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A Quantitative Study on Molecular Cluster Detection in Virally Suppressed Communities

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Abstract

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MPH, Walden University, 2008

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Abstract

Viral suppression within human immunodeficiency virus (HIV) care and treatment planning is the gold standard of care for most providers when engaging with their patients. In many settings, the patient has received a positive lab that is indicative of HIV antibodies being detected; this in turn means they need additional medical attention to manage the infection. Upon receiving linkage to care services and attending an initial appointment, an initial genetic sequence is usually completed to assess the patient's strain of HIV and how antiretroviral medications may antagonize or complement the HIV strain. It is possible that access, bias, and colorism played a role in the administration of genetic sequencing practices. The initial research questions aimed at reviewing zip codes to determine if there are racial differences in terms of achieving suppression and being sequenced. Logistic regression results showed no correlation between the zip codes and viral suppression and genetic sequence. However, the race and gender of newly diagnosed persons with HIV differed by zip code. The results also revealed that genetic material was sampled in White patients more often than in people of color. That genetic sequencing is being skipped is problematic when patients may not receive the right combination of medications at the start of their chronic management of HIV. Such practices prevent progress in getting to zero new infections.

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Dedication

This study and all the contents herein are being dedicated to my family, especially my mom, without whom I would not have made it this far. She has been a constant rock that I have been able to lean on, even in times when I didn’t know I needed to lean. I also feel obliged to honor the time and commitment needed to put the words to paper and continue the push to the finish line. So many nights of doubt and fear that I didn’t have the courage to see this through. To my chosen family and tribe for continually forgiving me for broken dates, conversations, and generally disappearing over the last few years. Your presence is a compliment to who I have become.

Acknowledgments

I would like to take this moment to acknowledge my committee members: Dr. Stacy Ann Nicola Christian, and Dr. Kai Stewart. Dr. Christian has been a mentor and cheerleader pushing me to get to the end and making sure the product I was developing was worthy of not only reading, but publishing. Thank you for ensuring feedback and guidance was delivered within a time frame that allowed for appropriate implementation and being hard and to the point when needed. Lastly, I would like to acknowledge the Colorado Department of Public Health and Environment for providing access to the data for this study. Without this access, the fidelity of the study would not be the same. I am also thankful for the years of experience I received as a public health practitioner within the walls of this organization.

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Section 1: Foundation of the Study and Literature Review

Introduction

Human immunodeficiency virus (HIV) prevention has been around for decades and continues to evolve based on the needs of communities. Molecular HIV surveillance (MHS) offers valuable public health information concerning the transmission of drug-resistant viruses and the dynamics of currently circulating variants (Hauser et al., 2017). However, a review of relevant literature revealed a need to review what was found to be an unbalanced and incomplete record of the potential stigma and victimization that befalls communities that (a) are virally suppressed, (b) may potentially have genetic profiling in communities of color, and/or (c) are potentially targeted for finding those unable to achieve viral suppression with medication adherence. It was also determined that ethical considerations of funding interventions specifically for HIV as it relates to communities of color and the areas in which people report residence was identified.

The intervention of HIV transmission and other infections has been provided through the efforts of Disease Intervention Specialist (DIS) for decades. DIS services originated in the 1930s to combat the growing incidence of syphilis infections in the United States (Cope et al., 2019). In the 1940s, the CDC funded a workforce to expand local jurisdiction’s ability to work together and help in other areas, which became historically significant. Today, DIS services are a mainstay in disease interruption. The current study was focused on the idea that MHS has been implemented at a time when viral suppression is successful by connecting those diagnosed with HIV to care and in turn, received antiretroviral therapy (ART) due in part to the efforts of the previously mentioned DIS. This implementation was done without the knowledge of the communities it was and is meant to aid in decreasing transmission and acquisition of infection. I used a data set from the Colorado Department of Public Health and Environment to assess viral suppression and status information of participants residing in Colorado.

Problem Statement

Two problems have been identified: first, ending the HIV epidemic, and second, determining how and where to begin the process of intervention strategies to lower the number of new diagnoses. According to HIV.gov (2021), there are four key strategies to end the epidemic: (a) diagnose all people with HIV as early as possible, (b) treat people with HIV rapidly and effectively to reach sustained viral suppression, (c) prevent new HIV transmission by using proven interventions including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs), and (d) respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them to suppress the transmission. MHS has been introduced as the next step towards ending the epidemic in conjunction with expedited linkage to care and obtaining resistance testing through additional blood work. While this effort is admirable and can potentially reduce new cases, communities are unaware of the process. In contrast, PrEP has received an abundance of marketing to spread the information to the public as a one-a-day pill that hinders the transmission of HIV. The lack of equitable sharing of knowledge exposes health promotion ethics within communities where the numbers are still prevalent.

Purpose of the Study

This study's overarching goal was to identify gaps in the current literature that show a lack of research on the ethical impact of the MHS implementation and any resulting community backlash. Devin Hursey remarked, "We are potentially threatening people's freedom just to get cleaner data, and I think it's a clear ethical concern; we can't look the other way or say we're doing our best effort when we're not addressing that HIV criminalization exists" (Nelson, 2020). MHS has expanded across the nation by funding efforts through the Centers for Disease Control and Prevention since 2014, and from its inception been used to identify ~249 growing HIV transmission clusters (Nelson, 2020).

During the expansion of HIV prevention, interventions to reduce acquisition and transmission have included targeted efforts to intercede associated with behavioral, biomedical, and structural risk factors (Vermund et al., 2009). The general purpose of gene sequence has been testing for medication resistance. Studies of the social networks of those diagnosed with HIV border ethical practices that may create a separation of public health and community benefit; however, it offers new methods of determining not only persons diagnosed with HIV and the drug resistance they may present to over 100 medications, but it also sheds light on the additional people who could be genetically related in two categories: transmission clusters, and risk networks.

The current research explored viral suppression in communities to determine systematic issues with continued profiling, marginalizing, and experimentation on unsuspecting and trusting persons being diagnosed with HIV. First, the social change implications begin with organizational transparency in communicating what happens after the diagnosis. Second, the intention is to access ethical care by educating providers to share a process that includes a chain of custody of genetic material obtained from the client. Third, with social networks being infiltrated at this level, conversations about the decriminalization of HIV should be initiated nationwide. An additional issue is that this tool in research diminishes the capacity for traditional partner notification, a voluntary service conducted by DIS. To expand on previous research, I focused on molecular cluster detection for HIV and the ethics surrounding the use, necessity, and value for prevention compared to the traditional means of contact tracing through partner/social network services.

Research Questions and Hypotheses

This research aimed to explore the relationship between race, gender, zip code, and HIV status for residents diagnosed in the state of Colorado to show the necessity of MHS if viral suppression has been working. The research questions for this project were:

RQ1: Is there an identifiable mean difference in race and gender among those diagnosed with HIV in the State of Colorado?

$H_0$1: There is no mean difference in race and gender among those diagnosed with HIV in Colorado.

$H_1$1: There is a mean difference in race and gender among those diagnosed with HIV in Colorado.

RQ2: Is there a correlation between the zip codes and the achievement of viral suppression among those diagnosed with HIV?

$H_0 2$: There is no correlation between the zip codes and viral suppression among those diagnosed with HIV.

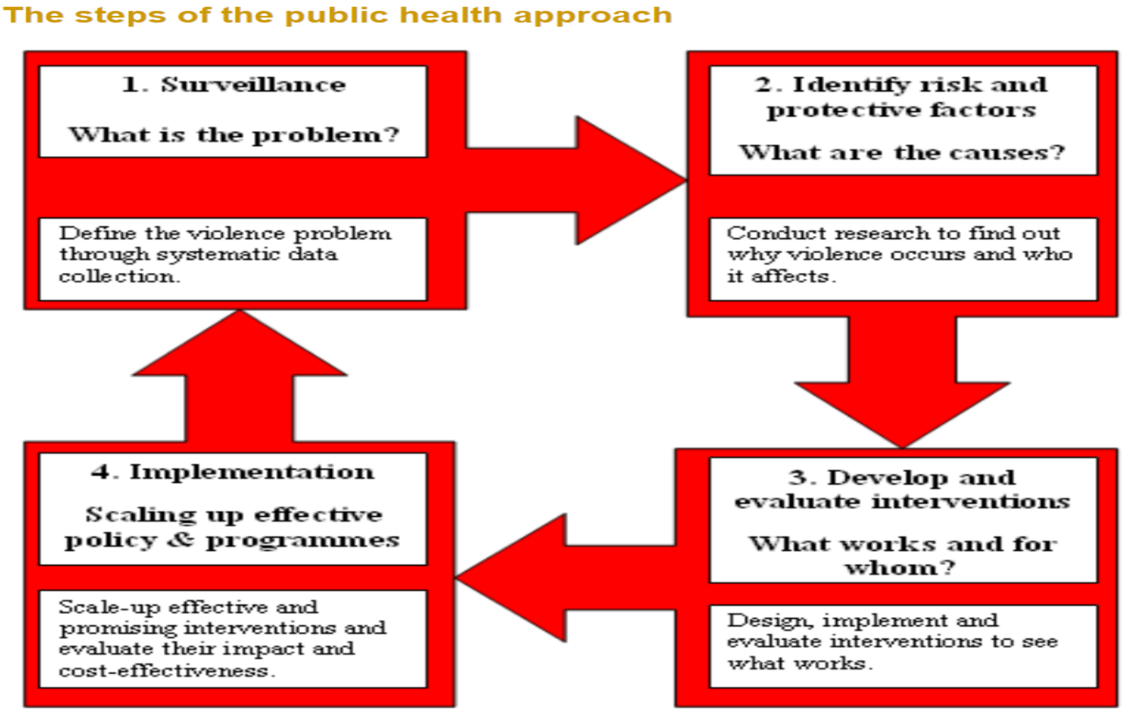
$H_1 2$: There is a correlation between the zip codes and viral suppression among those diagnosed with HIV.

Theoretical Foundation of the Study

The public health model (PHM), as presented by the World Health Organization (2019), was used for the current research. Figure 1 depicts the PHM as an intervention-based approach to identifying issues and implementing changes within communities that are sustainable.

Figure 1

The Public Health Approach Model by the World Health Organization, 2019.



Define the violence problem through systematic data collection.

Conduct research to find out why violence occurs and who it affects.

Design, implement and evaluate interventions to see what works.

Scale-up effective and promising interventions and evaluate their impact and cost-effectiveness.

The PHM, initially designed to study firearm and violence prevention within communities, has been used across many public health disciplines to address primary, secondary, and tertiary levels of prevention and intervention (Bulger et al., 2019). There are four elements to the PHM: (a) examine surveillance (what is the problem), (b) identify risk and protective factors (what are the causes), (c) develop and evaluate interventions (what works and for whom?), and (d) implementation (scaling up effective policy and programs). This approach requires engagement, responsibility, and partnership across disciplines, geographic regions, and philosophical differences. It also requires a commitment to civility, professionalism, humility, and mutual respect (Bulger et al., 2019).

The PHM aligns with the pillars of the U.S. Initiatives on Ending the HIV Epidemic to reduce new HIV infections by 90% by 2030 (Oster et al., 2021). The pillars are Diagnose, Treat, Prevent, and Respond (Healthy People, 2022). Cluster Detection and Response (CDR/MCD), per Oster et al. (2021), offers a framework to guide focused, expeditious implementation of proven HIV prevention strategies from all pillars where transmission occurs. Attaining community buy-in, the goal at the end ensures the adoption of the prevention intervention strategies for changes toward lower incident rates. This approach intensifies exposure to public health programs/interventions through an ethical lens to prevent communities from being stigmatized, marginalized, or demonized. Hopefully, it will curb additional traumatization of this unique population. In using the framework to evaluate the benefit of molecular cluster detection (MCD) when people are engaged in care and achieving some level of viral suppression, there is potential to uncover disparities within zip codes that lack accessible care and treatment for HIV.

