EXPANDING HIV PREVENTION OPPORTUNITIES DURING COVID-19 RESTRICTIONS; LESSONS LEARNED USING HIV SELF-TESTING AS A PUBLIC HEALTH TOOL IN GEORGIA

by

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ABSTRACT

Despite some lifted restrictions in Georgia and attempts to integrate COVID-19 response and HIV activities, provisions of HIV prevention services were still under performing. COVID-19 lockdowns imposed challenges with accessing primary prevention services-HIV testing and PrEP-through routine, conventional methods in clinic settings, outreach, and community settings; this made exploring the feasibility of free, home-based testing options essential. This study examines data from the implementation of a statewide self-testing initiative pilot conducted across Georgia. Responses to a pre- and post-survey instrument completed by individuals requesting to receive an HIV self-test (HIVST) by mail delivery or pick-up were analyzed to understand the impact of health insurance on testing history and predictors for requesting HIVST using different distribution request methods. Qualitative responses were provided from open-ended questions and analyzed to offer insight into individuals' experience with using the HIVST, attitudes about HIV prevention and health seeking behaviors. Results showed there is a statistically significant association between health insurance status and HIV testing history as well as an association between HIVST distribution request method and reasons for requesting an HIVST. The odds of having a requested HIVST mailed is 2 times greater for those with no health insurance compared to those participants with insurance and 9 times greater for those testing more than 1 year ago. In-home privacy was a primary reason across both request distribution methods for requesting an HIVST. 50% of respondents reported testing for HIV for the first time due to the option to use the HIVST at home. Also, participants reported having anxiety using the HIVST at home, but instructions were easy to follow and they noted an overall general appreciation for the convenience of testing at home. In conclusion, mailed HIVST distribution compared to pick-up is a feasible option to reach individuals who are not testing for HIV annually and a means to educate about PrEP. Individuals with health insurance are more likely to have a previous HIV testing and health insurance status can influence the decision to consider use of HIVST if there is a cost. Underserved and marginalized communities could benefit from the option of HIVST to encourage HIV/STI prevention and PrEP knowledge.

INDEX WORDS: HIV testing, HIV self-testing (HIVST), COVID-19, HIV prevention, Health insurance, PrEP, Health Departments, home-based testing

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DEDICATION

To my parents, siblings, other family, and friends who have supported me unconditionally along this journey through the doctoral program and encouraged me immensely. My dear father, for your great love and unwavering support which will forever shine its light.

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INTRODUCTION AND BACKGROUND

HIV testing in the context of COVID-19 response

The COVID-19 pandemic caused an unprecedented crisis in public health, with many resources shifted from Human Immuno-deficiency virus (HIV) activities to COVID-19 response. These resources included staffing, financial support, agency engagement and even community health facilities that offered provisions to HIV services. In addition, individuals were hesitant to seek health services such as HIV testing due to risks of COVID-19 exposure and transmission (Lesko & Bengtson, 2021) (Czeisler, et al., 2020). This disruption to accessing and providing service models typically assigned to HIV response negatively impacted HIV outreach and laboratory testing, leading to significant drops in rates of HIV/Auto-immune deficiency disease (AIDS) diagnosis across the country. Survey data from the UNAIDS assessing monthly HIV service provisions from 22 countries across the world found restrictions of the COVID-19 pandemic resulted in severe reductions in HIV diagnostic testing, HIV services for priority populations which include gay and bisexual men and women of color, condom distribution, pre-exposure prophylaxis (PrEP), harm reduction services and access to care which can be indicated by the number of people initiating antiretroviral (ART) medications (UNAIDS, 2020).

These impacts are most notable in areas with high HIV burden and have a direct effect on related health outcomes (Pinto & Park, 2020). Local public health programs in Georgia supporting HIV/Sexually Transmitted Infections (STI) testing and prevention

experienced disruptions as COVID-19 responses became priority. Georgia is among the top 5 states ranked for rates of new diagnosis of HIV and persons living with HIV/AIDS (PLWH) (Georgia Department of Public Health, 2022). By the end of 2019, 2,504 persons 13 years and older were diagnosed with HIV, a rate of 28.4 per 100,000 persons. In comparison, 2020 saw a reduction in diagnosis rates of 24.7 per 100,000 persons, with 2,016 new diagnosis (Georgia Department of Public Health, 2022).

While here in Georgia we saw minimal disruption in PLWH accessing HIV care due to the incorporation of telehealth visits by HIV care providers, mail delivery options for prescriptions along with extended refills and loosened AIDS Drug Assistance Program renewal criteria to help maintain coverage, by mid-2020 HIV prevention efforts in public sector saw a decrease in HIV testing upwards of 70% in some regions of the state compared to mid-2019. Further evidenced from COVID-19 related lockdown policies, statewide testing noted an overall 41% decline between 2019 and 2020 in Georgia according to Georgia Department of Public Health (DPH) testing data. Although COVID restriction policies were intended to mitigate COVID-19 infection risks, they also consequently created barriers to accessing traditional HIV testing services, especially those marginalized communities at greatest risk. These COVID restrictions included a ban on large gatherings, implemented shelter-in-place requirements for vulnerable populations, established safety guidelines for businesses, social distancing and required face coverings (State of Georgia, 2020).

Consequences of COVID-19 impacted individuals' ability to access PrEP services and HIV/STD testing, resulting in decreased frequency and utilization of these services among priority populations. A study conducted by Sanchez et al. (2020) among

young men of color aged 15-24 found that 23% of participants reported challenges with obtaining an HIV test. Another study conducted by Pampati et al. (2021) among young men of color, currently prescribed PrEP, reported 20% experienced difficulty obtaining an HIV test and 32% of the same cohort not having an HIV test in the previous 3 months, affecting adherence to PrEP prescription testing guidelines.

The attempt by clinics and community organizations to adhere to COVID precautions interrupted in-person visits for HIV prevention services. Visits for HIV counseling and testing or PrEP prescriptions had to either be made by appointment, providers were overbooked with limited appointment slots, or service centers closed altogether. PrEP initiation would be impacted for the same reasons. The lack of available in-person services or ability for community service centers to conduct prevention outreach, including HIV counseling and testing, challenged individuals who may have faced stigma at their local clinics so they typical choose to attend clinics outside of their local communities (Hill, Anderson, & Lock, 2021). Consequently, both reduced access to community-based clinics and institutional or community-level stigma influenced individuals' decisions to postpone PrEP initiation or routine HIV counseling and testing until COVID-19 restrictions were lifted.

Clinics and community centers with the capacity were able to shift efforts in order to maintain continuity of services by reducing the physical barrier of accessing HIV testing and PrEP services through the offering of telehealth services or at-home HIV testing. Still, telehealth initiatives saw their own challenges as some clients did not have access to sufficient internet services to support connections, clients may reside in a home with little to no privacy or where there were uncomfortable discussing sexual

health information. Guidance from various studies and governing bodies suggest identifying creative ways to deliver these key HIV prevention services is important, as the variations in sexual behavior or transmission had not been found to be associated with reduced diagnosis (Barbee, et al., 2020). Viable options to consider for maintained appropriate care during the COVID-19 pandemic response range from offering lab-only visits for HIV/STD tests among PrEP users, at-home HIV/STD testing, self-testing for HIV via oral swab, extending PrEP prescriptions to a 90-day supply to decrease trips to the pharmacy, and utilizing telehealth where feasible.

HIV testing and Health Insurance

The Affordable Care Act (ACA) was signed and amended in 2010 as a comprehensive health care reform law intended to make health coverage easier to navigate, access and afford for all, but especially for underserved, low-income individuals. The ACA requires plans to cover recommended preventative services for individuals aged 15 to 65 years. This requirement includes HIV testing as one of those services to be covered by health insurance without a copay or deductible. Medicare Part B, a federal health insurance, covers annual HIV screening for those 15 to 65 years or age, those younger than 15 or older than 65 and at increased risk for HIV, and pregnant women who can be screened up to 3 times during pregnancy (HIV Screenings, 2021). This coverage is similar across other insurers and payor programs including Medicaid and most private insurance.

For individuals without health insurance there is often an out-of-pocket cost for HIV testing. Conventional HIV testing can be offered at little or no cost at local, community health centers or public health departments for individuals without

insurance, Medicaid or Medicare. Still, with variations in eligibility requirements, cost sharing and other fragmented financial cover structure, the access to preventative services remains uneven, leaving gaps that result in many people with and at risk of HIV unable to utilize the system (Dawson, Kates, & Roberts, 2023). In addition, because these facility settings where individuals would go for affordable HIV testing are usually community, public health settings, individuals have concerns for or fear the lack of privacy and confidentiality as well as stigmatizing service delivery which can in turn be a barrier to HIV testing for those without insurance coverage. It has been maintained from studies that have collected data on individuals' experience in both rural and urban communities that treatment when seeking in-person HIV testing by healthcare professional can be perceived as poor, judgmental, isolating and stigmatizing, discouraging the desire to utilize public health/social service/STD clinic facility-based testing settings (Mathews, et al., 2020).

While HIV testing that is done in a health care setting or laboratory typical falls under covered preventative services for those with insurance, the availability for low-cost HIV self-testing (HIVST), a rapid home-based test using oral fluid or finger stick, largely conducted outside of a healthcare setting or lab, needs continued support as implementation and cost coverage is lagging. Home-based HIVSTs are not usually covered by insurance companies and therefore require an out-of-pocket cost that can range from $50-$100 (Kassel, 2023). HIV self-tests are typically available for purchase at retail pharmacy locations. These tests, which can be used at-home, look for either antibodies alone or both antigens and antibodies. If they are detected, the test returns a positive result for HIV. However, these results are preliminary and therefore require a

follow up laboratory test to confirm the positive result and presence of the HIV virus. Most HIVST initiatives to increase the uptake of HIV testing among key populations and those hard-to-reach remain largely donor-funded, which points to matters of sustainability and accessibility as HIVST implementation grows rapidly (Gupta-Wright, Barnabas, Ingold, Duneton, & Abubakar, 2021).

Problem Statement

Even with some lifted restrictions in Georgia and attempts to integrate COVID-19 and HIV through methods such as incorporating HIV testing during COVID testing and vaccinations events, provisions of HIV prevention services were still under performing. Limited staff capacity, the inability to conduct outreach efforts or test in non-traditional settings, and closure of community organizations along with non-essential services, all culminated as local contributing factors negatively impacting the continuity of HIV prevention services (Operario, King, & Gamarel, 2020). COVID-19 lockdowns imposed difficulties for individuals to access primary prevention services, HIV testing and PrEP, through routine conventional methods in clinic settings, outreach, and community settings, making the need to explore feasibility of free, home-based HIV testing options essential.

Recent Efforts at HIV home-based self-testing

Ending the HIV epidemic initiatives in Georgia requires leveraging of resources and efforts across community, public and private healthcare organizations to assist 1) individuals with unknown HIV status access HIV testing, 2) individuals with a negative HIV test results access PrEP to help remain negative, and 3) expedite access to care

and treatment for those testing positive for HIV. The COVID pandemic interrupted HIV testing which serves as the primary entry point into HIV prevention and care services. To better facilitate HIV testing disrupted due to barriers to service provisions created by the COVID response the offering of HIVST as a strategy to close testing gaps and increase testing coverage across the state of Georgia was conducted. HIVST presented the opportunity of being a high impact, low-cost intervention to target hard-to-reach populations, and to increase the number of people living with HIV in Georgia who are identified and linked to care. HIVST could also provide an opportunity to provide passive referrals – resource or service information given to a client for their own individual follow up, and active referrals – direct assistance given to a client involving staff personnel engagement to facilitate access of resource or service information, to HIV prevention services and providers for those who test negative.

Scaling up of HIVST across the state of Georgia had not been done previously. While some local health systems had offered point of care HIV testing for local or smaller initiatives, a large-statewide rollout of home-based HIVST had not been implemented. The strain on health systems resulting from the COVID-19 pandemic response presented an opportunity to expand HIVST to minimize the strain and advance the frequency of pre-screenings. The purpose of this study is to examine if expanding HIVST across Georgia is a feasible intervention to improve awareness of HIV status among key populations, influence health-seeking behaviors and aid the state's ability to address the HIV epidemic across hard-to-reach communities.

HIVST requests were made via an online order and could be obtained by delivery or pick up for use in the privacy of an individual's home. The pre-survey was completed

by individuals across the state to request receipt of up to two (2) HIVSTs per survey free of cost to them beginning November 2020. The participants were provided instructions making them aware that they were agreeing to complete an HIV test, that testing was voluntary, and their results were confidential per Georgia law (GA Code § 24-12-21, 2014). Georgia law treats HIV status as confidential medical information to be used for access to medical treatment and requiring individual consent. They also agreed to the acknowledgement and understanding that additional testing was needed for confirmation following an incomplete or positive HIV test result, which is considered preliminary until confirmed by a secondary confirmatory testing.

Follow up analysis of those individuals having used the home-based HIVST examined the post-survey self-reporting of test results, subsequent experience processing and interpreting results in the absence of an in-person testing and linkage counselor, and likelihood of recommending the test to others. Those surveyed resided in the state of Georgia and had the option to present to a local community location to pick-up a verified HIVST if they did not want it delivered to a place of residence or they were able to access a physical location in the community to receive the HIVST at no cost. A pickup distribution request option was also made available to communities during limited outreach activities conducted by local health departments or community-based organizations. This study was done to determine the answer to 4 research questions: 1) Is there an association between health insurance status and HIV testing history; health insurance status and HIVST distribution method?, 2) What are the predictors of requesting an HIVST via mail distribution versus pickup distribution option?, 3) What are the primary reasons for requesting an HIVST between the different

request distribution methods and is there an association?, and 4) What are respondents' experiences with using an HIVST?

