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Quantifying The Impact Of Laboratory And Care Systems On Relinkage To Hiv Care In A Southern, Urban Environment

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QUANTIFYING THE IMPACT OF LABORATORY AND CARE SYSTEMS ON RELINKAGE TO HIV CARE IN A SOUTHERN, URBAN ENVIRONMENT

by

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DEDICATION

To Grandpa Ralph

QUANTIFYING THE IMPACT OF LABORATORY AND CARE SYSTEMS ON RELINKAGE TO HIV CARE IN A SOUTHERN, URBAN ENVIRONMENT

by

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Presented to the Faculty of The University of Texas

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in Partial Fulfillment

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QUANTIFYING THE IMPACT OF LABORATORY AND CARE SYSTEMS ON RELINKAGE TO HIV CARE IN A SOUTHERN, URBAN ENVIRONMENT

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School of Public Health, 2018

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Background: HIV viral suppression reduces the likelihood of transmission to just 5%,[1] demonstrating the critical link between care and prevention, yet only 51% of people living with HIV (PLWH) were retained in care and 46% achieved viral suppression in the Houston area (2012), with the out-of-care (OOC) population increasing between 2008-2011.[2,3]

Methods: Record-search investigations across HIV surveillance and care data systems determined if potentially OOC persons referred to the Houston Health Department (HHD) from 2013-2015 (N=1287) qualified for public health follow up. A portion were randomized to a non-intervention group (n=200) to assess the program effectiveness. Participants without a disposition (n=381) were assigned to a service linkage worker (SLW) for assistance with returning to care. Multiple logistic regression assessed (1) differences between follow-up populations (2) associations of persons relinked to care (3) statistical yield of the SLW intervention. Firth's penalized likelihood approach analyzed rare events where applicable.

Results: The majority of PLWH presumed to be OOC failed to qualify for follow up primarily due to recent evidence of care (n=552, 67.3%) or having moved out of jurisdiction (OOJ) (n=131, 16.0%). Participants referred by Disease Intervention Specialists (DIS) or Texas jurisdictional health departments (incoming OOJ) (aOR:4.057, CI: 2.270-4.250; referent: provider), the Enhanced HIV/AIDS Reporting System (eHARS) surveillance referral source (aOR:2.054, CI:1.590-2.653; referent: provider), and having had an unsuppressed viral load at last report (aOR:1.368, CI:1.058-1.769; referent: viral suppression) had greater odds of qualifying for follow up while persons diagnosed with HIV longer (aOR: 0.968, CI:0.950-0.986) had lower odds. Even after exhausting HHD resources to identify persons for SL outreach (n=381, 35.1%), most persons were still unable to locate (n=157, 41.2%) and few relinked to care (n=31, 8.1%). Of those located (n=193), the majority self-reported already being in care (n=90, 46.6%) or refused SLW services once successfully contacted (n=59, 30.6%). DIS/incoming OOJ referral source (aOR:7.242, CI:2.603-20.343; referent: provider), surveillance referral source (aOR: 2.722, CI: 1.011-7.186; referent: provider), and 7+ client phone calls (aOR: 3.879, CI: 1.359-12.770; referent: two or fewer) were significantly related with returning to care via SLW. DIS/incoming OOJ referral source (aOR=3.489, CI:1.609-7.919; referent: provider) and 7+ client phone calls (aOR=2.341, CI: 1.130-5.003; referent: two or fewer) were associated with greater odds of successful SLW contact while persons with a last reported viral load that was unsuppressed (aOR:0.587, CI: 0.355-0.967; referent: viral suppression) and incrementally higher number of client field visits had lower odds [(three or more, aOR:0.017, CI:0.005-0.048; two, aOR:0.024, CI:0.007-0.065; one, aOR:0.074, CI: 0.022-0.0195) referent: zero]. Participants were about half as likely to return to care by an SLW vs. those who returned to care on their own (aOR: 0.459, CI:0.180-1.098), although results were insignificant (*P*-value=0.089).

Conclusions: HDs contribute key information about the OOC population, but these systems fall short in timeliness and completeness when it comes to producing the data needed to successfully contact and relink PLWH, requiring extensive resource management. More information is needed about the reasons for falling OOC to better address their specific needs and the dynamics influencing the fluid nature of HIV care.

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BACKGROUND

Literature Review

Measuring patients' engagement with HIV care is critically important to understanding the epidemiology of virus transmission and can identify gaps along the HIV spectrum of care, pinpointing key areas for impactful interventions.[4,5] It has been estimated that 61.3% of all HIV transmissions in the United States result from behaviors of individuals who were once in care for their HIV infection but have left care.[1] This is the result of individuals having elevated viral loads due to not being in care. It has been shown that individuals with suppressed viral loads through antiretroviral treatment are just 5% as likely to transmit HIV as those with unsuppressed viral loads.[1] A randomized-control trial showed that PLWH who were not receiving treatment for their HIV infection, and, therefore, did not have an undetectable viral loads were 20 times more likely to infect their partners.[6] Consequently, finding and re-engaging out-of-care individuals with their providers is crucial to controlling the HIV epidemic.

Unfortunately, not being engaged in care is a widespread problem as demonstrated in a study of over 100,000 HIV-infected individuals from 13 areas in the USA that documented 52% of people who were in HIV care at one point in time did not have more than one clinic visit for HIV care in a year.[1] Federal guidelines define continuous retention in care as having 2 or more laboratory tests (e.g., CD4+ T-lymphocyte count or viral load result) at 3 or more months apart, and being in medical care is defined as having greater than 1 laboratory test within a defined year.[7] National estimates indicate that only 66% of HIV-diagnosed individuals who were initially linked to care remain in HIV care, although these estimates vary widely. [8] A meta-analysis of 28 studies showed that 41% of PLWH were no longer engaged in care, but this might be an underestimate of the true number of out-of-care individuals because these data were based on cross-sectional studies while PLWH may enter and exit the care system several times over the course of their infection.[9] In the state of Massachusetts, where healthcare access is considered near universal, and retention rates are considered the highest in the country at 95-99%, viral suppression was still lagging at 70%.[10] These estimates were also based on a standard of care to start antiretroviral therapy, or ART, when the CD4+ T-lymphocyte count was below 350 cells/μL with divided opinions on whether to start at higher levels.[11] At the time, at least one expert group recommended that all PLWH should be offered ART regardless of their CD4+ T-lymphocyte count, standards which have been recently incorporated in the most recent guidelines for the use of antiretroviral agents in adults and adolescents living with HIV by the U.S. Department of Health and Human Services.[12,13] By this new standard, the percent of PLWH needing therapy and not being virally suppressed would be substantially higher. Being out of care is not only a public health hazard but also results in poorer quality health and reduced chances of survival.[1,6,14–17]

Determining who is out of care and how to locate them are the first steps to re-engage HIV-infected persons with medical care, thereby accomplishing reduction in HIV incidence and improvement of HIV-infected persons' health. Reaching this objective is not an easy task because people who have left care are often difficult to locate because they have moved out of the area, are incarcerated, have relocated within the area, have changed providers, or have died.[1,6] In addition, there is no universal template for identifying, finding, and reaching out-of-care persons because of variation in local data sources and data analysis capabilities. For example, when multiple data sources, sampling sources, and case investigation were utilized to investigate estimates of the HIV Care Continuum in King County, WA researchers found higher estimates of HIV-positive persons linked to care, retained in care, and virally suppressed, with almost twice the national estimates of viral suppression obtained in their population.[18] Similar investigations confirm these results, emphasizing that assumptions of patients' out-of-care status are disproved by migration out of the service area, death, or incarceration.[18,19] These studies demonstrate that multiple methods and data system investigations are needed to determine care status, most of them adapted to the specialized systems at each locality but there is no universal standard.

By Texas law, all laboratory tests that measure CD4+ T-lymphocyte counts and HIV viral load results must be reported to the Department of State Health Department (DSHS), and these results are made available to local health departments.[20] Performance of these tests at every routine HIV clinical visit constitutes absolute minimum standard of care for HIV-infected patients which should be performed every 3 months.[20] Therefore, any patient who has not had these tests in over a 6-month period may not be in care. However, laboratory surveillance systems have also been found to be inefficient ways to determine who is out of care. A study that used a single, national system of laboratory results to identify potentially out-of-care individuals found that only 65% of eligible participants qualified for public health outreach, which included a phone call and/or mailed letter before scheduling a baseline interview to subsequently offer referral to a coordinated program offering comprehensive linkage to care, navigation, and partner services, indicating that single data sources inadequately inform assessments of care status.[21] Of the 282 cases selected for follow-up investigation, 107 required enhanced searches of local databases for updated contact information, but, despite these efforts, 28% could not be located, 17% were located but had moved out of the jurisdiction, 1% were ineligible, and 2% were deceased.[21] Consequently, valuable resources were spent pursuing persons with neither the need nor the eligibility for relinkage services, highlighting the necessity of more rigorous investigation of available records across multiple types of data systems to improve data integrity. These investigations can also help determine if there are any sociodemographic predictors of engagement or gaps in care. However, record searches and data extraction also require valuable time and training, so determining which data systems produce the most valuable information is needed. It is also possible that the potential of laboratory and care data systems for producing the most relevant care information differs, highlighting a gap in research knowledge.

HIV Care Continuum

Engagement with medical care is fluid, with patients filtering in and out of care throughout their lifetime. Certain factors affect persons' willingness to stay in care or return to care, and Health Departments represent a unique opportunity to engage with individuals in their jurisdiction throughout their journey over the entire HIV Care Continuum although it is necessary to consider other factors that impact this Continuum, such as migration.[22] Their access to comprehensive reporting data and unique relationships with HIV-care providers allows for the design of outreach programs that are unique to the populations needing the most assistance with navigating the medical system.

This continuum of care is a useful assessment of the HIV epidemic response developed in recent years. Also known as the treatment cascade, it serves as a visual representation of the marked stages of HIV diagnosis and care that can help identify gaps for HIV prevention and treatment among populations of interest. One of the first Houston Treatment Cascades was published in 2012 for the Houston Eligible Metropolitan Area (EMA) and measured five critical points: HIV infected, HIV diagnosed, in HIV care, retained in HIV care, and suppressed viral load.[3] With the ultimate goal of reducing the number of new infections to zero, researchers and public health officials have recognized that an HIV-infected person must first know they are infected to begin treatment, and, once in treatment, must access ART and adhere properly to their medical regimen to obtain and sustain viral suppression.

Figure 1. Houston EMA HIV Treatment Cascade

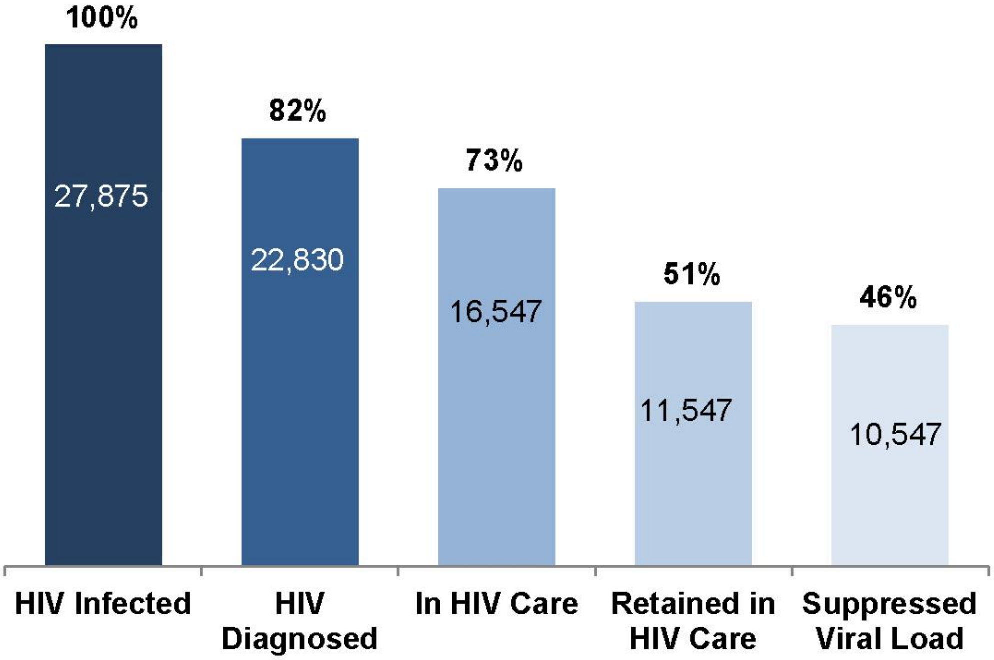


Figure 1 includes data reflecting the overall EMA, number and percent of people with HIV in selected stages of the continuum of HIV care, 2012[3]

Upon release of the first Houston Treatment Cascade, the difficulty in retaining these persons in care for uninterrupted access to ART was recognized, particularly noting that retention and viral suppression varied across subgroups. In 2012, White (52%) and Hispanic (53%) were more likely to be retained in care compared to Black/African American (48%), and Black/African American were also least likely to be virally suppressed.[3] Men who have sex with men (MSM) was the risk group that was least likely to be retained in care, and, among age groups, retention in care was lowest among youth (aged 13 to 24) and young adults (aged 25-34), each at 54%, as well as older PLWH (aged 65+) at 53%.[3]

Following national guidelines calling for a new practice known as Treatment as Prevention (TasP), the HHD launched an initiative to relink HIV-positive persons, who were once in care but had recently fallen out of care, to an HIV care provider. To optimize resources, multiple HIV surveillance and care data systems were utilized to record search potentially out-of-care persons for recent evidence of an HIV care appointment and/or a CD4+ T-lymphocyte count and/or HIV viral load laboratory result. These data systems were already in usage by various entities within the HHD but were never harnessed, particularly in conjunction with each other, for the purposes of identifying and/or confirming the current status of individuals potentially lost to care. Other outcomes can be collected to reduce expenditure of outreach resources, such as recent death, incarceration, or relocation to another jurisdiction. The usefulness of each data system for producing accurate, comprehensive, and recent evidence of care is currently unknown, but this critical knowledge is needed to determine the best practices for measuring the out-of-care population.

These data systems, and quantifying their utility, are also necessary to maximize the effectiveness of the SLW program. Once a record was searched and the person deemed likely to be out of care, any relevant locating information was extracted from the data systems and referred to an SLW who would subsequently attempt to locate the person and relink them to medical care. Once a person is in care, not only is their quality of life improved, but they are highly unlikely to transmit the virus to others because regular visits with a physician, who can prescribe and monitor ART, can reduce a patient's viral load to undetectable levels. However, the yield, that is, how many additional persons are relinked to care due to SLW interactions, of the relinkage program has not been established. The number of referrals successfully relinked to HIV care or ancillary services to support their care, in addition to the challenges of initially contacting and locating these clients based on surveillance and care data, is unknown. Research is needed to determine the effectiveness of the SLW program to establish the next steps for expanding TasP among the populations most in need of the HHD services.

Persons determined to be out of care were counseled by an SLW on the importance of returning and remaining in care and assisted in overcoming any barriers that prevented them from returning to care. Research has demonstrated that barriers to retention in care for HIV-positive persons include the following: competing life activities, feeling sick, stigma, depression and mental illness, expensive and unreliable transportation, insufficient health insurance, forgetfulness, substance abuse, negative experiences with clinic space and processes, challenges with appointment scheduling, difficult relationships with clinic staff including providers, and/or inconsistent or unstable or inadequate housing.[23,24] In one study, participants reported an average of 3 barriers to retention in care, indicating that assistance in navigating the healthcare system and overcoming hurdles to HIV care is complex.[23]

Service Linkage Program

The HHD identified potential ways, considered referral sources (Study Subjects), for identifying HIV-infected individuals who have left medical care. Furthermore, there were eight online data systems involved with collecting locating and contact information in addition to recent evidence of care so that SLWs could assist these persons with returning to care. Contacting individuals regarding their HIV infection status is a traditional role of health departments. Employees of the HHD are permitted, by Texas law, to contact any person who is potentially at risk of transmitting a sexually transmitted disease to connect those persons with treatments that will prevent further transmission of the disease. Contacting of HIV-infected persons is fully permissible by law.

The traditional role of the SL program is initial linkage to care following an HIV diagnosis, established in 2008 at the HHD. Linkage-to-care rates within one year of receipt of diagnosis are high, with most new diagnoses linked to a medical community within 12 months (>80%).[25] However, once a patient is established in a medical home, the traditional role of sustaining care has been considered the role of the provider. Upon development of the first HIV Care Continuum, the large discrepancy between initial linkage to care and remaining in care was demonstrated as a significant public health problem, both for care and prevention stakeholders. Primary data analysis indicated that people were not in care, but, once they removed themselves from a medical network, their last primary care facility had limited information and resources to find and re-engage them, and there was no public health safety net to catch these individuals.

The SL Program was originally designed to accept referrals from persons recently active in a pre-existing public health network because of a new diagnosis. Those referrals must have been tested recently, therefore they had been in contact with either a laboratory or a provider or a testing program of some sort; therefore, presumably, they were within the SLW's local jurisdiction and likely shared viable locating information and communicated other facts about their status that is vitally important to an SLW successfully managing their case. For persons lost to care, there is likely sparse, outdated information and no active data. Consequently, the purposes of this study were to create a method of identifying persons who were potentially out of care, utilize all potential data systems to confirm this out-of-care status while simultaneously collecting as much contact information as possible, then determine if the SLW's skills of initial linkage to care were transferable and adaptable to relinking persons to care.

Therefore, SLWs are individuals who can contact HIV-infected persons who are not receiving medical care, facilitate the return of these person to care, and work to keep these persons in care once they have re-engaged with the medical system. A subgroup of this population was randomized to a non-intervention arm (see Study Design), which would not receive the SLW intervention, for comparison to a subgroup of SLW-eligible individuals. Randomly assigning some individuals to receiving the services of SLWs and others to not receiving these services is ethical because the demand for the services of SLWs for relinkage to care far exceeds the available resources. With or without this random assignment, most persons who are out of care will not receive these services.

The basic process for SLW assignment after the initial surveillance investigation among online data systems involves a supervisor. The SLW supervisor would make the initial phone contact with the HIV-infected individuals and subsequently assigned these persons to an SLW. The SLW would then schedule and meet with the clients to provide non-medical case management within a 90-day period, based on the Ryan White Grant Administration's (RWGA) Standards of Care (SOC). The SOC are created by the Houston Eligible Metropolitan Area (EMA) RWGA and are based on multiple sources, including RWGA program monitoring results, consumer input, the US Public Services guidelines, Centers for Medicare and Medicaid Conditions of Participation (COP) for healthcare facilities, JCAHO accreditation standards, the Texas Administrative Code, Center for Substance Abuse and Treatment (CSAT) guidelines, and other federal, state, and local regulations.[26] The HHD receives funding from multiple source, including the RWGA, for various service linkage activities but adheres to these SOC to achieve program goals, grant deliverables, and full compliance. The supervisor can determine if additional time to relink the person to care is feasible and necessary based on the unique needs of the client. The SLWs would travel throughout the city to meet with out-of-care persons in environments fitting their comfort and assess their clients' willingness to return to care and the barriers that prevent them from seeking care. They would assist the clients in making appointments, both medical and non-medical, and help find the resources that would enable them to re-establish and remain in care. The SLW could assist with linkage to the following range of services: primary medical care, abuse history or domestic violence, adherence to treatment, dental, foster care or adoption, functional or homecare, general education, health insurance, hearing, HIV education, hospice care, housing, legal, mental health, nutritional supplements or food pantry, pain management, prescription assistance, rental or utility assistance, safer sex or family planning, substance abuse counseling, support system, transportation, vaccination, and vision.