Nature of the Study

The nature of this study was a quantitative cross-sectional research design to explore viral suppression among those diagnosed in various Colorado zip codes. In addition, I addressed the relationship between the HIV status of the individual testing and their suppression status after being linked to care. The research also associated the race and reported zip code at the testing time to determine if the implementation of MCD was an ethical intervention that would indicate needed funding if incidence were not supported.

This research included secondary data analysis solicited from the Colorado Department of Public Health and Environment (CDPHE). This organization is the hub for all disease reporting of any labs indicative of disease and is therefore made reportable by the Board of Health Regulations (CDPHE, 2022). Colorado not only collects disease information, it also is a repository for a complete and thorough report, including the client demographics, date of the test, results, location, and zip code of the testing organization, and the risk information for the client. They also protect client confidentiality.

Literature Search Strategy

The virus that causes acquired immunodeficiency syndrome (AIDS) moved rapidly through various communities when it got started, predominantly among gay men. In July 1981, documented cases of Kaposi’s sarcoma and pneumocystis pneumonia were found in 26 gay men, 25 Caucasian and one Black (HIV.gov, 2019). Over time, prevention and intervention methods were developed and implemented to arrest the spread of the infection. Per the CDC, there has been a marked decline in the reported incidence of new cases. From 2015 to 2018, incidence declined ~8% overall from 37,800 in 2015 to 34,800 in 2019 (HIV.gov, 2021).

Among those diagnosed, the age group with the highest representation in data was consistently persons aged 25-34. African Americans remained stable over time as the highest racial/ethnic group that received new HIV diagnoses. This group had a rate of 42.1 compared to Hispanic/Latino at 21.7, and those identified as multi-racial with a rate of 18.4 (HIV.gov, 2021). While African Americans are disproportionately affected by the diagnosis rates of HIV, there is an urgent push to achieve viral suppression and get the information into the hands of the community. Viral suppression happens when the client is prescribed the appropriate antiretroviral medication and takes it as ordered. The virus is suppressed when it reaches less than 200 copies of HIV antibodies per milliliter (HIV.gov, 2021).

The follow-up to diagnosis comes with some barriers for clients who may face economic, employment, or transportation issues that make viral suppression delayed but achievable. At the time of linkage to care, the client goes through additional testing that includes, unbeknownst to them, molecular sequencing. Molecular epidemiological approaches are used to identify groups of individuals with closely related HIV (Erly et al., 2020). While the existence of a cluster does not always equate to transmission happening, the CDC has established criteria to prioritize cluster investigation as follows, namely, investigate clusters that have grown by five cases linked by a genetic distance of

0/5% in the last 12 months (Erly et al., 2020). This biomedical intervention has sounded alarm bells for many HIV advocates in various communities about distortion of public health ethics, not to mention the potential of continued stigma and criminalization surrounding HIV.

Literature Review Related to Key Variables/Concepts

Molecular Cluster Detection

MCD, also called MHS and phylogenetic response, is a funded surveillance response that the CDC developed. The focus was understanding and stopping the spread of HIV by identifying groups of related HIV infections, called clusters (CDC, 2021). Clustering of HIV sequence has been used to determine patterns in transmission. Developed countries began using this tool for drug resistance mutations, creating large sequence databases that stored the genetic material (La Vu et al., 2018).

Per the CDC (Molldrem et al., 2020), "routine use of this systematic method in near real-time can automate the detection of increases in HIV diagnoses that potentially merit further investigation and help prioritize and target HIV prevention efforts." While this is a lofty effort for public health, this tool repurposes the original intention of identifying drug resistance in people diagnosed with HIV. Determination of directionality between person A and person B has been a major point that has come up during community activities that are pushing back on this intervention. Per Mutenherwa et al. (2020), this process should not be treated in isolation as it becomes possible for source and spread to be investigated when resources are available.

Molldremet et al. (2020) asserted that the collection of genetic material during initial intake for routine HIV care is accomplished without the patient's consent, or rather, without a mechanism for refusal. Such processes of non-disclosure of information have caused a move to action by those supporting people living with HIV and their choices. This type of surveillance poses bio-ethical concerns based on the risk of MHS disproportionately impacting marginalized communities and concerns posed by older forms of HIV data use (Mutenherwa et al. 2018). This is a new form of genetic profiling for communities already targeted in the name of public health advancement.

HIV/AIDS

In the 1980s, HIV was termed "The Grim Reaper" due to the number of people who succumbed to the diagnosis. Today, there has been a steady transformation from such a grim prognosis to HIV becoming a manageable chronic condition (Carrion et al., 2018). Researchers have gained knowledge and devise management strategies to curb the increase in new diagnoses each year concomitant with an increased mortality rate of those living with HIV. Although there are effective medications that enhance life expectancy, more research is needed to provide clarity in all matters concerning HIV (Carrion et al., 2018).

Education and evidence-based interventions have been created, implemented, and studied for decades to impact the incidence of new HIV cases being reported annually. Some of these interventions include Treatment as Prevention (TasP), Undetectable equals Untransmittable (U=U), and PrEP (Sauermilch et al., 2022). Aside from MHS, these interventions in some states promoted a need to look at HIV criminalization laws in various states, the premise being if patients are taking the prescribed ART or maintaining an undetectable viral load. The risk of transmission to seronegative partners becomes lower (Bavinton et al., 2018).

Medications appear to be doing what they were designed to do by suppressing the virus, and MHS is still an intervention being funded and used without the knowledge of the patients it is meant to assist by finding the right combination of therapies. Aside from genetic profiling, this is an extension of criminalizing sexual choice in communities that are already disproportionately making up the rates of HIV diagnosis.

Astronomical health disparities continue to show up in those most affected by HIV and targeted by surveillance practices that lead to race (Gupta et al., 2020). Although criminalization is not part of this research study, I would be remiss in raising it as a concern. There are 33 states with HIV-specific laws that mandate a person diagnosed with HIV to disclose their HIV status to all prospective partners. If disclosure does not happen because of morality, criminalization becomes the recourse based on archaic stigma and medically inaccurate information (Herrero-Saenz et al., 2018).

Public Health Ethics

The aim of public health programs that reuse HIV data for prevention is to advance the goal of reaching universal HIV treatment to prevent transmissions (Molldrem et al., 2020). Ending the HIV epidemic is a task many health departments, the CDC, and the White House have pursued by enhancing interventions that have demonstrated success, such as TasP and PrEP services (Eisinger et al., 2019). However, MHS creates uncertainty in ending the epidemic when it first takes away the patient's right of refusal through the omission of details (Rennie et al., 2020). Consent is a cornerstone of medical processes and procedures, and public health should accept no exemption regarding individual care. Rennie et al. (2020) contended that if the refusal were to happen in large numbers, MHS would become useless. Conversely, if some consent processes were in place, participation would be a vexing problem. One might ask, where are the rights of individuals?

In his research, Hedgecoe (2004) introduced the idea of critical bioethics drawing from a variety of fields such as social theory, critical theory, and medical sociology and anthropology to advance a critique of emergent practices in biomedicine where the benefits to society and individuals targeted by interventions are unclear and potentially harmful. A portion of the issue with MHS and consent in biomedicine incorporates understanding. If consent were to be sought from the individual, the process would need to be explained from the time of blood draw to the time of analysis to a careful explanation of what the provider is seeking. (Molldrem et al., 2020). This seems to be a loophole to avoid sharing the outcome of genetic material with the omission of verbal or written consent while being included in an unspecified study.

Operational Definitions

Human Immunodeficiency Virus (HIV)

HIV is the virus that causes AIDS, targets the immune system, and weakens the ability to fight off additional infections (WHO, 2020). WHO (2020) detailed the destruction and carnage the virus has on an individual over time and leading to an AIDS diagnosis via measurement of the cluster of differentiation cell count (CD4). In addition, once immunodeficiency happens, persons living with HIV may be diagnosed with certain HIV-related cancers or other long-term clinical manifestations (WHO, 2020).

Acquired Immunodeficiency Syndrome (AIDS)

According to WHO (2020), once HIV infection has destroyed the immune system, the CD4 (white blood cell) count can drop below 200. Someone in this range or lower meets AIDS-defining criteria and needs medical intervention to sustain optimal health and prevent opportunistic infections (WHO, 2020). The CD4 count is the most definitive way to measure disease progression aside from AIDS-defining opportunistic infections (AIDS.gov, 2020).

Cluster of Differentiation (CD4)

The CD4 is an inexpensive laboratory test used to assess the degree of immune depletion or immunodeficiency. This is the clinical standard to determine outcomes for patients. In a healthy person sans infection, CD4 cells measure more significant than 500. In the early days, less than 200 cells were deemed to be the threshold by which opportunistic infections become common (Institute of Medicine, 2010). Therefore, the CD4 is often drawn and evaluated in conjunction with the viral load.

Viral Load (V.L.)

HIV viral load refers to the number of viral particles found in each milliliter (WHO, 2020). The more virus detected, the more the CD4 cells are destroyed at a rapid pace and overall advancement to AIDS results (WHO, 2020). As mentioned previously, when drawn together, the CD4 and V.L. are important to the clinical impression for disease staging. The V.L. test should measure virus levels down to 50 copies/mL; this plays an integral role in assessing treatment response (WHO, 2020).

Phylogenetic Analysis

Phylogenetic analysis is also known as molecular surveillance, cluster detection, and genetic sequence, and among others "is a system of computational methods used to study how organisms are genetically related to each other" (Mutenherwa et al., 2019).

Assumptions

Leedy and Ormrod (2005) defined research assumptions as self-evident truths that prevail during the research process. I made the following assumptions pertinent to the current study:

1. The data entered was done with zero to minimal errors and fidelity.
2. Any missing data did not influence the study.
3. The data set had enough of a population representation to prevent identifying any individual.
4. Data were stored and un-manipulated to prevent marginalization of any one population.
5. The health department received the reported information in a complete and timely manner via provider and passive surveillance methods.

The assumptions made for this study were based on the nature of the reporting agencies, which are mandatory reporting agencies that have mandated guidelines on what information should be reported and when this information is to be reported. For example, HIV has a 72-hour turnaround for laboratory reporting in the electronic reporting system once a confirmation is established. The demographic information for the patient linked to the test also becomes part of this living document.

Scope and Delimitations

The current study was based on data collected from the period 2013-2018 as found in the records of the Colorado Department of Public Health and Environment HIV Surveillance Unit. I pursued individual HIV status, viral suppression with linkage to care, and the demographic area occupied at the time of genetic typing. The data were used in a secondary method with a 2-year gap from the last year of collection.

The delimitations of this study include the following:

1. The study was delimited by the date range of data collected to focus on 2013 to 2018.
2. The study was delimited by data collected for Colorado only.
3. The study was delimited by viral suppression and linkage to care being the factors for genotyping.
4. The Colorado Department of Public Health and Environment is the repository of the data reported by multiple entities. I did not have access to individual reporting agencies.

Significance, Summary, and Conclusion

Concerns surround the implementation and distribution of MCD as an intervention to end the HIV epidemic. The ethical implications include questions about how informed consent has been taken away from clients (Mutenherwa et al., 2019). The role of traditional partner services also is negatively affected after proving effective with named reporting with a disease intervention specialist (Wertheim et al., 2017). Interventions such as MCD are consistent in the profiling of vulnerable populations that may not have the educational background to comprehend what they are or are not agreeing relevant to care (Molldrem et al., 2020). HIV care from the time of diagnosis to linkage to an infectious disease provider should be client-centered and based on trust. Most of the clients that are testing positive have received a shocking, life-altering diagnosis and they need help in navigating an entirely new medical system.

The focus of this study was to bring awareness to the lack of ethics and genetic profiling of vulnerable communities that have achieved viral suppression. There is still a necessity for these communities to be informed of the new uses for their blood that expands beyond medication resistance. The community should be informed about what this intervention can and cannot do and what are still the unknown factors of the tool (Mutenherwa et al., 2020). The intervention in no way should override humanity and consent for the sake of scientific advancement.

