

Final Evaluation Report

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Executive Summary

AIDS United's multi-sponsored Access to Care (A2C) initiative was conceived for people living with HIV/AIDS (PLWH) to increase their access to and retention in effective HIV healthcare and support services. The A2C subgrantees included twelve sites located throughout the U.S. that implemented innovative, evidence-based HIV linkage and retention-in-care programs. A2C programs shared common program models, including peer/patient navigation, community health workers, care coordination, intensive case management, and motivational interviewing, to serve the most vulnerable populations.

The evaluation of A2C included impact, outcome, and implementation components. The impact evaluation assessed if individuals exposed to the BA₂C intervention (Birmingham, Alabama: Lead agency University of Alabama at Birmingham in partnership with Birmingham AIDS Outreach) had greater improvements in health outcomes (CD4 count and viral load) at 12 months compared to individuals who did not receive the intervention. In addition, the impact evaluation constructed continuums of care for program participants for comparison with geographically local continuums of care. The outcome evaluation assessed trends in participant health outcomes (CD4 and viral load) at baseline and 12 months. The outcome evaluation also included a network analysis, which described increases in interagency collaboration among subgrantee partner agencies, as well as a cost analysis. The cost analysis estimated, for each subgrantee, the cost of delivering the program locally and the cost-saving threshold. An implementation research component tracked the number of clients who were enrolled in the program, linked to HIV medical care, and retained in HIV medical care. In addition, the implementation evaluation qualitatively assessed barriers and facilitating factors of program implementation.

Implementation evaluation: The A2C program served a total 4,704 participants. Across the cohort, 86% were linked to HIV medical care during the program. The majority of subgrantees reported HIV retention in care percentages above 75% at twelve months (range 45%–92%). Across the cohort, 63% of participants (1570/2490) had current highly active antiretroviral treatment (HAART) prescriptions twelve months after enrollment.

We conducted 90-minute interviews with staff at lead subgrantee and implementing partner agencies to better understand barriers and facilitators to program implementation. Several themes emerged across all program sites. Common barriers to program implementation included: the intensity of client needs; recruiting and retaining participants; staffing and administrative hurdles; and challenges related to working with multiple partner organizations. The three themes that emerged as factors that facilitated SIF program implementation were strong relationships with partner organizations; the flexible and innovative nature of the SIF programs; and the expertise, dedication, and passion of staff.

Outcome evaluation: When we compared mean CD4 counts and mean viral load at baseline and 12 months for each subgrantee, we saw increases in mean CD4 from baseline to twelve months. These changes were significant (paired T-test) for participants enrolled in Boston, Chicago, New York, Los Angeles, San Diego, Indianapolis, Montgomery, St. Louis, Washington, DC, and Birmingham. Reductions

in viral load were observed across subgrantees. These reductions were significant for participants enrolled in the following program locations: Chicago, Los Angeles, Indianapolis, Montgomery, St. Louis, and Washington, DC. Increases in the percent of participants who were virally suppressed were seen across the cohort from baseline to twelve months, and were significant at eight locations.

The structure of A2C programs included a lead agency and at least one implementing partner agency. The majority of lead agencies worked with a number of implementing partners (range 2–7) including clinics, health departments, AIDS service organizations, and social service providers. To better understand change at the network level, the national evaluation assessed changes in A2C partner network density six months prior to A2C and during implementation of A2C. For all subgrantee networks except for two, we saw increases in network density as well as increases in average node degree.

Cost Analysis: The cost analysis assessed the cost program delivery as well as the cost-saving thresholds for the A2C programs, or the number of HIV infections that would need to be averted for a program to be cost-saving. Program costs varied considerably. Cost-per-client from the societal perspective ranged from \$1,109.45 to \$5,928.14 per client. Cost-saving thresholds ranged from .32 to 1.19, indicating that to be cost-saving the programs would need to avert one to two HIV infections (during the timeframe of the analysis.)

Impact evaluation: The primary outcome measure for the randomized control trial of the BA₂C program was viral suppression. The study observed that intervention arm participants were more likely to be virally suppressed at twelve months compared to control arm participants but the results were not significant (OR 1.1 (0.4-2.7) p=0.80). The construction and comparison of HIV continuums of care found that the majority A2C program continuums of care exceeded local continuums of care.