Significance and Relevance

This study will describe the knowledge, skills, demographics, insurance coverage status, and attitudes participants have related to use of HIVST as HIV prevention methods. The primary objective will be to investigate and compare the uptake of HIVST across Georgia, considering health insurance coverage status, as Georgia is a Medicaid non-expansion state, use of different HIVST distribution methods along with usefulness of the self-reported survey data for reaching clients at greatest risk of HIV exposure. The secondary objective is to identify the effects of HIVST on health seeking behavior including previous HIV testing history, reasons for seeking a self-test, awareness of PrEP and reporting of testing results. In order to improve health outcomes and minimize HIV transmission risk, the average protective effect of current levels of intervention provision should be relatively high (Uusküla A, 2020). As Uuskula et al have highlighted "primary HIV prevention reduces the incidence of transmission, whereas secondary HIV prevention focuses on early detection and prompt ART treatment (2020)." This study recognizes the areas of primary and secondary public health preventions with testing serving as a potential yet critical entry point in the HIV prevention and care continuum, integrated with PrEP education to streamline the prevention-side of the continuum.

The conceptual HIV prevention continuum framework will be used here to describe HIV prevention efforts that can improve HIV program implementation for those at greater risk of exposure to HIV. Analyses of the degree to which an HIV program effectively prevents HIV transmission, and whether a program is effectively treating

patients with HIV, have used the concept of prevention and care continuums to explore the steps required to prevent infection and achieve viral suppression (Gardner, McLees, Steiner, del Rio, & Burman, 2011). Just as the HIV treatment/care continuum demonstrates key steps needed for the treatment of HIV along guiding improved planning and monitoring, the HIV prevention continuum can be a useful tool to define critical steps needed for successful delivery of prevention interventions (McNairy & El-Sadr, 2014).

The HIV prevention continuum framework begins with services and activities targeting HIV negative persons such as testing in non-clinical settings and routine opt-out screenings, to promote risk-reduction, access to health insurance and engagement with primary care to ensure access to key prevention support. Next, is linkage to prevention care services such as case management for high-risk groups, i.e. Injection drug users, distribution of condoms, knowledge building for safer sexual health practices and linkage to PrEP as an intervention. Following linkage to intervention strategies is retention in prevention care services such as peer-support, ongoing STD/HIV screenings, and health education to remain HIV negative.

The characteristics and usefulness of the HIV prevention continuum depends on the availability of practical sources of data to guide the continuum. Preventative behaviors and products can be beneficial if the uptake is considered acceptable for adoption by susceptible individuals and adherence is largely influenced by delivery method and accessibility. HIV prevention services needed to reduce HIV infections illustrated in this framework are reflected in the following HIV Prevention Continuum (Figure 1). Accessibility and knowledge of HIV testing and PrEP services will be

explored in this study.

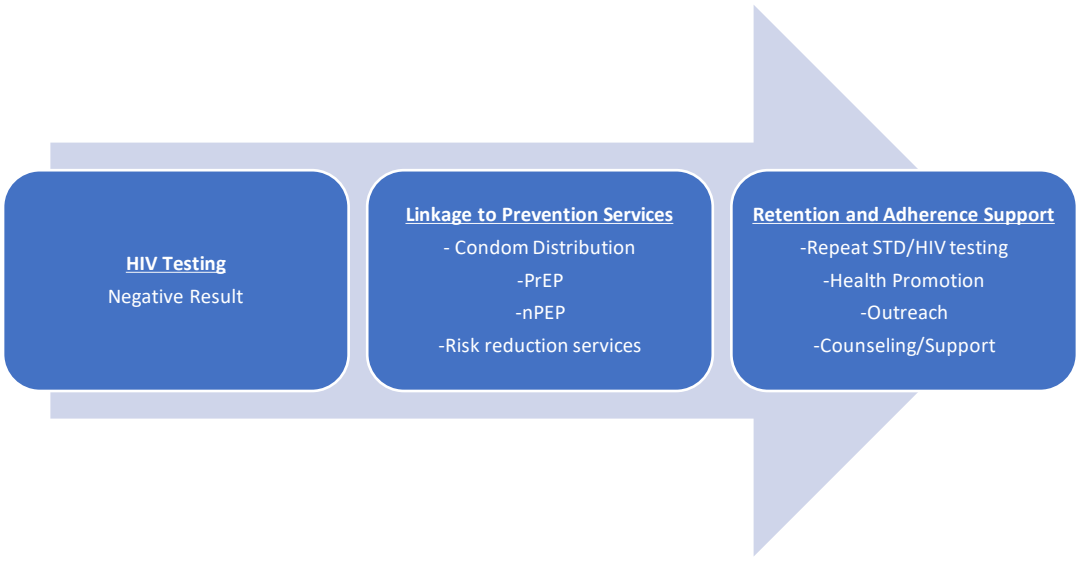

Figure 1. HIV Prevention Continuum Framework

PrEP – pre-exposure prophylaxis; nPEP - nonoccupational postexposure prophylaxis
McNairy, M. L., & El-Sadr, W. M. (2014).

The key steps within the continuum include HIV testing and PrEP offered to individuals of priority populations as inputs to inform the process measures of preventative and health promotion. Output variables of interests to this study will inform acceptability of HIVST, ease of use, and health seeking behavior following respective results.

The stark disproportionately high rates of health predictors seen among certain high impact groups such as women of color, black gay and bisexual men in Georgia are an indication that the health care system is not meeting the needs of all populations equally. According to Kaiser Permanente of Georgia's 2022 Community health needs

assessment, anxiety, depression, and suicide ideation were on the rise due to the COVID-19 pandemic, particularly among Black and Hispanic Americans along with a decline in mental health and worsening substance abuse, especially for immigrant, Hispanic, and LGBTQ+ communities (Kaiser Permanente of Georgia, 2022). Further assessment of Georgia's sexual health outcomes in 2020 notes that gay or bisexual males account for 84% of new HIV diagnoses with Black and Hispanic women, at a 7x and nearly 2x respectively, greater rate of new diagnoses compared to White women (Georgia Department of Public Health, 2020). With COVID-19 pandemic we saw people of color disproportionately represented among cases, hospitalizations and deaths, outcomes that intersect with the HIV epidemic. These implications of health inequity speak to a need to look at various gaps in health care resources beginning with access to preventative services and the incremental relationship between social advantage and health, noted by social determinants of health where less advantaged communities experience a disproportionate burden of poor health. This project will help to guide the development and better structure engagement in work that can demonstrate how local interventions inform policy and play a key role in changing current trends of HIV prevalence and disparities.

Another key component of HIVST programs or initiatives with policy implications of consideration is adherence support from follow up to treatment and care for unassisted HIVST. Unassisted HIVST refers to the absence of a trained HIV counselor, health educator or testing provider who would actively assist and document confirmatory testing as well as linkage to HIV care services with the goal of the diagnosed individual achieving viral suppression. Unassisted HIVST must utilize

passive tools such as helplines, written or online materials, and other applications to facilitate counseling and referrals to additional resources for prevention, treatment and support services; otherwise typically provided by a case manager/counselor staff position. In the absence of having a public health service provider traditionally tasked with ensuring confirmation of a positive HIV diagnosis and facilitating follow up linkage to care services, programs should consider ways to incorporated data systems as an alternative way to track the outcomes of positive HIVSTs not voluntarily reported by users.

While this study is focused on assessing data from HIVST distribution, approaches to linkage to ensure adequate support and results reporting of clients utilizing HIVST can also be explored. Questions to consider are, rather client-level data collected for HIVST requests can in turn be assessed using traditional surveillance systems for confirmed reactive HIV diagnoses or existing HIV lab measures? In addition, expanding the interoperability of data systems through data modernization initiatives could be beneficial when staff availability is not feasible, or workforce capacity does not allow for routine, active counseling and linkage assurance. In such cases, passive means of connected data and confirming results could be useful. Determining the barriers to using measures from traditional HIV surveillance systems to indicate confirmed HIV diagnoses following HIV self-testing will be considered in the limitations and recommendations section. Findings from this dissertation can help to inform target areas of priority in research or program design while leading to the development of policies and guidelines that can result in integrated prevention and care efforts for improved HIV prevention outcomes in Georgia.

The remainder of the study is outlined in a five-chapter structure, capturing a practical investigation that will look at correlations and evaluations of a home-based testing system for HIV prevention initiatives. The structure will reflect the five chapters as follows: Chapter 2 presents a review of the literature describing preferences and outcomes of free rapid self-test to increase HIV testing efforts. Chapter 3 details the data sources and collection procedure used, methods for analysis and limitations. Chapter 4 presents the summarized findings, identified themes, systematic challenges and best practices generated. A description of the study findings, conclusions drawn, and recommendations are presented in Chapter 5. A reference section and appendices conclude the dissertation study.

Chapter 2

LITERATURE REVIEW

Factors that influence HIV testing

CDC recommendations suggests that individuals between 13 to 64 years of age be tested for HIV at least once and for those at increased risk of exposure to HIV be tested more frequently, at least once a year or before initiate sex with a new partner (Center for Disease Control and Prevention, 2022). Still, delayed and infrequent HIV testing has been found by numerous studies to be associated with an increased rate of missing or late HIV diagnosis, especially among populations at greatest risk (Schwarcz, et al., 2011). In an effort to increase the utilization of HIV testing, studies have assessed factors that deter testing, such as lack of access to testing sites, no health insurance, cost of services and limited hours of operation, low perceived risk of HIV/STIs, fear of test results and mistreatment due to stigma. In addition, a lack of access to testing resources, poverty, stigma, discrimination, and low HIV risk perception all serve as barriers to HIV testing among key impacted communities and even the general population (Hamilton, et al., 2020).

A study investigating the effects of health insurance on HIV testing rates in the U.S. by Sood, Wagner and Wu (2015) asserted that insurance coverage increases HIV testing rates and insurance coverage increases HIV testing rates more among the high-risk populations. The expansion of Medicaid following the ACA resulted in an increase in insured individuals across the country, but this impact varied as some states, mostly in

the South, elected not to expand Medicaid. Not expanding Medicaid in these states created a coverage gap whereas a number of low and middle-income individuals are under or uninsured. The uninsured rates for those states not implementing the expansion is nearly double the rate of states that have expanded Medicaid (Drake & Tolbert, 2024). Even for those expansion states, this increase in the number of individuals who are insured was also accompanied by rising health care costs and cuts in public health funds which ultimately lead many public health or community care settings to implement payment structures for services that were previously at low costs or free charge regardless of insurance status.

In an attempt to offset the impact of declining public health funds that were typically directed to these preventative services, the response to this fragmented financial structure by public health care facilities was to adopt insurance use requirements that unfortunately present unintended challenges to patients. One of those challenges being the out-of-pocket cost of services, such as HIV testing, presented in the form of insurance copayments, coinsurance, and deductibles. The out of post costs and confidentiality concerns associated with insurance were found to be a major barrier for individuals' with insurance willingness to use insurance for HIV/STI services at publicly funded HIV/STI clinics (Montgomery, et al., 2017)

Stigma associated with HIV testing is also a known barrier to underserved populations getting routine HIV testing especially in their own communities and local health care centers. Community barriers to HIV testing include "fear of confidentiality breaches, discriminatory treatment by healthcare professionals, lack of consistent community presence by HIV test providers, stigmatization from religious leaders, lack of

information about post-test options, and fear of improper use of HIVST kits (Mathews, et al., 2020)." To address these inconsistencies in and barriers to testing, research has aimed to increase access to HIV testing while promoting health and social support (Wilson & Moore, 2009).

Institutional stigma or lack of health insurance can delay or keep people from vulnerable populations, people of color and LGBTQ communities, from getting preventative services like HIV testing or speaking with a medical provider about the importance of additional STD screenings they could be at risk of exposure to. Testing negative for HIV also leads to the opportunity to adopt other preventative services, specifically begin PrEP which serves as a highly effective, risk reduction prevention model (Eaton, et al., 2017). Therefore, such new testing technologies and methods that have surfaced can facilitate consistent HIV testing by removing barriers and increasing testing options to reduce undiagnosed HIV cases with more timely linkage to prevention or care support services.

HIV self-testing acceptability

HIVST is an acceptable testing modality that began seeing broader uptake over the past 5 years to increase HIV testing and diagnoses especially among those at greater risk of HIV exposure. It offers a feasible alternative to clinic-based testing to improve early detection and awareness of HIV status to adopt safer sexual behavior to prevent infection (Lippman, et al., 2018). Having been shown to have broader reach among first-time testers, undertested and those unlikely to test for HIV, when compared to clinic-based testing (Steehler & Siegler, 2019) ST uptake is far more optimal. HIVST options have evolved over time and range from blood-based, finger prick tests to saliva.