Social change will happen when there is more public knowledge and understanding of the collection and surveillance measures used as part of genetic sequencing. This may come in the form of changes to consent at intake, offering the client information, taking time to explain what remains to be done, and providing clients with the option to refuse. Providers have a duty to do no harm that should include the omission of information. If the medication resistance is not there, the client should be aware of what else labs are used for and this could have a long-term effect on funding and transparency for providers and health departments. If viral suppression is achieved, the client should still have a refusal right to name their sexual/needle sharing partners. Partner services per the CDC is a voluntary process in disease intervention. This surveillance method shrouds that and takes away the ability to say no.

Section 2: Research Design and Data Collection

Introduction

This section is a recitation of the study design, the chosen methodology, how the populations were selected, how the analysis of data proceeded, and the posed threats to validity. The previous review of relevant literature established a need to review an unbalanced and incomplete record of the potential stigma and victimization that befalls communities. It was found that ethical considerations of funding interventions specifically for HIV as they relate to communities of color were substantially lacking.

Research Design and Rationale

The purpose of this quantitative cross-sectional designed study was to explore MCD in relation to viral suppression achievement and the overall impact on communities unaware of the funded practice. This relationship was examined through data collected and stored by the CDPHE located in Denver, Colorado. I requested data that included race/ethnicity, zip codes, gender, viral suppression status, and if there was a genetic sequence collected on each client. In this study, data had already been collected and the use of secondary data in this instance was not only cost-effective, but the data set has previously been checked for validity and accuracy in reporting from external entities by the department. I also had no contact with the clients, thereby creating a barrier that protects privacy and anonymity.

Methodology

This section contains descriptions for the study population, sampling and sampling procedures, justification, threats to validity and the ethical procedures. These factors were covered while implementing a secondary data analysis process. I used a logistic regression as a measure to perform the analysis of the data set in SPSS.

Population

The intended population for this study included any resident in Colorado that received a positive HIV diagnosis and had diagnostic testing linking them to additional care. This population also had documentation of a genetic sample being drawn and verified if they had achieved viral suppression during the time frame of January 2015 through December 2020. Through interviews with the DIS and provider intake forms, CDPHE has collected information on ~2,500 persons where HIV has been reported as the chronic infection.

Sampling and Sampling Procedures

The electronic database used by CDPHE to store information about client background and infectious disease case management contains the reported elements in a secure environment. Reporting entities are held to Board of Health rules and regulations for meeting reporting standards. They are expected to report the demographics of the patient, test type that was performed with results, the date the patient was tested, and lastly, if they were counseled/notified and referred for additional care. Limited access is granted to staff on a need-to-know basis and data requests are submitted through unit program managers and the legal department. The data set collected for the current study was through a cluster sampling of reported information for a specific time. The inclusion of anyone with a positive result did not include consideration of behavior risk that is reported at the time of testing.

Justification for Effect Size, Alpha Level, and Power

The minimum size for this study was determined using a power analysis for Logistic Regression using G-POWER to determine the number of participants to achieve the sufficient power for this study. Based on the output for one tail, H1 p^2 effect size is 0.28, alpha of $p < .05$ and the minimum sample size needed was 51. There were approximately 2,500 participants in the study data set. The inclusion criteria for the participants were (a) residing in Colorado during the data period, (b) has a diagnosis of HIV positive during the collection period, and (c) has documented labs for viral load and genetic sequencing. Risk behavior was not included as this study focused on demographic versus lifestyle.

Instrumentation and Operationalization to Constructs

For the current study I conducted data analysis of secondary data that had been reported to CDPHE and extracted from their data management systems. All residents with the above-mentioned criteria were included in the analysis. The Department had a predetermined set of elements they stored in their system, and I needed to be specific in what was wanted to include in the extraction. In this study, both the independent and dependent variables were nominal. Race was based on what CDPHE had in their data collection system and could be classified under White, Black, Asian, American Native, Alaskan Native/Hawaiian, and Other. Ethnicity had two categories: Hispanic or Non-Hispanic. HIV status as the dependent variable was also nominal. This variable had two categories: positive or indeterminate. The client must have had a positive confirmation to be included in the study population.

Data Analysis

I used SPSS statistical software to conduct data analysis for this study. Descriptive statistics for both variables to calculate the medians and interquartile ranges were used to obtain the frequency foundation for the population showing reactive testing and connection to care. Logistic regression analysis was used to determine the differences in the variable measured for demographic variance in access and sustainability of viral suppression. I used the data to determine the likelihood that a client was able to transmit HIV given the achieved viral suppression. This supported the idea that a genetic sequence would need additional profiling when that information was used for a different purpose than originally intended: medication resistance.

Threats to Validity

The initial overview of threats to validity were handled in the methods described by Creswell (2019), the first being threats to internal validity. These posed little issue in the study as the data were secondary. Neither procedures, treatment, nor experiences of the participant had relevance for me to obtain the data elements. External validity per Creswell shows a pairing of selection and treatment, setting and treatment, and history and treatment. The participants in this study had not been used for a similar proposal, and there is no setting where they were engaged by me on any level. The use of secondary data in this study of this type allowed for initial errors to be handled by the original collector. In using SPSS, I was able to verify/validate the dataset once downloaded and analyzed.

Ethical Procedures

The initial entity collecting the secondary data set used for this study was CDPHE. To access the data, I first needed to obtain approval from the Walden University Institutional Review Board (IRB). I needed to petition the IRB with clear intentions on what my prospectus and goals were in conducting this research. As part of the approval process, CDPHE required a signed data use agreement to ensure privacy and protection as well as proper storage of the information that was to be shared via encrypted email. All data were uploaded into SPSS and stored on a password protected device that I alone had access to. Once IRB approval was received, I was able to share this acknowledgement with CDPHE data managers and the transfer was completed without hindrance.

Summary

In Section 2, the methodology for use of secondary data and how the data was collected and analyzed were described. The overall population for the study consisted of men and women diagnosed with HIV over a 5-year period of study. Finally, the threats to validity and ethical procedures relevant to the study were addressed. In Section 3, data collection and research results are presented in detail in response to the proposed research questions.

Section 3: Presentation of the Results and Findings

Introduction

The purpose of this quantitative study was to examine the outcomes of genetic sequencing and viral load suppression among persons diagnosed with HIV in Colorado between 2015 and the first quarter of 2020. I examined the data to determine if the implementation of genetic sequencing had implications for community profiling and how ethical the process was across populations. To process the findings of this study, I considered the following research questions:

RQ1: Is there an identifiable mean difference in race and gender among those diagnosed with HIV in the State of Colorado?

$H_0$1: There is no mean difference in race and gender among those diagnosed with HIV in Colorado.

$H_1$1: There is a mean difference in race and gender among those diagnosed with HIV in Colorado.

RQ2: Is there a correlation between the zip codes and the achievement of viral suppression among those diagnosed with HIV?

$H_0$2: There is no correlation between the zip codes and viral suppression among those diagnosed with HIV.

$H_1$2: There is a correlation between the zip codes and viral suppression among those diagnosed with HIV.

In Section 3, I included results of the study analysis that was conducted using a secondary data set and processed through SPSS version 27. The results cover the basic descriptive statistics, chi-square, and logistic regression. I conclude the section with a summary of the data analysis outcomes performed and the corroborating charts.

Data Collection of Secondary Dataset

The Institute of Medicine (IOM, 2004) defined public health surveillance as the ongoing, systematic collection of public health data where after analysis, and interpretation of findings allows for the discovery and of patients with contagious, infectious disease and those with whom they may have been exposed to. In June of 1981, health departments began requiring named reporting of newly diagnosed cases of AIDS per IOM. Colorado and Minnesota were two of the first states to successfully mandate HIV case reporting in 1985; this included names of persons diagnosed, and in so doing, they created push back from the community that was not present when AIDS was being reported according to IOM.

Currently, after many decades of effortless reporting, the mandate for named reporting is still in place and protections to safeguard personal information/data of persons diagnosed with HIV/AIDS are managed by strict HIV laws and policies (The Center for HIV Law and Policy, 2022). Under Colorado Revised Statute (CRS) 25-4-405 enacted through Colorado legislation, the reporting requirements have been outlined for providers, labs, and other HIV testing entities to follow. They are required to report any information that supports the diagnosis of a sexually transmitted infection (STI) to the state health department or local public health agency that would assist in disease investigation/intervention (CRS, 2018).

The state health department, CDPHE, maintains a reporting form that is available to providers on their main website that outlines the information they are to report. This includes patient information, the provider performing the test, the type of testing conducted with the client, and the laboratory that performed the testing (CDPHE, 2022). I was able to submit a data request form (Appendix) that detailed the data set necessary to analysis the hypothesis outlined in the research questions. For this study, the outcome of the request yielded ~2,600 individuals that received a positive HIV diagnosis between 2015 and 2020 and resided in Colorado. I was able to analyze the data using SPSS to create crosstab tables as well as chi-square to determine the significance of percentage of persons achieving viral suppression and those receiving genetic sequence testing. I also used logistic regression analysis to answer the two research questions posed. The outcomes are as follows:

Frequency

The following analysis represents a data sample of the population of persons living with HIV in the state of Colorado. The total population of those reviewed equaled 2,454 HIV diagnosed, and of those, only 1,735 were ever sequenced during the 2015-2020 timeframe. The descriptive analysis demonstrated the validity of the sample and what information was missing from the initial download from CDPHE as seen in Table 1:

Table 1

Statistics

		Risk	Current Gender	Race	Sequenced Date	Sequenced	Suppressed
N	Valid	2454	2454	2454	1735	2454	2454
	Missing	0	0	0	719	0	0

In Table 2, HIV diagnosis by year was gathered to demonstrate an increase or decrease in incidents reported for the period of research. In 2019, there was a numerical increase in reporting. The reason for this growth is not readily know and may bear some exploring. The breakdown of race, gender, and risk are presented in Tables 3, and 4 and 5 to continue painting the picture of who was accessing testing and the potential risk that exposed them to HIV acquisition:

Table 2

HIV Diagnosis Year

		Frequency	Percent	Valid percent	Cumulative percent
Valid	2015	378	15.4	15.4	15.4
	2016	428	17.4	17.4	32.8
	2017	435	17.7	17.7	50.6
	2018	414	16.9	16.9	67.4
	2019	471	19.2	19.2	86.6
	2020	328	13.4	13.4	100.0
	Total	2454	100.0	100.0	

Table 3

Current Gender

		Frequency	Percent	Valid percent	Cumulative percent
Valid	(FM) Transgender—female to male	4	0.2	0.2	0.2
	(MF)Transgender-male to female	1	0.0	0.0	0.2
	(MF)Transgender—male to female	31	1.3	1.3	1.5
	Female	309	12.6	12.6	14.1
	Male	2109	85.9	85.9	100.0
	Total	2454	100.0	100.0	

Table 4

Current Race

		Frequency	Percent	Valid percent	Cumulative percent
Valid	Hispanic, all races	851	34.7	34.7	34.7
	Not Hispanic, AIAN	33	1.3	1.3	36.0
	Not Hispanic, Asian/PI	38	1.5	1.5	37.6
	Not Hispanic, Black	372	15.2	15.2	52.7
	Not Hispanic, Multi Race	31	1.3	1.3	54.0
	Not Hispanic, White	1129	46.0	46.0	100.0
	Total	2454	100.0	100.0	

Table 5

Risk

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Heterosexual Contact	218	8.9	8.9	8.9
	IDU	107	4.4	4.4	13.2
	MSM	1493	60.8	60.8	74.1
	MSM & IDU	257	10.5	10.5	84.6
	No Identified Risk	369	15.0	15.0	99.6
	Pediatric	10	.4	.4	100.0
	Total	2454	100.0	100.0	

In Table 6 and 7, the frequency analysis shows the rates at which persons that were linked to care received a documented genetic sequence of blood being collected and initially processed for drug resistance. This process defined as transmitted HIV drug resistance is essential to comprehensive HIV strategies to lower the risk of transmission (Ji et al., 2010). The information garnered from genetic testing allows practitioners to decipher what antiretroviral medications is appropriate for each individual client. Of the 2,454 assessed for HIV, 719 did not receive a genetic sequence. The absence of genetic sequence potentially affects the outcomes of viral suppression in communities. This is noted in the 406 persons documented that have not achieved suppression at the time of this study.