In summary, participants in the A2C programs saw improvements in engagement in HIV medical care along the HIV continuum of care, including viral suppression. Change occurred at the network level as well; interagency collaboration increased during program implementation. Finally, at the policy level, the cost threshold analysis suggests that the A2C program models are a good use of resources.

Program Background

AIDS United's multi-sponsored Access to Care (A2C) initiative was conceived for people living with HIV/AIDS (PLWH) to increase their access to and retention in effective HIV healthcare and support services. In particular, the initiative focused on those living in poverty who knew their HIV status but were not receiving HIV-specific care or support. Emphasis on hard-to-reach populations was integral in AIDS United's A2C work, which sought to identify the systemic and/or personal barriers to care PLWH may experience and support the development of systems and interventions to alleviate those barriers and implement innovative approaches to ensuring access to and consistent engagement in care. A2C was designed to reach the most difficult populations with refined outreach strategies and with appropriate resources that otherwise would not be available. All funded projects within the A2C portfolio created networks of care in their communities that collaborated to reduce barriers to care, provide innovative solutions to long-standing access problems, and to change the way that systems operate in their community. AIDS United is committed to supporting projects that not only focus on individual level solutions to barriers to care, but also systemic change will last long after AIDS United support is gone.

Social Innovation Fund (SIF) grant dollars allowed AIDS United to greatly expand the A2C initiative. Subgrantee sites were selected by a diverse External Review Committee consisting of eight experts in the fields of HIV/AIDS, public health, program evaluation, and strategic philanthropy. The final subgrantees were selected using criteria that included such factors as:

- Serve low socio-economic-status areas that are highly affected by HIV
- Have a track record of using evidence-based practices
- Have innovative ideas with at least preliminary evidence of effectiveness
- Have the capacity to effectively manage a SIF project including evaluation and expansion/replication of successful programs

The subgrantee sites in the SIF cohort were: ActionAIDS, AIDS Action Committee of Massachusetts, AIDS Foundation of Chicago (AFC), AIDS Project Los Angeles (APLA), Amida Care, Christie’s Place, The Damien Center, Louisiana Public Health Institute, Medical AIDS Outreach, St. Louis Effort for AIDS, University of Alabama at Birmingham, and Washington AIDS Partnership. Each subgrantee worked with multiple partners (subcontractors) to implement the project. The SIF cohort was funded in two waves. Throughout this document, we refer to the first wave of subgrantees as the first cohort and the second wave of subgrantees as the second cohort¹. A brief description of the twelve SIF programs follows:

ActionAIDS: Philadelphia, PA

ActionAIDS, a Philadelphia-based HIV/AIDS service organization, implemented an intensive case management program designed to increase the rate of retention in health care for individuals who had been recently released from the Philadelphia Prison System. During the formative phase of this program, ActionAIDS designed an acuity assessment instrument that identified clients at intake who presented the greatest risk of being lost to care. These clients then received intensive “Care Coach” case management services, expedited housing and behavioral health services, and related support to remain engaged in care. ActionAIDS was joined by three other nonprofit service providers to help transform the delivery of services to recently incarcerated clients, as well as services to other clients who have mental health or drug and alcohol issues and who lack stable, affordable housing. The primary goals of the project were to:

- Identify sub-optimally engaged PLWH and link and retain them in care
- Increase the number of formerly incarcerated PLWH who obtain/maintain safe and affordable housing
- Increase the number of formerly incarcerated PLWH who participated in back-to-work programs
- Reduce recidivism for formerly incarcerated PLWH

AIDS Action Committee (AAC): Boston, MA

The primary goal of *LEAP 2.0* was to improve the health of PLWH by providing comprehensive bio-psycho-social support from crisis to stability and self-sufficiency. A collaborative effort between AIDS Action Committee of MA (AAC) and Partners in Health’s Prevention and Access to Care and Treatment (PACT) program, *LEAP 2.0* (Linking, Educating, and Advocating with Peers) aimed to increase the number