Houston/Harris County HIV Epidemic

In the Houston/Harris County area, 22,551 people were living with HIV as of 2013; 49.6% were Black/African American and 49.2% were aged 45 years and older.[27] Most of Harris County encompasses Houston city limits but not all. The total number of PLWH increased to 26,041 before 2016, the 11th highest rate of new HIV diagnoses in the nation, with the largest risk category among MSM who account for the largest percent of new diagnoses at 90%.[27,28]

Gaps in Knowledge

SLWs are a more recent addition to the workforce and their utility has not been fully evaluated. Studies are needed to demonstrate the capacity of SLWs in relinking HIV-infected individuals to medical care. However, persons who drop out of care might return to care of their own volition, although the length of time can vary greatly. The marginal contribution of the SLWs for relinking patients to care is unknown. Furthermore, an assessment of surveillance data has not been done to determine if surveillance reporting have any measurable impact on the ability of health departments to identify and successfully relink out-of-care, HIV-positive persons to a medical provider.

Public Health Significance

The proposed study helped fill a major gap in knowledge about the potential application of HIV surveillance and care data for identifying and relinking out-of-care persons to medical services in the Houston/Harris County area. It contributed knowledge about whether surveillance and care data systems produced wide variations in data quality and helped determine the eventual outcomes of using HIV data for relinking persons to care. Additionally, it assessed the marginal contribution of SLWs.

The results of this study also determined if possible differences between populations who might be out of care and those who are confirmed as currently out of care among multiple data systems. Additionally, it explored any predictors of successful relinkage to care by the SLW Program. Surveillance investigation and the SLW intervention are resource intensive and require significant manpower. Quantifying their impact and determining if certain differences exist between the populations served by this study can help prioritize future referrals to those most in need of assistance, thereby funneling finite resources for maximum impact.

Hypothesis, Research Question, Specific Aims or Objectives

Surveillance investigation across multiple data systems was expected to reduce the number of potentially out-of-care referrals to those individuals most likely to truly be out of care and in need of relinkage services because it eliminated subjects with other outcomes. For instance, a person who is deceased would not benefit from SLW services, nor would local Houston resources be useful to someone living outside of city limits. However, only the health department has the capacity to measure these outcomes given their access to myriad record sources. By identifying the data systems' ability to correctly assign outcomes for service linkage activities, finite resources are maximized to best serve the populations most in need of relinkage. Persons qualifying for SLW intervention are expected to have greater odds of returning to care compared to those individuals in the non-intervention subgroup.

A.1. Specific Aim 1

Aim 1 will employ cross-sectional analyses to assess significant differences between participants who qualified for follow up based on surveillance investigation outcomes and those who did not. Covariates of interest are birth sex, race, ethnicity, the most recent CD4+ T-lymphocyte count test result, the most recent viral load test result, age, referral source, and the time since HIV diagnosis.

A.1.a. Research Questions for Specific Aim 1

Table 1. Research Questions for First Aim

Question	**Data Type**	**Analysis/Output**
What databases were used for record searches, and what information did each system provide?	Narrative	N/A
What were the outcomes of the databases searches (i.e., how many referrals were administratively closed and why?)	Descriptive	Number/Percent
What databases had the most recent evidence of care?	Descriptive	Number/Percent
Which care or surveillance data system produced evidence of care in the most referrals?	Descriptive	Number/Percent
After record searches, what are the demographics of the assigned referrals versus those that are administratively closed?	Descriptive/Inferential	Number/Percent; t-test, chi square
Were there any significant predictors, such as referral sources or sociodemographic characteristics (see Table 3) of being classified as potentially out of care (per database disposition)?	Inferential	Logistic Regression

A.1.b. List of Variables

Table 2. Variables for First Aim

Variable	**Data Type**
Age	Categorical
Sex	Categorical
Race	Categorical
Ethnicity	Categorical (binary)
Referral Source	Categorical
Time since HIV diagnosis	Continuous
Database name	Categorical
Time since last care date	Continuous
Most recent CD4+ T-lymphocyte count	Continuous, Categorical (binary)
Most recent Viral Load	Continuous, Categorical (binary)

A.1.c. List of Outcomes

Table 3. Outcomes for First Aim

Outcomes
Assigned (to SLW)
Evidence of Care
Incarcerated
Deceased
Out of Jurisdiction (OOJ)
Ineligible

Ineligible includes pregnancy, under the age of 18, newly diagnosed with HIV, or lacking evidence of ever having been in HIV care

A.2. Specific Aim 2

Aim 2 will employ cross-sectional analyses to investigate potential associations of successful relinkage to care through SLW assistance for those who were confirmed as out of care from surveillance investigation. Possible differences between those successfully relinked and those who were not relinked to care might identify sub-populations with additional barriers to care and in need of further investigation to improve healthcare access. Quantifying the difficulty of contacting and relinking these people to care also emphasizes the need for optimal data collection through the utilization of multiple data sources to reduce wasted resources.

A.2.a Research Questions for Specific Aim 2

Table 4. Research Questions for Second Aim

Question	**Data Type**	**Analysis/Output**
What were the outcomes of all referrals sent to SLWs	Descriptive	Number/Percent
What was the mean number of days from the first contact by SLW to the intake? From intake to relinkage?	Descriptive	Mean, Median, Mode
Which referral source was associated with the highest SLW relinkage	Descriptive	N/A
What were the top reported reasons for falling out of care for those successfully contacted by the SLW?	Descriptive	Number/Percent
What were the resources exhausted for those referred to SLWs (number of contacts)?	Descriptive	Mean, Median, Mode
Were there any significant predictors, such as demographics or referral source or worker contact, of outcomes (relinkage to care via SLW outreach)?	Inferential	Logistic Regression

B.2.b. List of Variables

Table 5. Variables for Second Aim

Variable	Data Type
Data System Results	
Age	Categorical
Sex	Categorical
Race	Categorical
Ethnicity	Categorical
Referral Source	Categorical
Time since HIV diagnosis	Continuous
Most recent CD4+ T-lymphocyte count	Continuous, Categorical
Most recent Viral Load	Continuous, Categorical
Intervention Results	
Reason for Being Out of Care	Categorical
Days (received-intake date)	Continuous
Days (intake date-medical appointment date)	Continuous
Number of Phone Calls to Provider	Continuous
Number of Field Visits to Provider	Continuous
Number of Phone Calls to Patient	Continuous
Number of Field Visits to Patient	Continuous

Phone calls to providers or to patients were unlimited units, but there was an upper limit of 8 field visits per provider and per patient.

A.2.c. List of Outcomes

Table 6. Outcomes for Second Aim

Outcomes
Relinked to care
Incarcerated
Deceased
Already in care
OOJ
Refused services
Unable to locate
Other

Ineligible includes pregnancy, under the age of 18, newly diagnosed with HIV, or lacking evidence of ever having been in HIV care

A.3. Specific Aim 3

Aim 3 is an experimental design that will determine if intervention subgroup members were more likely to return to care compared to the non-intervention subgroup members. Quantifying the ability of SLWs to successfully return participants to care can be used for programmatic planning purposes.

Potentially out-of-care persons were randomized as 200 intervention subjects and 200 non-intervention subjects from the eHARS surveillance referral mechanism, so this subpopulation can be used to assess the marginal contribution (yield) of the SLWs in assisting patients with returning to care. The non-intervention subgroup was not assigned to an SLW, regardless of whether surveillance investigation determined a person was truly out-of-care. Instead, after the initial investigation, a second record search was conducted 90 days later to determine if the person returned to care on their own (Figure 3). This time period was equivalent to when a truly out-of-care referral would have been assigned for follow up with an SLW.

A.3.a. Research Questions for Specific Aim 3

Table 7. Research Questions for Third Aim

Question	**Data Type**	**Analysis/Output**
What were the outcomes of the intervention subjects sent to the SLWs	Descriptive	Number/Percent
What were the outcomes of the non-intervention subjects who qualified for 90-day follow up?	Descriptive	Number/Percent
What was the mean number of days for the intervention subjects from the first contact by SLW to the intake? From intake to relinkage?	Descriptive	Mean, Median, Mode
What was the mean number of days from the date of second Surveillance Investigation initiation to the date the non-intervention subjects returned to care on their own among the 90-day follow up?	Descriptive	Mean, Median, Mode
What were the top reported reasons for falling out of care for intervention subjects successfully contacted by the SLW?	Descriptive	Number/Percent
What were the resources exhausted for intervention subjects referred to SLWs?	Descriptive	Mean, Median, Mode
Were there any significant predictors, such as demographics or worker contact, of outcomes (relinkage to care via SLW outreach)?	Inferential	Logistic Regression
Randomized Subgroup - After the 90 day follow up, what was the care status of intervention subjects versus non-intervention subjects?	Descriptive/Inferential	Number/Percent, significant differences to be assessed inferentially

A.3.b. List of Variables

Table 8. Variables for Third Aim

Variable	Data Type
Data System Results	
Age	Categorical
Sex	Categorical
Race	Categorical
Ethnicity	Categorical
Referral Source	Categorical
Time since HIV diagnosis	Continuous
Most recent CD4+ T-lymphocyte count	Continuous, Categorical
Most recent Viral Load	Continuous, Categorical
Intervention Results	
Reason for Refused Services	Categorical
Reason for Being out of Care	Categorical
Days (received-intake date)	Continuous
Days (intake date-medical appointment date)	Continuous
Number of Phone Calls to Provider	Continuous
Number of Field Visits to Provider	Continuous
Number of Phone Calls to Patient	Continuous
Number of Field Visits to Patient	Continuous

A.3.c. List of Outcomes

Table 9. Outcomes for Third Aim

Outcomes for Non-intervention	Outcomes for Intervention
Assigned (to SLW)	Relinked to care
Evidence of Care	Incarcerated
Incarcerated	Deceased
Deceased	Already in care
Out of Jurisdiction (OOJ)	OOJ
	Refused services
	Unable to locate
	Other

Ineligible includes pregnancy, under the age of 18, newly diagnosed with HIV, or lacking evidence of ever having been in HIV care

METHODS

Study Setting

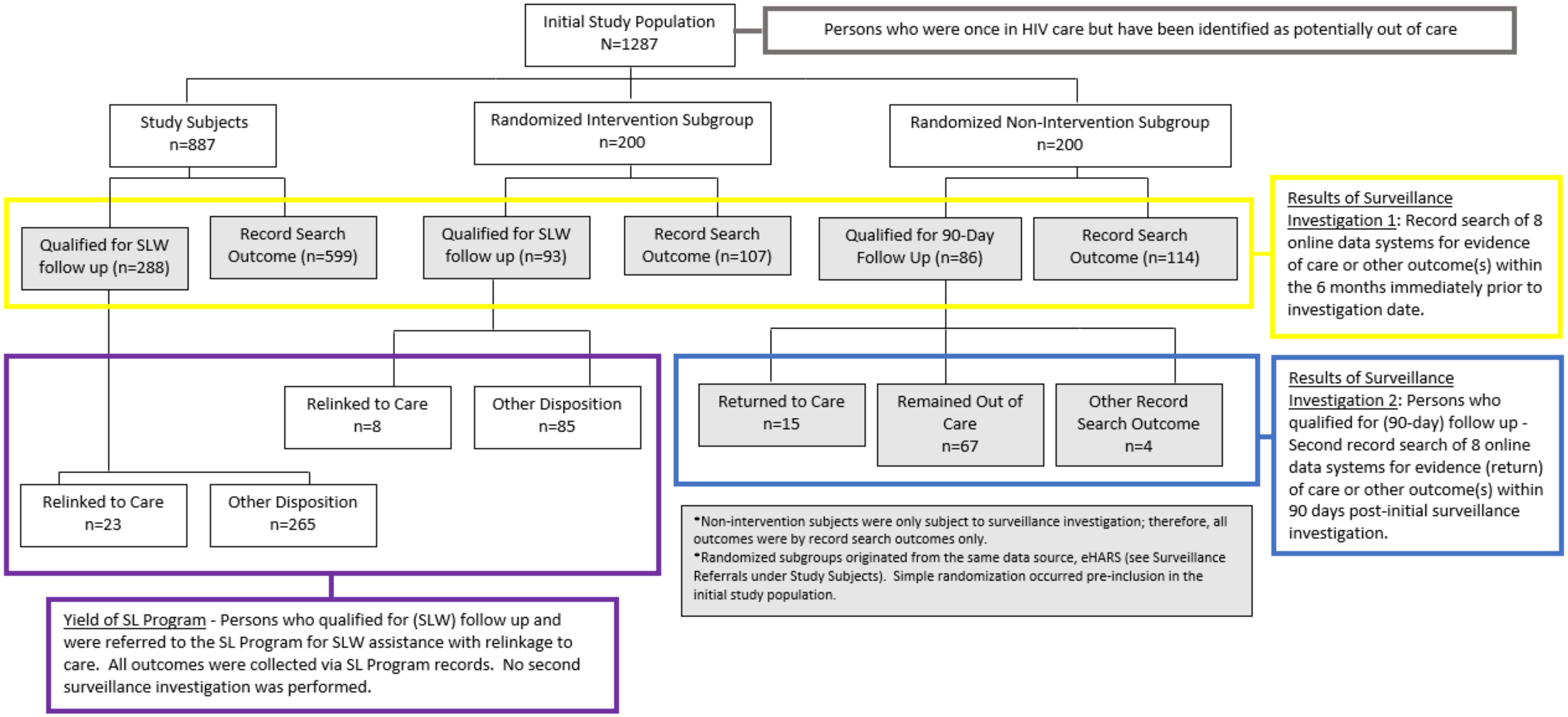
Houston is the fourth largest city in the United States and is the county seat of Harris County. The County has approximately 4.5 million residents. It is one of the most diverse areas in the United States with a population of 30.4% non-Hispanic white, 42.4% Hispanic, 19.7% African-American, and 7.2% Asian.[29] One-quarter of the population is foreign born and 43.4% of the population speaks a language other than English at home.[29] As of 2012, there were approximately 23,000 PLWH in Houston/Harris County and about 30% of those who were once in care were currently out of care.[30] An estimated 74.1% of PLWH were male, 49.8% were Black/African American, and 31.7% were aged 45-54, with the highest transmission risk among MSM (51.3%).[30]

Study Design

A cohort (N=1287) of potentially out-of-care PLWH in the Houston/Harris County area was selected from various referral sources (see Data Collection) from 20 June 2013 through 14 July 2015. Online records were reviewed among eight data systems to determine if 1087 of these referrals qualified for SLW intervention, and, subsequently, if qualified referrals were successfully relinked (i.e., attendance at an appointment with a medical provider) to HIV medical care. Using simple randomization, a subgroup of these referrals (n=400) were randomly selected from the same referral source, eHARS (see Data Collection), and randomly assigned to an intervention arm (n=200) or non-intervention arm (n=200). Analyses were restricted to living prevalent cases in City of Houston/Harris County who were 18+ years of age as allowed by governing public health policy. All CD4+ T-lymphocyte counts and viral load results with a valid month and year for specimen date were considered. Anyone with a last known address outside of Houston/Harris was also excluded.

The non-intervention subgroup did not receive the SLW intervention, but, if record searches in Data System Investigation A (see Figure 3) confirmed the non-intervention subject was likely to be truly out of care, they received an additional surveillance investigation follow up among the same data systems at 90 days after the initial record search (Data System Investigation B, see Figure 3) to determine if they returned to care on their own in comparison to intervention subjects. Three months is the usual timeframe for Ryan White service linkage, with a standard goal to close a case investigation by 90 days. Relinkage to care was modeled after RW service linkage; however, it was logistically easier to be granted an extension past 90 days for relinkage to care, which is a limitation of modeling a 90-day follow-up period for non-intervention subjects.

Figure 2. Flowchart of Study Population



Results of Surveillance Investigation 1: Record search of 8 online data systems for evidence of care or other outcome(s) within the 6 months immediately prior to investigation date.

Results of Surveillance Investigation 2: Persons who qualified for (90-day) follow up - Second record search of 8 online data systems for evidence (return) of care or other outcome(s) within 90 days post-initial surveillance investigation.

- Non-intervention subjects were only subject to surveillance investigation; therefore, all outcomes were by record search outcomes only.
- Randomized subgroups originated from the same data source, eHARS (see Surveillance Referrals under Study Subjects). Simple randomization occurred pre-inclusion in the initial study population.

Yield of SL Program - Persons who qualified for (SLW) follow up and were referred to the SL Program for SLW assistance with relinkage to care. All outcomes were collected via SL Program records. No second surveillance investigation was performed.

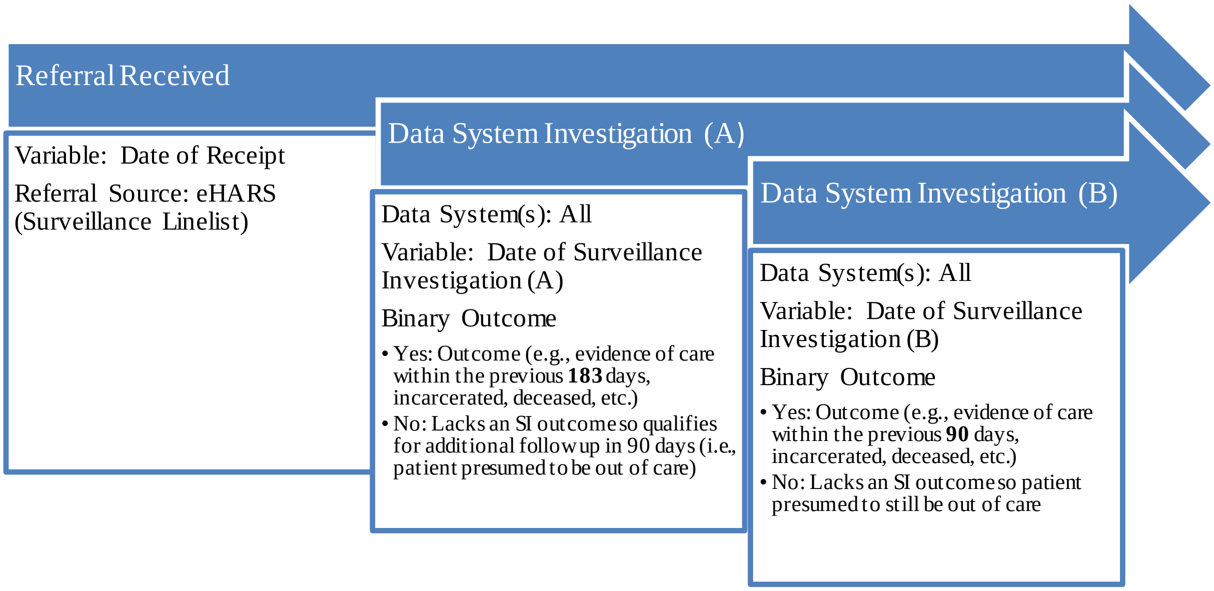
Data Description

Criteria for referral: The study unit is PLWH who were located in the Houston/Harris County area during their last evidence of care but who lacked any evidence of care within the six months (183 days) or more prior to the date of referral to the HHD for surveillance investigation.