Table 6

Sequenced

		Frequency	Percent	Valid percent	Cumulative percent
Valid	no	719	29.3	29.3	29.3
	yes	1735	70.7	70.7	100.0
	Total	2454	100.0	100.0	

Table 7

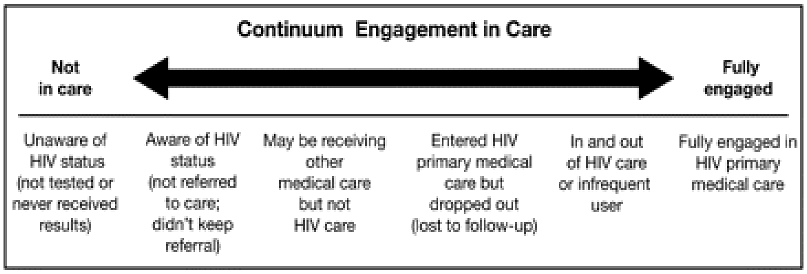
Sequenced Recoded

		Frequency	Percent	Valid percent	Cumulative percent
Valid	N	406	16.5	16.5	16.5
	Y	2048	83.5	83.5	100.0
	Total	2454	100.0	100.0	

HIV sequencing has become more available in the last few decades. The standing recommendation is to immediately provide drug resistance testing upon diagnosis and regardless of CD4 count, initiate some form of drug therapy (Oster et al., 2018). Viral suppression is the gold standard to interrupting the transmission of disease as part of the HIV care continuum to be considered fully engaged in primary care:

Figure 2

HIV Care Continuum



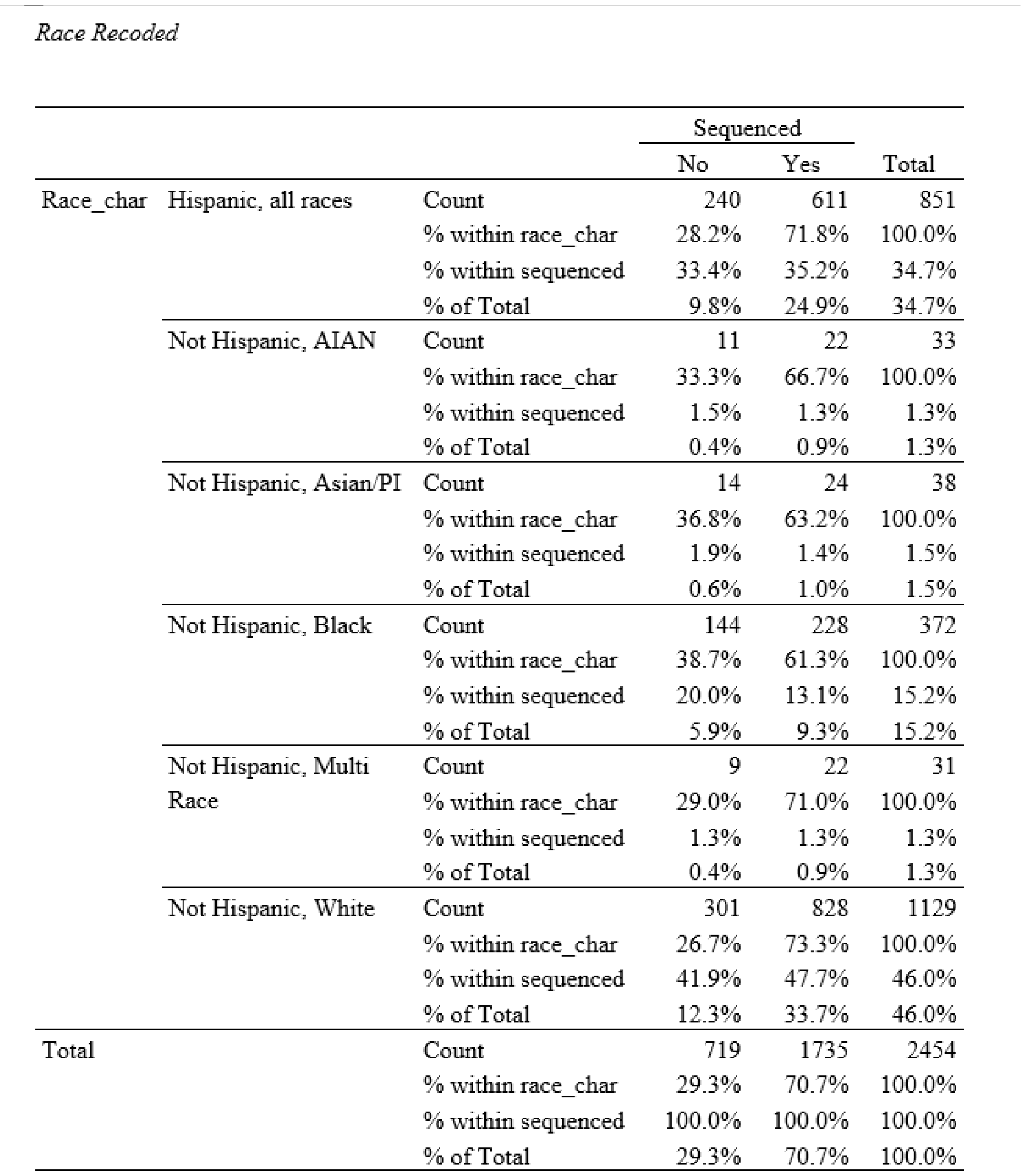
Note. From "Health care system and policy factors influencing engagement in HIV medical care: Piecing together the fragments of a fractured health care delivery system," by M. J. Mugavero et al., 2011, Clinical *Infectious Diseases*, *52*(suppl_2), S238-S246 (https://doi.org/10.1093/cid/ciq048).

While the care continuum allows for those diagnosed with HIV to move along the scale depending on life barriers that may exist, a reasonable amount of effort to assist clients in achieving viral suppression through engagement strategies. Based on the care continuum presented by Mugavero et al. (2011), the process of engagement is the new challenge; not only is linkage an issue, but the client is also assisted to maintain involvement in care (retention). Medical distrust should not be or become a barrier to achieving suppression.

Crosstabulations and Chi-Square

The first crosstab to assess the relationship between race and sequencing in Table 8 analyzed the percentage of racially identified person and their rates of sequencing. It is unknown to the research how the process was explained, if at all to the client at the time of intake for care. It was apparent in reviewing the table that Black and Indigenous persons were not sequenced at the rate of their counterparts. In Table 9, there is a significant difference in race that is sequenced at some point in their care. As Black, Not Hispanics make up most of the HIV diagnosis per the CDC, 2022, the numbers are not demonstrating that viral suppression is achieved if the medications are not being assessed for appropriate antagonist to antibodies as demonstrated in Table 10 and 11, Black and Indigenous people are less likely to have ever been suppressed in the study time frame.

Table 8



Race Recoded

			Sequenced		
			No	Yes	Total
Race_char	Hispanic, all races	Count	240	611	851
		% within race_char	28.2%	71.8%	100.0%
		% within sequenced	33.4%	35.2%	34.7%
		% of Total	9.8%	24.9%	34.7%
	Not Hispanic, AIAN	Count	11	22	33
		% within race_char	33.3%	66.7%	100.0%
		% within sequenced	1.5%	1.3%	1.3%
		% of Total	0.4%	0.9%	1.3%
	Not Hispanic, Asian/PI	Count	14	24	38
		% within race_char	36.8%	63.2%	100.0%
		% within sequenced	1.9%	1.4%	1.5%
		% of Total	0.6%	1.0%	1.5%
	Not Hispanic, Black	Count	144	228	372
		% within race_char	38.7%	61.3%	100.0%
		% within sequenced	20.0%	13.1%	15.2%
		% of Total	5.9%	9.3%	15.2%
	Not Hispanic, Multi Race	Count	9	22	31
		% within race_char	29.0%	71.0%	100.0%
		% within sequenced	1.3%	1.3%	1.3%
		% of Total	0.4%	0.9%	1.3%
	Not Hispanic, White	Count	301	828	1129
		% within race_char	26.7%	73.3%	100.0%
		% within sequenced	41.9%	47.7%	46.0%
		% of Total	12.3%	33.7%	46.0%
Total		Count	719	1735	2454
		% within race_char	29.3%	70.7%	100.0%
		% within sequenced	100.0%	100.0%	100.0%
		% of Total	29.3%	70.7%	100.0%

Table 9

Chi-Square- Likelihood "Race"

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	21.496[a]	5	.001
Likelihood Ratio	20.700	5	.001
N of Valid Cases	2454		

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 9.08.

Table 10

Suppression Crosstabulation

			Ever_suppressed_15_20		
			N	Y	Total
Race_char	Hispanic, all races	Count	119	626	745
		% within race_char	16.0%	84.0%	100.0%
		% within ever suppressed 15 20	33.1%	35.8%	35.3%
		% of Total	5.6%	29.7%	35.3%
	Not Hispanic, AIAN	Count	8	20	28
		% within race_char	28.6%	71.4%	100.0%
		% within ever_suppressed_15_20	2.2%	1.1%	1.3%
		% of Total	0.4%	0.9%	1.3%
	Not Hispanic, Asian/PI	Count	6	26	32
		% within race_char	18.8%	81.3%	100.0%
		% within ever_suppressed_15_20	1.7%	1.5%	1.5%
		% of Total	0.3%	1.2%	1.5%
	Not Hispanic, Black	Count	71	190	261
		% within race_char	27.2%	72.8%	100.0%
		% within ever suppressed 15 20	19.7%	10.9%	12.4%
		% of Total	3.4%	9.0%	12.4%
	Not Hispanic, Multi Race	Count	2	25	27
		% within race_char	7.4%	92.6%	100.0%
		% within ever_suppressed_15_20	0.6%	1.4%	1.3%
		% of Total	0.1%	1.2%	1.3%
	Not Hispanic, White	Count	154	862	1016
		% within race_char	15.2%	84.8%	100.0%
		% within ever_suppressed_15_20	42.8%	49.3%	48.2%
		% of Total	7.3%	40.9%	48.2%
Total		Count	360	1749	2109
		% within race_char	17.1%	82.9%	100.0%
		% within ever suppressed 15 20	100.0%	100.0%	100.0%
		% of Total	17.1%	82.9%	100.0%

Table 11

Chi-Square

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	26.651[a]	5	.000
Likelihood Ratio	24.505	5	.000
N of Valid Cases	2109		

a. 2 cells (16.7%) have expected count less than 5. The minimum expected count is 4.61.

Table 12

This presentation in Table 12 demonstrated the difference in men that were sequenced for genetic material as there was a stronger gap in the rates of suppression among men.

Race Crosstabulation

			Sequenced		
			No	Yes	Total
Race_char	Hispanic, all races	Count	202	543	745
		% within race_char	27.1%	72.9%	100.0%
		% within sequenced	33.7%	36.0%	35.3%
		% of Total	9.6%	25.7%	35.3%
	Not Hispanic, AIAN	Count	9	19	28
		% within race_char	32.1%	67.9%	100.0%
		% within sequenced	1.5%	1.3%	1.3%
		% of Total	0.4%	0.9%	1.3%
	Not Hispanic, Asian/PI	Count	12	20	32
		% within race_char	37.5%	62.5%	100.0%
		% within sequenced	2.0%	1.3%	1.5%
		% of Total	0.6%	0.9%	1.5%
	Not Hispanic, Black	Count	97	164	261
		% within race_char	37.2%	62.8%	100.0%
		% within sequenced	16.2%	10.9%	12.4%
		% of Total	4.6%	7.8%	12.4%
	Not Hispanic, Multi Race	Count	8	19	27
		% within race_char	29.6%	70.4%	100.0%
		% within sequenced	1.3%	1.3%	1.3%
		% of Total	0.4%	0.9%	1.3%
	Not Hispanic, White	Count	272	744	1016
		% within race_char	26.8%	73.2%	100.0%
		% within sequenced	45.3%	49.3%	48.2%
		% of Total	12.9%	35.3%	48.2%
Total		Count	600	1509	2109
		% within race_char	28.4%	71.6%	100.0%
		% within sequenced	100.0%	100.0%	100.0%
		% of Total	28.4%	71.6%	100.0%

Table 13

Chi-Square

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	13.291[a]	5	.021
Likelihood Ratio	12.742	5	.026
N of Valid Cases	2109		

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 7.68.