Each of these different testing modalities vary in their levels of accuracy, typically measured by sensitivity and specificity. While some individuals prefer blood-based specimen tests due to a belief of greater accuracy and reportedly higher sensitivity, oral HIV ST are favored by individuals who are apprehensive about blood or finger pricks and seek faster results turnaround, usually less than 30 minutes (Frye, et al., 2018), (Stevens D. R., Vrana, Dlin, & Korte, 2018). Data from several developed and underdeveloped countries found HIV self-tests to be usable and acceptable among populations at high risk of HIV/STD acquisition (Lee, et al., 2022) with oral-fluid swabs regarded as the easiest self-test method. In 2012, the U.S. Food and Drug Administration (FDA) approved the OraQuick® in-home HIV test to be sold in stores and used over-the-counter (OTC) in private by anyone 17 years of age or older at a cost that can range between $50-$100. It is an oral fluid, rapid test that delivers results within 20 to 40 minutes, without the need to send samples to a laboratory (U.S. Food and Drug Administration, 2022).

Public health HIV testing programs are implemented to aid populations in adherence to HIV/STI testing guidelines to help reduce HIV transmission and control the epidemic. Evidence shows HIV testing used as a prevention strategy can be effective in identifying high-risk persons with undiagnosed infections (Sharma, et al., 2017). HIV screening is the first step to proven HIV treatment and prevention strategies, whether it is to remain HIV negative via PrEP or engage in care to reduce viral load and transmission, care as prevention.

Issues around the effectiveness and acceptability of HIV self-test kits have shaped efforts to implement self-testing as a wide-scale public health strategy. Other

themes that have presented as implications that have impacted self-testing uptake as a program strategy include the timely presence of formal counseling, ability of users to perform the self-test correctly, test sensitivity most notably in early infection, expectations to follow up on reactive tests with confirmatory testing, instruction and supervision, and cost (Stevens D. R., Vrana, Dlin, & Korte, 2018). HIVST can help to reach individuals who otherwise may never seek testing on their own and can facilitate mutual partner screening, allowing for the choice of safer sex practices between partners. The facilitation of decision-making and de-stigmatization around self-testing could also aid partner disclosure, with status awareness being a motivator for preventative behavior.

Still, false-negative results during early infection and high transmissibility periods and well as missed opportunities to screen for other STIs have been key arguments against expanding HIV self-testing (Myers, El-Sadr, Zerbe, & Branson, 2013). Additional challenges included affordability which was seen as prohibitive to access of STs especially in low- to middle-income communities, where communities are disproportionately affected by HIV burden. Figueroa et al. theorized that participants had a greater willingness to pay for unsupervised HIVST when compared to supervised HIVST, believing the latter to be more comparable to clinic-based testing (2015).

Some steps taken to combat these disadvantages include cautioning the importance for confirmatory testing of positive ST results, use of blood specimens to test for other STIs, and agencies offering free in-home STs. Notwithstanding, HIVST presents an option to screen for HIV considering convenience, control and privacy in the hands of those who want to know their HIV status however, challenges associated with

verifying results leading to subsequent delayed entry to care and insufficient counseling need to be better understood (Tahlil, et al., 2020), (Wood, Ballenger, & Stekler, 2014). Yet, when self-tests are considered an alternative for reaching individuals who are not routinely screening in healthcare settings or have relative risk and not a replacement for clinical based testing, this approach is beneficial at overcoming barriers to testing that contribute to the HIV health disparities as well as point-of-care entry to the HIV prevention and care continuum.

HIVST has been shown to be acceptable to many diverse population groups in a variety of settings (World Health Organization, n.d.). It is generally accurate when performed with regulated and quality rapid diagnostic tests (UNITAID, WHO and PSI, 2018). When provided in conjunction with adequate instructions for use and post-test support information, self-testing is also an effective and efficient strategy requiring fewer human resources than other approaches. HIVST can be convenient and empowering for individuals who do not utilize traditional healthcare facilities offering HIV testing services. HIVST can also be distributed using a variety of delivery models including home-based direct distribution to individuals, such as mailing, facility-based distribution or community-based distribution, where an individual can pick up and/or use at a local community facility or outreach event (Jamil, et al., 2021). There are likely to be variations in the feasibility and sustainability of the different distribution models along with their required support options; as home-based distribution is unassisted not involving staff or personnel, whereas facility-based distribution incorporates local health department staff and related resources. A study done by Maheswaran et al. conducting a cost analysis of HIVST found that “HIVST reduces the economic burden on clients but

is a costlier strategy for the health provider…The provider cost of HIVST could be substantially lower under less restrictive distribution models (2016)." This implication can have a different financial impact when Health Departments are covering the costs to make HIVST free to clients. As policies advance to help deliver HIVST to public, private sector and community service delivery channels; HIVST has the potential to support standard HIV testing and enhance the overall uptake of HIV testing across populations.

COVID-19 and HIV-Self Testing

COVID-19 response led to decreasing access to HIV prevention services, notably HIV testing and PrEP, directly effecting efforts to control the HIV epidemic. Implications for public health practice resulting from COVID-19 are described by Pinto and Park to include "resources shortages, low staff morale and a disruption to patient-centered service provisions (2020)." Because in-person interactions, outreach in the community and referrals are not feasible in a COVID pandemic environment, as human organizational resources are directly interrupted; HIVST presents an alternative to keeping clients on the prevention continuum. Integration of HIV services with COVID-19 services has helped countries scale-up HIV service delivery at an accelerated rate that would not have been achieved if solely focused on COVID-19 response (The Lancet, 2020). Adapting approaches of home delivery care to HIV testing has helped HIV prevention services rebound.

The COVID-19 pandemic saw lockdown measures that created barriers to facility/clinic-based HIV testing that stemmed from closures and staff shortages, thus HIV ST could ease the strain placed on facilities unable to cover clinic-based testing at pre-COVID rates (Mhango, Chitungo, & Dzinamarira, 2020). Extending access to HIV

ST could be valuable to reduce the strain on health care systems overwhelmed with COVID-19 related response. Data reported from the Health Resources and Services Administration's Uniform Data System, CDCs National HIV Prevention Program Monitoring and Evaluation system and the National Syndromic Surveillance Program found the number of HIV tests reported had declined sharply in 2020 compared to 2019 and that populations at heighten risk for acquisition of HIV (i.e., Black, Hispanic, MSM and transgendered persons) experienced decreases in HIV testing (DiNenno, et al., 2022). HIVST has largely been found to be a feasible, acceptable point-of-care test in nonclinical settings to be preferred over clinical-based testing. HIVST can be successfully used repeatedly as well as distributed among partners and peers to promote early detection that may reduce health disparities (O'Byrne, 2021).

This dissertation aims to examine the implementation of the first statewide self-testing initiative pilot conducted across Georgia. Use of this intervention strategy has yet to be evaluated comprehensively in Georgia, in addition to the role of state-level systems, structural approaches, policy development and regulation on reducing the risk of HIV transmission and deaths. It will look at the approaches in which HIV self-testing can be delivered to reach priority populations and if these methods were effective as well as whether they can be improved or replicated for broader public health implementation across the state, considering payment methods and the impact of insurance, in both metro Atlanta and non-metro Atlanta areas noting any divergence or convergence of findings.

Chapter 3

METHODOLOGY

Evaluation of HIVST Survey Data

This mainly quantitative study assessed responses to a pre- and post-survey instrument completed by individuals residing in Georgia, requesting to receive an HIV ST by delivery or pick up. Qualitative responses were also provided from open-ended questions and analyzed to offer insight into experience with using the HIVST, individual knowledge and attitudes around HIV prevention along with health seeking behaviors. Additional quantitative analysis of secondary data was conducted to capture self-reported receipt of HIVSTs using redemption codes, identifying use of HIVST and self-reporting of results. This chapter is organized into sections to present the purpose, research design, research ethics and human subjects protection, population and sample, instrumentation, data collection/analysis and limitations of the study.

Purpose

Restrictive measures associated with minimizing the spread of COVID-19 pandemic led to stifled HIV testing across Georgia, furthering testing gaps among priority populations including gay and bisexual men, transgender persons and women of color. HIVST was piloted across the state to address the layered barriers to key HIV prevention testing efforts with the intent to increase access to HIV testing and coverage by offering home-based HIVST.

The purpose of this study is to examine if expanding HIVST across Georgia is a feasible intervention to improve awareness of HIV status among key populations, influence health-seeking behaviors and aid the state's ability to address the HIV epidemic across hard-to-reach communities. It will also identify challenges to implementing a non-traditional testing intervention that may impact patient follow up and individual results reporting.

Research Questions and Hypotheses

Research Question #1: Is there an association between health insurance status and HIV testing history; health insurance status and HIVST distribution method?

Hypothesis #1: CDC recommends individuals 16 to 64 years of age who are sexually active to be tested for HIV at least once a year. HIVST survey data will provide information about individuals HIV testing history prior to requesting an HIVST and alternative platforms from the standard traditional clinical and non-clinical settings used to reach individuals who otherwise do not want to or are unable to present to a clinic for routine HIV testing. It is hypothesized that having health insurance is associated with a greater likelihood of accessing HIV testing and testing more frequently.

In addition, utilization of different distribution methods in which individuals request an HIVST is likely connected to the availability in their local community and the perception or presence of stigma which could impact willingness to present in-person. Individuals without insurance would be more likely to use public health centers and associated services, such as pick up sites for HIVST. Therefore, it is hypothesized that individuals with health insurance are more probable to use the mail distribution option

compared to those without health insurance, who are more likely to present to an in-person pickup distribution location.

Research Question #2: What are the predictors of requesting an HIVST via mail distribution versus pickup distribution option?

Hypothesis #2: Differences between those requesting a HIVST pickup option versus mail option were compared. It was expected that participants who typically experience barriers to utilizing preventative services would be more likely to access HIVST. Therefore, HIVST would help reach individuals who are more likely to experience health disparities so respondents will likely not have health insurance, younger in age, represent as a racial-ethnic minority, and not accessed routine HIV testing. HIVST using mail distribution is an unassisted process where individuals are not likely to engage directly with a public health educator or navigator, having the kit sent directly to them after submitting a request online. HIVST using pick up distribution usually involves in-person interaction with a public health navigator or access to a traditional healthcare setting/facility and the related resources, whether those resources are used or not, they are still in proximity.

Populations that are difficult to reach in traditional settings are likely more inclined to utilize a testing distribution option that does not involve engagement with traditional healthcare/clinical settings or healthcare personnel. This also reduces their likelihood of engaging with HIV prevention and related resources. In addition, more complete information is generally collected for tests conducted in traditional clinical and non-clinical settings with the help of a public health or clinical facilitator, therefore reporting of positive test results and risk factors will likely be fewer for HIVST compared

to traditional HIV testing. These are common types of data limitations that are experienced when implementing an intervention reliant on self-reporting and reduced data burden to consumers, in the absence of a public health or clinical facilitator. Still, HIVST will provide insight into the groups most reached among HIVST requests comparing mail distribution with pick up distribution methods.

Research question #3: What are the primary reasons for requesting an HIVST between the different request distribution methods and is there an association?

Hypothesis #3: Individuals requesting a HIVST are likely to do so because of the privacy it provides and the ease of receiving it without having to travel a distance from their home residence to an outside clinic setting. Individuals requesting a mailed kit will be more likely to note privacy reasons and observing distance as a favorable factor compared to a pickup distribution method, since those willing to pick up a test kit probably are likely not as concerned about transportation or distance to access the HIV test option. Furthermore, certain populations such as homeless, housing insecure, some rural communities or individuals without access to internet would have difficulty accessing an online link to request a mailed option HIVST. So, there are implications that individuals requesting a pickup option would also have different reasons for selected that preferred distribution method compared to those without limitations to certain resources and would be more likely to encounter an outreach event or facility where an individual could assist them with obtaining an HIVST directly via pick up distribution. It is expected that there will be some challenges with incomplete self-reporting of HIVST results for both mailed kit distributions and pick up kits distribution, in

the absence of traditional testing conducted by a counselor as well as follow up for prevention support or care engagement.

Research Question #4: What are respondents' experiences with using an HIVST?

Hypothesis #4: HIVST across Georgia has not been implemented on such a large scale, and considering the out-of-pocket costs from pharmacies, most respondents will likely be first-time users of HIVST. Considering the privacy provided by having the opportunity to conduct in one's home or trusted location, this option will have favorable agreement. Yet, the absence of a counselor or health educator to facilitate interpretation of test use and results could be a prohibitive factor and contribute to more anxiety. Lastly, reliance on self-report has challenges with complete reporting of results and could delay the opportunity for immediate follow up to public health related questions to a screening test.

Research Design

This study incorporated a largely quantitative method as the primary design, collecting numerical responses from a pre-survey conducted before receiving a HIVST and post-survey questions conducted after completing the initial request for and receiving a HIVST. The post-survey included a few qualitative, open-ended questions about knowledge related to HIV prevention, reason for selecting a ST, individual response of their test result and experiences with completing the HIVST. The research analysis was considered descriptive in nature, providing a snapshot of where addressing testing barriers through the provision of HIVST resulted in additional HIV testing reach to individuals across the state, determining which sub-population groups

were more likely to access HIVST via different request method options, and geographic areas where there was greater frequency of requests.

Some analytical research integrated would inform any new concepts identified that are related to HIV prevention methods under review such as use and awareness of PrEP or actual use of HIVST. The overall analysis involved assessing secondary data collected from an online survey presented at two different points in time which included receipt of an HIVST followed by voluntary reporting of the HIVST result. Of additional interest is the possibility of analyzing subsequent HIV laboratory measures, test confirmation or viral load, to confirm clinical HIV positive status reported or unreported from the HIVST respondents. The subsequent HIV lab confirmatory testing and viral load are data measures that can be used as a proxy indicator for linkage to a care provider either voluntary or aided by a health department/provider staff member. However, this data analysis was not explored in this project but will offer insight into opportunities for further research.