¹ The first cohort includes: AIDS Action Committee of Massachusetts, AIDS Foundation Chicago, AIDS Project of Los Angeles, Amida Care, Christie’s Place, Medical AIDS Outreach, St. Louis Effort for AIDS, and Washington AIDS Partnership. The second A2C cohort includes: ActionAIDS, Damien Center, Louisiana Public Health Institute, and University of Alabama.

of PLWH who were linked to and retained in high quality HIV medical care and supportive services. The *LEAP 2.0* Integrated Advocacy Team minimally consisted of a Client Advocate, a Peer Leader, and a non-traditional Mental Health Specialist. Others may join the team depending on individual client needs. *LEAP 2.0* priority areas were:

- Linkage to and retention of PLWH in HIV medical care
- Enhanced and expanded access and retention in supportive services (including non-traditional mental health services and self-management support groups)
- Improved self-sufficiency of PLWH who are not engaged in care through participation in benefits, treatment adherence, and workforce readiness workshops
- Expanded continuum of care for PLWHA to better support long-term self-sufficiency

AIDS Foundation of Chicago (AFC): Chicago, IL

The Connect2Care (C2C) project was a collaboration between AFC and two experienced HIV/AIDS organizations to create regional C2C hubs that conducted outreach and networking activities, creating seamless systems from HIV diagnosis to care as envisioned in the National HIV/AIDS Strategy. Focusing on PLWHA of color, these hubs worked with medical and support service providers in their regions to meet client needs and preferences and supported early and continuous care engagement. The overarching goal of the C2C project was to increase access to and consistent retention in HIV care for PLWH. The four primary intervention components for the project included:

- System-level enhancements
- Client-level outreach
- Linkage to care
- Client-level education

Amida Care: New York, NY

AmidaCONNECT utilized an Assertive Community Treatment (ACT) model in employing three field-based Mobile Engagement Teams (METs) to provide intensive outreach, care navigation, case management, and reengagement services to the most difficult to reach HIV-positive population—those dually and triply diagnosed with mental health and/or substance use issues and were unconnected to care (or at risk of becoming disconnected from care)—and connected them to long-term community service providers. The enrollees of AmidaCONNECT were not only living with HIV and un/under treated, but were often facing additional challenges that affect overall health and well-being, such as homelessness, poverty, lack of nutritious food, and legal issues. The METs engaged members in appropriate and ongoing primary and behavioral health care and substance use treatment in an effort to suppress HIV viral load, reduce health disparities, and generate positive health outcomes, while decreasing the utilization of costly hospitalizations and long term care that is often preventable.

AIDS Project Los Angeles (APLA): Los Angeles, CA

The Care and Access Network represented a partnership among leading HIV/AIDS service organizations, APLA, Northeast Valley Health Corporation, and REACH LA, in Los Angeles County (LAC). All of the agencies provided a wide variety of clinical, support, and prevention services to a diverse client base across the vast geography of LAC. Each of the partners demonstrated a long history of engaging racial/ethnic and sexual minorities in the continuum of care. In addition, many of the agencies provided HIV counseling and testing services to high-risk populations and were connected to a broader network of service providers in their individual communities, inclusive of HIV primary medical care. Patient

Navigators helped PLWH address individual barriers to care in order to increase access and retention in medical care, access treatment, and participate in other supportive services (e.g., case management, housing, food and nutrition services, mental health, and HIV risk reduction programs) to enhance and maintain engagement in care, and to reduce the incidence of new HIV infections by reducing the community viral load. Strategies for reducing community viral load included Patient Navigators advocating for earlier initiation of ART as well as helping clients improve adherence.

Christie's Place (CP): San Diego, CA

CHANGE 4 Women functioned as a network of care model. It was designed to improve timely entry, access to and retention in HIV care for women living with HIV in San Diego County, with an emphasis on women of color. The intervention had two levels of innovation—with individuals and among service agencies. The individual-level element focused on increasing the number and capacity of peer navigators and the CP peer coordinator to do outreach to and provide support for HIV-positive women. The agency innovations included CP's "one-stop shop" approach to improving client knowledge of their health and social service situation and access to care via medical home electronic record access. CP was also a nationally recognized model for trauma-informed care and presented their model at numerous conferences as well as at the 2015 observance of National Women and Girls HIV/AIDS Awareness Day at the White House. Other systems-level innovations included increased formalization and coordination among the major HIV health care agencies in San Diego. The project goals were to:

- Improve underserved women's access to and retention in comprehensive HIV care
- Improve utilization of HIV medical care and treatment for HIV-positive women
- Strengthen health care and social services systems and community linkages through innovative and replicable interventions and new collaborations that improve engagement and retention in care by HIV-positive women

Damien Center: Indianapolis, IN

Damien CareLink provided coordinated HIV services and linkage to care for PLWH who were currently not in care. According to the Centers for Disease Control and Prevention, timely linkage to care has a variety of benefits, including delaying disease progression and increasing positive health outcomes, reducing transmission and therefore preventing new infections, decreasing health care expenditures, and keeping community viral loads low. Numerous and complex barriers to care linkage exist and may include issues such as mental health and substance issues, fear and stigma, homelessness, lack of co-located facilities, and many others. Damien CareLink addressed these and other barriers for the target populations, which included PLWH who were tested confidentially and did not receive post-test counseling and those who had been lost to care, African Americans between the ages of 18-44, and Hispanics between the ages of 18-44. The priority areas to be addressed in accomplishing these goals included:

- Early HIV detection
- Connecting those PLWH who are not in care, into care
- Identifying those who are HIV positive, yet unaware of their HIV status
- Referrals of HIV negative individuals to HIV prevention, health education, and risk reduction

Louisiana Public Health Institute (LPHI): Baton Rouge, LA

The overall goal of the Louisiana Reentry Initiative (LRI) was to link and retain formerly incarcerated individuals living with HIV infection in Louisiana with an initial focus in Baton Rouge and services also provided in New Orleans. The project goals were to:

- Strengthen the current linkage and retention system for formerly incarcerated PLWH
- Implement a social stabilization intervention to link/retain formerly incarcerated PLWH
- Create broader statewide dialogue surrounding the impact of stigma on access and retention in care
- Promote the expansion and sustainability of retention programs for formerly incarcerated PLWH
- Improve the coordination between the Greater New Orleans Health Information Exchange (GNOHIE) and the electronic medical record in the Orleans Parish Prison, to enable more effective coordination of care for individuals living with HIV releasing from the prison system back to the community

LPHI served as the lead agency and evaluator for the LRI.

Medical AIDS Outreach: Montgomery, AL

Medical AIDS Outreach, Inc. (MAO) is a private, non-profit, community-based AIDS service organization that was established in 1987. It has transitioned from a volunteer education and service organization to a full-time primary care facility. By installing telemedicine equipment in satellite clinics staffed with a nurse throughout their network of partnering agencies, HIV-positive individuals living in rural areas of Alabama gained access to HIV specific medical care without the burden of driving to an HIV-specific medical clinic. The telemedicine equipment allowed a physician or nurse practitioner in the main office to look at a client who may be miles/hours away. This coordinated system of care ensured that all HIV positive individuals living in Alabama received the same level and quality of care.

St. Louis Effort for AIDS: St. Louis, MI

The Barrier Elimination and Care Navigation (BEACON) Project sought to locate and return to care PLWH in the Saint Louis region with no evidence of HIV primary care within the past year. The Project was a collaboration between the City Health Department, Saint Louis Effort for AIDS, and Washington University's Project ARK. When PLWH who were out of care were identified, they received services from one of the Care Navigation Teams. Each team was made up of an Engagement Coordinator (who also serves as their Ryan White Case Manager), two HIV-positive Peer Advocates, and a shared Community Nurse. BEACON clients had:

- Access to Peer Advocates to manage barriers of stigma, disclosure, and fear
- Support from Peer Advocates and Engagement Coordinators who assist clients in navigating social service resources
- Access to the Community Nurse for education and support in managing their treatment for HIV and any other medical conditions

Washington AIDS Partnership: Washington, DC

Positive Pathways was a program in the District of Columbia that assisted HIV-positive African Americans living in Wards 5–8 to participate with HIV medical care and supportive safety net services, with a particular focus on HIV-positive women and their partners. Led by Washington AIDS Partnership, Positive Pathways was a collaboration between eight community partners and the DC Department of