Logistic Regression

Table 14

This is a good model that predicts likelihood of suppression by demonstrating out of the number of clients sequenced, the likelihood that certain races had a higher rate of suppression over minority populations should be noticed and calls for more attention and study. The significance is 0.000 according to the model and per the note, this reduced model is equivalent to the final model because omitting the effect does not increase the degrees of freedom.

Model fitting

Model	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood	Chi-Square	df	Sig.
Intercept Only	410.243			
Final	256.335	153.908	13	0.000

Table 15

Likelihood Ratio test

In table 15, the outcome of the likelihood model shows significance in the predictors risk, gender, sequenced and the gaps that there should be some additional research. This would look at a process for example that males presenting with a higher behavioral risk for HIV transmission are more apt to be suppressed over women. Also race recoded is a significant predictor meaning, the White Non-Hispanic identifying men were at higher rates achieving viral suppression over other races (also Table 12).

Effect	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood of Reduced Model	Chi-Square	Df	Sig.
Intercept	256.335[a]	0.000	0	
Risk recoded	309.748	53.413	5	0.000
Gender recoded	279.694	23.359	2	0.000
sequenced recoded	331.135	74.800	1	0.000
race recoded	263.951	7.616	5	0.179

The chi-square statistic is the difference in -2 log-likelihoods between the final model and a reduced model. The reduced model is formed by omitting an effect from the final model. The null hypothesis is that all parameters of that effect are 0.

[a] This reduced model is equivalent to the final model because omitting the effect does not increase the degrees of freedom.

Summary

In this section, I presented the analysis of the secondary dataset that was provided by CDPHE. In total there were 2, 454 participants reported to the health department with confirmed HIV diagnoses and currently resided in C.O. at the time of their diagnosis. The data was analyzed with frequency distributions, cross-tabulations to review the relationship between two variables, and Logistical Regression. The analysis revealed that Black and Indigenous persons may not have been getting a base line sequence that would determine the best course of treatment prior to ascribing ART. Section 4 will cover this researcher's interpretation of the findings as they relay to the Public Health Model as previously mentioned in this study. It will cover the limitations of the study, recommendation for social justice, policy change and the conclusions.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

Viral suppression when done with the proper medication and supported adherence through biomedical interventions such as genetic sequencing to identify resistant strains of HIV is a standard that should not be put at risk by questionable implementation efforts (Haire, 2020). The provisions of PrEP and other interventions to interrupt the transmission of HIV has become instrumental in gaining the public trust. During efforts to educate, provide testing and treatment to decrease the numbers of new diagnosis through comprehensive mechanisms, genetic sequence is not one of the interventions readily familiar to persons connecting to care.

This study was aimed at shedding light on the potential to racially exploit communities of color by conducting targeted testing. This process, while directionality was not a factor, allowed partners services staff to determine a network of partners that could be linked to an index patient where a sequence is collected. The data set demonstrates there was a significant difference in how often Black and Indigenous persons were receiving genetic sequence labs. In turn, viral suppression was less likely to be achieved within these subpopulations of persons diagnosed with HIV.

Interpretation of Findings

The results of this study in relation to RQ1 (Is there a mean difference in race and gender among those tested for HIV?) determined there is a mean difference in race and gender of persons tested for HIV in Colorado. The statistical analysis shows ~86% of those tested self-disclosed their gender orientation at the time of diagnosis to be male.

Within the same analysis, race, also based on self-identification showed that 46% of the 2,454-study population identified as non-Hispanic White. The CDC claims that the Black populations overall has higher rates of HIV acquisition accounting for 42% of the new diagnosis in 2018 (Waryold et al., 2022). Hispanics, however, make up about 17% of the population and attribute 27% to the new diagnoses of HIV (Waryold, 2022). In showing there is a racial difference in HIV testing, the null hypothesis was rejected for RQ1.

In RQ2 (Is there a correlation between zip code and achieving viral suppression among those diagnosed with HIV in Colorado?), the results of statistical analysis did not yield significant outcome to prove the alternate hypothesis to be correct. It would have been more insightful if there were a larger number of participants (incidence) to potentially demonstrate significance. Colorado by rates of reporting has a medium level of incidence compared to a state like Mississippi. What was revealed from this study was the identified gap in minorities achieving viral suppression after being linked to HIV care. It is not known what the dynamics of engagement are once they enter care, if they are provided enough information that helps make informed decisions or given the educational materials that speak to the importance of suppression and how they can make this happen.

Limitations of the Study

There are a few limitations to this study. First the study was conducted with one state of persons that were identified as HIV positive during the period of focus. The data being limited to Colorado lacked comparison for rate of incidence for those living with

HIV. The second limitation, barriers to care were not collected and reported to fully measure how the Black and Indigenous people were received and maintained during their linkage to care. Also, it was not possible to measure medical mistrust/distrust once it was determined that Black and Indigenous people in fact were receiving genetic sequencing at a lower rate than their White counterparts. Lastly, the use of secondary data posed its own limitations as there was not an interaction with the participants. The data were already organized for exporting specific elements and logging them into SPSS. I was not able to delve deeper into zip code and race due to geographical limitations to prevent identification of any person that has tested in the period of study.

Recommendations

There is a consistent need to continue studying the promotion and implementation of molecular surveillance as it pertains to HIV care and treatment is a primary consideration in next steps. Information needs to be shared with a level of transparency and with culturally appropriate language where communities can weigh the information to buy into the interventions proposed. This study focused on the state of Colorado and with other regions being funded to conduct this intervention, it would be beneficial to uncover any trends in lower suppression among people of color in areas with higher incidence of reported new diagnosis of HIV, namely the Southern region states where minorities are higher in the census. This study also showed statistical significance in the viral suppression outcomes among people of color. White men achieved higher rates of viral suppression that men represented in the BIPOC community. The reasons should be addressed such as adherence, accessibility, insurance coverages as a start to see where the gaps can be narrowed. The idea of medications not being the right combination for the strain of HIV the person presents with becomes a stressor for change in provider practice, this is a simple adjustment as to the barriers standing in the way of a blood draw and using the surveillance practice as it was originally intended and pause the genetic sequence practice for partner services. DIS have been charged with delivering partner services interviews and this has been a standard that yields successful interactions during a voluntary process.

Implications for Professional Practice and Social Change

Molecular surveillance for HIV is currently funded through the CDC for 23 states across the nation. With this funding, there has been resistance from the community of those living with HIV and their allies. Several recommendations should be considered in the wake of prevention tools that have been introduced to the fight against HIV/AIDS. The first recommendation would be federal and state laws that decriminalize HIV. The stigma that still surrounds the diagnosis especially for women in the Black and Indigenous communities tends to lead to medication adherence issues, isolation/loneliness, along with other intersectional stigmas such as class often plays a role in the rates of achieving viral suppression (Relf et al., 2019).

Second, the practitioners of HIV care have a responsibility to inform their patients. They have a right to have deniability restored in the way of informed consent. The patient should have some knowledge of how their genetic material is being repurposed for additional testing beyond medication resistance. This may have a dual effect; patients may go ahead and consent or they will forgo the process. In turn they are likely to be on a variety of medication until one works to lower the viral load over time. In the outcomes above, there is already a disparity in Black and Indigenous people achieving viral suppression as currently 73% White Non-Hispanic are sequenced and Black Non-Hispanic are 62.8%, and Asian/Pacific Islanders follow closely at 62.5%. This is problematic if Black and Hispanics are making up such large numbers of new diagnosis. Cranston (2020) declared the public health officials are obligated to describe reasons for expansion of data sources and how they are to be used to ensure confidentiality. The same should be expected of health care providers when collecting genetic information.

It comes as no surprise that many researchers agree that Black and Indigenous people have different levels of interaction with medical providers where racial/ethnic disparities persist and continue to grow in the rates of engagement along the care continuum, (He et al., 2021). Blacks that are in the care system still account for lower levels of care and have more difficulty achieving viral suppression than other races diagnosed with HIV (Waryold et al., 2022). At first glance in this project, I assumed that the practice of molecular surveillance had a potential to unjustly target minority populations and set out to show there was a higher rate of sequencing being conducted. This was partially incorrect. In fact, the rate is lower for people of color to receive genetic sequence at the time of connection to care. Clinicians and anyone working in infectious disease have a responsibility to various communities and they seem to be falling short with the availability of tools to prevent and manage HIV, the BIPOC community is falling behind.

Discussion/Findings

While conducting research for this study, there were many other practitioners that reviewed the impact of molecular sequencing as part of surveillance. Many happened to come to the same conclusion, there is a gap in viral suppression achieved among those tested for HIV and linked to care. A few looked at local jurisdictions where they reside or found interest in the community that showed promise in analyzing. Another gap noticed, there is little to no comparison of two or more jurisdictions where HIV care and treatment along with intervention practices becomes a focus of health care equity. Many of the interventions are researched in silo type mechanisms. The goal of ending the HIV epidemic by 2030 with newly instituted strategies will be a struggle without some reduction or elimination of racial/ethnic inequities that fall along the HIV care continuum (Gwadz et al., 2022). In evaluating the initiation of a conceptual model to study minority participants connected to HIV care and treatment, Gwadz et al. (2022) expressed the importance of validating and listening to clients as well as emphasizing the need to include discussion on medical trust/distrust to maintain open communication and engagement. It is difficult to say if critical race theory, policy change that requires full disclosure of chain of custody for genetic samples or monitoring of distribution of services will be the catalyst that closes the gap in achievement of viral suppression. What is known is the need to close the gap is what will intervene on the potential for HIV transmission and thus affects the 2030 ending the epidemic outcomes.

Conclusion

The results of this study revealed what several other researchers had found: there is a disparity among people color who are attached to HIV care after diagnosis. This study looked at the whole population of Colorado by race and gender; it did not break out into subpopulations such as BW (Black women) compared to BM (Black men) and what percentage achieved viral suppression. Bradley et al. (2018) suggested that there are benefits to equal access across populations and that by ensuring black women are not left behind in the battle to eliminate HIV would in turn influence other populations. The engagement that providers have with their clients was also not assessed for this study as all data was already collected. It would have potentially been advantageous to conduct satisfaction surveys six months to one year after the client had established care. An assessment of trust/distrust, educational understanding of HIV care and treatment and barriers to medication adherence when suppression is not achieved within the first year. Clients need to not only be talked to for transfer of information, but they also need to be listened to in a culturally affirming environment that begins with clinicians eliminating policies and practices that contribute to the lack of trust (He et al., 2021). Clients need all the information that allows for informed decisions and informed consent. Sharing the complete process of blood sampling beyond medication resistance plays a role in honoring the trust that clients are prepared to instill in a provider. Due to lack of access, many are already connected to a provider by default. They are the only one available in a care dessert, or the client is under insured and goes to a sliding scale clinic where provider training is dismal. If practitioners are to have a hope of eliminating HIV, putting the dynamic of partner services fully in the hands of the DIS to establish rapport and work with the client to notify their partners, the need for expanded molecular surveillance would prove to be an unnecessary funding opportunity in Colorado and possibly many of the other states conducting this surveillance activity.