The primary design of the pilot project which sources the secondary data being analyzed was not to track linkage to HIV care, due to limitations of the data collection methods and lack of interoperability among the data system. Therefore, my analysis provides insight into later research that can conduct a tertiary assessment separate from the primary outcomes, to simply explore if it is feasible to identify matches within existing public health HIV databases to validate an HIV care health outcome with results of preventative survey respondents, considering limitations of self-reported survey data.

The overall design can be considered generalizable to the population across the state of Georgia and was found to be a feasible program intervention to reach

individuals amid a pandemic when transportation could be challenging, outreach interaction with groups or individuals was discouraged, as well as privacy concerns and stigma related to HIV could impede testing in public settings. In response to the COVID-19 pandemic, the CDC also recommended HIVST as a supplement to traditional HIV prevention efforts that would otherwise occur at local health departments and community organizations (Center for Disease Control and Prevention, 2022).

Research Ethics and Human Subjects Protection

This study was reviewed and determined not to involve human subjects as defined by DHHS and FDA regulations. The study activities were limited to analyses of de-identified data and are related to a public health surveillance project supported by the Georgia Department of Public Health. Approval was granted by the University of Georgia Institutional Review Board.

Population and Sample

Data collected is sourced from completion of Georgia's self-testing survey which compiles and summarizes data from an online questionnaire completed by individuals who reside in Georgia. The state of Georgia includes 159 counties that are further divided into 18 public health (PH) districts (Figure 2). 7 counties constitute 5 of the metro-Atlanta area PH districts which reflect the highest burden of HIV positive new diagnoses and PLWHA in Georgia. These 5 geographic metro areas include Fulton, DeKalb, GNR (Gwinnett, Newton, Rockdale), Cobb-Douglas, and Clayton counties (Figure 2).

Figure 2. Georgia Public Health Districts Map
Source: Department of Public Health
https://dph.georgia.gov/public-health-districts

Individuals would request to receive a free OraQuick® HIV Self-Test, a point-of-care oral rapid antibody test that detects HIV-1 and HIV-2 antibodies, via a secure weblink (Figure 3).

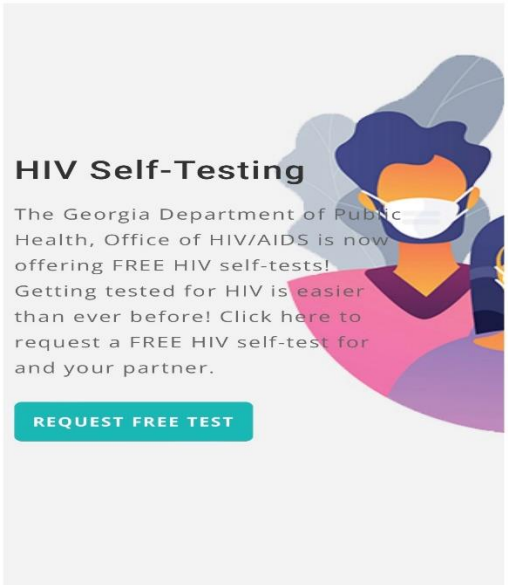

Figure 3. HIVST request Link, DPH HIV website

The online weblink was accessible to any individual residing in Georgia via a phone or computer. The link was available on various state and local public health websites and promoted to individuals during COVID-19 community events to encourage uptake. Within each HIVST kit received, manufacturer instructions were provided to the user with clear, concise directions accommodated with graphic illustrations on how to conduct the self-testing and ensuring individuals obtain accurate results. Additional quality assurance measures were put in place to facilitate correct interpretation of test results and resources for follow-up include contact information for local providers and health educators to assist with questions as well as referrals to related services.

Instrumentation and Data Collection

The Office of HIV/AIDS (OHA) developed the survey, pre and post, which could be accessed online via DPH HIV program and various local HIV program websites. The survey was administered beginning November 2020 among Georgia residents who were seeking access to a HIVST. Results used for this research assessed pre-survey data collected through December 2021. Both surveys were available in both English and Spanish, prefaced by a consent highlighting the test is voluntary and confidential (Figure 4a/b).

HIV Testing Consent Form

By agreeing to participate in the Georgia Home Self-Test Project, I acknowledge the following:

- Testing is voluntary and can be done confidentially at a public testing center.
- Georgia law [O.C.G.A. § 31-22-9.2] protects the confidentiality of HIV test results and other related information.
- Georgia law [O.C.G.A. § 31-22-9.2] prohibits discrimination based on an individual's HIV status and services are available to help with such consequences.

☐ I agree to complete an HIV test. If the results are positive or if the test does not work properly, I understand that additional testing is required to confirm results. I also agree to be contacted by a local District Counselor to determine next steps and to help navigate HIV prevention and care needs.

Date: _____

Figure 4a. HIVST Consent prompt

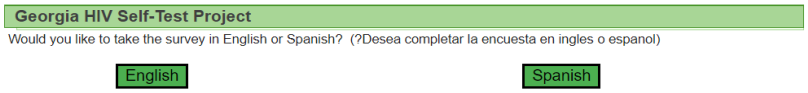

Figure 4b. HIVST Pre-survey, DPH HIV internal secure link

There are 15 questions capturing demographic information, HIV testing history, PrEP knowledge, Health insurance status, reasons for requesting a self-test and method for receiving a kit (Appendix 1). Following completion of the survey, a redemption code is then provided to redeem on the OraSure website for the requested test(s). A maximum of 2 test kits could be received per request which was connected to an email address and physical address provided via the pre-survey.

After a 2-week period, individuals who requested a self-test were sent a link to complete an (up to)15 question post-survey assessing use of their requested self-test,

sexual behavior history, and allowing for self-reporting of their result as well as any follow up steps for treatment or prevention taken, if applicable (Appendix 2).

Data cleaning removed ineligible responses based on age reported under 16 years and duplicate records (Figure 5). Although Georgia does not have a minimum age to consent for an HIV test, the exclusion criteria for age is due to age of consent for HIV testing being 16 years of age across most countries according to the World Health Organization, thus this also applies to HIVST (PEPFAR, 2020). This resulted in a total of 1,850 eligible pre-survey responses entered and analyzed from the DPH internal State Electronic Notifiable Disease Surveillance System (SENDSS), self-testing module. A separate Orasure database tracks redeemed discount codes and helps verify survey records that were complete with validated receipt of the free test kits received via mail request for each submitted record.

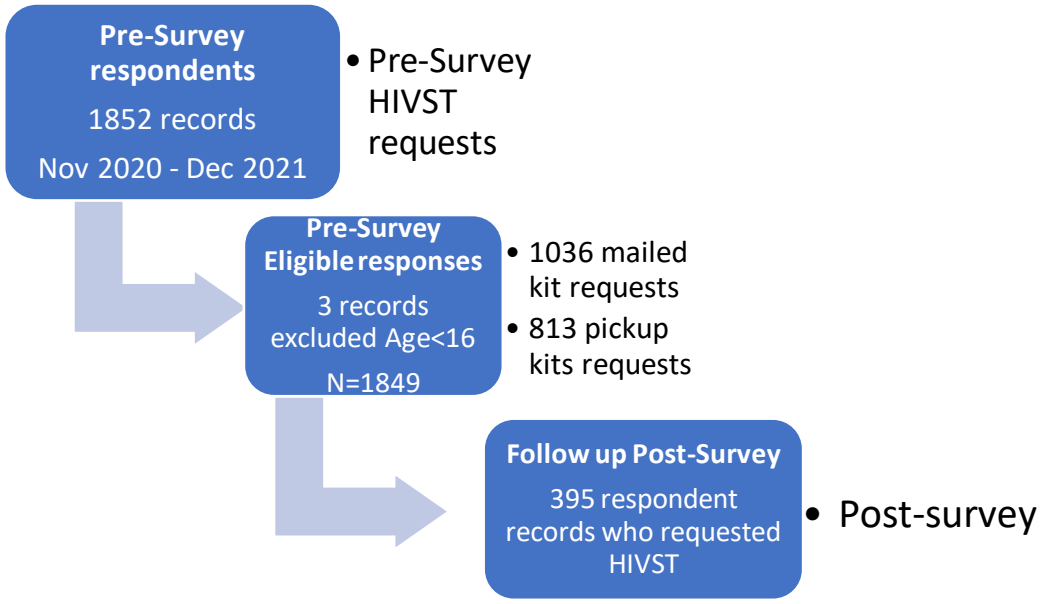

Figure 5. Georgia HIVST Project Survey Responses-Study Population

Data Analysis

Research Question #1: Is there an association between health insurance status and HIV testing history; health insurance status and HIVST distribution method?

Descriptive Analysis

Descriptive analysis was used for research question 1, applied to the pre-survey datasets. Descriptive statistics, such as frequencies and proportions, were determined to describe trends in demographics, proportion of respondents categorized by distribution request method in mailed group option versus pickup group option, history of previous HIV testing, testing frequency to examine adherence to routine HIV test and PrEP knowledge used to describe the population characteristics.

Univariate analyses

Summary statistics were analyzed for 'Age' among number and percentage of participants who completed the process for pre-survey HIVST request. Mean and standard deviation of 'Age' distribution is assessed to determine if it is consistent with trends of routine HIV Testing across age of HIV and stage 3 diagnosis in Georgia.

Bivariate analysis

Bivariate analysis measured the associations between health insurance and history of a HIV test among those requesting an HIVST as well as between health insurance and HIVST distribution request method. To compare frequencies and test the null hypothesis of no association between the noted variables, Pearson chi-square (X^2) test was used, considering the large sample size of responses. The observed and expected counts of frequencies along with p-value reported helped to determine significance of the variable associations and whether or not to reject the null hypothesis.

Research Question #2: What are the predictors of requesting an HIVST via different distribution methods, mail versus pickup option?

Descriptive Analysis

Descriptive analysis was used for research question 2, presenting differences in access to HIVST via mail request versus pick up request method. In addition, analysis applied to the pre-survey dataset examined geographic distribution of HIVST across the state by HIVST kit request method comparing 5 metro health districts with the remaining non-metro health districts.

Logistic Regression Analysis

Binary logistic regression was used to determine factors that affect (predictors of) the method preferred by individuals to request a HIVST. I explored how variables - gender, race, ethnicity, age, insurance status and last HIV test effected whether an HIVST kit was requested to be received via two dependent categories for distribution 'Option of kits' of mailed request and pickup request, by pre-survey question respondents. The point estimate used for the binary predictor of the model is the odds ratio (OR) and respective confidence interval.

Research Question #3: What are the primary reasons reported for requesting an HIV ST between the different distribution methods and is there an association?

Descriptive analysis was used for question 3 analyzing the pre-survey dataset. Frequencies and proportion of respondent indicating their reasons for requesting an HIVST categorized by requested method of distribution option - mailed versus pick up.

Multivariate analysis

Multivariate analysis measures the associations between HIVST request distribution method and reason for requesting an HIVST. To compare frequencies and test the null hypothesis of no potential associations between the noted variables, Pearson chi-square tests were used, considering the large sample size of responses. The observed and expected counts of frequencies along with p-value reported would determine significance of the variable associations and whether or not to reject the null hypothesis.

Research Question #4: What are respondents' experiences with HIVST?

Descriptive Analysis

Descriptive analysis was used for research question 3, applied to the post-survey datasets. Descriptive statistics, such as count and percent frequencies, determined to describe trends among individuals reporting the HIVST as their 1st HIV test, reported anxiety, recommended use, and ease of using the HIVST. The post-survey data set was used for comparative analysis of those completing a Post-survey following receipt and use of the HIVST.

Qualitative Analysis

Qualitative analysis assessed respondents' reported experience with using the HIVST within 2 weeks of receipt and status of the test if not used withing the 2-week time period. Thematic analysis was done based on the responses to 3 key post-survey questions: "Tell us about your experience with HIV Self-Testing", "What did you like?", "What can we do to improve?". Two independent observers/raters, myself and a public health professional, reviewed responses to identify key themes that were categorized

accordingly. Categories for themes were determined by the raters and corresponding responses evaluated and coded, calculating the degree of agreement in categorization to determine inter-rater reliability (IRR).

Survey data results following data cleaning used Microsoft Excel and data matches were exported to SAS (Statistical Analysis Software) and STATA® 17 (Stata Statistical Software, StataCorp, College Station, TX) for analysis of outcomes and associations. Summary statistics and frequency tables generated describe population demographics along with characteristics. Responses to some qualitative questions assessing knowledge and experience with HIVST were reviewed via qualitative analyses of categorical, ordinal data responses using Microsoft excel.

Chapter 4

RESULTS

As indicated in Chapter 1, this study examines data from an HIVST distribution intervention to define the acceptability and reach of HIVST frequency across Georgia, along with usefulness of reported survey data for client service follow up helping the DPH HIV program to implement effective prevention initiatives among Georgia residents. The chapter provides a summary of findings from data collected from both pre- and post- survey responses and is organized in terms of 4 specific research questions. The questions begin with assessing potential association between insurance status and participants history of previous HIV testing, next predictors for requesting a test between the different request methods offered to distribute HIVSTs to respondents along with exploring reasons for requesting an HIVST by preferred request method. Lastly, this chapter explores respondents' experiences with and the potential influence of HIVST on preventative health behaviors for those who did report use.