Health. Through a network of 12 trained peer Community Health Workers (CHWs) placed in community and primary care settings, Positive Pathways worked to support program participants to take full advantage of HIV medical care and other community services to improve their health and quality of life. CHWs worked at their employing organizations and in the community to identify individuals who were HIV-positive and not receiving HIV medical care in order to build trust and inform them about living with HIV, to provide personalized assistance to help them enter medical care, and to support them throughout the early part of their care until they were fully involved. Peers utilized their unique position to address barriers to care that could present challenges for other medical professionals. These CHWs provided trust-based information and education; helped clients overcome fear, denial, and stigma; conducted outreach and support deep in the community; took the time to walk clients through the often overwhelming healthcare system; and helped clients strategize to manage the logistics of caring for oneself in the context of a complicated life.

University of Alabama at Birmingham (UAB): Birmingham, AL

Birmingham Access to Care (BA₂C) was a collaborative effort between UAB 1917 Clinic and Birmingham AIDS Outreach (BAO). HIV primary care and social service providers have, for years, recognized the profound public health implications of the "lost to follow-up," or fallen out of care, population. Improving engagement in HIV care for PLWH not currently seeking primary care treatment may have other beneficial effects for the public health. Reductions in risk transmission behaviors among individuals linked to care and the beneficial effects of ART in reducing HIV viral load and transmissibility may result in decreased secondary cases of HIV infection if the program is successful in improving linkage, retention, and re-engagement in HIV care. BA₂C had a team of two Board-Licensed Social Workers, data programmers, and project supervisors to focus on the following goals:

- Increase re-engagement/linkage to HIV primary care among HIV-infected individuals lost to follow-up
- Obtain information regarding individual-level facilitators and barriers to HIV primary care linkage
- Increase the proportion of individuals lost to follow-up annually retained in comprehensive and coordinated outpatient medical services

In collaboration with Johns Hopkins University (JHU), AIDS United conducted a single, multi-part evaluation of 12 subgrantee programs, all of which provided services to people living with HIV (PLWH) to improve access to care and health outcomes. The overall program, Access to Care (A2C), aimed to increase access to and retention in HIV healthcare and support services. SIF served PLWH who were at greatest need, including individuals who knew their HIV status but were not in care due to barriers such as poverty, homelessness, untreated mental health issues, and substance abuse. SIF was a national program with projects located in the East Coast, South, Midwest, and West Coast. While the specifics of each SIF program were unique, all were evidence based. In addition, SIF programs shared common program models, including peer/patient navigation, community health workers, care coordination, intensive case management, and motivational interviewing.

SIF served a total of **4,704²** participants. Details of the 12 programs, the populations they serve, the program model, program activities, and the number of enrolled participants are outlined below in Table 1. Because intervention models and populations served vary from site to site, numbers of participants served also vary.

² UAB Control arm (83 clients enrolled) not included in this total. The total enrolled, including UAB's control arm, is 4,787.

Table 1: SIF subgrantees and number of participants served

Lead organization and location	Target population	Program model	Program activities	# Participants served
ActionAIDS, Philadelphia	Recently incarcerated	Intensive case management	Case management, expedited housing, back to work, and behavioral health services	78
AIDS Action Committee, Boston, MA	PLWH who are non-US born women, MSM or injection drug users	Integrated advocacy team	Peer support, health navigation, care coordination, motivational interviewing	342
AIDS Foundation Chicago (AFC), Chicago, IL	PLWH with a focus on people of color	Peer navigation and care coordination	System level enhancements, client level outreach, linkage to care, client level education	639
Amida Care: New York, NY	Low-income PLWH	Assertive community treatment	Mobile Engagement Teams, community health workers, care coordination, and motivational interviewing	833
AIDS Project Los Angeles (APLA): Los Angeles, CA	Low-income PLWH who are MSM, women, transgender, or heterosexual men	Strengths-based case management	Peer navigation and motivational interviewing	327
Christie s Place (CP): San Diego, CA	PLWH who are women of color with an emphasis on Latinas	Network of care	Peer navigation, care coordination, motivational interviewing, trauma-informed care	226
Damien Center: Indianapolis, IN	PLWH, 18-44, African American, Latino/a	Peer navigation, care coordination	Linkage to care, coordinated services	149
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	PLWH, African American, Latino/a, 25-44, recently incarcerated	Intensive case management	Peer navigation, ARTAS, pre/post release case management; disease intervention specialists	144
Medical AIDS Outreach (MAO),	PLWH in the rural	Telemedicine	HIV medical care, nursing services, mental health	244

