public justification / engagement	Klingler et al., 2017	
	Participation	Désy, Filiatrault, and Laporte, 2012	
	Engagement	Xafis et al., 2019	
Procedures and Application	Transparency	Marckmann et al., 2015 Xafis et al., 2019	Fair Decision-Making Process
	Consistency		
	Participation / Engagement		
	Revision / Reflexivity		
	Identify and clearly articulate the presumptive ethical issue or problem at hand	Xafis et al., 2019	Application
	Evaluation of the public health intervention using the specified criteria	Marckmann et al., 2015	
	Select the option that has the strongest ethical weight attached to it and reflect on how your personal or the group's position and interests have influenced the decision	Xafis et al., 2019	
	Communicate the decision transparently to all stakeholders	Xafis et al., 2019	
	Monitoring	Marckmann et al., 2015	