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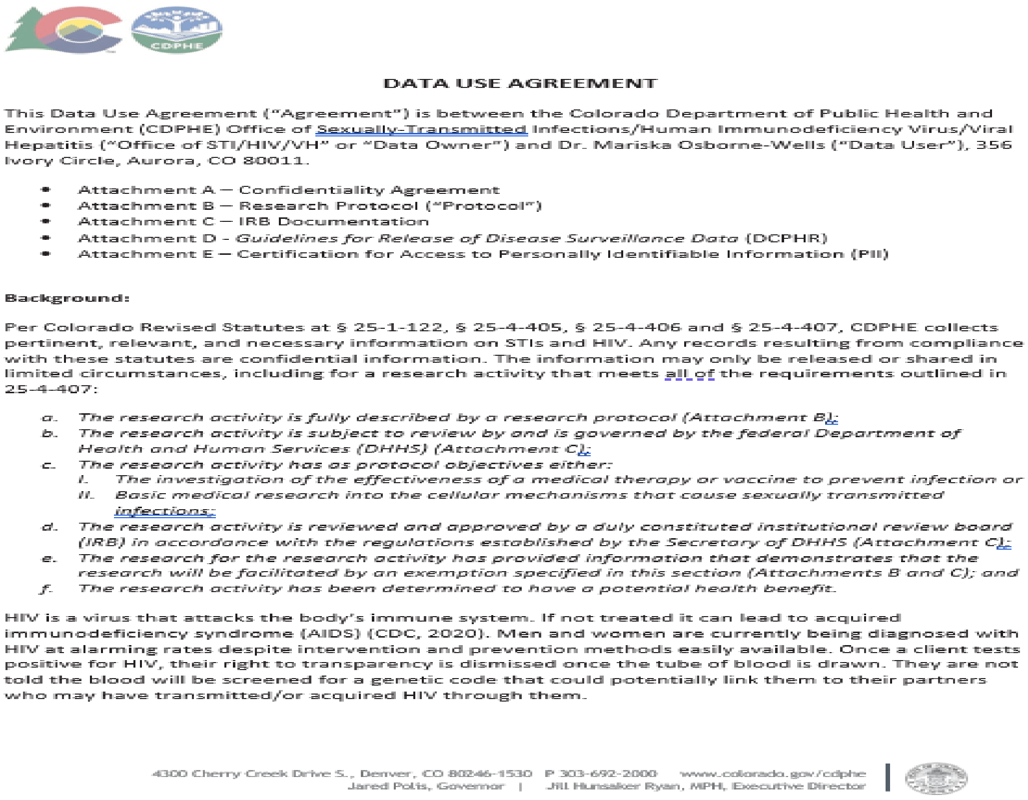
Appendix A: Data Use Agreement



DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is between the Colorado Department of Public Health and Environment (CDPHE) Office of Sexually-Transmitted Infections/Human Immunodeficiency Virus/Viral Hepatitis ("Office of STI/HIV/VH" or "Data Owner") and Dr. Mariska Osborne-Wells ("Data User"), 356 Ivory Circle, Aurora, CO 80011.

- Attachment A — Confidentiality Agreement
- Attachment B — Research Protocol ("Protocol")
- Attachment C — IRB Documentation
- Attachment D - *Guidelines for Release of Disease Surveillance Data* (DCPHR)
- Attachment E — Certification for Access to Personally Identifiable Information (PII)

Background:

Per Colorado Revised Statutes at § 25-1-122, § 25-4-405, § 25-4-406 and § 25-4-407, CDPHE collects pertinent, relevant, and necessary information on STIs and HIV. Any records resulting from compliance with these statutes are confidential information. The information may only be released or shared in limited circumstances, including for a research activity that meets all of the requirements outlined in 25-4-407:

a. The research activity is fully described by a research protocol (Attachment B);
b. The research activity is subject to review by and is governed by the federal Department of Health and Human Services (DHHS) (Attachment C);
c. The research activity has as protocol objectives either:
    I. The investigation of the effectiveness of a medical therapy or vaccine to prevent infection or
    II. Basic medical research into the cellular mechanisms that cause sexually transmitted infections;
d. The research activity is reviewed and approved by a duly constituted institutional review board (IRB) in accordance with the regulations established by the Secretary of DHHS (Attachment C);
e. The research for the research activity has provided information that demonstrates that the research will be facilitated by an exemption specified in this section (Attachments B and C); and
f. The research activity has been determined to have a potential health benefit.

HIV is a virus that attacks the body's immune system. If not treated it can lead to acquired immunodeficiency syndrome (AIDS) (CDC, 2020). Men and women are currently being diagnosed with HIV at alarming rates despite intervention and prevention methods easily available. Once a client tests positive for HIV, their right to transparency is dismissed once the tube of blood is drawn. They are not told the blood will be screened for a genetic code that could potentially link them to their partners who may have transmitted/or acquired HIV through them.

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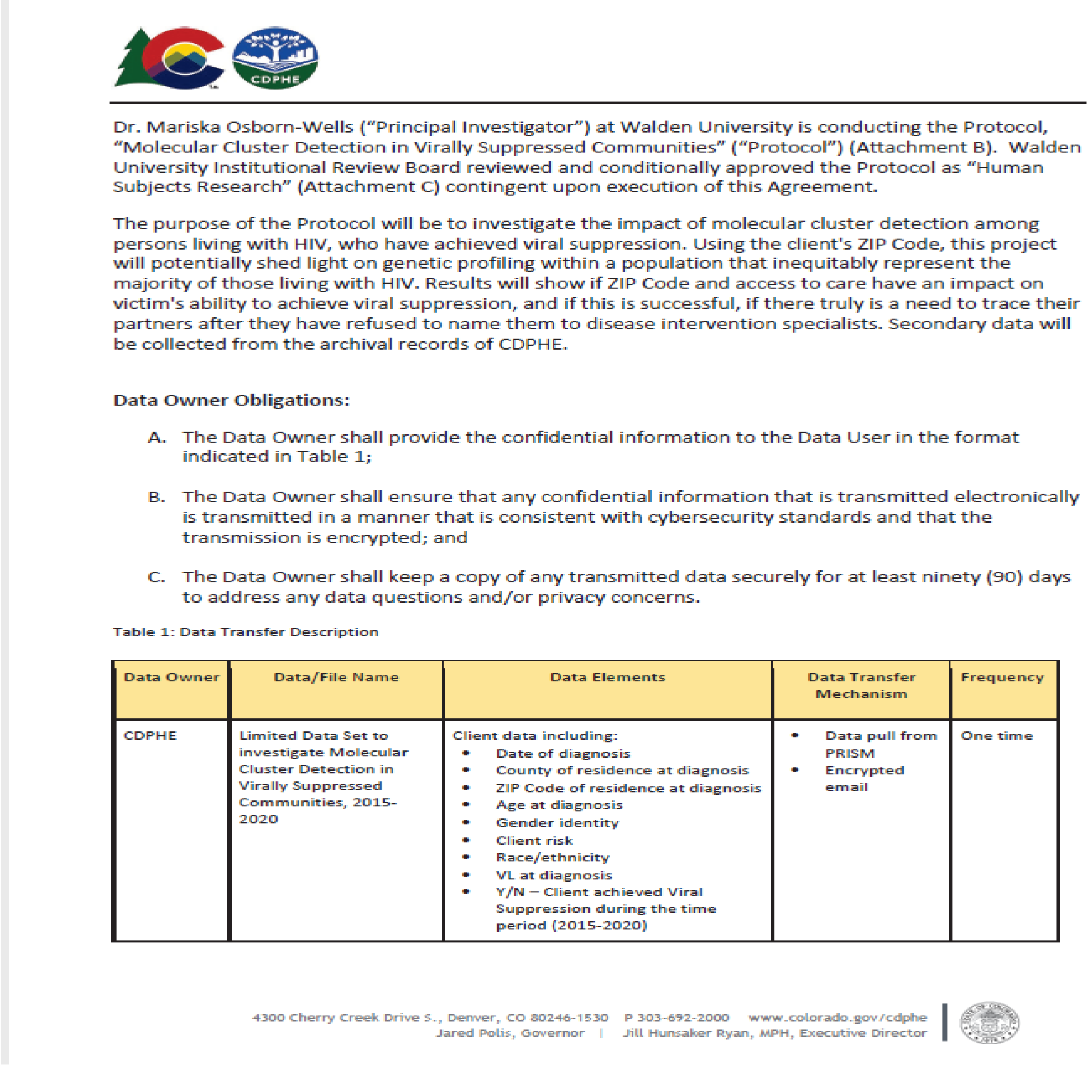


Dr. Mariska Osborn-Wells ("Principal Investigator") at Walden University is conducting the Protocol, "Molecular Cluster Detection in Virally Suppressed Communities" ("Protocol") (Attachment B). Walden University Institutional Review Board reviewed and conditionally approved the Protocol as "Human Subjects Research" (Attachment C) contingent upon execution of this Agreement.

The purpose of the Protocol will be to investigate the impact of molecular cluster detection among persons living with HIV, who have achieved viral suppression. Using the client's ZIP Code, this project will potentially shed light on genetic profiling within a population that inequitably represent the majority of those living with HIV. Results will show if ZIP Code and access to care have an impact on victim's ability to achieve viral suppression, and if this is successful, if there truly is a need to trace their partners after they have refused to name them to disease intervention specialists. Secondary data will be collected from the archival records of CDPHE.

Data Owner Obligations:

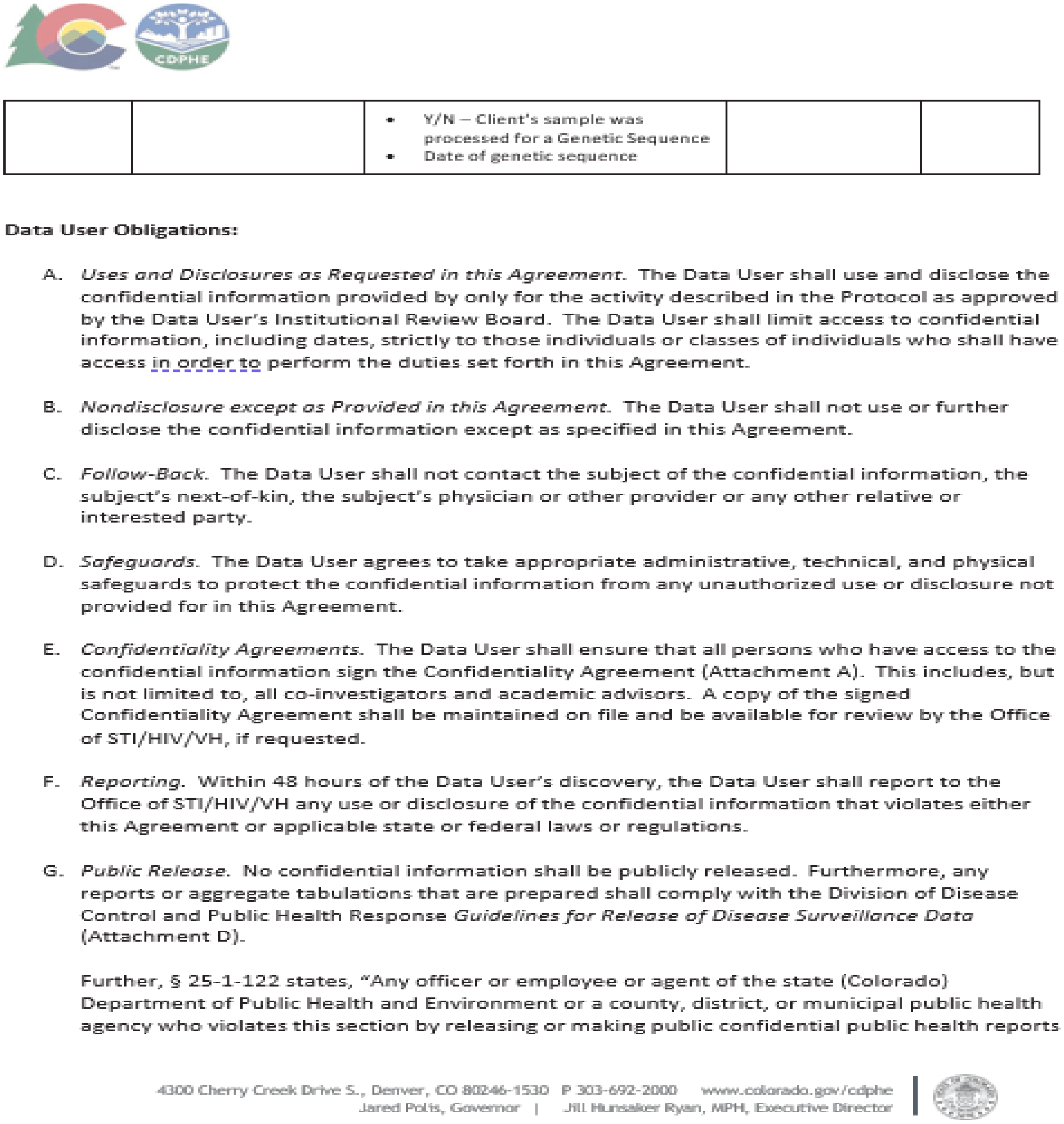
A. The Data Owner shall provide the confidential information to the Data User in the format indicated in Table 1;

B. The Data Owner shall ensure that any confidential information that is transmitted electronically is transmitted in a manner that is consistent with cybersecurity standards and that the transmission is encrypted; and

C. The Data Owner shall keep a copy of any transmitted data securely for at least ninety (90) days to address any data questions and/or privacy concerns.