Evidence of care from surveillance investigation (SI): Evidence of care as determined during surveillance investigations was defined as a medical appointment completed with a healthcare provider for HIV-related follow up and/or a CD4+ T-lymphocyte count and/or viral load laboratory result within the six months prior to the date of surveillance investigation among online records, not the date the referral was received by the HHD.

For the non-intervention subjects, 200 potentially out-of-care persons were investigated (Data System Investigation A) among online data systems for an outcome. If no outcomes were found, the person was presumed to still be out of care. Unlike the intervention subgroup, non-intervention subjects lacking any outcome after the initial investigation (Stage A) were not assigned to the SL Program. However, they were re-investigated (Data System Investigation B) among online data systems 90 days after the initial date of investigation (Date A). The primary measure of interest was binary: Yes (the patient had any outcome within the previous 90 days, e.g., in care, out of jurisdiction, deceased, etc.) or No (the patient lacked any outcome so was presumed to still be out of care).

Figure 3. Non-intervention Subgroup - primary timeline of investigation with 90-day follow up



Variable: Date of Receipt

Referral Source: eHARS (Surveillance Linelist)

Data System(s): All

Variable: Date of Surveillance Investigation (A)

Binary Outcome

- Yes: Outcome (e.g., evidence of care within the previous **183** days, incarcerated, deceased, etc.)
- No: Lacks an SI outcome so qualifies for additional follow up in 90 days (i.e., patient presumed to be out of care)

Data System(s): All

Variable: Date of Surveillance Investigation (B)

Binary Outcome

- Yes: Outcome (e.g., evidence of care within the previous **90** days, incarcerated, deceased, etc.)
- No: Lacks an SI outcome so patient presumed to still be out of care

Study Subjects

The study investigated four sources of referrals of potentially out-of-care PLWH and assessed whether further investigation across multiple data systems confirmed that a referral truly appeared to be out-of-care or had evidence of other outcomes.

Surveillance Referrals. Under Chapter 97 of Texas Administrative Code, all CD4+ T-lymphocyte count and HIV viral load laboratory results are subject to required reporting to the local health authority. In Houston/Harris County, the local health authority is the City of Houston Health Department. If individuals had at least one of these tests reported from 1 July 2011 through 31 June 2012 in a surveillance database, eHARS, they were considered in care during this time period, arbitrarily defined in the beginning of the study. It was assumed that having had more recent evidence of care, relative to falling out of care and qualifying for inclusion in this study, would adhere most closely to the HHD's commitment to offer services as soon as they are determined to be needed. Laboratory records for these individuals were subsequently reviewed again from 1 July – 31 December 2012. The second time period was selected because current recommendations state laboratory results should be performed every 3 - 6 months, so missing these tests within the six months after a previous appointment were proxy indicators of missing care. Over 6,000 persons were identified, a population substantially larger than available resources for subsequent investigation. Therefore, 200 intervention subgroup members were randomly selected for public health follow up to determine the utility of this source for locating out-of-care persons. These individuals were referred in one batch to surveillance investigation, and, due to limited personnel and staff time, only a few persons could be record searched per day resulting in a varied delay period.

Provider Referrals. Three HIV providers, funded by Harris County Public Health through the Ryan White Care act, transmitted lists of patients to the HHD of persons their respective systems deemed to have fallen out of care. These providers included Harris Health System, St. Hope Foundation, and Houston Area Community Services. Each of these organizations is required, as a condition of receiving funds from Houston's Ryan White Grant Administration in the local area, to identify their patients who have seemingly dropped out of care. They must attempt contact with each of these individuals three times by more than one method (e.g., phone, mail, email, text, home visit) to encourage them to return to care. The HHD created Point-of-Entry agreements with each of these organizations in order to establish guidelines for sharing of client-level data in accordance with health authorities mission to control and treat communicable disease (Chapter 81 of the Texas Health and Safety Code). These agreements made it possible for the HHD to obtain a list of potentially out-of-care individuals from each provider. In total, 806 persons were referred by these providers. These individuals were referred in batches to surveillance investigation, and due to limited personnel and staff time, only a few persons could be record searched per day resulting in a varied delay period.

Disease Intervention Specialist (DIS) Referrals. DISs are responsible for obtaining the names and contact information of the partners of persons diagnosed with sexually transmitted diseases (STD) and subsequently notifying and testing partners of possible exposure. This process, known as partner elicitation and notification, interrupts disease transmission in the community. In Houston/Harris County, DIS attempt to locate and interview all suspected cases of HIV and syphilis as part of the elicitation and notification process. Those already living with HIV who are pregnant or have a new reportable STD (chlamydia, gonorrhea, or syphilis) are also initiated for intervention. During an encounter with a newly STD-diagnosed patient or partner, a DIS might discover a previously diagnosed PLWH who reveals that he or she is no longer receiving HIV-related medical care. DIS referred 70 persons to this study. DIS referrals were submitted individually and surveillance investigation was completed within 24 hours of receipt during business hours.

Incoming Out of Jurisdiction (OOJ) Referrals. Migration is a major factor that impacts an individual's ability to establish care efficiently and effectively. State and/or local jurisdictions have routinely shared data so that health departments do not duplicate clients in surveillance records and so that they may share information to locate partners of newly diagnosed cases. More recently, some health departments have used this established communication pathway to also ensure that PLWH who have moved between jurisdictions receive assistance to navigate the local care system. 11 individuals were referred from this source. OOJ referrals were submitted individually and surveillance investigation was completed within 24 hours of receipt during business hours.

All referrals were 18 years of age or older and not pregnant. They had documented evidence of care through a medical record, provider account, confirmation from another health department, or CD4+ T-lymphocyte and/or viral load laboratory result at some previous point in time and had evidence of a positive HIV diagnosis.

These referrals served as the starting point for determining who was actually out of care. Subsequent record searches across multiple care and surveillance data systems provided additional information on current care status and locating information. If a referral had evidence of an attended medical appointment for HIV care or CD4+ T-lymphocyte or viral load laboratory results within the immediate six months prior to the investigation date, they were considered currently in care. If available records confirmed a PLWH was likely to be out of care, they were assigned to an SLW. SLWs are non-medical case managers who specialized in finding and facilitating HIV-positive clients' return to care for this study intervention.

Sample Size Calculation and/or Study Power

Subgroup of Intervention and Non-Intervention Members

Although literature is sparse given the lack of experimental designs to measure the impact of non-medical case managers on relinking HIV-positive persons to care, assuming the expected proportion of those unexposed to an SLW who return to care is 0.05, the expected proportion of those exposed to an SLW who relink to care is .15, a 95% confidence level, and a desired power of 0.80 (i.e., the percent chance of detection), the sample size per group should be 141 participants, and the total sample size should 282 participants at minimum.[31] Exposure to a non-medical case manager was defined as any initial attempt at contact by said worker, such as any phone call or mailed letter or home visit, etc. The expected proportion of those exposed to an SLW who relink to care with an outcome was estimated from literature published closest to study initiation, ranging from 15-16% as reported by relinkage to care programs similar in design amongst urban populations.[32,33] The proportion of unexposed with an outcome was unknown and informed by internal surveillance data.

This method was used with the following formula, for the required sample size:

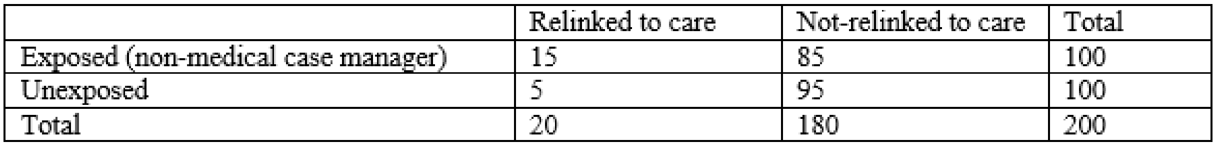
$$n' = \left[\frac{z_{\propto}\sqrt{P_0(1-P_0)} + z_{\beta}\sqrt{P_1(1-P_1)}}{P_1 - P_0}\right]^2$$

According to Fleiss, Levin, and Paik (2003), $z_{\propto}$ is the "critical value of cutting off the probability alpha in the upper tail of the standard normal distribution," (*Chapter 2, Section 5*) and z_{β} is the "critical value of cutting off the probability beta in the upper tail of the standard normal distribution" (*Chapter 2, Section 5*).[31]

$$n = \frac{\mathrm{n}'}{4}\left(1 + \sqrt{1 + \frac{2}{\mathrm{n}'|P_1 - P_0|}}\right)^2$$

Here, P_1 is the estimated proportion relinked to care in the exposed, and P_0 is the estimated proportion returned to care in the unexposed.[31]

The resulting odds ratio would be 3.4 based on the contingency table below:



	Relinked to care	Not-relinked to care	Total
Exposed (non-medical case manager)	15	85	100
Unexposed	5	95	100
Total	20	180	200

Data Collection

Eight online data systems were record searched to gather information about each referral. Two of these systems serve as repositories of laboratory results while two others store medical care records. The care and laboratory data systems provided recent evidence of care or confirmed that a referral was likely to be out of care, thus qualifying for SLW intervention. All databases were used to collect client contact information and other identifying factors so there would be substantial evidence to verify that each person found in each system was the correct identity and to determine if the referral might be ineligible for relinkage services because of other outcomes (e.g., incarcerated, deceased, out of jurisdiction, or ineligible due to pregnancy, under the age of 18, newly diagnosed with HIV, or lacking evidence of ever having been in HIV care). Persons who were 18 or pregnant were excluded for research purposes. The outcome of interest was whether surveillance investigation produced evidence that a referral was currently in care or currently out of care.

<u>eHARS</u>. Known as the Enhanced HIV/AIDS Reporting System, eHARS is a national HIV surveillance system that houses HIV testing results, patient demographics, and patient contact information. These data are imported or entered based upon reports from providers, laboratories, or other sources of HIV testing as required by Texas Administrative Code. Aside from HIV diagnostic tests, reportable since 1999, CD4+ T-lymphocyte and viral load laboratory results have been mandatory since 2010,[34] and these laboratory results can serve a proxy for the

most recent evidence of care. The primary contribution of this system was HIV diagnostic and laboratory measures of care.

Maven. This software is a customizable disease surveillance and case management system. The HHD's Maven system, Houston Electronic Disease Surveillance System (HEDSS), includes a module that serves as a repository for electronic laboratory reports of HIV. It collects and houses results from commercial, state, and local hospital laboratories. For this study's purposes, "most recent evidence of care" was defined as the most recent CD4+ T-lymphocyte, viral load result, or CD4:CD8 ratio laboratory result housed in HEDSS. It is considered a real-time source of laboratory results given automatic electronic imports of these data from linked hospital and/or healthcare systems within the local jurisdictional area. The primary contribution of this system was HIV diagnostic and laboratory measures of care.

CPCDMS. Known as the Centralized Patient Care Data Management System, CPCDMS is overseen by the Ryan White (RW) Grant Administration to store RW-funded client information and track medical appointments among their consumers, including RW eligibility documentation and care attendance at RW-funded providers. From this system, "most recent evidence of care" was defined as the most recently attended HIV medical care appointment, the primary contribution of this system.

Epic. This software houses and manages electronic health records and is the system used by the Harris Health System. It is employed as a care database and produces records of consumer visits within the Harris Health System provider network, collectively serving the Harris County area which includes most of the geographic spread of Houston. Epic captures all patient office visits, irrespective of HIV status or history, so "most recent evidence of care" was defined as only the most recently attended medical appointment described as a primary care visit for HIV, the primary contribution of this system.

STD*MIS. A free database application, or Medical Information System, supported by the Centers for Disease Control and Prevention (CDC). The Texas DSHS maintains the system for local and state usage for STD surveillance and public health investigation throughout Texas. Data is collected by the HHD to track public health follow-up activities and outcomes of partner elicitation and notification. This data system contains relevant contact information, identification of aliases and/or other names, patient histories, STD morbidity reports, and some details regarding past HIV care and HIV/STD diagnostic and laboratory results. Since a substantial amount of the care information is self-reported and the laboratory results are not comprehensive, for the purposes of this study, it was primarily used to collect contact information and client identifiers.

Accurint. This comprehensive database of over 37 billion public records provides the most recent contact and locating information to verify a person resides within the service jurisdiction limits while increasing the likelihood that an SLW will be able to find the person if the individual qualifies for relinkage services. The primary contribution of this system of client contact information. Furthermore, it supplies mortality records, potential incarceration status, and additional aliases.

JIMS. The Justice Information Management System is the Harris County Sheriff's Office's public information inquiry. It provides the most recently updated incarceration status for inmates of Harris County Jail for usage by the general public. Information is updated during working days only, so information is over 24 hours old. The primary contribution of this system was current incarceration status.

TDCJ. The Texas Department of Criminal Justice online offender search is the State of Texas' public information inquiry. It provides the most recently updated incarceration status for inmates of the TDCJ facilities for usage by the general public. Information is updated during working days only, so information is at least 24 hours old. The primary contribution of this system was current incarceration status.

All data systems contributed information regarding client contact/locating information, demographics, vital statistics, incarceration status, and eligibility except for JIMS and TDCJ which could only contribute incarceration-related details. Collected information from each data system was stored in an encrypted and password protected database using Microsoft Access 2010 software. After record searches were completed, the final outcome of each person was entered into STD*MIS. Referrals that qualified for the intervention were securely assigned to the SLW program through STD*MIS with the most recent contact and locating information available attached to the transmission. Per referral, all data systems were record searched and assigned a final outcome within a single business day so the data utilized by the SLWs was the most recent and complete.

Data Analysis

The patient population was the 1287 initial potentially out-of-care persons. Data was collected from the data systems described in section I. All analyses were performed using SAS 9.4 software. Data was stored in a secure and encrypted Microsoft Access database.

Demographic characteristics were age, birth sex, race, ethnicity, referral source, age, time since HIV diagnosis, most recent CD4+ T-lymphocyte count, most recent viral load result, client phone calls, client field visits, provider phone calls, and provider field visits. Laboratory measures were reviewed for potential meaningful categorical breakdowns. CD4+ T-lymphocyte count and viral load laboratory results are extraordinarily useful clinical and public health measures when categorized. HIV infection, according to the CDC, is classified in 3 stages, with the 3rd Stage (AIDS) indicating when a person's immune system has become severely compromised as marked by a low CD4+ T-lymphocyte count (<200 cells/µL) or opportunistic infection.[35,36] Therefore, CD4+ T-lymphocyte count was recategorized as <200 cells/µL, ≥200 cells/µL, and none reported (Table 11). Viral load laboratory results are important measures of HIV medication adherence, quality of health, and risk of transmission to others, with the ideal goal of viral suppression, as defined by the CDC as having a plasma HIV RNA of either <200 copies/mL or 400 copies/mL.[37] The CDC's endorsement of the international Prevention Access Campaign, Undetectable=Untransmissable, or U=U, emphasizes an undetectable viral load blocks HIV transmission, and it is based on the value of <200 copies/mL, so this threshold was selected.[38] Therefore, viral load laboratory results were categorized as <200 copies/mL, ≥ 200 copies/mL, and none reported (Table 11).

Age was presented as continuous and categorical for participant characteristic tables but only considered in its categorical format for statistical analyses per literature standards of known studies of similar outcomes.[32,39] The following categories for this study were chosen to reflect the HIV EMA Care Continuum except for the youngest category which, for this study, had a cutoff of 18 given exclusion criteria. These groupings reflect community measures which might prove useful for interpretation and practical application.[25]

For univariable analyses, simple logistic regression or chi-square analyses assessed initial relationships between independent variables and dependent variables with significance set at *P*-value <.25, as levels lower than this threshold might not detect variables of potential importance.[40–42] For independent categorical variables, contingency tables were also used to identify possible areas of sparse data which might cause numerical instability in the multiple logistic regression model. Categories with cell sizes fewer than 5 were absorbed in the next related category if possible and logical to the sequence of data or assessed using Fisher's exact test. Significant variables in the univariable analyses were selected for inclusion in the primary multiple logistic regression model.

Multiple logistic regression assessed significant differences between binary outcome measures. The Hosmer-Lemeshow test was used to assess goodness of fit, adequate for non-replicated data, with *P*-value >0.05 indicating no evidence of lack of fit.[43] If all independent variables were significant in the initial multiple logistic regression model and the Hosmer-Lemeshow test signaled no concern for lack of fit, then this model was considered the final model, unless multicollinearity diagnostics required adjustments. If any independent variables were not significant in the primary multiple logistic regression model, backwards elimination removed variables from the primary equation using the automatic variable selection tool in SAS 9.4 software, code "selection=backward fast slstay=0.2".[44,45] To describe this process in detail, the variable with the smallest significance, or largest *P*-value, was eliminated and the model was refitted with all statistics recalculated. The procedure was restarted, eliminating another variable, until the only remaining factors were those with a *P*-value >0.20. Given the exploratory nature of this study and small number of starting independent variables, with little known about the potential associations of these factors and no specific exposure->outcome relationship of interest except for specific aim 3, the cutoff for inclusion in the final model was set at a moderate significance of 0.20. The linear relationship between continuous independent variables and the logit was evaluated using loess plots; no transformations needed to be considered.

To test for multicollinearity, the variance inflation factor (VIF) and tolerance were examined as diagnostics measures, with VIF>2.5 and tolerance<0.1 investigated further. The condition index and regression coefficient variance-decomposition matrix were subsequently assessed for additional information about these relationships. For the condition index, a representation of the collinearity between combinations of variables, the threshold was set at 15.[46] If a condition index exceeded this threshold and was responsible for a large proportion of variance (>0.90) in two or more coefficients, collinearity was considered present.[46] Spearman correlations, for ordinal variables, and Pearson correlations, for continuous variables, provided additional insights into the specific relationships between independent variables, in addition to other underlying considerations of importance such as known literature. Problematic bivariate correlations resulted in deletion of one of the two variables. Collinearity and correlation diagnostics are discussed in the results section when potentially problematic associations were identified and required resolution.

If missing data were less than 5%, then they were assumed to be missing at random and list-wise deletion eliminated these observations from final analysis.

Primary outcomes of interest per specific aim are further described below by specific aim.

B.1. Aim 1

The patient population was the 1287 initial referrals with outcomes and covariates originating from data collection via surveillance investigation databases.

B.1.a. Statistical Analysis

For univariable analyses, simple logistic regression or chi-square analyses assessed initial relationships between independent variables and the dependent variable with significance set at *P*-value <.25. Categories with cell size counts fewer than 5 were absorbed in the next related category if possible and logical to the sequence of data or assessed using Fisher's exact test. Associations between significant relations were further examined together in multiple logistic regression.