Lead organization and location	Target population	Program model	Program activities	# Participants served
Montgomery, AL	South		and pharmacy services	
St. Louis Effort for AIDS: St. Louis, MI	PLWH who are ethnic minorities with a focus on African Americans	Care navigation team	Peer navigation and care coordination	322
Washington AIDS Partnership (WAP): Washington, DC	Low-income, female, African American PLWH	Peer navigation, care coordination	Community health workers, linkage to care	1313
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm only)	PLWH who have fallen out of care/lost to follow up	Strengths-based case management	Care coordination, motivational interviewing	87
TOTAL				4,704

Research Questions

The evaluation of A2C included impact research questions, outcome research questions, and implementation research questions. All subgrantees participated in the outcome and implementation evaluation. Only one program site (lead grantee University of Alabama at Birmingham) conducted an impact evaluation. SIF research questions are outlined below by question type.

Impact research questions (UAB)

Q1. Are participants who receive the BA₂C intervention more likely to have a suppressed viral load at 12 months than participants who receive standard of care? (Confirmatory)

Outcome research questions (all subgrantees)

Individual level

Q2. What is the trend in mean CD4 from baseline to 12 months among SIF participants?

Q3. What is the trend in mean viral load from baseline to 12 months among SIF participants?

Q4. What is the trend in % of clients reporting an unsuppressed viral load from baseline to 12 months among SIF participants?

Q5. Compared to national statistics, does the SIF program have a higher percentage of participants linked to care, retained in care, on HAART, and with a suppressed viral load?

Network level

Q6. Compared to the network six months prior to SIF, has the subcontractor network increased in density?

Q7. Compared to the network six months prior to SIF, does the subcontractor network average node degree increased?

Cost-analysis questions

Q8. What is the cost saving threshold for SIF?

Q9. What is the cost effectiveness threshold for SIF?

Q10. What is the cost per quality adjusted life-year (QALY) saved by delivering services in each program area?

Implementation research questions

All subgrantees will contribute data to answer the implementation research questions except for Q13 and Q15, which will only be answered by UAB.

Q11. How many clients were served by SIF?

Q12. How many clients were linked to care?

Q13. Are participants in UAB's BA₂C intervention arm more likely to be linked to care than participants in the standard-of-care arm? (UAB only)

Q14. How many clients were retained in care?

Q15. Are participants in UAB's BA₂C intervention arm more likely to be retained in care than participants in the standard-of-care arm? (UAB only)?

Q16. How many clients have a current prescription for ART?

Q17. How have subgrantees implemented peer navigation models/strategies?³

Q17a. What have been the biggest barriers to implementing peer navigation models/strategies?

Q17b. What methods have been employed to overcome these barriers?

Q17c. What has facilitated implementation of the peer navigation models/strategies?

Q17d. What has fostered these facilitating factors?

Q18. How have subgrantees implemented community health worker models/strategies?⁴

Q18a. What have been the biggest barriers to implementing community health worker models/strategies?

Q18b. What methods have been employed to overcome these barriers?

Q18c. What has facilitated implementation of community health worker models/strategies?

Q18d. What has fostered these facilitating factors?

Q19. How have subgrantees implemented care co-ordination models/strategies?⁵

Q19a. What have been the biggest barriers to implementing care co-ordination models/strategies?

Q19b. What methods have been employed to overcome these barriers?

Q19c. What has facilitated implementation of care co-ordination models/strategies?

Q19d. What has fostered these facilitating factors?

³ Sites will only be asked about the strategies/models that pertain to their programs.

⁴ Sites will only be asked about the strategies/models that pertain to their programs.

⁵ Sites will only be asked about the strategies/models that pertain to their programs.

Q20a. How have subgrantees implemented motivational interviewing?⁶

Q20b. What have been the biggest barriers to implementing motivational interviewing models/strategies?

Q20c. What methods have been employed to overcome these barriers?

Q20d. What has facilitated implementation of motivational interviewing models/strategies?

Q20e. What has fostered these facilitating factors?