Table 1: Data Transfer Description

Data Owner	Data/File Name	Data Elements	Data Transfer Mechanism	Frequency
CDPHE	Limited Data Set to investigate Molecular Cluster Detection in Virally Suppressed Communities, 2015-2020	Client data including: • Date of diagnosis • County of residence at diagnosis • ZIP Code of residence at diagnosis • Age at diagnosis • Gender identity • Client risk • Race/ethnicity • VL at diagnosis • Y/N – Client achieved Viral Suppression during the time period (2015-2020)	• Data pull from PRISM • Encrypted email	One time



		- Y/N – Client's sample was processed for a Genetic Sequence - Date of genetic sequence		

Data User Obligations:

A. *Uses and Disclosures as Requested in this Agreement.* The Data User shall use and disclose the confidential information provided by only for the activity described in the Protocol as approved by the Data User's Institutional Review Board. The Data User shall limit access to confidential information, including dates, strictly to those individuals or classes of individuals who shall have access in order to perform the duties set forth in this Agreement.

B. *Nondisclosure except as Provided in this Agreement.* The Data User shall not use or further disclose the confidential information except as specified in this Agreement.

C. *Follow-Back.* The Data User shall not contact the subject of the confidential information, the subject's next-of-kin, the subject's physician or other provider or any other relative or interested party.

D. *Safeguards.* The Data User agrees to take appropriate administrative, technical, and physical safeguards to protect the confidential information from any unauthorized use or disclosure not provided for in this Agreement.

E. *Confidentiality Agreements.* The Data User shall ensure that all persons who have access to the confidential information sign the Confidentiality Agreement (Attachment A). This includes, but is not limited to, all co-investigators and academic advisors. A copy of the signed Confidentiality Agreement shall be maintained on file and be available for review by the Office of STI/HIV/VH, if requested.

F. *Reporting.* Within 48 hours of the Data User's discovery, the Data User shall report to the Office of STI/HIV/VH any use or disclosure of the confidential information that violates either this Agreement or applicable state or federal laws or regulations.

G. *Public Release.* No confidential information shall be publicly released. Furthermore, any reports or aggregate tabulations that are prepared shall comply with the Division of Disease Control and Public Health Response *Guidelines for Release of Disease Surveillance Data* (Attachment D).

Further, § 25-1-122 states, "Any officer or employee or agent of the state (Colorado) Department of Public Health and Environment or a county, district, or municipal public health agency who violates this section by releasing or making public confidential public health reports

or records or by otherwise breaching the confidentiality requirements of subsection (4) or (5) of this section commits a class 1 misdemeanor and, upon conviction thereof, shall be punished as provided in § 18-1.3-501(1), CRS."

H. *Amendments.* The Parties shall negotiate in good faith to amend this Agreement to equitably and fairly reflect any changes that alter either or both Parties' obligations under this Agreement. Any amendments to this Agreement must be made in writing and signed by representatives of both Parties.

I. *Destruction of Confidential Information at End of Activity.* The confidential information shall be destroyed or returned to the Data Owner upon completion of the work described in the Protocol. The Data User agrees to send the Data Owner written notification that the data have been destroyed or return the data within 30 days of the completion of work described in the Protocol.

J. *Minimum Necessary.* The Data User attests that the confidential information requested represents the minimum information necessary for the Data User to perform duties described in the Protocol and that only the minimum necessary individuals shall have access to the confidential information in order to perform such work.

K. *Institutional Review Board.* If the activity involves research, the Data User agrees to furnish all documentation concerning IRB reviews and approvals. The Data User agrees to submit required documentation of any changes to the research protocol to an IRB prior to implementation of protocol changes. The Data User also agrees to submit to the Data Owner any change in protocol, or any changes in either the waiver status or conditions for IRB approval of the Protocol.

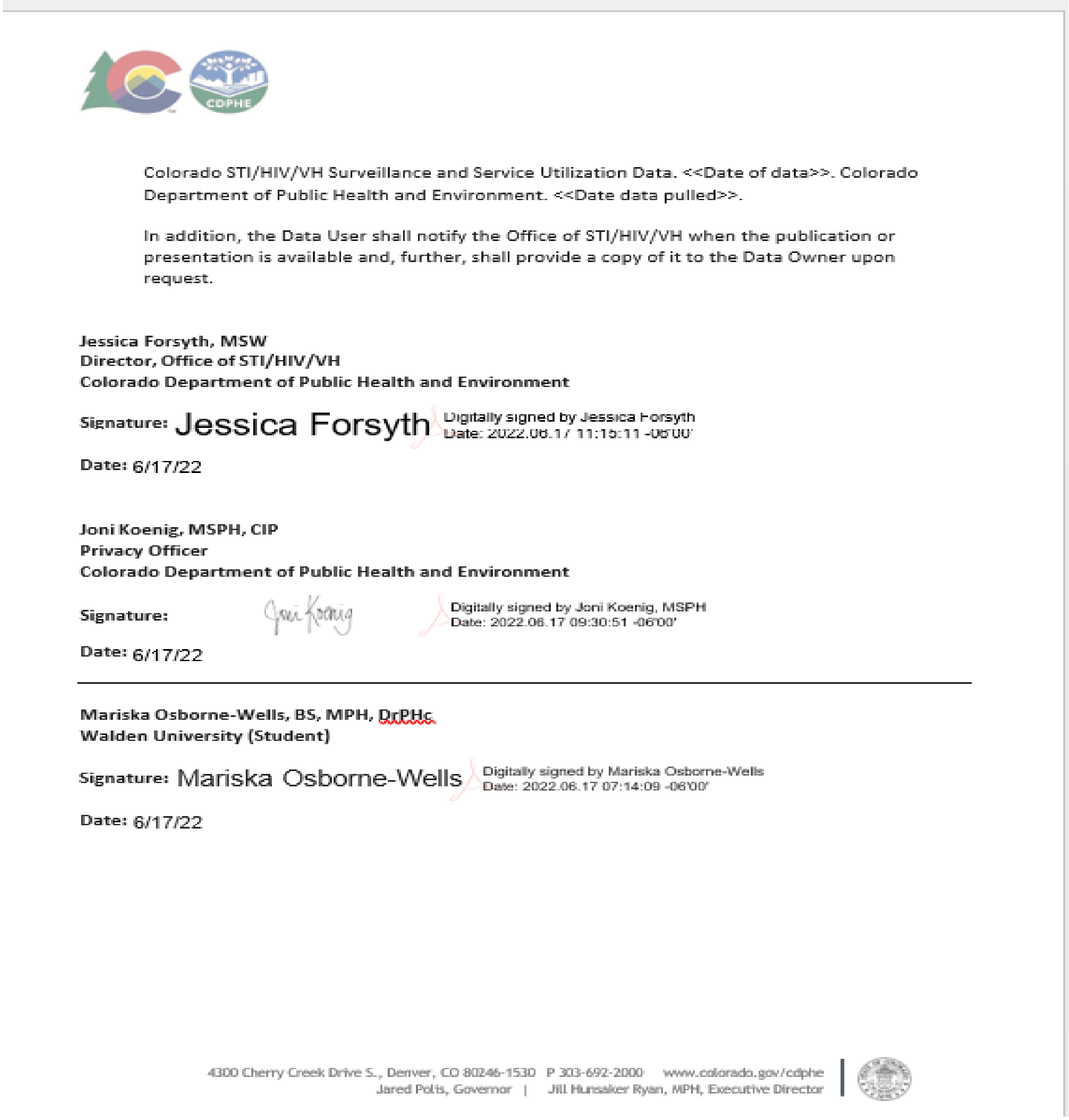
L. *Authorizations.* The Data User agrees to obtain individual authorizations to the confidential information if the activity entails research, unless an IRB or Privacy Board approves a waiver of such an authorization. Documentation shall be provided prior to receipt of the confidential information.

M. *Data Ownership.* The Data Owner is the Office of STI/HIV/VH. The Data User does not obtain any right, title, or interest in any of the data furnished by the Data Owner.

N. *Publication/Release Requirements.* Any release of information shall include the following statement:

This data was obtained from the Office of STI/HIV/Viral Hepatitis in the Colorado Department of Public Health and Environment.

Please use the following citation format in formal publications and presentations:



Colorado STI/HIV/VH Surveillance and Service Utilization Data. <<Date of data>>. Colorado Department of Public Health and Environment. <<Date data pulled>>.

In addition, the Data User shall notify the Office of STI/HIV/VH when the publication or presentation is available and, further, shall provide a copy of it to the Data Owner upon request.

Jessica Forsyth, MSW
Director, Office of STI/HIV/VH
Colorado Department of Public Health and Environment

Signature: Jessica Forsyth Digitally signed by Jessica Forsyth Date: 2022.06.17 11:15:11 -06'00'

Date: 6/17/22

Joni Koenig, MSPH, CIP
Privacy Officer
Colorado Department of Public Health and Environment

Signature: Joni Koenig Digitally signed by Joni Koenig, MSPH Date: 2022.06.17 09:30:51 -06'00'

Date: 6/17/22

Mariska Osborne-Wells, BS, MPH, DrPHc
Walden University (Student)

Signature: Mariska Osborne-Wells Digitally signed by Mariska Osborne-Wells Date: 2022.06.17 07:14:09 -06'00'