Multiple logistic regression assessed significant differences between participants who qualified for follow up and participants who did not qualify. The primary outcome was binary: No, the client did not qualify for follow up, or Yes, the client qualified follow up (N=1287). The secondary analyses focused on the sub-group of referrals who qualified for follow up and those who did not due to recent evidence of care. The secondary outcome was binary: No, the client did not qualify for the follow up due to recent evidence of care within the previous 183 days, or Yes, the client qualified follow up (n=1019). Covariates of interest were birth sex, race, ethnicity, the most recent CD4+ T-lymphocyte count test result, the most recent viral load test result, age, referral source, and the time since HIV diagnosis.

B.2. Aim 2

The patient population was the 381 referrals assigned to SLW relinkage services after qualifying for follow up post-surveillance investigation. Data were collected via paper charts that was manually entered into the STD*MIS data system by the SLW assigned to the individual referral. Possible outcomes were that a client was relinked to care versus not linked due to other outcomes such as the client reported already being in care, refused SLW assistance, unable to locate, etc. (n=381). Secondary analyses assessed whether persons who qualified for the SL Program were located by an SLW. The outcome was binary: No, the client was not located by an SLW, or Yes, the client was located by an SLW (n=381).

B.2.a. Statistical Analysis

For univariable analyses, simple logistic regression or chi-square analyses assessed initial relationships between independent variables and the dependent variable with significance set at P-value <.25. Categories with cell size counts fewer than 5 were absorbed in the next related category if possible and logical to the sequence of data or assessed using Fisher's exact test. Associations between significant relations were further examined together in multiple logistic regression.

Primary multiple logistic regression analysis assessed the likelihood of being relinked to care for referrals who qualified for the intervention. The primary outcome was binary: Yes (the patient was relinked to care) or No (the patient was not relinked to care). Secondary multiple logistic assess the odds of being located by SLW outreach. The primary outcome was binary: Yes (the patient was located) or No (the patient was not located). Being successfully located was defined as at least one incident of verbal and/or physical contact via phone and/or field visit by an SLW with the persons of interest. Identity was confirmed by the SLW via date of birth and legal name. Other documentation might also be used.

Persons lost to care can be difficult to find due to substantial lengths of time missing from the medical system and/or sparse locating information, despite extensive surveillance investigation prior to referral. Determining if the time and resources spent by the SLWs in their attempts to contact these persons is fruitful and/or whether other characteristics might yield higher response could assess best practices moving forward.

Due to the small proportion of those successfully relinked to care, as stated previously, variables were recategorized where possible. If recategorization failed to correct for expected cell counts fewer than 5 and/or resulted in unmeaningful categories if reduced further, Fisher's exact test was substituted for chi-square analysis during univariable analyses. However, continuous variables were assessed using Firth's penalized likelihood method, proposed by King and Zeng in 2001, to reduce the bias of the small sample size.[47] According to Greenland and Mansournia in their evaluation of Firth's method versus traditional maximum likelihood estimation (MLE) in logistic regression analyses, MLE fails to minimize expected error or loss.[48] With small sample sizes, weak penalties subsequently yield questionable estimates, but Firth's penalty (see Appendix C) offers an alternative approach.[48–50] Consequently, the final logistic regression model also applied the Firth method due to the small sample size.[47]

The backwards selection tool cannot be employed in SAS 9.4 in combination with the Firth method, therefore backwards selection was performed manually using the same selection criteria of a *P*-value>0.20. The procedures were the same as described previously, with the variable with the smallest significance, or largest *P*-value, eliminated first and the model refitted with all statistics recalculated. The procedure was restarted, eliminating another variable, until the only remaining factors were those with a *P*-value >0.20. For additional guidance, the adjusted R-squared and Akaike information criterion (AIC) were reviewed upon deletion and restructuring of the model as relative measures of fit, with higher R-squared values and lower AIC values generally indicating better model selection.

The yield of the SL program was assessed in terms of cumulative resources spent (i.e., number of contacts and number of field visits to the provider and patient, respectively) attempting to relink clients to care and stratified via outcomes and/or categories of interest, depending on exploratory analyses.

B.3. Aim 3

The patient population was the 200 intervention subgroup members and 200 non-intervention subgroup members (see Study Design under METHODS). For intervention subjects who qualified and were referred to the SL Program, data was collected via paper charts that was manually entered into the STD*MIS data system by the SLW assigned to the individual case. Possible outcomes included a client was successfully relinked to care versus other outcomes such as a client reported already being in care, refused SLW assistance, unable to locate, etc. Subject information was collected via data systems for non-SLW outcomes (i.e., surveillance investigation prior to SLW referral). For non-intervention subgroup members, the information was collected solely via data systems.

B.3.a. Statistical Analysis

A comparison of the subjects randomized into the intervention group (n=200) and non-intervention group (n=200) from the same referral mechanism (i.e., surveillance list generated from eHARS data source, see Data Analysis under METHODS) was performed to assess if differences existed between the samples which could impact the results. For continuous variables, a two-sample t-test was performed to determine if mean differences existed in the non-intervention group versus the intervention group among normally-distributed variables. Non-normal variables were analyzed using the Wilcoxon rank-sum test and, where possible, also in its categorical format. A difference of proportions between these variable types were assessed using the chi-square test.

For univariable analyses, simple logistic regression or chi-square analyses assessed initial relationships between independent variables and dependent variables with significance set at *P*-value <.25. Due to the small proportion of those successfully relinked to care, variables were recategorized where possible. If recategorization failed to correct for expected cell counts fewer than 5 and/or resulted in unmeaningful categories if reduced further, Fisher's exact test was substituted for chi-square analysis during univariable analyses. Continuous variables were assessed using Firth's penalized likelihood method. Associations between significant relations were further examined together in multiple logistic regression.

Multiple logistic regression analyses compared intervention subjects and non-intervention subjects to determine the odds of returning to care. Covariates of interest are birth sex, race, ethnicity, age, referral source, and the time since HIV diagnosis. The final logistic regression model applied the Firth method due to the small sample size, with steps described in *B.2.a Statistical Analysis*.[47]

Human Subjects, Animal Subjects, or Safety Considerations

The parent study, under which all data was collected, was titled "Determining the most efficient and effective ways of identifying and returning HIV-infected persons to care: Evaluation of the Expanded Linkage to Care Initiative (ELCI),"and received approval to begin research from the Committee for the Protection of Human Subjects of the University of Texas Health Science Center at Houston on 25 September 2013. This study was processed for closure by the Committee on 1 December 2015. The proposed analyses herein were submitted for review to the Committee for Protection of Human Subjects of the University of Texas Health Science Center at Houston and was determined to qualify for exempt status.

The HHD conducts regular public health activities under Chapter 81 of the Health and Safety Code. Data are stored under a local area network system with restricted access to the network, including but not limited to authorized usernames and firewall-protection. The databases for storing the collected and analyzed data are password-protected and encrypted within these networks, managed and tracked by the HHD's information technology division, and accessible only through a pre-determined approval process which includes mandatory client safety and confidentially training.

RESULTS

A cohort (N=1287) of potentially out-of-care PLWH in the Houston/Harris County area were referred from 20 June 2013 through 14 July 2015. Most referrals were male (73.3%), black (60.0%), and non-Hispanic (77.2%), with a mean age of 42 years.

Table 10. Participant characteristics overall and by initial surveillance investigation outcome

Demographic Characteristics	**Total** **N=1287**		**Qualified for Follow Up[1]** **n=467**		**Other Outcome[2]** **n=820**	
	n	%	n	%	n	%
Age*						
18 to 24	91	7.1	39	8.4	52	6.3
25 to 34	311	24.2	131	28.1	180	22.0
35 to 44	347	27.0	131	28.1	216	26.3
45 to 54	336	26.1	107	22.9	229	27.9
55 or older	202	15.7	59	12.6	143	17.1
Sex						
Male	943	73.3	349	74.7	594	72.4
Female	344	26.7	118	25.3	226	27.6
Race						
Black	771	60.0	281	60.2	490	59.8
White	499	39.0	177	40.0	322	39.3
Other	17	1.3	9	1.9	8	1.0
Ethnicity						
Non-Hispanic	994	77.2	353	75.6	641	78.2
Hispanic	293	22.8	114	24.4	179	21.8
Referral Source						
Provider	806	62.6	236	50.5	570	69.5
DIS/OOJ	81	6.3	52	11.1	29	3.5
Surveillance	400	31.2	179	38.3	221	27.0
	Mean	[SD]	Mean	[SD]	Mean	[SD]
Age (years)	41.7	±11.9	40.1	±11.8	42.7	±11.9
Time since HIV diagnosis (years)	10.0	±6.8	8.9	±6.3	10.6	±7.0
Most recent CD4 count (cells/µL)	444.8	±360.8	462.4	±397.6	434.9	±338.4
Most recent Viral Load (copies/mL)	75713.0	±489112.0	45540.6	±150437.6	92624.9	±600019.0

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1. Referrals were assigned for follow up because they lacked any evidence of recent care and/or other outcome (e.g., incarcerated, out of jurisdiction, etc.) within the previous six months so were presumed to be currently out-of-care. For intervention subjects, follow up includes referral to the SL Program for further case investigation. For non-intervention subjects, follow up includes an additional surveillance investigation 90 days after the initial record search date.

2. Referrals were not assigned to follow-up due to an initial surveillance investigation outcome of recent evidence of care, incarceration, death, migration (OOJ), or ineligibility.

Of the total participants with a surveillance investigation outcome disqualifying them from additional follow up, 15 (1.8%) were incarcerated, 104 (12.7%) deceased, 552 (67.3%) had evidence of care, 131 (16.0%) were out of jurisdiction, and 18 (2.2%) were classified as ‘other.’ The ‘other’ category included pregnancy, being under 18 years of age, having no evidence of an HIV diagnosis, and no locating information was received upon referral nor found during surveillance investigation. For more information about exclusion criteria, please see Data Collection.

CD4+ T-lymphocyte count and viral load laboratory results were only considered for subsequent analyses in their categorical formats due to the health importance of their clinical categories.

Table 11. Subgroups – breakdown of participant characteristics into clinical categories for select independent variables

Demographic Characteristics	**Total**		**Qualified for Follow Up[1]**		**Other Outcome[2]**	
	N=1287		**n=467**		**n=820**	
	n	%	n	%	n	%
Most recent CD4 count						
≥200 cells/µL	919	71.4	348	74.5	571	69.6
<200 cells/µL	320	24.9	96	20.6	224	27.3
None reported	48	3.7	23	4.9	25	3.1
Most recent Viral Load						
≥200 copies/mL	599	46.5	231	49.5	368	44.9
<200 copies/mL	626	48.6	209	44.8	417	50.9
None reported	62	4.8	27	5.8	35	4.3

1. Referrals were assigned for follow up because they lacked any evidence of recent care and/or other outcome (e.g., incarcerated, out of jurisdiction, etc.) within the previous six months so were presumed to be currently out-of-care. For intervention subjects, follow up includes referral to the SL Program for further case investigation. For non-intervention subjects, follow up includes an additional surveillance investigation 90 days after the initial record search date.

2. Referrals were not assigned to follow-up due to an initial surveillance investigation outcome of recent evidence of care, incarceration, death, migration (OOJ), or ineligibility.

Results for Aim 1

Table 12. Significant factors associated with qualifying for follow up (N=1287) based on univariable analyses

Characteristic	χ^2	β (SE)	*P*-value
Age[c] (years)	13.8475	N/A	0.0078
Time since HIV diagnosis (years)	N/A	-0.0382 (0.0090)	<.0001
Referral Source	56.7996	N/A	<.0001
Most recent CD4 count[a]	9.2716	N/A	0.0097
Most recent Viral Load[b]	5.0355	N/A	0.0806

[a] *Most recent CD4 count is the most recent CD4+ T-lymphocyte count in cells/μL categorized as >200 cells/μL, <200 cells/μL, or no evidence found of ever having had a CD4+ T-lymphocyte count reported.*

[b] *Most recent Viral Load is the most recent viral load laboratory result in copies/mL categorized as >200 copies/mL, <200 copies/mL, or no evidence found of ever having had a viral load reported.*

[c] *Age was analyzed in its categorical format only, 18-24, 25-34, 35-44, 45-54, 55+*

Collinearity diagnostics produced values of VIF<2.5 and tolerance values greater than 0.1. Furthermore, the largest condition index value was 7.61806 with the highest, non-intercept proportion of variance equaling 0.60590 for age followed by time since HIV diagnosis at 0.59932 before dropping substantially to 0.05564 for referral source. Indications were not strong for collinearity, but given these results, the relationship between age and time since HIV diagnosis was examined further among correlation matrices, which supported a significant relationship between age and time since HIV diagnosis (*P*-value <.0001).

Since HIV infection is a lifelong diagnosis, a correlation between age and time since HIV diagnosis is logical, and these variables might be useful proxy measures for each other given one ages with the disease. However, a person could be older and newly diagnosed with HIV, ergo not everyone of older age is necessarily a long-term survivor. Given an interaction term would contribute no useful clinical interpretation and one method of dealing with correlated independent variables is deletion of one of the two variables,[51] only time since HIV diagnosis was retained in the multiple logistic regression models where both were significant since it is a useful measure of longevity with the infection. However, age was still considered during univariable relationship assessments and reflected in the narrative where significant for model transparency as it might be considered for future analyses or of interest to researchers conducting similar studies.

Other significant variables identified in the simple analyses and retained in the multiple logistic regression model were referral source, most recent CD4+ T-lymphocyte count, and most recent viral load laboratory result. All other independent variables were insignificant (*P*-value>.25).

Table 13. Regression analyses of factors associated with qualifying for follow up (N=1287)

Characteristic	**Multiple Logistic Regression**		
	Odds Ratio	**95% CI**	***P*-value**
Time since HIV diagnosis (years)	0.968	0.950,0.986	0.0007
Referral Source			
Provider	referent	referent	referent
DIS/OOJ	4.057	2.270,7.250	<.0001
Surveillance	2.054	1.590,2.653	<.0001
Most recent CD4 count			
≥200 cells/µL	referent	referent	referent
<200 cells/µL	0.752	0.555,1.020	0.0667
None reported	0.875	0.321,2.386	0.7944
Most recent Viral Load			
<200 copies/mL	referent	referent	referent
≥200 copies/mL	1.368	1.058,1.769	0.0168
None reported	0.874	0.357,2.142	0.7689

There were 15 observations deleted due to missing values for the response or explanatory variables. Post-investigation revealed these missing observations were from the explanatory variable time since HIV diagnosis.

Results from multiple logistic regression indicate that time since HIV diagnosis (β=-0.6505, SE=0.1370, *P*-value=0.0007), referral source (DIS/OOJ: β=1.4004, SE=0.2962, *P*-value=<0.0001; Surveillance: β=0.7197, SE=0.1307, *P*-value=<0.0001), and having an unsuppressed (>200 copies/mL) viral load (β=0.3133, SE=0.1311, *P*-value=0.0168) last reported were associated with qualifying for follow up. DIS/OOJ and provider referrals had greater odds of qualifying for follow up compared to provider referrals, as did persons with an unsuppressed viral load as last reported at the time of surveillance investigation when compared to those with suppressed viral loads. However, persons diagnosed with HIV longer had lower odds of qualifying for follow up. All other results were insignificant (*P*-value>0.05).

Incoming referrals were presumed to be out of care, yet each referral source presents its own limitations for being able to determine the accurate and current care status of their respective clientele. An assessment was performed to determine if certain characteristics, particularly referral source, were associated with having recent evidence of care (i.e., not qualifying for follow up) despite being presumptively identified as having fallen out of care.

Table 14. Participant characteristics of referrals sent for follow up or closed because of evidence of care

Demographic Characteristics	**Total** N=1019		**Qualified for Follow Up**[1] n=467		**Evidence of Care**[2] n=552	
	n	%	n	%	n	%
Age (years)						
18 to 24	77	7.6	39	8.4	38	6.9
25 to 34	259	25.4	131	28.1	128	23.2
35 to 44	273	26.8	131	28.1	142	25.7
45 to 54	261	25.6	107	22.9	154	27.9
55 or older	149	14.6	59	12.6	90	16.3
Sex						
Male	752	73.8	349	74.7	403	73.0
Female	267	26.2	118	25.3	149	27.0
Race						
Black	601	59.0	281	60.2	320	58.0
White	401	39.4	177	37.9	224	40.6
Other	17	1.7	9	1.9	8	1.5
Ethnicity						
Non-Hispanic	776	76.2	353	75.6	423	76.6
Hispanic	243	23.9	114	24.4	129	23.4
Referral Source						
Provider	586	57.5	236	50.5	350	63.4
DIS/OOJ	71	35.5	52	11.1	19	33.2
Surveillance	362	7.0	179	38.3	183	3.4
	Mean	[SD]	Mean	[SD]	Mean	[SD]
Age (years)	41.2	±11.7	40.1	±11.8	42.1	±11.7
Time since HIV diagnosis (years)	9.6	±6.7	8.9	±6.3	10.3	±6.9
Most recent CD4 count (cells/µL)	473.0	±362.8	462.4	±397.6	481.6	±332.1
Most recent Viral Load (copies/mL)	53838.7	±397145.8	45540.6	±150437.6	60525.9	±516461.1

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1. Referrals were assigned for follow up because they lacked any evidence of recent care and/or other outcome (e.g., incarcerated, out of jurisdiction, etc.) within the previous six months so were presumed to be currently out-of-care. For intervention subjects, follow up includes referral to the SL Program for further case investigation. For non-intervention subjects, follow up includes an additional surveillance investigation 90 days after the initial record search date.

2. Referrals had evidence of care within the previous six months of initial surveillance investigation if there was a medical record appointment and/or CD4+ T-lymphocyte count and/or viral load laboratory result within this timeframe and were not sent for follow up.

Low cell counts for the category of no reported CD4+ T-lymphocyte count resulted in recategorization of this group to the referent. This action might bias results towards the null. However, this decision also reflects the scenario where it might be assumed if this person lacks evidence of laboratory tests, a proxy for steady care and monitoring adherence to ART treatment, then, as best represented by accessible records, they might be at risk of lower CD4+ T-lymphocyte counts.

Table 15. Subgroups – breakdown of participant characteristics into clinical categories for select independent variables

Demographic Characteristics	**Total** **N=1019**		**Qualified for Follow Up**[1] **n=467**		**Evidence of Care**[2] **n=552**	
	n	%	n	%	n	%
Most recent CD4 count[a]						
≥200 cells/µL	812	79.7	371	79.4	441	79.9
<200 cells/µL	207	20.3	96	20.6	111	20.1
Most recent Viral Load[b]						
≥200 copies/mL	451	44.3	231	49.5	220	39.9
<200 copies/mL	535	52.5	209	44.8	326	59.1
None reported	33	3.2	27	5.9	6	1.1

1. Referrals were assigned for follow up because they lacked any evidence of recent care and/or other outcome (e.g., incarcerated, out of jurisdiction, etc.) within the previous six months so were presumed to be currently out-of-care. For intervention subjects, follow up includes referral to the SL Program for further case investigation. For non-intervention subjects, follow up includes an additional surveillance investigation 90 days after the initial record search date.