Descriptive characteristics findings

Table 1 demonstrates the distribution of demographic characteristics of the HIVST respondents during the study period among those who requested pick up option and mailed option. Among all respondents, the mean age was 32 years of age, with similar means seen in respondents from the mailed option group (33.6) and slightly younger for the pickup option group (30.6), most respondents were between 20-29 years (39%) followed by those 30–39 years (29%). Consistent with current HIV testing

trends, women were represented at a higher percentage across the total respondents gender identification (60%) as well as mailed option group (62%) and pickup option group (58%). Despite offering a bilingual version of the survey, only 10% of respondents reported as Hispanic/Latino. Further examining racial distribution trends, while Black/African Americans made up a majority of overall respondents, more Black respondents used the pickup option compared to mailed options, nearly a 10% difference. However, more White respondents used the mailed option compared to the pickup option, 27% versus 18%.

When assessing health insurance status among the respondents, there are variations between overall total, pickup option group and mailed option group. The mailed group reports a greater percentage of respondents do not have Health Insurance (52%) compared to the pickup group (34%) and overall respondents (44%), where a majority report having Health Insurance.

Table 1. Descriptive Analyses of participant demographics and behavioral characteristics reported by request method option for HIVST, Pre-survey (N = 1849)

Participant Demographics	Total **(n=1849) (%)**	Mailed to me request option **(n=1036) (%)**	Pickup request option **(n=813) (%)**
Age mean (standard deviation)	32.1 (11.0)	33.6 (10.3)	30.3 (11.6)
Gender			
Female	1115 (60)	640 (62)	475 (58)
Male	687 (37)	378 (36)	309 (38)
Transgender	30 (2)	11(1)	19 (2)
Other	17 (1)	7 (1)	10 (1)
Ethnicity			
Hispanic/Latino	180 (10)	100 (10)	80 (10)
Non-Hispanic or Latino	1669 (90)	936 (90)	733 (90)
Race			
Asian	32 (2)	22 (2)	10 (1)
Black/African American/Afro-Caribbean	1221 (67)	639 (62)	582 (72)
White	431 (23)	283 (27)	148 (18)
Native American/Alaskan Native	12 (1)	8 (1)	4 (0.5)
Native Hawaiian/Pacific Islander	8 (0.4)	4 (0.4)	4 (0.5)
More than one race	95 (5)	52 (5)	43 (5)
Other	50 (3)	28 (3)	22 (3)
Age Group			
16 - 19	155 (8)	35 (3)	120 (15)
20 - 29	717 (39)	371 (36)	346 (43)
30 - 39	535 (29)	352 (34)	183 (23)
40 - 49	284 (15)	191 (18)	93 (11)
50 +	158 (9)	87 (8)	71 (9)
Health Insurance			
No	822 (44)	543 (52)	279 (34)
Yes	1027 (56)	493 (48)	534(66)
Previous HIV Test			
No	586 (32)	313 (30)	273 (34)
Yes	1263 (68)	723 (70)	540 (66)

Further assessment was done among those respondents who reported history of having a previous HIV test done. Particular interest was in potential variations with frequency of getting an HIV test and knowledge of PrEP for those with a self-reported history of exercising preventative health measures.

History of previous HIV test and prior test frequency. Table 2 shows the proportion of respondents reporting the time of their last HIV test for each mailed option and pickup option group. The majority of overall respondents (34%) and mailed option group (47%) reported their last HIV test was more than one year before. Among those who opted for the pickup option HIVST, 30% reported being unsure of the time of their last HIV test followed by 22% reported having tested within the past 3 months.

Table 2. HIV Testing frequency among those with a previous HIV Test (N= 1263)

Time of last HIV test	Total N (%)	Mailed Option	Pickup Option
4 to 6 months ago	188 (15)	112 (15)	76 (14)
7 to 12 months ago	219 (17)	135 (19)	84 (16)
In the past 3 months	196 (16)	75 (10)	121 (22)
More than a year ago	432 (34)	336 (47)	96 (18)
Not sure/Don't remember	228 (18)	65 (9)	163 (30)
Total	1263	723	540

History of previous HIV test and PrEP knowledge. Figure 6 shows the trends of reported familiarity and knowledge about PrEP for those with a previous history of taking a HIV test compared to those without a previous HIV test. Distribution across both groups is similar, a majority reporting "none of the PrEP facts as true" (29%;17%) followed by "I have never heard of PrEP" (16%;10%) prior to the survey. Less than 2% reported having used PrEP themselves with a sex partner.

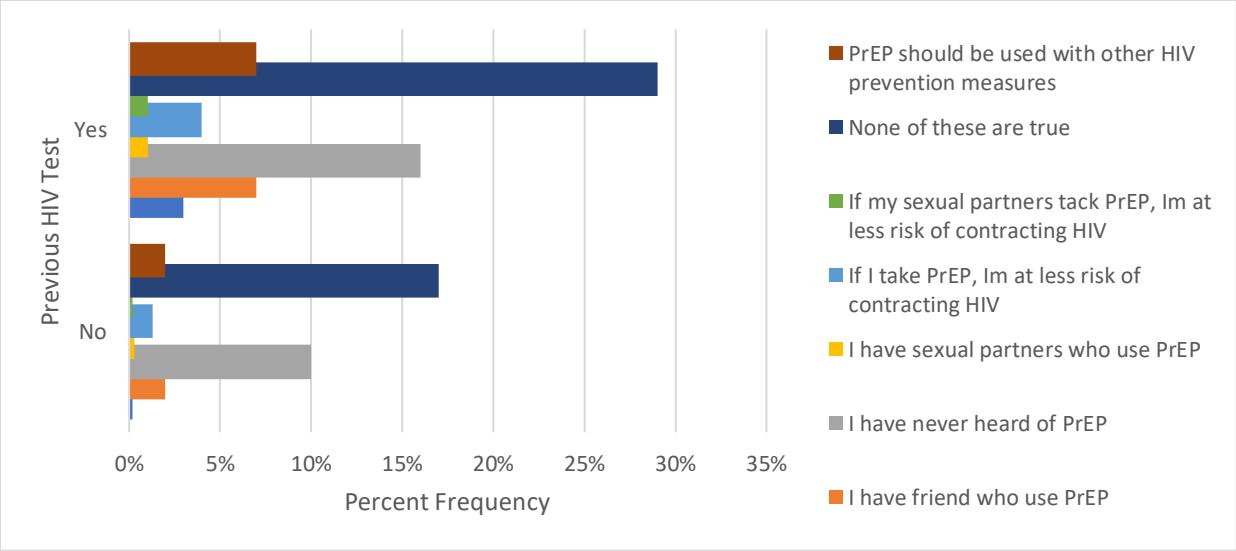

Figure 6. PrEP Knowledge based on History of a Previous HIV Test

Research Question #1: Is there an association between health insurance and HIV test history; health insurance status and HIVST distribution method?

Bivariate analysis for Question 1: Cross-tabulation and Pearson Chi-square

Bivariate analysis was done using cross-tabulation of Health Insurance and Previous HIV Test History with Pearson chi-square test to measure association. Table 3a shows the cross-tabulation table comparing actual observed frequency and expected frequency. The expected frequency is the predicted frequency under the assumption that there is no association between the two variables health insurance and previous HIV test history. Based on the marginal frequencies, if health insurance and previous HIV test history are not dependent on the other, there are more people with an actual history of an HIV test who also have health insurance than would be expected and more actual reported people without health insurance with no previous HIV Test than would be expected. Results from the table indicate that fewer people reported a history of HIV test and no health insurance AND no previous testing history with no health insurance

than predicted under the assumption that there is no association. The noted divergence in frequency counts in each category supports the high chi-square value of 9.2 and p-value, that there is more than likely significant association between health insurance status and previous HIV testing history, and we would therefore reject the null hypothesis.

Table 3a. Bivariate Analysis: Cross-tabulation for Health Insurance and Previous HIV Test with Chi-Square Association

Actual Frequency (%) Expected Frequency	**Previously Tested for HIV**		
Health Insurance	No	Yes	Total
No	**291 (15)** 260.8	**531 (29)** 561.2	**822** 44.4
Yes	**295 (16)** 326.2	**732 (40)** 701.8	**1027** 55.6
Total	**587 (31.7)**	**1263 (68.3)**	**1849 (100)**

Referring to Pearson X^2 test to measure association between health insurance and previous HIV test. X^2= 9.2 with a p-value= 0.0024 < .05 (Table 3b) declared the result as significant, therefore we do have evidence for an association that is different than 0 here between Health Insurance and HIV Test History, we dismissed the null hypothesis of no association and concluded there is a statistically significant association between health insurance status and having a previous HIV test for this study.

Table 3b. Chi-square statistics for Health Insurance and Previous HIV Test

Statistic	**DF**	**Value**	**Prob**
Chi-Square	1	9.2065	0.0024

Table 4a. Bivariate Analysis: Cross-tabulation for Health Insurance and Distribution Request Method option with Chi-Square Association.

Actual Frequency (%) Expected Frequency	**Distribution Request Method Option**		
Health Insurance	Mail in	Pickup (site)	Total
No	543(29.4) 460.57	279 (15.1) 361.43	822 (44.5)
Yes	493(26.7) 575.43	534 (28.9) 451.57	1027 (55.5)
Total	1036 (56.0)	813 (44.0)	1849 (100)

Table 4b. Chi-Square statistics for Health Insurance and Distribution Request Method

Statistic	**DF**	**Value**	**Prob**
Chi-Square	1	60.4087	<.0001

Again, comparing observed and expectant frequency counts, instead for health insurance and distribution request method (Table 4a); based on the marginal frequencies, if health insurance and distribution request method are not dependent on the other, there are more people requesting an HIVST using the mail-in distribution method who do not have health insurance than would be expected and more actual reported people with health insurance that requested an HIVST using the pickup option than would be expected. Fewer people actually requested an HIVST using mail-in distribution method and reported having health insurance and requested an HIVST using the pickup distribution with no reported health insurance than predicted under the assumption there is no association. This difference in frequency counts in each of the categories described supports the high chi-square value of 60.4 and p-value of less than 0.0001 (Table 4b), that there is a statistically significant association between health

insurance and HIVST distribution request method, therefore rejecting the null hypothesis of no association.

Research Question #2**:** What are the predictors of requesting an HIVST via mail distribution versus pickup distribution option?

Logistic regression analysis was done to determine the probability of having a HIVST kit mailed versus not having a kit mailed (picked up) predicted by health insurance status, last HIV test, gender, ethnicity, race and age (Table 5).

Table 5. Odds Ratio (OR) from logistic regression analysis for predictors of having a HIVST mailed among those requesting a test kit.

Participant Demographics	Odds Ratio **(OR)**	95% Confidence Interval (CI)	P value
Insurance			
Yes	1.00	Reference Group	-
No	1.811	1.398, 2.346	<.0001
Gender			
Transgender	1.000	Reference Group	-
Female	3.181	1.145, 8.838	0.0265
Male	2.619	0.938, 7.313	0.0662
Other	1.783	0.342, 9.288	0.4921
Ethnicity			
Non-Hispanic/Latino	1.000	Reference Group	-
Hispanic or Latino	1.452	0.906, 2.326	0.1212
Race			
White	1.000	Reference Group	-
Asian	1.195	0.319, 4.484	0.7916
Black/African American/Afro-Caribbean	0.450	0.318, 0.637	<.0001
Other	0.319	0.142, 0.717	0.0057
Native American/Alaskan Native	0.666	0.122, 3.652	0.6401
Native Hawaiian/Pacific Islander	0.490	0.081, 2.981	0.4391
More than one race	0.367	0.193, 0.698	<.0001
Last HIV Test			
Not sure/Don't remember	1.000	Reference Group	-
4 to 6 months	4.300	2.760, 6.699	<.0001
7 to 12 months	4.245	2.778, 6.487	<.0001

In the past 3 months	1.741	1.124, 2.695	0.0129
More than a year ago	9.431	6.374, 13.956	<.0001
Age Group			
50+	1.000	Reference Group	-
16 - 19	0.126	0.047, 0.339	<.0001
20 - 29	0.505	0.320, 0.796	0.0035
30 - 39	0.875	0.552, 1.387	0.5696
40 - 49	0.844	0.508, 1.403	0.5131

Assessing the effect of each of the parameters on the odds scale, the odds of having a HIVST request mailed was nearly 2 times greater for those with no Health Insurance compared to those with Insurance.

When assessing testing frequency among those with a previous HIV test, those testing more than 1 year ago had a 9 times greater odds of requesting a test via mail compared to the reference group reporting not sure/don't remember; a nearly 5 times greater odds is seen for those testing 4 to 6 months and 7 to 12 months respectively, followed by an almost 2 times greater odds of having a self-test mailed for those testing with in the past 3 months. Mailed HIVST is a reasonable option compared to pickup option to reach individuals who are not testing for HIV annually.

Assessing among race, Black, Native Hawaiian/Pacific Islander, those selecting more than one race and Other were less likely to request a HIVST via mail option than Whites. Native American were 0.7 times less likely to request a mailed HIVST than Whites. However, Asian participants were 1.13 times more likely to request a mailed HIVST, however the association is not considered to be statistically significant. Participants had a greater odds of requesting a HIVST by mail with each increasing year of age. Age group 16 to 19 were less likely to request a test via mail distribution and more likely to use the pickup distribution, while age group 20 – 29 were slightly

more likely to request the mail distribution option. Confidence interval interpretation indicates the association found between no health insurance, age groups 16 – 19 years, 20 – 29 years, last HIV testing of more than 1 year, 4 to 6 months, 7 to 12 months and the past 3 months on the outcome of mail distribution Request Method are statistically significant.