Evaluation Overview

The evaluation of the SIF programs included three components: an impact assessment, an outcome evaluation, and an implementation evaluation. There were five main methods used: a randomized control trial, monitoring of patient-level data, economic analyses, case studies, and monitoring of sub-contractor networks. Table 2 below outlines the methods used for each of the three components of the SIF evaluation (impact, outcome, and implementation). The randomized control trial of BA₂C contributed to the implementation evaluation as well as the impact assessment. Monitoring of patient-level data tracked data for the implementation evaluation as well as the outcome evaluation. The economic analysis and the monitoring of sub-grantee networks both contributed to the outcome evaluation while the case studies are a methodology used for the implementation evaluation.

Table 2: Methods used for the SIF implementation, outcome, and impact evaluation

	Impact Assessment	Outcome Evaluation	Implementation Evaluation
Method			
Randomized control trial	Comparison of viral suppression in intervention arm to control arm		Monitoring of fidelity to program model, quality of program delivery, participant responsiveness, program differentiation, participant satisfaction. Comparison of linkage and retention in care in the intervention arm to the control arm
Monitoring of patient-level data		Monitoring of trends in mean CD4, mean viral load, and undetectable viral load	Number of clients: served, linked to care, retained in care, with HAART prescription
Economic analysis		Cost-saving and cost-effective thresholds; cost per QALY	
Case studies			Qualitative exploration of SIF program models and barriers to implementation
Monitoring sub-grantee networks		Comparison of network density and average node degree	

⁶ Sites will only be asked about the strategies/models that pertain to their programs.

In the following sections, we outline the following for each of the three components of the A2C evaluation, starting with the implementation evaluation and followed by the outcome evaluation and the impact assessment:

- Study design and procedures
- Analysis methods
- Findings
- Lessons learned

Implementation Evaluation

Study design and procedures

Three methods were employed to conduct the implementation evaluation: monitoring of patient-level data, case studies, and the randomized control trial (RCT) impact assessment.

Monitoring of patient-level data: The SIF project aimed to improve health outcomes by increasing utilization of HIV primary care services. Specifically, the program linked PLWH who were out of care into HIV care and treatment services. Linkage to care is necessary for participants to be retained in care and for access to HIV medication. SIF programs target various populations and work in variety of locations (refer to Table 1).

SIF programs do not have sampling frames and do not employ sampling strategies. Rather, they use a variety of methods to identify individuals in need of program services, and then recruit these individuals into their programs using recruitment techniques such as in-reach and peer-led outreach. Table 3 outlines enrollment and twelve-month follow-up by site and enrollment targets over the grant period.

Table 3: Number of SIF participants enrolled, 12-month follow-up, and target enrollment over the five-year grant period for the first cohort/three-year grant period for the second cohort.

Lead organization and location	Baseline n	Twelve-month n	Target enrollment
ActionAIDS, Philadelphia	78	49	100
AIDS Action Committee, Boston, MA	342	211	463
AIDS Foundation Chicago (AFC), Chicago, IL	639	334	680
Amida Care: New York, NY	833	690	1068
AIDS Project Los Angeles (APLA): Los Angeles, CA	327	245	695
Christie s Place (CP): San Diego, CA	226	161	200
Damien Center: Indianapolis, IN	149	93	160
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	144	75	130
Medical AIDS Outreach (MAO), Montgomery, AL	244	189	225
St. Louis Effort for AIDS: St. Louis, MI	322	213	360
Washington AIDS Partnership (WAP): Washington, DC	1313	310	2,314
University of Alabama at Birmingham (UAB): Birmingham, AL	170	119	250

As noted below in the Lessons Learned section, AIDS United and our subgrantees have found through the course of this initiative that the effort required to enroll and retain people with multiples barriers into HIV care was much greater than initially anticipated. Because of this, as well as delays in initial IRB approval, enrollment numbers have been lower than initially projected.

The national evaluation for SIF gathered data on three measures of implementation at the patient-level: linkage to care, retention in care, and having a current prescription for HAART. Linkage to care was our primary process measure. Table 4 provides information on the measure statement, cite, indicator, and frequency of data collection for linkage to care, retention in care, and HAART.