2. Referrals had evidence of care within the previous six months of initial surveillance investigation if there was a medical record appointment and/or CD4+ T-lymphocyte count and/or viral load laboratory result within this timeframe and were not sent for follow up.

[a] *Most recent CD4 Count is CD4+ T-lymphocyte count in cells/µL dichotomized as ≥200 cells/µL or <200 cells/µL; no evidence found of ever having had a CD4+ T-lymphocyte count reported was recategorized to the referent group of ≥200 cells/µL due to cell counts less than 5.*

Table 16. Significant factors associated with having recent evidence of care as the reason for not qualifying for referral to the SL Program (N=1019) based on univariable analyses

Characteristic	**χ^2**	**β (SE)**	***P*-value**
Time since HIV diagnosis (years)	N/A	0.0318 (0.00964)	0.0010
Referral Source	30.6829	N/A	<.0001
Most recent Viral Load[a]	32.3537	N/A	<.0001

[a] *Most recent Viral Load is the most recent viral load laboratory result categorized as ≥ 200 copies/mL or <200 copies/mL or no evidence of ever having had a viral load laboratory result.*

Age was significant in univariable analyses (continuous: β=0.0142, SE=0.00541, *P*-value=0.0088; categorical: χ^2=8.3722, *P*-value=0.0789) but dropped in the multiple logistic regression model due to the significance and retention of time since HIV diagnosis (see correlation diagnostics post Table 12). Other significant variables identified in the simple analyses included referral source and most recent viral load laboratory result; these variables were retained in the multiple logistic regression model. All other factors were insignificant (*P*-value>0.25).

Table 17. Factors associated with having recent evidence of care as the reason for not qualifying for referral to the SL Program (N=1019) based on multiple logistic regression

Characteristic	**Multiple Logistic Regression**		
	Odds Ratio	**95% CI**	***P*-value**
Time since HIV diagnosis (years)	1.029	1.009,1.049	0.0048
Referral Source			
Provider	referent	Referent	referent
DIS/OOJ	0.376	0.203,0.696	0.0019
Surveillance	0.624	0.476,0.819	0.0007
Most recent Viral Load[b]			
<200 copies/mL	referent	Referent	referent
$\geq$200 copies/mL	0.640	0.494,0.831	0.0008
No report	0.158	0.044,0.572	0.0049

There were 10 observations deleted due to missing values for the response or explanatory variables. Post-investigation revealed these missing observations were from the explanatory variable time since HIV diagnosis.

Results suggest surveillance referral source (DIS/OOJ: β=-0.9787, SE=0.3145, *P*-value=0.0019; Surveillance: β=-0.4715, SE=0.1385, *P*-value=0.0007), having an unsuppressed viral load at last report (β=-0.4456, SE=0.1328, *P*-value=0.0008) or no viral load reported (β=-1.8455, SE=0.6562, *P*-value=0.0049**)**, and time since HIV diagnosis (β=0.3709, SE=0.1440, *P*-value=0.0100) are significantly associated with having recent evidence of care (i.e., not being currently out of care and needing follow-up services). Persons originating from the DIS or OOJ list had 0.4 odds of having recent evidence of care and persons originating from the surveillance list 0.6 odds of having recent evidence of care compared to persons referred to the program by providers. Furthermore, persons with unsuppressed viral loads or no reported viral loads had less odds of recent evidence of care and were more likely to be confirmed as presumably out of care and sent for follow up. Persons longer diagnosed with HIV infection had greater odds of having recent evidence of care.

Since verification of a referrals' current care status is difficult and time consuming, more information is needed about the specific value of each laboratory and/or care data systems for producing this vital information, especially since the most diverse and comprehensive access to these records is housed by Health Departments. HEDSS/Maven and eHARS contributed CD4+ T-lymphocyte count and viral load laboratory results while CPCDMS and Epic provided HIV-care appointment dates. Evidence of care within the previous six months was found for 465 (84.2%) referrals in eHARS, 83 (15.0%) referrals in HEDSS/Maven, 100 (18.1%) referrals in Epic, and 172 (31.1%) referrals in CPCDMS. The average number of days between the most recent date for evidence of care and date of surveillance investigation was 142.4 (±134.8) for eHARS, 70.3 (±51.5) for Maven, 59.7 (±46.2) for Epic, and 76.8 (±55.6) for CPCDMS.

Evidence of care could be found in multiple data systems within the same timeframe, with either matching or varied dates. For instance, a person could attend a medical appointment twice in the same timeframe as captured by Epic and CPCDMS and/or had laboratory tests ordered for either of those appointments as reported to eHARS. Evidence of care was found exclusively in a single data system for 348 (63.0%) referrals, among two data systems for 150 (27.2%) referrals, among three data systems for 44 (8.0%) referrals, and among four data systems for 10 (1.8%) of referrals. For eHARS, evidence of care was found exclusively in this database for 283 referrals, exclusively in Maven for 9, exclusively in Epic for 16, and exclusively in CPCDMS for 40.

Results for Aim 2

A total of 467 subjects qualified for follow up after initial surveillance investigation given their lack of recent evidence of care. They could have originated from any of the original data sources for potentially out-of-care persons, e.g., surveillance, provider, and DIS/OOJ (see Study Subjects). However, a portion of the surveillance subjects were randomized as a non-intervention subgroup; therefore, while they could qualify for 90-day follow up, they could not be referred to the SL Program. Consequently, of the 467 referrals qualifying for follow up, only 381 (81.6%) were sent to the SL Program for SLW assistance with returning to care. Subsequent analyses focus on assessing the yield of the SL Program.

Table 18. Participant characteristics of SL Program referrals and by SLW outcome

Demographic Characteristics	**Total**		**Relinked to Care[1]**		**Other Outcome[2]**	
	N=381		**n=31**		**n=350**	
	n	%	n	%	n	%
Age (years)						
18-34	147	38.6	12	38.7	135	38.6
35-44	100	26.3	8	25.8	92	26.3
45 or older	134	35.2	11	35.5	123	35.1
Sex						
Male	282	74.0	25	80.7	257	73.4
Female	99	26.0	6	19.4	93	26.6
Race						
Black/Other	248	65.1	25	80.7	223	63.7
White	133	34.9	6	19.4	127	36.3
Ethnicity						
Non-Hispanic	292	76.6	25	80.7	267	76.3
Hispanic	89	23.4	6	19.4	83	23.7
Referral Source						
Provider	236	61.9	10	32.3	226	64.6
DIS/OOJ	52	13.7	13	41.9	39	11.1
Surveillance	93	24.4	8	25.8	85	24.3
Client Phone Calls						
Two or fewer	94	24.7	5	16.1	89	25.4
Three to six	150	39.4	8	25.8	142	40.6
Seven or more	137	36.0	18	58.1	119	34.0
Client Field Visits						
Zero	102	26.8	5	16.1	97	27.7
One	86	22.6	8	25.8	78	22.3
Two	108	28.4	9	29.0	99	28.3
Three or more	85	22.3	9	29.0	76	21.7
Provider Phone Calls						
Zero	342	89.8	5	16.1	337	96.3
One	15	3.94	10	32.3	5	1.4
Two or more	24	6.30	16	51.6	8	2.3
Provider Field Visits						
Zero	344	90.3	--	--	--	--
One or more	37	9.7	--	--	--	--
	Mean	[SD]	Mean	[SD]	Mean	[SD]
Age (years)	39.6	±11.9	39.3	±13.1	39.6	±11.8
Time since HIV diagnosis (years)	8.7	±6.4	8.2	±4.7	8.8	±6.5
Most recent CD4 count (cells/µL)	453.0	±414.8	410.8	±322.5	456.1	±421.1
Most recent Viral Load (copies/mL)	46980.1	±156607.5	134940.8	±348622.6	40028.8	±128626.3

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1. SLW clients were relinked to care if they attended a medical appointment.

2. Other outcomes include incarcerated, deceased, (self-reported) already in care, out of jurisdiction, refused (SL Program services), and other.

--. Cells suppressed due to cell counts less than 5 and no meaningful recategorizations possible.

Client sent to the SL Program were, on average, aged 40 years old, had been diagnosed with HIV for about 9 years, and were majority male, black/other race, and non-Hispanic. The original category of 'other race' was recategorized to 'black' due to too few counts, and this classification was chosen to represent persons of color.

Table 19. Subgroups – breakdown of participant characteristics into clinical categories for select independent variables

Demographic Characteristics	**Total**		**Relinked to Care**[1]		**Other Outcome**[2]	
	N=381		**n=31**		**n=350**	
	n	%	n	%	n	%
Most recent CD4 count						
≥200 cells/µL	276	72.4	15	48.4	261	74.6
<200 cells/µL	83	21.8	10	32.3	73	20.9
None reported	22	5.8	6	19.4	16	4.6
Most recent Viral Load						
≥200 copies/mL	195	51.2	15	48.4	180	51.4
<200 copies/mL	160	42.0	11	35.5	149	42.6
None reported	26	6.8	5	16.1	21	6.0

1. SLW clients were relinked to care if they attended a medical appointment.

2. Other outcomes include incarcerated, deceased, (self-reported) already in care, out of jurisdiction, refused (SL Program services), and other.

Of the 381 persons referred to the SL Program, 31 (8.1%) were relinked to care, 193 (50.7%) were located but had another disposition, and 157 (41.2%) were unable to locate. Of the 193 located with an 'other' disposition, these dispositions were: 11 (5.7%) deceased, 9 (4.7%) incarcerated, 59 (30.6%) located and refused SLW services, 90 (46.6%) located and already in care, 18 (9.3%) out of jurisdiction, and 6 (3.1%) other (e.g. client claims stolen identity, false positive/HIV-negative, mental or physically incapacitated due to other health conditions).

Locating clients who have been out of care is a laborious task. Every available phone number sent to the SLW was supposed to be called a minimum of two times, and, if the client could not be reached via phone, a field visit should have been made at least one time to each of the addresses provided during surveillance investigation, and a certified letter was left at the residence if no one was available to speak to the SLW regarding the client of interest. The two most recent addresses for the client were collected during the initial record searches if there were at least two addresses linked to the referral. Occasionally, although rare, a client might not have any phone numbers available, and a SLW might only be able to make field visits in their attempts to find the client during outreach.

For those referrals sent to an SLW, per client, the SLWs made zero phone calls 7 times, one phone call 50 times, two phone calls 37 times, three to four phone calls 87 times, five to six phone calls 63 times, seven to eight phone calls 48 times, and nine or more phone calls 89 times. For the same set of referrals, per client, the SLWs made zero field visits 102 times, one field visit 86 times, two field visits 108 times, three field visits 52 times, four field visits 21 times, and five more field visits 12 times.

Provider phone calls and visits could occur at multiple points of SLW outreach to the client. Examples include confirming a self-reported outcome of "already in care" where, if a specific provider was named, an SLW would attempt to follow up with that provider to confirm the care status. During patient chart construction to determine eligibility for Ryan White services, laboratory results are needed (e.g., to confirm diagnosis), and an SLW might need to contact a provider to obtain this information on behalf of a client to alleviate the client's burden of having to obtain more paperwork themselves. Furthermore, an SLW will assist the client by attending the first medical appointment with them during relinkage to care to ensure remaining paperwork is completed as easily as possible, help communicate the process between the network and the client, and provide any other resources as necessary. For those referrals sent to an SLW, per client, the SLWs made zero phone calls 336 times, one phone call 15 times, two to four phone calls 19 times, and five or more phone calls 5 times to the provider(s). For the same set of referrals, per client, the SLWs made zero field visits 344 times, one field visit 9 times, two field visits 13 times, three field visits 6 times, and four or more field visits 9 times to the provider(s).

Table 20. Self-reported reasons for falling out of care for those successfully contacted by SLWs

Self-Reported Reasons for Being Out of Care	**Total**
Unknown – no show at scheduled intake/medical appointments	31
Unknown – refused to disclose to SLW	24
Feels good/was healthy at last doctor appointment	9
Claims to already be in care but no provider reported	7
Unfriendly care setting	6
Does not want/need HHD services	4
SLW lost contact*	3
Does not believe HIV test results	3
Reportedly has private/other insurance, no supplemental services needed	2
Lives out of the United States and is provided care out of the United States	2
Only ancillary services requested	2
Relinked to care on their own without SLW assistance	2
Lack of support (e.g., economic, medical, social, mental, etc.)	2
Cost of HIV Care	1
Other life issues more important	1
Believes they do not qualify for assistance/services	1
Moved out of the jurisdiction and established care	1
Other life issues more important	1
Wait times (to schedule an appointment)	1
Financial Difficulties	1
Work Schedule	1
Does not want to take medication	1
Does not want to register every year for (Ryan White) eligibility	1
Wants holistic medicine/alternative treatments	1

Note1. Results are not mutually exclusive.

**. Includes but is not limited to working/established phone number disconnected, client moved and provided no viable forwarding address, client stopped returning phone calls and/or responding to additional follow up attempts, etc.*

Of the 224 clients with some sort of successful contact and/or relinkage to care, an attempt was made to determine their reasons for falling out of care. Clients could report multiple reasons, totaling 3 per person, therefore Table 20 does not represent mutually exclusive results. Most persons were out of care for unknown reasons and were subsequently lost to relinkage attempts when they failed to attend their intake or medical appointment. The primary reason reported to SLWs for being out of care is that the client feels good and/or reported they were in good health at their last care appointment. The second reason was the clients reported being already in care although they failed to report evidence of a current provider and/or recent appointment followed by a third reason of they did not believe they needed HHD services. The remaining reasons for having fallen out of care are diverse and seemingly unique to the situation of the individual.

Table 21. Significant factors associated with being successfully relinked to care by an SLW (N=381) from univariable analyses

Characteristic	χ^2	***P*-value**
Race	3.5926	0.0580
Referral Source	24.6117	<.0001
Most recent CD4 count	15.1729	0.0005
Most recent Viral Load	4.6736	0.0966
Client Phone Calls	7.1614	0.0279
Provider Phone Calls	N/A	<.0001[a]
Provider Field Visits	N/A	<.0001[a]

[a]. *Fisher's exact test.*

Two independent variables, provider phone calls, dichotomized as 0 vs 1 or more, and provider field visits, dichotomized as 0 vs 1 or more, were significantly associated with the relinkage outcome variable during univariable analyses using Fisher's exact test (*P*-value<.0001) but were dropped from the final multivariable model due to numerical instability. Observed and/or expected cell counts for some cells were at or close to 0 despite recategorizing to the lowest possible level, creating large variations between groups in a small sample size. Variables of significance (*P*-value<0.25) in simple analyses and retained in the multiple logistic regression model include race, referral source, most recent CD4 count, most recent viral load laboratory result, and client phone calls. All other variables were insignificant (*P*-value>0.25).

Table 22. Factors associated with being successfully relinked to care by an SLW (N=381) from multiple logistic regression

Characteristic	**Multiple Logistic Regression** **Odds Ratio**	 **95% CI**	 ***P*-value**
Race			
White	referent	referent	referent
Black/Other	1.974	0.822,5.381	0.1436
Referral Source			
Provider	referent	referent	referent
DIS/OOJ	7.242	2.603,20.343	0.0001
Surveillance	2.722	1.011,7.186	0.0396
Most recent CD4 count			
≥200 cells/µL	referent	referent	referent
<200 cells/µL	2.347	0.965,5.512	0.0508
None reported	2.768	0.726,10.234	0.1324
Client Phone Calls			
Two or fewer	referent	referent	referent
Three to six	1.571	0.487,5.586	0.4541
Seven or more	3.879	1.359,12.770	0.0143

There were no observations deleted due to missing values for the response or explanatory variables.

Most recent viral load result was eliminated from the final model upon backwards selection. DIS/OOJ referral source was associated with successful relinkage to care (β=1.9799, SE=0.5175, *P*-value=0.0001) as was surveillance referral source (β=1.0015, SE=0.4865, *P*-value=0.0396). A last reported CD4+ T-lymphocyte count of less than 200 cells/µL was borderline significant (β=0.98530, SE=0.4366, *P*-value=0.0508), while a total of seven or more phone calls to the client by the SLW (β=1.3556, SE=0.5536, *P*-value=0.0143) was significantly related to returning to care. It is interesting to note that a high number of phone calls (≥7 times) per client was significantly related with relinkage to care, but the middle range of three to six was not. An SLW is required to attempt each phone number available per client a minimum of two times until they reach the client and/or the phone number is disconnected, then they stop.

For example, if a client has 4 numbers, an SLW would make a minimum of 8 attempts to reach that person if none of the outreaches are successful. Clients called seven or more times had more than 3 times the odds of successful relinkage to care. Persons from the DIS/OOJ referral source had an almost 8 times greater odds of being relinked to care than those from the provider source, while persons from the surveillance list had almost 3 times greater odds compared to those from the provider source.

There was an average of 69.7 (±95.5) days from the date of receipt by the SL Program to the intake date with an SLW. There was an average of 24.0 (±18.1) days from the intake with an SLW to the first medical appointment.

An exploratory analysis was conducted to determine if there were any significant associations with being located by an SLW if persons qualified for the SL Program. Persons lost to care are difficult to find due to sometimes substantial lengths of time missing from the medical system and/or sparse locating information, despite extensive surveillance investigation prior to referral. Determining if the time and resources spent by the SLWs in their attempts to contact these persons is fruitful and/or whether other characteristics might yield higher response could assess best practices moving forward.

Being successfully located was defined as at least one incident of verbal and/or physical contact via phone and/or field visit by an SLW with the persons of interest. Identity is confirmed by the SLW via date of birth and legal name. Other documentation might also be used.

Table 23. Participant characteristics of SL Program referrals and by SLW outreach attempt outcome

Demographic Characteristics	**Total N=381**		**Located by SLW[1] n=224**		**Unable to Locate[2] n=157**	
	n	%	n	%	n	%
Age (years)						
18 to 24	37	9.7	20	8.9	17	10.8
25 to 34	110	28.9	63	28.1	47	29.9
35 to 44	100	26.3	48	21.4	52	33.1
45 to 54	88	23.1	58	25.9	30	19.1
55 or older	46	12.1	35	15.6	11	7.0
Sex						
Male	282	74.0	169	75.5	113	72.0
Female	99	26.0	55	24.6	44	28.0
Race						
Black/Other	248	65.1	149	66.5	99	63.1
White	133	34.9	75	33.5	58	36.9
Ethnicity						
Non-Hispanic	292	76.6	175	78.1	117	74.5
Hispanic	89	23.4	49	21.9	40	25.5
Referral Source						
Provider	236	62.0	127	56.7	109	69.4
DIS/OOJ	52	13.7	40	17.9	12	7.6
Surveillance	93	24.4	57	25.5	36	22.9
Client Phone Calls						
Two or fewer	94	24.7	64	28.6	30	19.1
Three to six	150	39.4	87	38.8	63	40.1
Seven or more	137	36.0	73	32.6	64	40.8
Client Field Visits						
Zero	102	26.8	--	--	--	--
One	86	22.6	--	--	--	--
Two	108	28.4	43	19.2	65	41.4
Three or more	85	22.3	29	13.0	56	35.7
Provider Phone Calls						
Zero	342	89.8	--	--	--	--
One or more	39	10.2	--	--	--	--
Provider Field Visits						
Zero	344	90.3	--	--	--	--
One or more	37	9.7	--	--	--	--
	Mean	[SD]	Mean	[SD]	Mean	[SD]
Age (years)	39.6	11.9	9.3	6.7	37.9	10.8
Time since HIV diagnosis (years)	8.7	6.4	40.8	12.5	8.0	5.8
Most recent CD4 count (cells/µL)	453.0	414.8	440.9	291.8	468.8	536.0
Most recent Viral Load (copies/mL)	46980.1	156608.0	42394.3	147117.6	53104.6	168754.7

1. Successfully located was defined as at least one incident of verbal and/or physical contact via phone and/or field visit by an SLW with the persons of interest.