The odds of the effects of gender and ethnicity occurring at two different levels of requesting HIVST find that a participant requesting a HIVST via mail is 2 times higher for those identifying as females and males than the odds that a person identifying transgender (the reference group). The OR of 1 for ethnicity shows there is no association between ethnicity and method of requesting HIVST. Confidence Interval results indicate that there is no association and the effect for females, males, other and ethnicity are not statistically significant.

Descriptive analysis to support research question #2 also assessed the geographic distribution of HIVST across Georgia (Appendix 3) comparing the two different request distribution methods by metro Atlanta PH districts, made up of the previously referenced 5 metro-Atlanta public PH districts, and non-metro Atlanta PH districts. Table 6. shows that the metro Atlanta PH districts had a greater proportion of HIVST requests distributed by pick up option (24%) compared to non-metro Atlanta PH (20%). Non-Metro Atlanta PH districts accounted for 38% of HIVST requests distributed by mail compared to the 17% distributed by mail seen among metro Atlanta area PH Districts.

Table 6. Distribution of HIVST by Metro Atlanta and non-Metro Atlanta PH Districts (N=1849[1])

	Mail option n (%)	**Pickup option n (%)**
Metro Atlanta Health Districts[2]	319 (17)	443 (24)
Non-Metro Atlanta Health Districts[3]	706 (38)	367 (20)

[1]14 records missing county information, thus categorized as unknown health district
[2] Metro Atlanta PH Districts include-Fulton, DeKalb, Clayton, Cobb-Douglas, East Metro (GNR)
[3] Non-metro Atlanta PH Districts include the remaining 13 districts

Research Question #3: What are the primary reasons reported for requesting an HIVST between different request distribution methods and is there an association?

Multivariate analysis was done using cross-tabulation of variables HIVST request method and Reasons for requesting HIVST with Chi-Square Association to determine if there is a connection between the specified reasons for requesting a test and method used to request a test, mailed option versus pickup option. Table 7 shows the proportion of respondents identifying reasons for requesting HIVST by the request method group. Trends among respondents for the top primary reasons for requesting a HIVST were similar across subgroups for those requesting via mail and pickup as compared to the larger cohort totals. A large majority of respondents selected “other” for their reason.

In-home privacy was the next commonly selected reason among respondents for requesting an HIVST. The frequency of selections followed “In-home privacy” sees differences between subgroups depending on method of request. Participant respondents requesting mailed HIVST selected “observing social distancing” (8%) and “Confidentiality” (7%) as the subsequent most selected reasons for requesting a HIVST. Participant respondents requesting HIVST by pickup option were more aligned with the total cohort frequency trends, with “Confidentiality” (16%) and “Use with a Partner” (10%) being the most reported reason for requesting HIVST following In-home privacy.

Table 7. Reasons for Requesting HIVST Kit by HIVST Distribution Request Method

Reported Reasons	N (%)	Mailed Option n(%)	Pickup Option n(%)
Confidentiality	197 (11)	68 (7)	129 (16)
Distance from Testing Site	59 (3)	27 (3)	32 (4)
In-home Privacy	258 (14)	104 (10)	154 (19)
Nervous to take test at a clinic	62 (3)	37 (4)	25 (3)
No childcare	10 (1)	5 (1)	5 (1)
Observing Social Distancing	111 (6)	81 (8)	30 (4)
Transportation to Testing Site	26 (1)	18 (2)	8 (1)
Use with partner	133 (7)	49 (5)	84 (10)
Other	994 (54)	647 (62)	347 (43)

Multivariate analysis for Question 3: Cross-tabulation and Pearson Chi-square

The null hypothesis of this research question 3 is that there is no association or connection between reported reasons for requesting a HIVST and the method used to request the HIVST, thus these variables are independent of each other. The Pearson X^2 test was used to test this hypothesis. Under the null hypothesis of no dependence, the predicted frequency for those requesting a HIVST by mail for confidentiality, distance from test site, in-home privacy, and use with a partner are larger than the observed frequency counts for those respective reasons. The predicted frequency for those requesting pickup HIVST show divergence from the mailed option, with the same category reasons being less than the observed frequency counts. The divergence noted in these values, including “other” selection, along with the large chi-square value of 133.6 and p-value of <0.0001 indicate we will reject the null hypotheses of no association and conclude there is an association between the different distribution Request Method and Reasons for Requesting an HIVST.

Table 8a. Cross-tabulation of HIVST Request method and Reasons for Requesting HIVST with Chi-Square Association.

Actual Frequency (%) Expected Frequency	**Reason for Requesting Home HIVST Kit**									
HIVST Distribution Request Method	**Confidentiality**	**Distance from Testing Site**	**In-Home Privacy**	**Nervous to take a test at a clinic**	**No childcare**	**Observing Social Distancing**	**Other**	**Transportation to Testing Site**	**Use with partner**	**Total**
Mailed to me	68 (3.7) 110.38	27 (1.5) 33.06	104 (5.6) 144.56	37 (2.0) 34.74	5 (0.3) 5.60	81 (4.4) 62.19	647 (35.0) 556.38	18 (1.0) 14.57	49 (2.7) 74.52	1036 (56)
Pickup	129 (7.0) 86.62	32 (1.7) 25.94	154 (8.3) 113.44	25 (1.4) 27.26	5 (0.3) 4.40	30 (1.6) 48.80	346 (18.8) 436.62	8 (0.4) 11.43	84 (4.5) 58.48	813 (44)
Total	197	59	258	62	10	111	993	26	133	1849

Table 8b. Chi-Square statistics for Table of Request method by reason for requesting HIVST

Statistic	**DF**	**Value**	**Prob**
Chi-Square	8	134.1090	<.0001

Research Question #4: What is the respondent's experience with using an HIVST?

A total of 395 participant respondents used the link provided to them via email to complete the follow up post-survey sent after 2 weeks of requesting their HIVST. Six (6) questions were completed to capture respondents' individual use of and experience with the provided HIVST. Tables 9 – 11 display the responses from participants reflecting on their use and experience with HIVST. Table 9 indicates that a majority of participants (65%) reported having taken the HIVST at the time of completing the post-survey. 11% reported that they gave their HIVST to someone else for use. This was often reported as a friend or sexual partner.

Table 9. Have you taken your HIV self-test? (N=395)

Response	**Count (%)**
NO	94 (24)
SOMEONE ELSE	43 (11)
YES	258 (65)

The remaining data tables capture responses for those 258 respondents who reported having used the HIVST. Nearly 50% of respondents reported testing for HIV for the first time due to the option to use the HIVST at their home.

Table 10. Participating respondents who reported having used the HIVST (N=258)

Responses	Count (%)
I tested for HIV for the first time because of the option to test at home.	
Strongly Disagree	47 (18)
Disagree	45 (17)
Neutral	39 (15)
Agree	23(9)
Strongly Agree	104 (40)
I had anxiety testing for HIV because I was at home.	
Strongly Disagree	1(<1)
Disagree	0
Neutral	7 (3)
Agree	39(15)
Strongly Agree	211(82)
I would recommend HIV home testing to a friend and/or sexual partner.	
Strongly Disagree	113 (44)
Disagree	65 (25)
Neutral	44 (17)
Agree	22 (9)
Disagree	14 (5)
I was able to follow the instructions easily and test myself without any problems.	
Strongly Disagree	0
Disagree	0
Neutral	1 (<1)
Agree	20 (8)
Strongly Agree	237 (92)
What was the result of your HIV Self-Test?	
Negative	255 (99)
Not work	3 (1)

Nearly all respondents reported experiencing anxiety while completing the HIVST home, 97% selected they either “Agree” or “Strongly Agree” with the statement. When asked about their likelihood of recommending a HIVST to a friend or sex partner, about two-thirds of respondents (69%) disagreed that they would make such a

recommendation. Less than 15% reported that they would recommend HIVST to a friend or partner.

All but one respondent reported agreeing that the instructions provided were easy to follow and they did not have problems using the HIVST for themselves. None of the respondents reported a negative test result following use of their HIVST and only 1% reported an incomplete or invalid result following use of their HIVST. Participants who completed the post-survey and used their HIVST were asked to report how they used a second HIVST, if an additional test kit was requested. 39% reported they would keep it for later use and 30% reported they gave it to a friend or partner.

Two hundred and twenty-three (223) of those participants that completed the post-survey and used the HIVST responded to the open-ended question to share about their experience using the HIVST. Key themes were identified based on their responses and reported in Table 11. Several reported appreciations for the convenience of testing in the comfort of their home, the option of the process being confidential and that the instructions were easy to follow. A common recommendation was to offer other STI tests that can be completed in a similar manner and offer other prevention supplies with the HIVST kits.

Table 11. Thematic analysis of responses about participant experience with HIV Self-Testing

Major Themes of Reported User Experience	Supportive response quotes
Ease or Usefulness of Instructions	✓ "The instructions were a little drawn out, but the thoroughness was much appreciated." ✓ "Very efficient and also easy to follow instructions. Confidential too." ✓ "Everything was easy after watching the video about the self-test."
Convenience and Comfort from Home	✓ "I enjoyed the convenience of being home as to being at a professional place." ✓ "Thank you for allowing me to take in the comforts of my home. The kit was very easy to use. I don't like using the Chatham county health department for services because the wait is insane and sometimes the people seem unfriendly or judgmental. I try to avoid visiting." ✓ "This testing at home is more comfortable and relaxing." ✓ "It was easy and in the comfort of my own home. I was able to test with my partner."
Allowed for Privacy and Confidential	✓ "I am very glad this option is available to young people like me who don't have the best access to things and/or privacy from parents. Now I need to look into a program for PrEP since I don't want it showing on my parents insurance. Thank you for this option." ✓ "I liked the privacy and confidentiality of at home testing." ✓ "The test was very simple and convenient. I like the privacy of testing in my home and the quick results. In my opinion, there are no improvements needed."
Not Invasive	✓ "It was fast and easy. I like that I did not have to get bloodwork done because needles are one of the things I just cannot deal with. I cry every time I get stuck. Idk why. They scare me. So this help with my fear of needles."
Control of Sexual Health/knowledge of status	✓ "It was amazing, thank u so much for giving me the chance to know my status." ✓ "Very easy simple and straight to the point. I think that this is a good way to know your

	status if you are afraid or have anxiety about testing in an office."
Kit Was Not Discrete or Efficient	✓ "The testing kit is very wasteful, lots of plastic straight into the trash. Would prefer a more sustainable option." ✓ "It is a little bit bulky." ✓ "Kit is too big when trying to be discrete"
Availability of additional HIVSTs or other STI screenings	✓ "It's great! Make it more available please." ✓ "All good. Very good on Richmond County to have this option. Next maybe at home urine panel STD tests?" ✓ "Allow an individual to get up to 24 at home HIV tests a year."
Inclusion of other prevention supplies	✓ "Thanks for making it easy and free to get and take the tests at home. The tests should come with condoms and lube."
General Appreciation	✓ "Thanks so much for making it easy and providing for the home kits." ✓ "It was a smooth experience and I believed people at risk of HIV who are reluctant to get tested because of stigmatization will find it useful." ✓ "Very easy to use. Instructions were very clear. I appreciate the GA department of public health for covering the costs of the test kit."
Suggestions for improvement	✓ "Maybe make it an auto ship since PrEP requires testing every 3 months." ✓ "I think this needs to be promoted more. I don't think enough people can do it for free and in their own home without anyone knowing." ✓ "More people should be able to get this test. Perhaps it would lead to more people being aware."

Summary of Key Findings

- The age distribution among participants is similar to what is seen with current testing trends with the average age of 32 years; the 20 – 29 year age group accounted for the greatest proportion of HIVST requests.
- Frequency of testing history indicated that a majority of participants had tested for HIV more than 1 year ago, with a difference seen among those requesting to receive the

HIVST by pick up method where unknown or not sure was the most report response of previous test history.

- Similarity was seen in trends of PrEP knowledge among those with a previous history of HIV testing and those without a history of HIV testing.
- An overwhelming majority of participants did not have any knowledge or awareness of PrEP and its use.
- There is a statistically significant association between health insurance status and HIV testing history as well as health insurance status and HIVST distribution request method.
- There is an association between HIVST distribution request method and reasons for requesting an HIVST.
- Odds of having a requested HIVST mailed is 2x greater for those with no health insurance compared to those participants with insurance; 9x times greater for those testing more than 1 year ago and 5x greater for those with last reported test 7 to 12 months than those with unknown testing history.
- 65% of participants reported using the HIVST and among those who used their HIVST, nearly 50% of respondents agreed that they tested for HIV for the first time due to the option to use the HIVST at their home.
- Participants reported having anxiety using the HIVST at home, but it allowed for privacy and confidentiality, also instructions were easy to follow and an overall general appreciation for the convenience of testing at home in order to know their HIV status.
- Recommendations from participants suggested including other STI tests and prevention supplies as options to accommodate HIVST kits, more promotion to increase community awareness, and greater frequency of shipping availability to consider PrEP adherence.

Chapter 5

CONCLUSION

This chapter presents a summary of the study examined along with key conclusions drawn from the data presented in the results chapter. The discussion addresses the presented research questions and implications for HIV prevention programs in public health. The chapter concludes by offering useful guidance and recommendations based on review of the data for future research.