Date: 6/17/22

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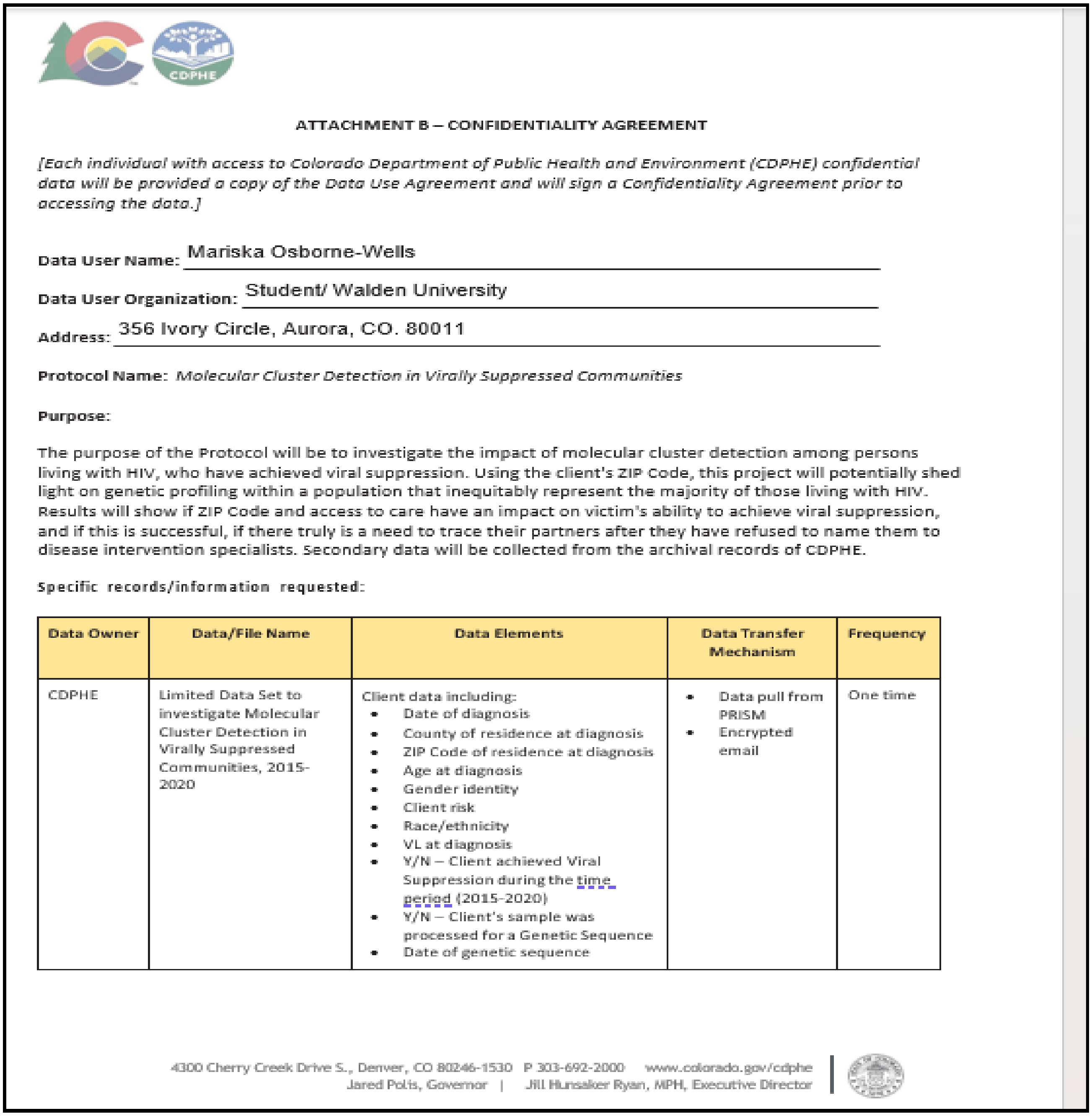

ATTACHMENT B – CONFIDENTIALITY AGREEMENT

[Each individual with access to Colorado Department of Public Health and Environment (CDPHE) confidential data will be provided a copy of the Data Use Agreement and will sign a Confidentiality Agreement prior to accessing the data.]

Data User Name: Mariska Osborne-Wells

Data User Organization: Student/ Walden University

Address: 356 Ivory Circle, Aurora, CO. 80011

Protocol Name: *Molecular Cluster Detection in Virally Suppressed Communities*

Purpose:

The purpose of the Protocol will be to investigate the impact of molecular cluster detection among persons living with HIV, who have achieved viral suppression. Using the client's ZIP Code, this project will potentially shed light on genetic profiling within a population that inequitably represent the majority of those living with HIV. Results will show if ZIP Code and access to care have an impact on victim's ability to achieve viral suppression, and if this is successful, if there truly is a need to trace their partners after they have refused to name them to disease intervention specialists. Secondary data will be collected from the archival records of CDPHE.

Specific records/information requested:

Data Owner	Data/File Name	Data Elements	Data Transfer Mechanism	Frequency
CDPHE	Limited Data Set to investigate Molecular Cluster Detection in Virally Suppressed Communities, 2015-2020	Client data including: • Date of diagnosis • County of residence at diagnosis • ZIP Code of residence at diagnosis • Age at diagnosis • Gender identity • Client risk • Race/ethnicity • VL at diagnosis • Y/N – Client achieved Viral Suppression during the time period (2015-2020) • Y/N – Client's sample was processed for a Genetic Sequence • Date of genetic sequence	• Data pull from PRISM • Encrypted email	One time

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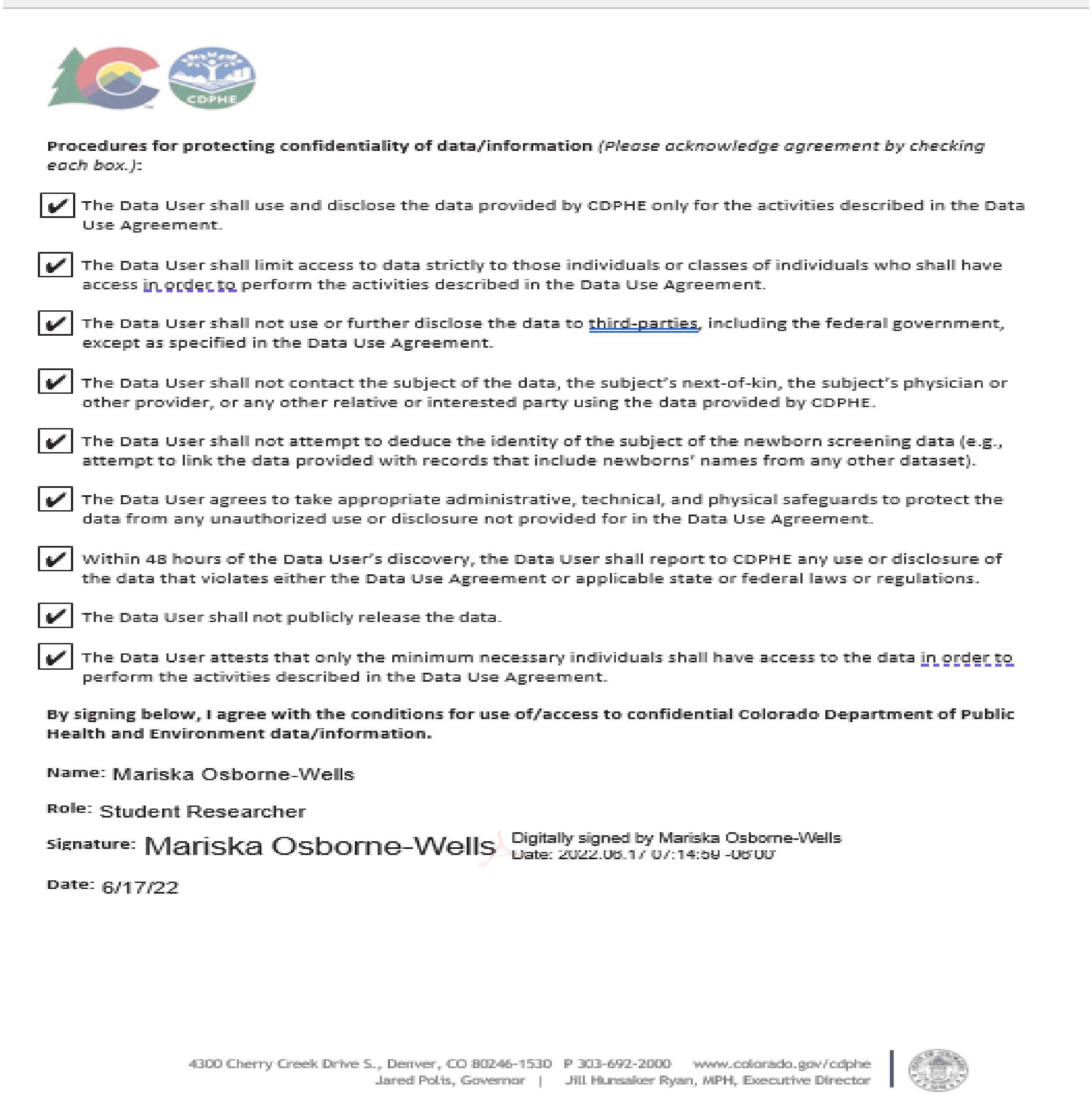

Procedures for protecting confidentiality of data/information *(Please acknowledge agreement by checking each box.)*:

☑ The Data User shall use and disclose the data provided by CDPHE only for the activities described in the Data Use Agreement.

☑ The Data User shall limit access to data strictly to those individuals or classes of individuals who shall have access in order to perform the activities described in the Data Use Agreement.

☑ The Data User shall not use or further disclose the data to third-parties, including the federal government, except as specified in the Data Use Agreement.

☑ The Data User shall not contact the subject of the data, the subject's next-of-kin, the subject's physician or other provider, or any other relative or interested party using the data provided by CDPHE.

☑ The Data User shall not attempt to deduce the identity of the subject of the newborn screening data (e.g., attempt to link the data provided with records that include newborns' names from any other dataset).

☑ The Data User agrees to take appropriate administrative, technical, and physical safeguards to protect the data from any unauthorized use or disclosure not provided for in the Data Use Agreement.

☑ Within 48 hours of the Data User's discovery, the Data User shall report to CDPHE any use or disclosure of the data that violates either the Data Use Agreement or applicable state or federal laws or regulations.

☑ The Data User shall not publicly release the data.

☑ The Data User attests that only the minimum necessary individuals shall have access to the data in order to perform the activities described in the Data Use Agreement.

By signing below, I agree with the conditions for use of/access to confidential Colorado Department of Public Health and Environment data/information.

Name: Mariska Osborne-Wells

Role: Student Researcher

Signature: Mariska Osborne-Wells Digitally signed by Mariska Osborne-Wells Date: 2022.06.17 07:14:59 -06'00'

Date: 6/17/22

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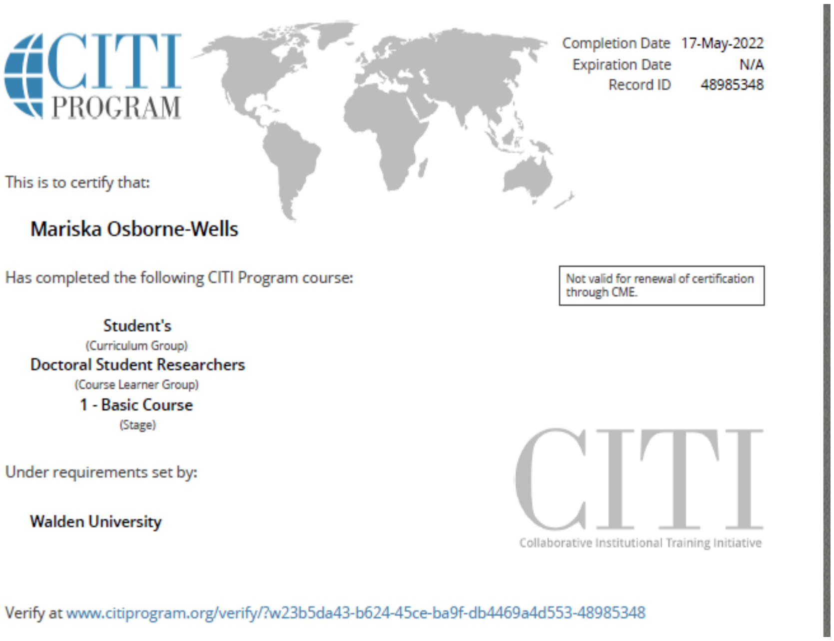
Appendix C: CITI Certification of Ethics



CITI PROGRAM

Completion Date 17-May-2022
Expiration Date N/A
Record ID 48985348

This is to certify that:

Mariska Osborne-Wells

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Student's
(Curriculum Group)
Doctoral Student Researchers
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Walden University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w23b5da43-b624-45ce-ba9f-db4469a4d553-48985348