2. Unable to locate includes client could not be contacted via phone and/or field visit (e.g., no response).

--. Cells suppressed due to cell counts less than 5 and no meaningful recategorizations possible.

Table 24. Subgroups – breakdown of participant characteristics into clinical categories for select independent variables

Demographic Characteristics	**Total**		**Located by SLW**[1]		**Other Outcome**[2]	
	N=381		**n=224**		**n=157**	
	n	%	n	%	n	%
Most recent CD4 count[a]						
≥200 cells/µL	298	78.2	175	78.1	123	78.3
<200 cells/µL	83	21.8	49	21.9	34	21.7
Most recent Viral Load[b]						
≥200 copies/mL	195	51.2	100	44.6	95	60.5
<200 copies/mL	186	48.8	124	55.4	62	39.5

1. Successfully located was defined as at least one incident of verbal and/or physical contact via phone and/or field visit by an SLW with the persons of interest.

2. Unable to located includes client could not be contacted via phone and/or field visit (e.g., no response).

[a] *Most recent CD4 Count is CD4+ T-lymphocyte count in cells/µL dichotomized as ≥200 cells/µL or <200 cells/µL.*

[b] *Most recent Viral Load is the most recent viral load laboratory result dichotomized as ≥ 200 copies/mL or <200 copies/mL.*

Table 25. Significant factors associated with being located by an SLW (N=381) from univariable analyses

Characteristic	χ^2	β **(SE)**	***P*-value**
Referral Source	9.7099	N/A	0.0078
Client Phone Calls	5.1048	N/A	0.0779
Client Field Visits	96.5158	N/A	<.0001
Provider Phone Calls	N/A	N/A	<.0001[a]
Provider Field Visits	N/A	N/A	<.0001[a]
Most recent Viral Load Result[b]	9.3003	N/A	0.0023
Time since HIV Diagnosis (years)	N/A	0.0338	0.0474

[a] *. Fisher's exact test.*

[b] *Most recent Viral Load is the most recent viral load laboratory result dichotomized as ≥ 200 copies/mL or <200 copies/mL; no evidence of ever having had a viral load laboratory result was recategorized to the referent group of ≥200 copies/mL due to small cell sizes.*

Two independent variables, provider phone calls, dichotomized as 0 vs 1 or more, and provider field visits, dichotomized as 0 vs 1 or more, were significantly associated with the relinkage outcome variable during univariable analyses using Fisher's exact test (*P*-value<.0001) but were dropped from the final multivariable model due to numerical instability. Observed and/or expected cell counts for some cells were at or close to 0 despite recategorizing to the lowest possible level, creating large variations between groups in a small sample size and numerical instability. Age was significant in univariable analyses (continuous: β=0.0216, SE=0.00901, *P*-value=0.0165; categorical: χ^2=12.7742, *P*-value=0.0124) but dropped in the multivariable model due to the significance and retention of time since HIV diagnosis.

Table 26. Factors associated with being located by an SLW (N=381) based on multiple logistic regression.

Characteristic	**Multiple Logistic Regression**		
	Odds Ratio	**95% CI**	***P*-value**
Time since HIV Diagnosis (years)	1.029	0.988,1.074	0.1707
Referral Source			
Provider	referent	referent	referent
DIS/OOJ	3.489	1.609,7.919	0.0023
Surveillance	1.356	0.753,2.449	0.3140
Most recent Viral Load			
<200 copies/mL	referent	referent	referent
≥200 copies/mL	0.587	0.355,0.967	0.0386
Client Phone Calls			
Two or fewer	referent	referent	referent
Three to six	1.634	0.808,3.381	0.1794
Seven or more	2.341	1.130,5.003	0.0255
Client Field Visits			
Zero	referent	referent	referent
One	0.074	0.022,0.195	<.0001
Two	0.024	0.007,0.065	<.0001
Three or more	0.017	0.005,0.048	<.0001

There were 10 observations deleted due to missing values for the response or explanatory variables. Post-investigation revealed these missing observations were from the explanatory variable time since HIV diagnosis.

DIS/OOJ referral source was significantly associated with locating the client (β=1.2497, SE=0.4098, *P*-value=0.0023), as was having a recent viral load laboratory result last reported as ≥200 copies/mL (β=-0.5320, SE=0.2572, *P*-value=0.0386), calling the client seven or more times (β=0.8506, SE=0.3809, *P*-value=0.0255), and making incrementally higher number of field visits to the client's addresses (one: β=-2.6091, SE=0.5399, *P*-value=<.0001; two: β=-3.7123, SE=0.5417, *P*-value=<.0001; three or more: β=-4.0468, SE=0.5645, *P*-value=<.0001). DIS/OOJ referrals had 3.5 greater odds of being located by an SLW than provider referrals, and clients contacted seven or more times via phone by an SLW had 2.3 greater odds of being located than those contacted two or fewer times. In comparison, persons with a last reported viral load that was unsuppressed or any number of field visits from an SLW had lower odds of being successfully reached by an SLW.

Results for Aim 3

A subgroup of the population was randomized as intervention (n=200) and non-intervention subjects (n=200) from the surveillance data source (see Study Subjects). Intervention participants were referred to the SL Program if record searches determined they did not have recent evidence of care nor any other disposition. Non-intervention participants were assigned for surveillance investigation follow up 90 days later if the first record search determined they did not have recent evidence of care nor any other disposition. Priority population information was only reported for these subjects given its original data source, the surveillance list (i.e., eHARS), contains an existing field with this information. However, this field is sparsely populated (unrecorded: n=332) with preset indicators chosen by the National HIV/AIDS Strategy and adapted by the CDC.[52,53] This information was excluded from tables and analyses given the lack of data, but overall information is provided here to better represent the population.

Of the total randomized population (n=400), 5 (1.3%) were transgender persons, all identifying as male-to-female (birth sex male), 9 (2.3%) were young (i.e., 13-24 years old, as preset by the data system, although all participants in this study were aged 18+) and black, 54 (13.5%) were injection drug users (IDU), and 332 (83.0%) were unrecorded. For the IDU group, among non-intervention subjects, 13 qualified for follow up and 14 did not qualify for follow up; among intervention subjects, 14 qualified for follow up and 13 did not qualify for follow up. For the same priority population, IDU, of those who qualified for follow up among non-intervention subjects, 3 returned to care and 10 remained out of care; of those who qualified for follow up among intervention subjects, 0 were relinked to care and 14 remained out of care. All other priority populations reported were too few counts. Unrecorded was not included.

The randomized subgroup was aged 44 years on average with 11 years as the mean time since HIV diagnosis and majority male, black, and non-Hispanic. Greater than half of all randomized subjects had CD4+ T-lymphocyte counts ≥200 cells/µL and viral load results <200 copies/mL at last report.

Table 27. Participant characteristics of randomized intervention and non-intervention subjects overall and by initial surveillance investigation outcome (N=400)

Demographic Characteristics	**Total**				**Qualified for Follow Up**[1]				**Other Outcome**[2]			
	Intervention Group		Non-Intervention Group		Intervention Group		Non-Intervention Group		Intervention Group		Non-Intervention Group	
	N=200		N=200		n=93		n=86		n=107		n=114	
	n	%	n	%	n	%	n	%	n	%	n	%
Age (years)												
18 to 34	47	23.5	42	21.0	17	18.3	23	26.7	30	28.0	19	16.7
35 to 44	58	29.0	63	31.5	31	33.3	31	36.1	27	25.2	32	28.1
45 to 54	60	30.0	55	27.5	30	32.3	19	22.1	30	28.0	36	31.6
55 or older	35	17.5	40	20.0	15	16.1	13	15.1	20	18.7	27	23.7
Sex												
Male	156	78.0	151	75.5	73	78.5	67	77.9	83	77.6	84	73.7
Female	44	22.0	49	24.5	20	21.5	19	22.1	24	22.4	30	26.3
Race												
Black/Other	113	56.5	97	48.5	58	62.4	42	48.8	55	51.4	55	48.3
Race												
White	87	43.5	103	51.5	35	37.6	44	51.2	52	48.6	59	51.8
Ethnicity												
Non-Hispanic	159	79.5	145	72.50	74	79.6	61	70.9	85	79.4	84	73.7
Hispanic	41	20.5	55	27.50	19	20.4	25	29.1	22	20.6	30	26.3
	Mean	[SD]	Mean	[SD]	Mean	[SD]	Mean	[SD]	Mean	[SD]	Mean	[SD]
Age (years)	43.9	±11.2	44.2	±11.0	43.8	10.2	42.3	±10.9	43.9	12.0	45.6	±10.9
Time since HIV diagnosis (years)	10.5	±6.3	11.1	±6.5	9.8	6.3	9.5	±6.1	11.1	6.3	12.3	±6.5
Most recent CD4 count (cells/µL)	473.9	±324.6	467.1	±277.6	448.2	257.8	502.1	±313.7	496.3	372.9	441.0	±245.6
Most recent Viral Load (copies/mL)	75918.8	±411051.6	32641.4	±113130.9	74203.1	253722.8	39528.4	±121949.9	77394.0	510235.8	27460.9	±106277.6

1. Intervention and non-intervention subjects were assigned for follow up because they lacked any evidence of recent care and/or other outcome so were presumed to be currently out-of-care. For intervention subjects, follow up entailed assignment to the SL Program for SLW assistance with returning to care. For the non-intervention subjects, follow up entailed an additional surveillance investigation (i.e., record search) 90 days after the initial record search date.

2. 'Other Outcomes' for intervention and non-intervention subjects were identical and include: incarcerated, deceased, evidence of care, out of jurisdiction, and ineligible. 'Other Outcomes' originated from the first surveillance investigation.

Table 28. Subgroups – breakdown of randomized intervention and non-intervention participant characteristics into clinical categories for select independent variables (N=400)

Demographic Characteristics	**Total**				**Qualified for Follow Up[1]**				**Other Outcome[2]**			
	Intervention Subgroup		Non-Intervention Subgroup		Intervention Subgroup		Non-Intervention Subgroup		Intervention Subgroup		Non-Intervention Subgroup	
	N=200		N=200		n=93		n=86		n=107		n=114	
	n	%	n	%	n	%	n	%	n	%	n	%
Most recent CD4 count[a]												
≥200 cells/µL	156	78.0	168	84.0	73	78.5	73	84.9	83	77.6	95	83.3
<200 cells/µL	44	22.0	32	16.0	20	21.5	13	15.1	24	22.4	19	16.7
Most recent Viral Load[b]												
≥200 copies/mL	80	40.0	74	37.0	37	39.8	35	40.7	64	59.8	39	34.2
<200 copies/mL	120	60.0	126	63.0	56	60.2	51	59.3	43	40.2	75	65.8

1. Intervention and non-intervention subjects were assigned for follow up because they lacked any evidence of recent care and/or other outcome so were presumed to be currently out-of-care. For intervention subjects, follow up entailed assignment to the SL Program for SLW assistance with returning to care. For the non-intervention subjects, follow up entailed an additional surveillance investigation (i.e., record search) 90 days after the initial record search date.

2. 'Other Outcomes' for intervention and non-intervention subjects were identical and include: incarcerated, deceased, evidence of care, out of jurisdiction, and ineligible. 'Other Outcomes' originated from the first surveillance investigation.

[a] *Most recent CD4 Count is CD4+ T-lymphocyte count in cells/µL dichotomized as ≥200 cells/µL or <200 cells/µL; no evidence found of ever having had a CD4+ T-lymphocyte count reported was recategorized to the referent group of ≥200 cells/µL due to cell counts less than 5.*

[b] *Most recent Viral Load is the most recent viral load laboratory result dichotomized as ≥ 200 copies/mL or <200 copies/mL; no evidence of ever having had a viral load laboratory result was recategorized to the referent group of ≥200 copies/mL due to small cell sizes.*

Of the 200 non-intervention subjects, 114 (57.0%) received an initial record search disposition. Of these, primary surveillance investigation found 2 (1.75%) persons were incarcerated, 1 (0.88%) was deceased, 92 (80.7%) had recent evidence of care, and 19 (16.7%) were out of jurisdiction. A remaining 86 (43%) qualified for 90-day follow up without SLW intervention. The second surveillance investigation after the 90-day follow up period found that 15 (17.4%) had evidence of care, i.e., had returned to care, while 4 (4.7%) were out of jurisdiction and 67 (77.9%) had no evidence of care or any other outcome and were presumed to still be out of care within the Houston/Harris County area. Within the 90-day follow-up period, the mean number of days for the non-intervention subjects to return to care was 45.9 (±31.7).

Of the 200 intervention subjects, initial surveillance investigation produced 107 (53.5%) dispositions. Of these, 2 (1.9%) were deceased, 14 (13.1%) were out of jurisdiction, and 91 (85.1%) had recent evidence of care. Ninety-three (46.5%) individuals qualified for follow up and were referred to the SL Program. Of these, 8 (8.6%) were relinked to care; remaining dispositions were 1 (1.1%) deceased, 2 (2.2%) incarcerated, 34 (36.6%) already in care, 2 (2.3%) located out of jurisdiction, 35 (37.6%) were unable to locate, and 11 (11.8%) were located but refused SLW services. The mean number of days for intervention subjects to be relinked to care from the intake date with an SLW was 12.0 (±11.0).

A comparison of the subjects randomized into the intervention group (n=200) and non-intervention group (n=200) from the same referral source (e.g., surveillance list) indicated no differences existed between the samples (*P*-value>0.05).

Table 29. Participant characteristics of randomized intervention and non-intervention subjects assigned for follow up and by follow-up outcome (N=179)

Demographic Characteristics	**Total**				**Returned to Care[1]**				**Other Outcome[2]**			
	Intervention Subgroup		Non-Intervention Subgroup		Intervention Subgroup		Non-Intervention Subgroup		Intervention Subgroup		Non-Intervention Subgroup	
	N=93		N=86		n=8		n=15		n=85		n=71	
	n	%	n	%	n	%	n	%	n	%	n	%
Age (years)												
<45	48	51.6	35	40.7	--	--	9	60.0	--	--	45	63.4
≥45	45	48.4	51	59.3	--	--	6	40.0	--	--	26	36.6
Sex												
Male	73	78.5	67	77.9	--	--	--	--	--	--	--	--
Female	20	21.5	19	22.1	--	--	--	--	--	--	--	--
Race												
Black/Other	58	62.4	42	48.8	--	--	5	33.3	--	--	37	52.1
White	35	37.6	44	51.2	--	--	10	66.7	--	--	34	47.9
Ethnicity												
Non-Hispanic	74	79.6	61	70.9	--	--	9	40.0	--	--	52	26.8
Hispanic	19	20.4	25	29.1	--	--	6	60.0	--	--	19	73.2
	Mean	[SD]	Mean	[SD]	Mean	[SD]	Mean	[SD]	Mean	[SD]	Mean	[SD]
Age (years)	43.8	10.2	42.5	±10.9	36.1	6.4	42.7	±11.7	44.5	10.2	42.5	±10.8
Time since HIV diagnosis (years)	9.8	6.3	9.5	±6.1	7.5	3.4	9.5	±4.9	10.0	6.5	9.5	±6.4
Most recent CD4 count (cells/µL)	448.2	257.8	502.1	±313.7	450.8	410.1	472.9	±299.6	448.0	242.5	508.4	±318.4
Most recent Viral Load (copies/mL)	74203.1	253722.8	39528.4	±121949.9	264147.3	549703.2	51325.3	±104360.1	56113.2	203191.9	37000.5	±125929.5

1. Intervention subjects returned to care if they were successfully relinked to medical care through SLW assistance. Non-intervention subjects returned to care if record searches during the second surveillance investigation yielded a medical appointment and/or CD4+ T-lymphocyte count and/or viral load laboratory result during the 90-day follow up period.

2. 'Other Outcomes' for intervention subjects include: incarcerated, deceased, already in care, out of jurisdiction, refused services, unable to locate, and other. 'Other Outcomes' for non-intervention subjects include: evidence of care, incarcerated, deceased, and out of jurisdiction.

**. Time in years, with smallest categorize absorbed into the next closet group.*

--. Cells suppressed due to cell counts less than 5 and no meaningful recategorizations possible.

Table 30. Subgroups – breakdown of randomized intervention and non-intervention participant characteristics into clinical categories for select independent variables (N=179)

Demographic Characteristics	**Total**				**Returned to Care**[1]				**Other Outcome**[2]			
	Intervention Subgroup		Non-Intervention Subgroup		Intervention Subgroup		Non-Intervention		Intervention Subgroup		Non-Intervention Subgroup	
	N=93		N=86		n=8		n=15		n=85		n=71	
	n	%	n	%	n	%	n	%	n	%	n	%
Most recent CD4 count[a]												
≥200 cells/µL	69	81.2	73	84.9	--	--	--	--	--	--	--	--
<200 cells/µL	16	18.8	13	15.1	--	--	--	--	--	--	--	--
Most recent Viral Load[b]												
≥200 copies/mL	37	39.8	35	40.7	--	--	5	33.3	--	--	30	42.3
<200 copies/mL	56	60.2	51	59.3	--	--	10	66.7	--	--	41	57.8

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1. Intervention subjects returned to care if they were successfully relinked to medical care through SLW assistance. Non-intervention subjects returned to care if record searches during the second surveillance investigation yielded a medical appointment and/or CD4+ T-lymphocyte count and/or viral load laboratory result during the 90-day follow up period.

2. 'Other Outcomes' for intervention subjects include: incarcerated, deceased, already in care, out of jurisdiction, refused services, unable to locate, and other. 'Other Outcomes' for non-intervention subjects include: evidence of care, incarcerated, deceased, and out of jurisdiction.

[a] *Most recent CD4 Count is CD4+ T-lymphocyte count in cells/µL dichotomized as ≥200 cells/µL or <200 cells/µL; no evidence found of ever having had a CD4+ T-lymphocyte count reported was recategorized to the referent group of ≥200 cells/µL due to cell counts less than 5.*

[b] *Most recent Viral Load is the most recent viral load laboratory result dichotomized as ≥ 200 copies/mL or <200 copies/mL; no evidence of ever having had a viral load laboratory result was recategorized to the referent group of ≥200 copies/mL due to small cell sizes.*

To assess whether the SL Program impacts relinkage to care, analyses were performed to determine if, among those persons qualifying for follow up (n=179) for the randomized group, subjects were successfully relinked to care based on intervention group status.