Summary of the study

Attempts to integrate COVID-19 response and HIV prevention activities did not mitigate the challenges of reaching communities affected and effected by HIV/AIDS through prevention services. The response to COVID-19 pandemic directly impacted the continuity of HIV prevention services. It resulted in limited staff capacity in community clinic settings that typically provided tradition HIV prevention services, a reduction in outreach efforts among those at-risk of HIV exposure, and closure of community organizations as well as other non-clinical/non-traditional settings that provide services to populations that are more difficult to reach.

The purpose of this study was to explore the use of home-based HIVST as an effective intervention to increase access to HIV testing across the state of Georgia, while identifying barriers to HIV testing as a prevention measure, experienced during the COVID pandemic. Implications could potentially be translated to other emergency responses or general prevention program practices.

HIVST had been explored by several other states on and was considered to be a potentially high impact prevention method, when the right resources were available to ensure access, awareness, and use. Noted benefits of HIVST were that it could be done at home or in a private setting of one's choice and it allows for programs to focus on engaging with difficult to reach populations, who are often most at risk for HIV. The following four research questions were developed to evaluate HIVST implementation as a practical intervention: 1) Is there an association between health insurance status and HIV testing history; health insurance status and HIVST distribution method?, 2) What are the predictors of requesting an HIVST via mail distribution versus pickup distribution option?, 3) What are the primary reasons for requesting an HIVST between the different request distribution methods and is there an association?, and 4) What are respondents' experiences with using an HIVST?

This study analyzed secondary data from the GDPH HIVST project which included pre- and post-survey responses from individuals residing in Georgia requesting an HIVST using an online weblink that direct them to complete the survey questions. The link was made available on various social media pages, dating websites, local public health district websites and during COVID-19 community events. The pre-survey was completed initially in order to request receipt of the OraSure HIVST, and individuals had the opportunity to select to receive the HIVST via two different distribution methods, mail or pickup site location. A link to the post-survey was provided via email as follow-up 2 weeks after requesting a test through completion of the pre-survey. From November 2020 through December 2021, 1,849 eligible pre-survey responses were received and used for analysis while 395 eligible post-survey response records were

used for analysis. Quantitative analysis was conducted on the participant responses using SAS and STATA. Qualitative analysis was used to analyze responses to the open-ended questions, identifying key themes and synthesizing feedback to inform potential barriers to use of and experience with the HIVST.

Findings were presented as a whole and across participants using the two different distribution request methods. Results indicated that HIVST trends seen among demographic characteristics was similar to current testing trends in Georgia. The average age was 32 years with the largest age group represented among those reporting 20-29 years of age. Looking at differences between self-test distribution groups, the average age of those requesting HIVST via mail was older at 34 years of age and the average age of those requesting HIVST via pick up site was younger at 30 years of age. Participants were majority female, Black, had health insurance and had previously tested for HIV.

Notable differences were seen when examining health insurance across participant cohorts. A greater proportion of participants requesting HIVST via mail reported not having health insurance (52%) compared to those requesting via pickup site (34%) and the total participants (44%). The largest proportion of participants reporting having health insurance was among those requesting HIVST via pickup site (66%). Lastly, findings among those reporting a previous history of completing an HIV test, a majority (34%) reported having tested more than a year ago. The difference in this percentage was even greater when comparing the two different request distribution groups. Nearly 50% of participants requesting HIVST via mail reported having tested more than a year ago compared to only 18% of participants requesting HIVST via pick

site. The majority of pickup requesting participants reported the time of their last HIV test as either unsure/don't know (30%) or in the past 3 months (22%). This larger categorization of unsure/don't know response among the pickup site group may have been impacted by public health workers who assisted individuals with completing their survey during community outreach events centered around COVID-19 or other similar settings where time may not have permitted the opportunity to go through each response sufficiently, thus rushing through questions that may have required more time for recall or thought for reference.

Primary findings to answer the 4 research questions indicate the following: 1) There was a statistically significant association between health insurance and previous HIV testing history as well as health insurance and request distribution method. 2) Predictors of requesting an HIVST via mail found the statistically significant odds of having a HIVST requested by mail is nearly 2 times greater for those with no health insurance, 9 times greater for those testing more than a year ago, 4 times greater for those testing 4 to 6 months and 7 to 12 months, and less likely compared to the pickup request option to identify as Black and represent those aged 16 to 19 years. 3) *In-home privacy, Confidentiality* and *Observing social distancing* are the key reasons mailed HIVST are preferred. Instead of Observing social distance, *Option to use with a partner* was the most referred reason for requesting an HIVST for those using pickup site option. With *Other* selection option being the most selected across all groups, additional work is needed to assess the specific text responses from participants giving their detailed other reasons beyond the options provided. This information was not available in the secondary data set that was provided for analysis, thus limiting further analysis in

this area for the study. 4) About 50% of participants reported completing their first HIV test using the HIVST because of the option to test at home and nearly all participants reported some level of anxiety but no problem following instructions when using the HIVST. None of the participants reported a positive HIV test result and 69% of participants reported they would not recommend the HIVST to a friend or partner. This reported unwillingness to recommend to a friend or partner is presumed to be a coding issue with the likert response options and how they were captured, as the responses are not supported by the open-ended responses provided from participants about their experience. This potential issue should be explored by the IT team within the existing survey to ensure likert response options are presented to the user correctly and coded accordingly. Key themes to describe participants thoughts and experiences with the HIVST were categorized as: Ease or usefulness of instruction, Convenience and comfort from home, Not invasive, Individual control of sexual knowledge/HIV status, Availability of additional STI screenings, Inclusion of other prevention supplies, General Appreciation, Conspicuous Kit, and Suggestions for improvement.

Conclusion

HIVST is an acceptable prevention strategy to reach individuals across Georgia who have not previously tested for HIV or do not test for HIV routinely according to CDC's recommendations for annual testing. HIVST lends itself to support the HIV prevention continuum framework serving as a notable entry point to engage with those at greatest risk of exposure to HIV and be integrated with PrEP education to improve PrEP knowledge across all communities, furthering the prevention cycle. The health insurance status of individuals should continue to be monitored as public health

resources become further constrained. Just as health departments explore ways to charge insurance companies for traditional HIV tests to help offset other public health program expenses or redirect freed funds to where there is a need or a lack of insurance coverage, the potential for health insurance companies to cover the cost of HIVSTs should also be further explored. Health insurance status can influence the decision to consider use of an HIVST if there is a cost. Public health agencies can and should incorporate the cost of HIVSTs into their prevention budgets; this also includes advertising to ensure community awareness as well as the cost to include other prevention supplies such as condoms, dental dams, and lube to accommodate the kits while supporting safe sexual behaviors. Because individuals with health insurance are more likely to have a previous HIV testing history and are more likely to use the pickup site request option, this demonstrates the existence of an established connection with healthcare or traditional clinical settings, such as those associated with public health clinics. Individuals without health insurance were more likely to use the mail distribution request option, thus not presenting to a public health clinic or associated site, indicating a lack of connection to a community health care setting. This may be due to various reasons as supported by the literature such as stigma, medical mistrust, transportation challenges, and distance.

Individuals with no health insurance, who have not completed their annual HIV test, who experience stigma or are from marginalized communities – specifically among those priority populations, could benefit from the option of HIVST to encourage HIV/STI prevention behaviors and promote PrEP knowledge along with resources. Mailed requested HIVST can be a more reasonable option compared to pickup site to reach

individuals who are not testing for HIV annually, who are more likely to frequent non-traditional community settings for health care or treatment and those representing communities that are considered more difficult to reach.

As the geographic map and data show, metro-area counties/PH districts had more pickup request distributions compared to non-metro area counties. PH districts in more rural parts for Georgia are much larger spread out. This leads to more areas where there are probable gaps or healthcare deserts causing individuals in the community to have to travel long distances for health and preventative services. Local health departments should consider this potential barrier and establish partnerships with non-traditional community centers or locations that are professional and confidential to expand the availability of pickup sites where individuals can access HIVST. Individuals at these partnering locations should be educated about HIV/STI prevention, including the importance of testing along with PrEP, and/or health department staff - health educators can be available in shifts to support HIVST pickup. Scheduling of appointments for pickup was also explored by some health departments.

Nevertheless, because the current opportunity to request a mailed kit was via an online weblink, there are disproportionately affected populations that are missed due to the inability to access the internet, a computer, or smartphone. Some of these populations include those who are homeless, in communities without internet coverage in their home, sex workers, and those unskilled in using technology. In this regard, distribution of HIVSTs could be incorporated during community outreach activities conducted by community center staff or health department staff, as some did report utilizing, to reach those communities that are not accessing HIVST via the online

platform. While this outreach effort allows for interaction with public health staff and those disproportionately affected populations, it does make collection of survey data and follow up somewhat more difficult as these populations are also more likely to not have stable housing or contact information that can ensure engagement for prevention or care referrals that could accompany an HIVST result. Collection of survey data among these populations in an outreach setting would require the appropriate portable device and technology for staff, such as a tablet with Wi-Fi, as well as interview skills that will ensure a level of comfort and confidentiality that would compel these individuals to provide private responses in the setting, if assisted by a public health worker.

Follow up responses from the post-survey indicate that although anxiety when using an HIVST is high, making resources, referrals and direct contact information available via active and passive guidance is essential for an effective HIVST program, especially for those who are testing for the first time. Incorporating other STI tests along with HIVST can further promote prevention behaviors, while encouraging other STI testing and identification of cases that would otherwise go undiagnosed or have delayed diagnosis. Also, while follow up responses for the post-survey after requesting and receiving the HIVST was anticipated to be low based on the literature and similar implemented programs, finding ways to encourage reporting of positive HIVST results is important. When incentives to encourage completion of the post-survey or reporting of results through means such as gift cards are not a sustainable option, an alternative way to ensure follow-up for needed confirmatory testing should be in place.

Recommendations

This study recognizes the areas of primary public health preventions combining HIV testing with PrEP education to streamline the prevention-side of the continuum. To initiate advancement in the topics explored I suggest updating the pre-survey to determine if the appropriate essential questions are reflected to further inform the next stage broadening use of HIVST and incorporating the strategy as a standard prevention program activity. This should also include considering current length of the survey and determining if questions should be removed or added based on what is most meaningful for the program. In addition, these initial results from the project data should be share with Georgia's statewide integrated prevention and care planning group to exchange information and seek feedback on potential changes to the implementation.

A relaunch of marketing efforts and overall campaign should accompany any changes to implementation to assist with expanding awareness of HIVST project across Georgia and among community zip codes with the highest rates of new HIV diagnosis. More communities should be aware of the availability of HIVST as an ongoing activity throughout the year. State and local jurisdictions' HIV and STI programs should review their program workplans and budgets to include HIVST as a funded activity through the grant year to allow minimum resources to support the availability of either or both distribution request methods along with PrEP education and staff to assist with individual follow up. Resources to monitor and support next steps after an HIVST is received and used are critical. Requiring a clearly outlined method or plan to assist linkage to confirmatory testing should be incorporated into HIVST programs. Some components to consider for use in a developed plan should include an enhanced

process to connect a local contact for each respondent in addition to use of a back-end data system for local staff contacts to document and monitor respondents requesting an HIVST.

Next, working with local PH districts to integrate HIVST into HIV/STI prevention activities especially to reach priority or difficult to reach populations should be further investigated by state health departments. A focus group or interviews with program staff could explore methods to ensure reporting of positive test results and follow up for confirmatory testing using existing or new resources. This should not be limited to personnel or processes. Use of home tests that have to be sent to a laboratory for processing and interpretation have been recently used by some STI programs to promote home-based testing. The use of data systems must also be examined. A data match between primary pre & post survey data and secondary HIVST fulfillment data from OraSure, the company distributing mailed kits, can assist with verifying user information which can further lend to data matches with HIV Surveillance data to follow up on potential seroconversion for participants who may not self-report their HIVST result or STI surveillance data for participants with a history of other reportable STIs.

To examine the reliability of self-test reporting, further analysis will need to be explored to identify and confirm positive HIV cases following use of an HIVST. This should include analyzing public health data from Georgia's enhanced HIV/AIDS Reporting System (eHARS) to support self-reporting from respondents via post survey, which was anticipated to be underreported. The eHARS system captures state-wide data on HIV case surveillance in Georgia, reports to CDC, and represent diagnosis or other care related laboratory data of Georgia residents who are living with HIV or AIDS.

A data match with the online survey system data and eHARS would be intended to determine if any individuals who completed a self-test request were also reported within the state HIV surveillance system as 1) existing cases, or 2) seroconverted from a negative HIV status between the time the survey was completed, and self-test requested up to 6 months after the respective reporting period. Reportable viral load and CD4 lab data also served as a proxy measure to confirm entry into or engagement in HIV care. A possible source of confirmation for actual medical visits could also involve confirming client-level data within the Ryan White care services via the internal OHA DPH CareWARE data system.

Suggested future research also includes conducting a data match using pre- and post-survey data from the GDPH HIVST project and Georgia's CDC-supported statewide HIV testing data system, EvaluationWeb®. This will compare the supplemental reach of HIVST with statewide testing data reporting publicly supported HIV testing conducted throughout the state. The proposed research question is: How does the cumulative reach of HIV testing conducted in traditional clinical/non-clinical settings across Georgia differ from HIVST incorporated during the same period? My hypothesis is that: HIVST will provide insight into the geographic regions reached among HIVST requests compared to the standard, historical HIV testing. However, there are expected data limitations when implementing an intervention reliant on self-reporting and reduced data burden to consumers. Assisted HIV testing conducted in traditional clinical or non-clinical settings will likely be more complete and include testing results at a higher rate due the facilitation of public health staff who typically incorporate counseling and confirm reporting completion during the testing process.