Table 31. Significant factors associated with returning to care (N=179) from univariable analyses

Characteristic	χ^2	**β (SE)**	***P*-value**
Ethnicity	1.4815	N/A	0.2235
Age (years)	1.7044	N/A	0.1917
Intervention Status	3.1179	N/A	0.0774

**. Age is categorical; 44 years or less vs 45 years or greater*

Unlike previous analyses, the variable Age was significantly associated (*P*-value>0.25) in univariable analyses and time since HIV diagnoses was not. Given these results, Age was included in the final multiple logistic regression model since the correlation between Age and time since HIV diagnosis was negated.

Table 32. Factors associated with returning to care (N=179) based on full multiple logistic regression model.

Characteristic		**Multiple Logistic Regression**	
	Odds Ratio	**95% CI**	***P*-value**
Age (years)			
44 or fewer	referent	referent	referent
45 or greater	0.636	0.238,1.575	0.3408
Ethnicity			
Non-Hispanic	referent	referent	referent
Hispanic	1.560	0.590,3.888	0.3511
Intervention Status			
Non-SLW	referent	referent	referent
SLW	0.504	0.197,1.218	0.1350

Results in the full multiple logistic regression model are provided in Table 32 prior to backwards elimination. Based on a significance level of *P*-value<0.05, none of the variables were significant predictors of the outcome prior to subsequent model fit evaluation. Ethnicity was subsequently eliminated, with remaining significance values indicating further adjustment was still needed (*P*-value>0.20), so Age was omitted. Therefore, the final model was $\log(p/(1-p))=\beta0 + \beta1$*Intervention Status. Although the Hosmer-Lemeshow test failed to reject the null hypothesis for the full model, so there was no evidence for lack of fit, and a comparison of AIC and R-square values suggests the full model (Table 32) is the best fit, there was minimal variation between the AIC and R-square values across the full model, model with the elimination of Ethnicity, and model with the elimination of Age (e.g., less than a 0.012 difference for R-square values between the highest and lowest; less than a 3.0 difference for AIC values between the highest and lowest).

Given these results and to further inform the primary relationship of interest, backwards elimination was still performed, leading to the eventual final model. The Hosmer-Lemeshow test failed to produce a significant value as there was only one binary categorical predictor in this model.

Table 33. Factors associated with returning to care (N=179) based on reduced multiple logistic regression model.

Characteristic	**Multiple Logistic Regression**		
	Odds Ratio	**95% CI**	***P*-value**
Intervention Status			
Non-SLW	referent	referent	referent
SLW	0.459	0.180,1.098	0.0890

Intervention Status was insignificant (β=-0.3898, SE=0.2292, *P*-value=.0890). Persons randomized to an SLW were about half as likely to be relinked to care compared to those who returned to care on their own without the intervention, although results were above the cutoff for significance at *P*-value>0.05.

Figure 4. Description of probability of returning to care based on intervention status (SLW vs. non-SLW) for persons randomized and qualifying for follow up (N=179)

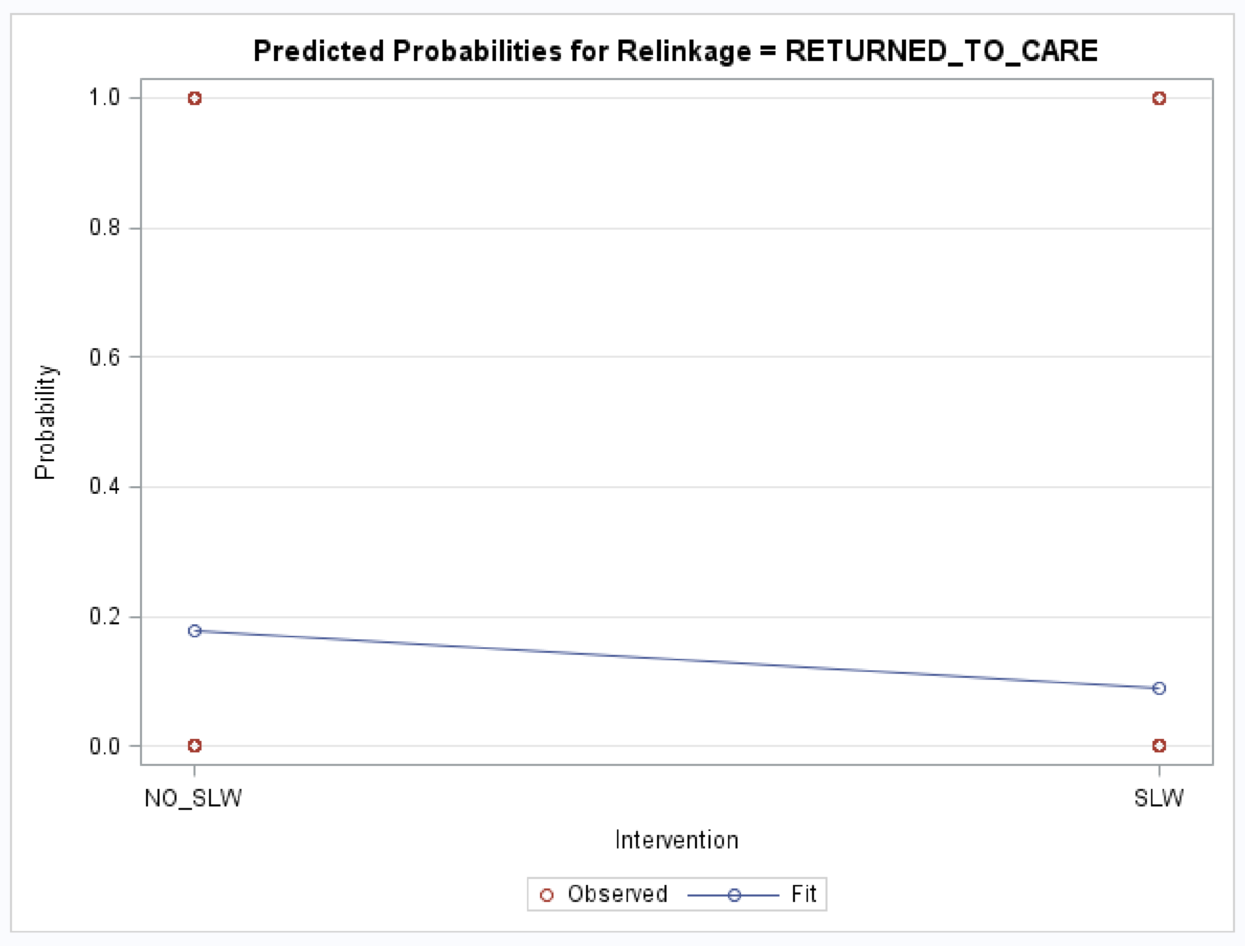

Figure 4 is a visual representation of the relationship between the main independent variable of interest, intervention status (e.g., assigned to an SLW vs. not assigned to an SLW after qualifying for follow up post-surveillance investigation), and the outcome of interest (e.g., returned to HIV care vs. not returned to HIV care). As depicted, persons not assigned to the SL program had a slightly higher probability of returning to HIV care compared to those assigned to the SL Program, although results were insignificant at an alpha of 0.05 (P-value=.0890).

Discussion

The majority of PLWH presumed to be out of care and referred to the HHD for record search investigation failed to qualify for follow up. The primary reason was they had evidence of care (67.3%) followed by out of jurisdiction (16.0%), validating the contribution health departments can make in comprehensive health record knowledge while highlighting the majority of presumptions about the out-of-care population are likely inflated. Despite differences in methodologies, D2C programs using various surveillance and care investigations to identify and locate presumed out-of-care persons have consistently learned greater than 50% of all presumed lost-to-care persons failed to qualify for public health follow up, having been found to be in recent care with other factors such as migration, death, and incarceration distorting engagement-in-care estimates.[18,19,21,32,54] Migration might be particularly characteristic in Houston given its proximity to the Mexico border, as some people reported being in care but out of country (.

Table 20).

DIS/incoming OOJ referrals, surveillance referrals, and having had an unsuppressed viral load at last report were associated with greater odds of qualifying for follow up while persons diagnosed with HIV longer had lower odds of qualifying for follow up. Although not equal measures, age was eliminated from the statistical models because it was strongly correlated with time since HIV diagnosis, and retaining time since HIV diagnosis contributed a unique measure which has been often overlooked in D2C programs. However, when one considers the correlation with age, the significance of persons diagnosed with HIV for a longer period having less odds of qualifying for follow up might reflect trends in the Houston EMA Care Continuum. When broken down by age groups in 2016, ranging from 13-24, 25-34, 35-44, 45-54, to 55+, retention in care and viral suppression increased sequentially across all groups. Literature supports persons of older age being more likely to be virally suppressed with greater retention and treatment adherence.[55–58] Someone of older age might not be newly diagnosed, but given, as someone both ages and lives longer with HIV, they might be more likely to face an increasing number of health challenges, so they also might be more likely to seek out medical care and have more motivation to stay in care. This possibility is reflected in .

Table 20, where some persons reported being out of care because they "feel good/was healthy at last doctor appointment," although this relationship might be extraneous. Future studies might consider measuring the effects of the length of HIV diagnosis given the lack of knowledge of this factor on relinkage to care. They might also consider a new variable factoring in both measures of time since HIV diagnosis and year of birth.

DIS/incoming OOJ referrals had recent contact with PLWH, thereby making it more likely that a person would be correctly identified, initially, as out of care and in the jurisdiction, alive, and not incarcerated. One D2C study acknowledged an usually high rate of relinkage to care at 71.2% for persons confirmed out of care, and this program employed expanded partner services (ExPS) in lieu of service linkage workers.[59] Although their study population originated solely from surveillance sources and served a markedly differently population, one which was non-metropolitan and cross-county in upstate New York, all record-search investigations and patient outreach were conducted by ExPS-designated staff members, which might speak to an alternative relinkage-to-care strategy worth exploring.

Provider referrals might benefit from additional outreach by program staff and/or restrictive criteria for out-of-care persons. Providers reserve a specific scope of knowledge for the patients they serve in that they are restricted to the electronic medical records (EMRs) under their purview and authority, which might explain why clinic-based data has yielded potentially out-of-care clients who have simply moved out of jurisdiction or to another care system.[33] Nonetheless, providers are integral to the care-prevention foundation upon which D2C programs rest, and other studies have taken more progressive steps towards provider inclusivity.[21,32,33,39,59,60] Within the Houston/Harris County program, the separation of HIV prevention and care services by City and County governing bodies is a significant hurdle towards similar approaches, but the foundational partnerships established in this study are a valued achievement. These partnering providers often lack dedicated staff to identify and refer PLWH to the HHD, and their systems might not be easily adaptable for this purpose, requiring significant manual effort without outside assistance, support, or other allocated resources. The mechanism for referral to the HHD was via paper, sometimes extracted by hand, making prioritization of these lists for surveillance investigation difficult. Resource support for providers and/or emphasizing more restrictive criteria might improve the quality of these lists and relinkage to care outcomes. Additionally, the SL Program might leverage unique qualities of providers, such as their ability to identify persons loosely engaged with care, marked by repeatedly missed/canceled appointments or high viral loads despite antiretroviral treatment, and open a new referral system for this at-risk population, although refinement of this definition might prove challenging.[61] Capturing persons before they are lost to the system completely by falling out of care would improve health outcomes for PLWH and assist each institution with achieving programmatic goals.

One potential, immediate possibility for improved provider-health department relations is the HHD's prospective role in fulfilling necessary standards of care, an avenue worth exploring. Ryan White Part A requires documentation of three attempts by more than one method to contact clients, a critical component of medical case management.[26] Operating under respective regional administrative codes and the guidance of state health authorities, health departments might be able to alleviate this burden through D2C follow up by reporting aggregate or individually-based outcomes to the original referring provider, a bilateral information exchange undertaken by other D2C programs.[21,32,39] Studies have demonstrated that reminder telephone calls reduce missed appointments, but some clinics had difficulty following up with patients solely via this method due to disconnected phones, with the percent disconnected as high as 50%.[62,63] The SL Program can leverage greater locating data through surveillance investigation and larger outreach resources beyond the telephone. This expanded partnership would strengthen services to the HIV community and create more possibilities to understand persons at-risk and potentially most receptive to targeted interventions such as described here.

Laboratory results from hospitals, if they were CD4+ T-lymphocyte count and/or viral loads, counted as care for this study, but hospital networks are poor markers for health outcomes given they are not a primary HIV medical home, yet they might provide an opportunity for HIV-care reengagement. Louisiana is a remarkable example of a bidirectional, public-health information exchange leveraging the strengths of a state-wide, relinkage-to-care effort.

Combining the best of two worlds, provider networks and active referrals, it was designed to produce real-time provider alerts when PLWH lacking any CD4+ T-lymphocyte count/viral load monitoring within the past 12 months seek non-HIV related care in their integrated delivery network.[64,65] This alert permits immediate relinkage to HIV specialty care. Within two years, alerts were received across 60 clinics, 223 clinics, and 7 facilities for 419 out-of-care PLWH, of which 76% were once in care previously, and 85% of those persons had at least one CD4+ T-lymphocyte count/viral load result during follow up.[64,65] This program, implemented in a Southern environment, suggests there is an opportunity to capture persons lost to care while they are actively seeking medical treatment for other conditions, with elements potentially applicable in the Houston area.

This study was distinct in its analysis of differences between persons qualifying for follow up and those who had recent evidence of care, an attempt to understand if there were certain characteristics associated with a critical measure of interest, the truly out-of-care population. Associations were similar to the analyses among persons qualifying for follow up, which was not unexpected given the majority of persons who did not qualify for follow up did so because of recent evidence of care. The only newfound relationship was the significance of persons with no viral load at last report having less odds of having recent evidence of care, which might indicate that persons without these laboratory measures are more likely to abstain from care. However, other factors could easily be influencing this measure as well, like faulty reporting, none of which are known. Future analyses might implement multinomial logistic regression to determine if there are differences across dispositions, should they exist.

Results of this study support eHARS as the most comprehensive HIV care system for the HHD, with 84.2% of evidence of care found in this database during surveillance investigation, exclusively 63.0% of the time. Selecting potentially out-of-care persons from this source is reasonable but likely needs adjustments in parameters as its major weakness is reporting lag-time and lack of real-time participant selection. Buchacz and colleagues found about 25% of originally presumed out-of-care persons extracted from eHARS had altered eligibility upon re-investigation 12 months post-initiation date, emphasizing the impact of reporting delays.[21] Although the HHD continues to improve timeliness and efficiency of HIV-case reporting through provider education, electronic laboratory reporting through expansion of HEDSS (Maven), data system integration, and routine review of internal processes and protocols, delays remain an issue.[66,67] Future analyses can perform an assessment of eHARS surveillance referrals using the laboratory specimen date and reporting date to determine if the difference in time within the HHD system was potentially impactful. Careful consideration of the HHD's usage might entail the decree of some sort of buffer period to account for these delays, similar to the original CDC recommendations to account for reporting delays when performing trend analyses prior to significant advances in data management and bioinformatics.[68] Despite the identification of each data systems' usefulness, acting alone and in conjunction, data system integration would eliminate the labor costs of manual surveillance investigations and create more actionable processes.[69]

The HHD might produce the surveillance list at increased intervals (e.g., biannually, quarterly, etc.) to avoid data expiration. As the HHD has demonstrated, prioritization will continue to be necessary because the number of potentially out-of-care persons will far exceed the manpower and resources available to public health institutions. Viral suppression and a low CD4+ T-lymphocyte count might be one consideration for ranking priority referrals. Viral suppression at last report was associated with qualifying for follow up services while having a last reported CD4+ T-lymphocyte count <200 cells/µL was marginally associated with relinkage to care. One study found patients were more likely to return to care on their own if they had a suppressed viral load.[70] Recent D2C demonstration projects reflect these results through incorporation of CD4+ T-lymphocyte count and viral load laboratory results as part of their eligibility criteria, emphasizing that persons with low CD4+ T-lymphocyte counts or unsuppressed viral loads were prioritized or considered for inclusion.[21,39] This inversely begs the question of whether persons with suppressed viral loads and/or high CD4+ T-lymphocyte counts at last report are possibly lower priority. The HHD cannot access AIDS Drug Assistance Program records, meaning no data is available regarding prescription distribution, negating any ability to assess its effect on care indicators. Others have noted that, although the absence of care over a defined interval is the current standard of lost to care, patients without care >12 months are often found to be virally suppressed, indicating a portion of this population almost certainly continues treatment of some manner.[32] Access to prescription-level data could have led to their initial omission from D2C programs, reducing the number of persons with recent evidence of care via surveillance investigation or self-reported care to the SLWs, increasing the sample size and reducing resource expenditure.

The relinkage to care program yield was low. Even after exhausting health department data system resources (n=381, 35.1%), the majority of persons were still unable to locate (n=157, 41.2%) and few were relinked to care (n=31, 8.1%). Of those located (n=193), the majority self-reported already being in care (n=90, 46.6%) or refused SLW services once located (n=59, 30.6%). Unable to locate and/or refusal of services also made it difficult to collect information about the reasons for being out of care, although the top 5 reported reasons after unknown included feels good/was health at last doctor appointment, unfriendly care setting, does not want/need HHD services, does not believe HIV test results, has private/other insurance and does not need ancillary services. Being a no show at scheduled intakes and/or medical appointments remains a significant hurdle to collecting data from this population, requiring changes in methodology or other alternatives to data collection.[70] A reciprocal but critical relationship exists between a person's engagement with other stages of the Care Continuum and being out of care. In the 2011 Houston Needs Assessment, the most common reason for seeking an HIV diagnostic test among PLWH was "feeling sick,"[2] inverse to the third leading cause of being out of care as reported in this study which was "feels good/was health at last doctor appointment." This result might be more common in Houston and highlights the discordant nature of care delivery and inadequate public health messaging. Other studies have not replicated a perceived lack of need for HIV care as an access barrier in a state with near universal healthcare delivery.[71]

The 2011 Houston needs assessment and other jurisdictions have likewise documented similar barriers to care as reiterated in .

Table 20, such as long wait times, difficulty making/keeping appointments, and problems with paperwork.[2,71] Notably, a D2C study in Seattle/King County and the Houston Area Comprehensive HIV Prevention and Care Services Plan for 2012-2014 found substance abuse, homelessness/lack of stable housing, and variations of does not want HIV medication/doctor to be conspicuously high reasons for having fallen out of care. PLWH in Houston reported the two most needed core HIV services were primary care (94%) and case management (84%), respectively, yet 93% stated primary care was accessible and 88% stated case management was accessible, each within the top five accessible services. Considering a lack of case management has been significantly associated with being out of care in some studies, as well as ancillary-specific conditions such as mental health or substance abuse services, more local research is needed.[72] The diversity in answers and difficulty in reaching this population to begin with create a significant and continuing gap in knowledge about HIV care accessibility, which might be confined to each jurisdiction. This study takes a step in the first direction, but larger samples and expanded needs assessments are needed.