Public Health Implications

Topics explored and findings from this study can guide the development of improved prevention initiatives that can demonstrate how local interventions inform policy around HIV testing. As the uptake of HIVST as a part of High impact HIV prevention programs becomes more widespread, this effort can impact current trends of HIV prevalence and disparities. Access to HIVST should consider marginalized communities and those disproportionately affected by STIs to ensure there are not unintended gaps in health care resources as well as prevention services resulting from social advantage and health.

HIVST is an initiative that should be incorporated in emergency response planning as a means to assist with the continuation of key HIV prevention strategies when health centers or traditional clinics that provide HIV prevention and care services maybe interrupted or become unavailable due to the need to shift public health resources. Still, regardless of HIVST being used for emergency/preparedness response or integrated into routine prevention services, findings from this study inform policy implications emphasizing the need for prevention adherence support from testing follow up to PrEP, confirmatory testing, treatment and care, where applicable, for unassisted HIVST. Unlike the positive result from a home-based COVID-19 test, a positive HIVST if left untreated can lead to further spread and potential development of molecular clusters along with late-stage diagnosis or advancement to AIDS. Therefore, identifying ways to incorporate data systems or staff personnel to assist as alternative ways to track the outcomes of positive HIVSTs is critical as the use of HIVST as a strategy among prevention programs expands.

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APPENDICES

Georgia HIV Self-Test Project Pre Survey

1. Would you like to take the survey in English or Spanish?
   Choose an item.

2. In what county do you reside?
   Choose an item.

3. What is your 5-digit zip code?
   _____

4. How did you first learn about HIV Self-Testing?
   ☐ Social Media
   ☐ Local Health Department
   ☐ GA CAPUS Resource Hub
   ☐ Friend/Referral
   ☐ Other (please specify): _____

5. What is your date of birth?
   _____

6. How would you describe your gender?
   ☐ Male ☐ Transgender Male-to-Female
   ☐ Female ☐ Transgender Female-to-Male
   ☐ Another gender (specify): _____

7. What is your ethnicity?
   Choose an item.

8. What racial group do you consider yourself to be a member of (**Check all that apply**)?
   ☐ Asian
   ☐ Black/African-American/Afro-Caribbean
   ☐ More than one race
   ☐ Native American/Alaskan Native
   ☐ Native Hawaiian/Pacific Islander
   ☐ White
   ☐ Not applicable

9. Do you have health insurance?
   Choose an item.

10. Have you ever been tested for HIV? (If no, skip to number 12)
    Choose an item.

11. When was your last HIV test?
    Choose an item.

12. Are you familiar with or have you ever taken Pre-Exposure Prophylaxis for HIV (PrEP)? **Check all that apply.**
    - ☐ I am currently using PrEP.
    - ☐ I have friends who use PrEP.
    - ☐ I have sexual partners who use PrEP.
    - ☐ If my sexual partners take PrEP, I'm at less risk of becoming infected with HIV.
    - ☐ If I take PrEP, I'm at less risk of becoming infected with HIV.
    - ☐ PrEP is not affordable/not available to me.
    - ☐ I have never heard of PrEP.
    - ☐ PrEP should be used with other HIV prevention measures.
    - ☐ None of these are true.

13. Why do you want a home HIV test kit? **Check all that apply.**
    - ☐ Distance from Testing Site
    - ☐ Transportation to Testing Site
    - ☐ No childcare
    - ☐ In-Home Privacy
    - ☐ Confidentiality
    - ☐ Nervous to take a test at a clinic
    - ☐ Use with partner
    - ☐ Observing Social Distancing
    - ☐ Other (please specify): _____

14. How would you like to receive your test kit?
    (Test Kit Identifier generated based on selection option below)
    - ☒ Mailed to me

- Redemption code/Test Kit Identifier (ID): _____ (no textbox, just notation)

- Use the redemption code that is generated to redeem your at-home self-test kit from Oraquick in partnership with GDPH using the following link *www.xxxxxx.com*. *The redemption code serves as your **unique test kit ID**. Thank you for completing the survey. Please keep this **unique test kit ID** handy and return to complete the follow up survey once you have taken your HIV self-test.*

☐ Picked up at local location

-What is the zipcode where you will pick up your test kit?
(A list of locations in the area based on zip code will be made available)
*Please contact the local pick up location before you arrive to ensure test availability and appointment (if applicable).

- (After submitted display) Auto-generated/Test Kit Identifier (ID): ____ (no textbox, just notation) This is your unique test kit ID, please keep for reference. *You must provide your **unique test kit ID** in order to receive your kit and to complete the follow up survey once you have taken your HIV self-test. Thank you for completing the survey. Please keep this unique test kit ID handy and return to complete the follow up survey once you have taken your HIV self-test.*

Georgia HIV Self-Test Project Post Survey

Thank you for returning to complete the follow up survey for the Georgia Home Self-Test Project!!

Tell us about your experience with this test.

1. Have you taken your HIV Self-Test?
   ☐ Yes
   (If Yes) Please enter your unique Test Kit Identifier Code:
   _____
   ☐ No
   ☐ I gave it to someone else.

2. I took the HIV home testing kit within_____
   ☐ 1 day to 1 week of receiving it.
   ☐ 2 weeks of receiving it.
   ☐ 1 month of receiving it.

3. If you waited longer than a week or more, or did not use the kit, what is the **MAIN** reason?
   ☐ I don't think I've been exposed to HIV.
   ☐ I was afraid to find out I was HIV positive.
   ☐ I don't trust the results to be confidential, and/or was worried my name would be reported.
   ☐ I was afraid of losing my job, insurance, housing, friends, family, if people knew I was HIV positive.
   ☐ Some other reason (specify_____)
   ☐ Don't Know/No particular reason

How much do you agree or disagree with the following statements:

4. I was able to follow the instructions easily and test myself without any problems.
   ☐ Strongly Agree
   ☐ Agree
   ☐ Neutral
   ☐ Disagree
   ☐ Strongly Disagree

5. I tested for HIV for the first time because of the option to test at home.
   - ☐ Strongly Agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree
   - ☐ Strongly Disagree

6. I had anxiety testing for HIV because I was at home.
   - ☐ Strongly Agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree
   - ☐ Strongly Disagree

7. I would recommend HIV home testing to a friend and/or sexual partner.
   - ☐ Strongly Agree
   - ☐ Agree
   - ☐ Neutral
   - ☐ Disagree
   - ☐ Strongly Disagree

Tell us about your Self-Test Outcome:

8. What was the result of your HIV Self-Test?
   - ☐ Positive
   - ☐ Negative
   - ☐ Test did not work properly

9. If your result was negative, have you accessed PrEP (HIV prevention) medication since ordering your home test?
   - ☐ Yes
   - ☐ No

10. If your result was HIV positive, did you present to a local clinic for follow-up/confirmation testing?
    - ☐ Yes
    - ☐ No

    10a. If no, why?
    - ☐ Not yet, but I plan to
    - ☐ Fear

☐ Transportation Issues
☐ Did not want to
☐ Other: _____

11. If your result was positive, were you able to make an appointment to meet with a provider to start HIV care?
☐ Yes
☐ No

11a. If no, why?
☐ Did not know the contact information to make an appointment
☐ Not yet, but I plan to
☐ Fear
☐ Did not want to
☐ Other: _____

12. In the past 12 months, have you done any of the following? **Check all that apply.**
☐ Sex with a male
☐ Sex with a female
☐ Sex with a transgender partner
☐ Sex without a condom
☐ Sex with an HIV positive partner
☐ Sex with an injection drug user
☐ Injected drugs, or shared needled or other materials for injecting drugs
☐ None of the above

13. Have you ever been told by a healthcare professional that you have any of the following conditions? **Check all that apply.**
☐ Chlamydia
☐ Gonorrhea
☐ Hepatitis B
☐ Hepatitis C
☐ HIV
☐ Syphilis
☐ None
☐ Other (please specify): _____

14. If you ordered more than one test, what did you do with the second test?
☐ I gave it to a partner or friend
☐ I am saving it to take it later, myself

☐ Other: _____

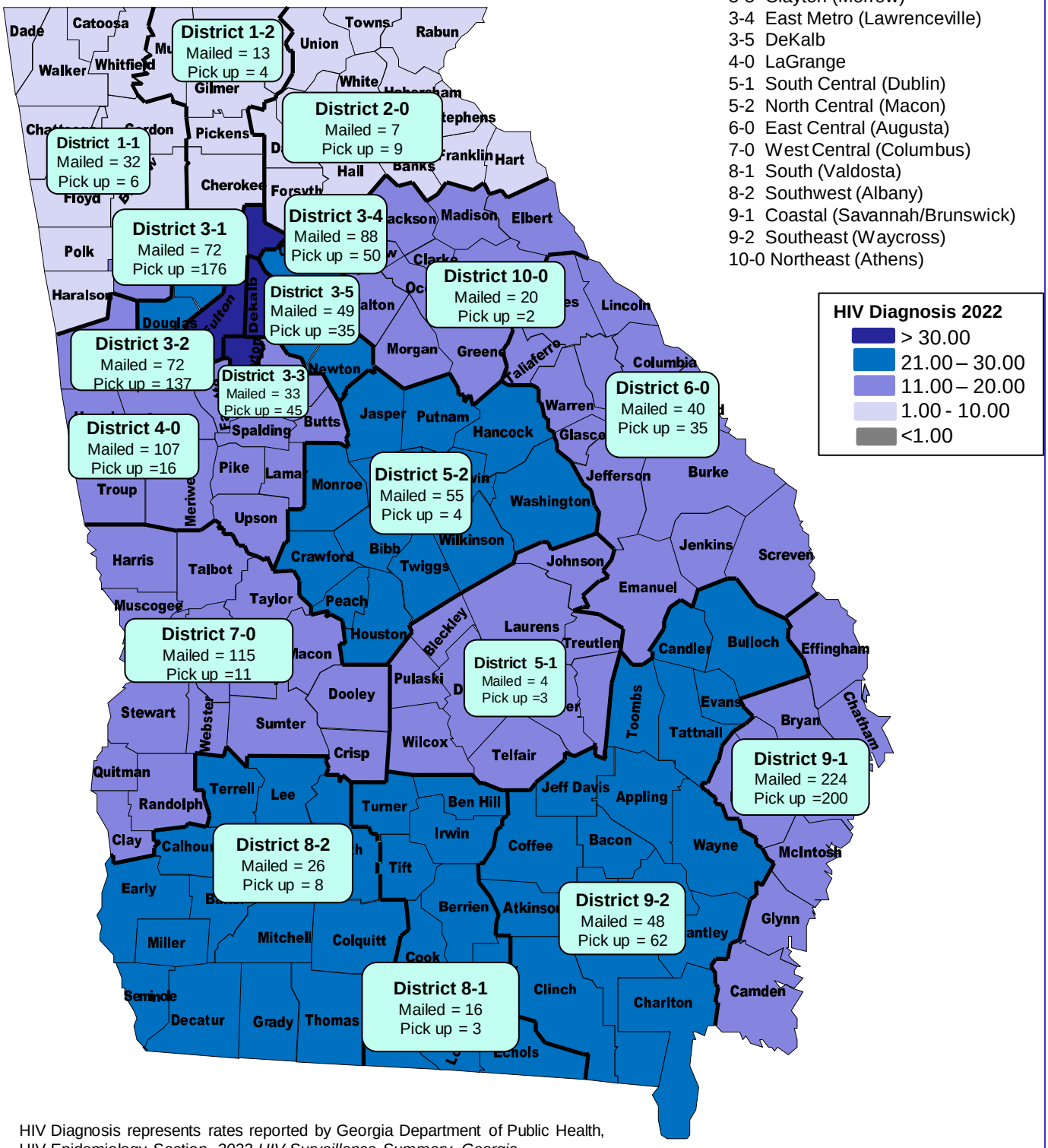
15. Is there anything else you would like to tell us about your experience with HIV Self-Testing? What did you like? What can we do to improve?

_____
_____
_____
_____
_____

HIV Self Test Kit Distribution by Public Health District, Georgia 2022

GDPH HIV Program Self Test Kit Distribution
Mailed total = 1025
Pickup total = 810
Missing district = 14
Total = 1849

1-1 Northwest (Rome)
1-2 North Georgia (Dalton)
2-0 North (Gainesville)
3-1 Cobb-Douglas
3-2 Fulton
3-3 Clayton (Morrow)
3-4 East Metro (Lawrenceville)
3-5 DeKalb
4-0 LaGrange
5-1 South Central (Dublin)
5-2 North Central (Macon)
6-0 East Central (Augusta)
7-0 West Central (Columbus)
8-1 South (Valdosta)
8-2 Southwest (Albany)
9-1 Coastal (Savannah/Brunswick)
9-2 Southeast (Waycross)
10-0 Northeast (Athens)



HIV Diagnosis represents rates reported by Georgia Department of Public Health, HIV Epidemiology Section, *2022 HIV Surveillance Summary, Georgia*, https://dph.georgia.gov/epidemiology/georgias-hivaids-epidemiology-section/hivaids-case-surveillance, *Published March 2024.*