The major strength of this study was the randomized, non-intervention group to assess differences between persons assigned to an SLW versus persons relinked to care on their own, but the sample size was small and diminished further by initial surveillance investigation eliminations, reducing effect size and power. Furthermore, original sample size calculations estimated a large odds ratio which can only detect large effects, a shortcoming in practice, yet a valuable lesson learned about the need for cross-jurisdictional data sharing about D2C program results for improved methodology design and implementation. This study contributed important knowledge by providing some of the first estimates of persons who return to care on their own. Among the randomized subgroups, participants in the intervention were about half as likely to be relinked to care by an SLW compared to those who returned to care on their own without the intervention, although results were insignificant (P-value>0.05). The absence of any impact of relinkage-to-care programs has been replicated in the few other studies with control groups. One study out of in a Seattle clinic designed a historical control group and found that time to relinkage was significantly shorter among persons in the intervention group and had higher relinkage rates in the intervention arm (15% vs. 10%), but this study had a year follow up period which included relinkage to care with different measures of direct intervention assistance when compared to this study.[32] A cluster-randomized evaluation of another D2C initiative found no difference between persons relinked to care and/or achieving viral suppression, with almost half of their initial study population returning to care prior to attempted intervention contact.[39] Researchers noted the lack of the control group in previous D2C studies might have led to false perceptions of the effectiveness of D2C programs as originally reported, a conclusions this study appears to support.[39]

Similar to the immediately aforementioned studies, our study found 46.6% of persons contacted by SLWs self-reported already being in care, and given the non-intervention group was dependent upon persons returning to care on their own, it is possible that excluding persons self-reporting being in care from the intervention group during the final analyses might impact the final relationship of interest. However, given the circumstances, they were not relinked by the SL Program, and it was not possible to determine if/when these persons might have truly returned to care, nor was second surveillance investigation performed to confirm their current care status. Future studies might consider alternative approaches to overcome this quandary.

This study employed a combination of surveillance-based, clinic-based, and internal-based referral sources to identify initially presumed, out-of-care persons, which uniquely allowed for a comparison of potential differences between these sources in their D2C abilities. Consistently, active referral sources, such as DIS-initiated or incoming OOJ referrals, had greater odds of qualifying for SL follow up and successful relinkage to care. Unfortunately, this mechanism also produced the fewest incoming participants, so health departments might consider leveraging their programmatic strengths to increase the availability of active referral sources and efficiency of their use. Future programs might explore internal mechanisms afforded by their own health departments, given existing and easily modifiable trainings, STD clinical resources, educational resources, and established community relationships.

Although race and ethnicity was not significantly associated in final analyses with outcomes of interest, other studies have found relationships with race/ethnicity and relinkage to care, with one particularly noting non-white PLWH were associated with greater likelihood of care reengagement.[59,73] Evaluation of the HIV Care Continuum at the national level has demonstrated that persons of color, particularly black, are disproportionately impacted by the HIV epidemic.[56,74] Within the black population, similar trends emerge regarding the discrepancies of age, with younger populations being less likely to link to care, achieve retention, and reach viral suppression, suggesting trends might be different with further research and better sampling.[56] This study also lacked complete data on transmission risk category and any data regarding sexual orientation and gender identity (SOGI), highlighting the limitations of existing data systems to properly collect and report this information, rendering these vulnerable populations invisible to public health analysis and potential outreach. As of 2015, a nationwide call to action was initiated by the Centers for Medicare and Medicaid Services under the Meaningful Use program to update electronic health record systems with SOGI data parameters,[75,76] and as of 2016, the Health Resources and Services Administration has mandated SOGI data collection and reporting for improved outcome measures.[77] Additional covariates of interest would strengthen understanding of the influencers on successful follow up and care reengagement.

Future studies might quantify the cost of service linkage outreach as a monetary measure. Colleting the total minutes spent on the phone during each call attempt could produce a cumulative time unit which could be assigned a labor cost/minute. The time spent traveling to each field address could also be assessed for the same unit output. Furthermore, the City of Houston assigns a pre-designated mileage allocation for travel reimbursement. It is possible to geocode the addresses and determine the total distances traveled by SLWs in their attempts to contact potential out-of-care clients in addition to the cost of these outreach attempts and analyze the yield in terms of relinkage success.[78,79] Additionally, stratifying these results by the significant variables in these analyses might help determine if there are variations in certain variables and determine if specific sub-populations are harder to reach and might need more tailored approaches. Contact attempts should also not just be limited to phone and field visits but additional expansion to emails and text messages, as successful pilot programs built around linkage, relinkage, and retention have been initiated with additional follow up needed.[78]

Additional limitations of the current study include using time since HIV diagnosis as a proxy for age given it eliminates a true measure for this variable, but using this measure strengthens the assumptions of the multivariable logistic regression model, the benefits outweigh the potential loss of data. Categorization of continuous variables results in some loss of information and loss of power, but the only variables retained permanently in the final analyses in their categorical format were most recent CD4+ T-lymphocyte count and most recent viral load laboratory result, and there was strong clinical and public health justification for this action.[80] Confounding factors are of potential concern, and additional literature is needed.[81] Limitations of the Firth penalized likelihood method include potential upwards bias.[82] However, given that the Firth method offsets the restrictions of small sample sizes when using maximum likelihood estimation in multivariable logistic regression analyses, the statistical gain overcomes the primary weakness of the data. Additionally, given the exploratory nature of this pilot project, much was learned about the lower than expected proportion of the outcome of interest, i.e., relinkage/return of PLWH to care, including both practical lessons learned and statistical implications for recreating similar randomized interventions to determine if trends are repeatable. More efforts are needed to enroll persons for larger samples sizes and more time might be needed to allow for proper population estimates to occur. List-wise deletion of missing variables might be biased with better methods available for handling these data, yet missing data were small (<5%) and limited to few analyses, thereby minimizing its impact, if any.[83]

CONCLUSION

Health departments contribute key information about the out-of-care population, but these systems fall short in timeliness and completeness when it comes to producing the necessary information needed to successfully contact this hard to reach population, requiring extensive resource input and management. More information is needed about their reasons for falling out of care to better assess their specific needs and the dynamics influencing the fluid nature of HIV care in order to capture this population before they are lost from the medical system.

APPENDICES

Appendix A. List of Definitions

Administratively Closed – Outcomes assigned via record searches only as determined by data system information and not assigned to the intervention (i.e., the SL Program). Both the initial cohort and the intervention subgroups could be administratively closed.

Qualified for SLW Assistance – Referrals without a surveillance investigation outcome from online record searches qualified for the intervention (i.e., outreach by an SLW). These persons, upon completion of the first surveillance investigation among the care and laboratory data systems, did not have evidence of care in the immediate six months prior to the date of the investigation and were presumed to be out of care. They also lacked evidence of any other outcome such as incarceration, death, out of jurisdiction, etc. Non-intervention subgroup members could also have database evidence of being truly out of care with no other outcome based on the set parameters during the first surveillance investigation timeframe, but they were never officially assigned to SLW assistance.

Intervention Subjects – A subgroup of incoming referrals from the surveillance (eHARS) referral source. The eHARS referrals were randomly assigned an intervention or non-intervention status. Intervention subgroup members were non-distinct from the other referrals in the study except for their respective non-intervention arm. They were record searched in the same timeline as the other study subjects, excluding the non-intervention subgroup, and assigned to the SLWs using the same criteria for inclusion.

Non-intervention Subjects – A subgroup of incoming referrals from the surveillance (eHARS) referral source. The eHARS referrals were randomly assigned an intervention or non-intervention status. Non-intervention subgroup members were managed by the same initial surveillance investigation criteria and timeline. However, if a non-intervention subject was confirmed to be out of care, it was not assigned to an SLW. Instead, surveillance investigation would re-occur after a 90-day period to determine if the non-intervention subject returned to care without SLW intervention for comparison to the intervention members who were assigned to an SLW for assistance with returning to care.

Surveillance Investigation (SI) – Electronic record searches among HIV care, surveillance, and public records data systems to assess the following outcomes: evidence of care, incarcerated, deceased, ineligible, or out of care within the previous six months. This step determined if incoming referrals were currently considered out of care per available data systems and would subsequently be assigned to an SLW and/or additional surveillance investigation if the referral was assigned to the non-intervention subgroup.

Out of Care – A referral was determined to be out of care when there was no evidence of a CD4+ T-lymphocyte count and/or viral load laboratory result and/or HIV care appointment within the previous six months of a surveillance investigation date. An incoming referral should have been out of care for at least six months prior to the referral date (i.e., the date the referral was received by the HHD) according to the referral source's internal record system.

CD4+ T-lymphocyte count - A CD4+ T-lymphocyte count is a measure of the number of CD4+ cells (aka T-helper cells) in a sample of blood. A simple blood test can count the cells. CD4+ cells are a type of immune system cell in the body that HIV attacks and kills over time. It is considered a proxy of HIV care because a person's CD4+ T-lymphocyte count increases as the HIV virus is controlled through adherence to treatment and consistent medical care.[84,85] Therefore, conducting regular CD4+ T-lymphocyte count tests is considered a standard of HIV care because it is a marker of a PLWH's current health status.[85–87]

Viral Load – A viral load is the amount of virus in the blood. It is measured by a simple blood test. Like a CD4+ T-lymphocyte count, treatment adherence influences a person's viral load by decreasing it to undetectable levels, serving as an indicator of consistent medical care.[84,85] Therefore, conducting regular viral load tests is considered a standard of HIV care because it is a marker of a PLWH's current health status.[85–87]

Service Linkage Worker (SLW) – SLWs are a type of non-medical case manager who, for the purposes of this study intervention, contacted HIV-infected persons not currently receiving medical care who were once in HIV care and facilitated the return of these persons to care.

Service Linkage (SL) Program – The SL Program houses the SLWs. In existence before the implementation of this study, it was originally designed to assist with initial linkage to care for newly diagnosed, HIV-positive persons.

Appendix B. Logistic Regression Model

$$\pi(x) = \frac{e^{x'\beta}}{(1 + e^{x'\beta})}$$

$\pi(x)$ is the probability of a Bernoulli random variable which takes the value 1 or 0 evaluating at a covariate matrix x, and β is the parameter vector[48]

Appendix C. Firth correction: estimates β as the maximum of the penalized loglikelihood

$$\ell^{*}(\beta) = \ell(\beta) + \frac{1}{2} ln|I(\beta)|$$

$\ell(\beta)$ is the model loglikelihood, ½ln|I| is the penalty term[48–50,82]

Appendix D. SAS 9.4 software code for Aim 1 multiple logistic regression results in Table 12 and associated diagnostics

```
proc logistic data=FULL2 order=data;
   class Merck2 (ref="NO" param=ref) TAB3 (ref="PROV" param=ref) VL4
(ref="suppressed" param=ref) CD44 (ref="greater200" param=ref);
   model Merck2=HIV2 TAB3 VL4 CD44 /  selection=backward fast slstay=0.2
ctable lackfit rsq;
run;

ods graphics on;
proc logistic data=FULL2 order=data;
   class Merck2 (ref="NO" param=ref) TAB3 (ref="PROV" param=ref) VL4
(ref="suppressed" param=ref) CD44 (ref="greater200" param=ref);
   model Merck2=HIV2 TAB3 VL4 CD44 / lackfit rsq TECHNIQUE=NEWTON OUTROC=ROC
CLPARM=WALD CLODDS=WALD
            SCALE=NONE PPROB=0.5 CTABLE NODUMMYPRINT NOLOGSCALE NOCHECK;
            OUTPUT OUT=pred RESDEV=resdev RESCHI=reschi H=hat p=phat
lower=lcl upper=ucl PRED=pred PREDPROB=(individual crossvalidate);
   effectplot slicefit;
run;

ods graphics on;
proc univariate data=pred;
      histogram resdev reschi /
            NORMAL (COLOR=red W=3
            PERCENT=20 40 60 80
            MIDPERCENTS) CFILL= blue
            CFRAME= yellow;
RUN;

ods graphics on;
proc loess data=Test;
      model Merck3=HIV2/smooth=0.1 0.25 0.4 0.6 residual;
      ods output OutputStatistics=Results;
run;

proc loess data=Test;
   model Merck3=HIV2 / details(ModelSummary OutputStatistics);
run;

proc reg data=Test;
      model Merck3=HIV2 TAB5 VL CD4 / vif tol collin;
run;

proc corr data=Test spearman;
      var AGE6 TAB5 VL CD4;
run;

proc corr data=Test pearson;
      var HIV2 AGE2;
run;
```

Appendix E. SAS 9.4 software code for Aim 1 multiple logistic regression results in Table 17 and associated diagnostics

```
proc logistic data=care order=data;
   class DISPO3 (ref="outofcare" param=ref) TAB3 (ref="PROV" param=ref) VL4
(ref="suppressed" param=ref);
   model DISPO3=HIV2 TAB3 VL4 / selection=backward fast slstay=0.2 ctable
lackfit rsq;
run;

ods graphics on;
proc logistic data=care order=data;
   class DISPO3 (ref="outofcare" param=ref) TAB3 (ref="PROV" param=ref) VL4
(ref="suppressed" param=ref);
   model DISPO3=HIV2 TAB3 VL4 / lackfit rsq TECHNIQUE=NEWTON OUTROC=ROC
CLPARM=WALD CLODDS=WALD
            SCALE=NONE PPROB=0.5 CTABLE NODUMMYPRINT NOLOGSCALE NOCHECK;
            OUTPUT OUT=pred RESDEV=resdev RESCHI=reschi H=hat p=phat
lower=lcl upper=ucl PRED=pred PREDPROB=(individual crossvalidate);
   effectplot slicefit;
run;

ods graphics on;
proc loess data=Test2;
      model DISPO=HIV2/smooth=0.1 0.25 0.4 0.6 residual;
      ods output OutputStatistics=Results;
run;

proc loess data=Test;
   model DISPO=HIV2 / details(ModelSummary OutputStatistics);
run;

proc reg data=Test2;
      model DISPO=HIV2 TAB5 VL / vif tol collin;
run;

proc reg data=Test2;
      model DISPO=HIV2 AGE6 TAB5 VL / vif tol collin;
run;
```

Appendix F. SAS 9.4 software code for Aim 2 multiple logistic regression results in Table 23 and associated diagnostics

```
proc logistic data=SLWonly order=data;
   class SLWDISPO2 (ref="Other" param=ref) TAB3 (ref = "PROV") CLIENT_PCS
(ref = "2orless") RACE2 (ref = "W") PROV PCSS (ref = '0')
                              PROV_FVS (ref = "0") CD44 (ref="greater200"
param=ref)/ param=ref;
   model SLWDISPO2=RACE2 TAB3 CD44 CLIENT_PCS / firth clodds=pl lackfit rsq;
   effectplot;
run;

ods graphics on;
proc logistic data=SLWonly order=data;
   class SLWDISPO2 (ref="Other" param=ref) TAB3 (ref = "PROV") CLIENT_PCS
(ref = "2orless") RACE2 (ref = "W") PROV PCSS (ref = '0')
                              PROV_FVS (ref = "0") CD44 (ref="greater200"
param=ref)/ param=ref;
   model SLWDISPO2=RACE2 TAB3 CD44 CLIENT_PCS / firth clodds=pl lackfit rsq
TECHNIQUE=NEWTON OUTROC=ROC CLPARM=WALD CLODDS=WALD
            SCALE=NONE PPROB=0.5 CTABLE NODUMMYPRINT NOLOGSCALE NOCHECK;
            OUTPUT OUT=pred RESDEV=resdev RESCHI=reschi H=hat p=phat
lower=lcl upper=ucl PRED=pred PREDPROB=(individual crossvalidate);
   effectplot slicefit;
run;

ods graphics on;
proc univariate data=pred;
      histogram resdev reschi /
            NORMAL (COLOR=red W=3
            PERCENT=20 40 60 80
            MIDPERCENTS) CFILL= blue
            CFRAME= yellow;
RUN;

proc reg data=Test2;
      model DISPO=TAB5 RACES CD4 C_PCS / vif tol collin;
run;
```

Appendix G. SAS 9.4 software code for Aim 2 multiple logistic regression results in Table 26 and associated diagnostics

```
proc logistic data=SLWonly order=data;
      class SLWDISPO5 (ref="UnabletoLocate" param=ref) TAB3 (ref = "PROV")
CLIENT_PCS (ref = "2orless") CLIENT_FVS (ref = '0')
                             VL5 (ref = 'suppressed') / param=ref;
    model SLWDISPO5= HIV2 TAB3 VL5 CLIENT_PCS CLIENT_FVS  / firth clodds=pl
lackfit rsq;
      effectplot;
run;

ods graphics on;
proc logistic data=SLWonly order=data;
    class SLWDISPO5 (ref="UnabletoLocate" param=ref) TAB3 (ref = "PROV")
CLIENT_PCS (ref = "2orless") CLIENT_FVS (ref = '0')
                             VL5 (ref = 'suppressed') / param=ref;
    model SLWDISPO5=TAB3 VL5 CLIENT PCS CLIENT FVS / lackfit rsq
TECHNIQUE=NEWTON OUTROC=ROC CLPARM=WALD CLODDS=WALD
            SCALE=NONE PPROB=0.5 CTABLE NODUMMYPRINT NOLOGSCALE NOCHECK;
            OUTPUT OUT=pred RESDEV=resdev RESCHI=reschi H=hat p=phat
lower=lcl upper=ucl PRED=pred PREDPROB=(individual crossvalidate);
   effectplot slicefit;
run;

ods graphics on;
proc univariate data=pred;
      histogram resdev reschi /
            NORMAL (COLOR=red W=3
            PERCENT=20 40 60 80
            MIDPERCENTS) CFILL= blue
            CFRAME= yellow;
RUN;

ods graphics on;
proc loess data=Test2;
      model DISPOS2=HIV2/smooth=0.1 0.25 0.4 0.6 residual;
      ods output OutputStatistics=Results;
run;

proc loess data=Test2;
   model DISPOS2=HIV2 / details(ModelSummary OutputStatistics);
run;

proc reg data=Test2;
      model DISPOS2=TAB5 VL C_PCS C_FVS / vif tol collin;
run;
```

Appendix H. SAS 9.4 software code for Aim 3 multiple logistic regression results in Table 32 and associated diagnostics

```
proc logistic data=Final3 order=data;
      class FINALDISPO ORIGIN (ref='90DAYONLY') ETH (ref='NH' param=ref) AGE5
(ref='44orless' param=ref);
      model FINALDISPO=ORIGIN ETH AGE5 / firth clodds=pl lackfit rsq;
      effectplot;
      where Merck='YES';
run;
```

Appendix I. SAS 9.4 software code for Aim 3 multiple logistic regression results in Table 33 and associated diagnostics

```
proc logistic data=Final3 order=data;
      class FINALDISPO ORIGIN (ref='90DAYONLY');
      model FINALDISPO=ORIGIN/ firth clodds=pl lackfit rsq;
      effectplot;
      where Merck='YES';
run;
```

.

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