Table 4: Implementation measures collected by SIF subgrantees

Construct	Measurement statement	Cite	Indicator	When collected
Linked to care	One medical visit with a provider who has prescribing privileges within 30 days of enrollment (in a medical care setting with the purpose of receiving HIV related care)	Adapted from NYC State Department of Health AIDS Institute, 2006	% of SIF clients linked to care with 30 days of enrollment	Once at baseline (+30 days)
Retained in care	Two or more medical visits with a provider with prescribing privileges in a HIV care setting at least two months apart during the prior year	Horberg, 2010	% of clients retained in care	Baseline, 6 mo., 12 mo.
HAART	Current prescription for HAART	NA	% of clients with a current prescription for HAART	Baseline, 6 mo., 12 mo.

Table 5 provides an overview of data collection procedures—specifically, the source for the data, how the data were collected, and who collected or abstracted the data for the program. These procedures varied by site. While this might be a limitation to the study design, the SIF programs were designed with sustainability as a focus, and therefore subgrantees did not develop entirely new data collection systems (which would have been necessary for total standardization across sites), but rather were asked to refine and enhance established systems. While the sources and methods for data collection were not standardized across sites, as outlined above in Table 4, the measures used were standardized across sites.

As outlined in Table 5, the majority of subgrantees collected data on implementation measures through data abstraction from clinical records or surveillance.

Table 5: Implementation data collection procedures by subgrantee

Site	Linked to Care			Retained in Care			HAART Prescription		
	Source	Means	Individual	Source	Means	Individual	Source	Means	Individual
ActionAIDS: Philadelphia	CAREware	Interviewer administered or data abstracted from medical record	Care coach or care outreach specialist	CAREware	Interviewer administered or data abstraction from medical record	Care coach or care outreach specialist	CAREware	Interviewer administered or data abstraction from medical record	Care coach or care outreach specialist
AIDS Action Committee (AAC): Boston, MA	CM verification of medical appointments	Interviewer administered with data abstracted from ETO database and phone or paper verification from clinics	Case manager	Self report in case management assessment and/or case management verification of medical appointments	Interviewer administered with data abstracted from ETO database and phone or paper verification from clinics	Case manager	Case manager assessment	Interviewer administered with data abstracted from ETO database	Case manager
AIDS Foundation Chicago (AFC): Chicago, IL	Client Medical Record	Data abstraction	Regional care coordinators	Client Medical Record	Data abstraction	Regional care coordinators, evaluation manager	Client medical record, survey	Data abstraction, interviewer administered	Regional care coordinators
AIDS Project Los Angeles (APLA): Los Angeles, CA	Clinic records	Phone call	Peer navigator	Clinic records	Phone call	Peer navigator	Intake assessment, lab slips or medical release consent to clinics	Interviewer administered or data abstraction	Peer navigator
Amida Care: New York, NY	Pharmacy data & MET client Survey	Abstraction and interviewer administered	Program manager, case manager, peers	Claims data	Abstraction	Program manager, case manager, peers	Pharmacy data, MET client survey	Abstraction and interviewer administered	Program manager, case manager, peers
Christie's Place (CP): San Diego, CA	Management reports/client survey	Data abstraction/interviewer administered	Project coordinator/peer navigator	Management reports/client survey	Data abstraction/interviewer administered	Project coordinator/peer navigator	Management reports	Data abstraction	Peer navigator
The Damien Center (TDC): Indianapolis, IN	Management report/client survey	Data abstraction/Interviewer administered	Director quality assurance/linkage to care staff	Management report/client survey	Data abstraction/Interviewer administered	Director quality assurance/linkage to care staff	Management reports	Data abstraction	Director quality assurance
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	Surveillance data	Data abstraction from state surveillance data	OPH data management/analysis manager	Surveillance data	Data abstraction from state surveillance data	OPH data management/analysis manager	NA	NA	NA
Medical AIDS Outreach (MAO): Montgomery, AL	CAREware	Data abstraction	Registered nurse/social worker	CAREware	Data abstraction	Registered nurse/social worker	CAREware	Data abstraction	Registered nurse/social worker
St. Louis Effort for	SCOUT	Data abstraction	Lead navigator	SCOUT	Data abstraction	Lead navigator	NA	NA	NA

Site	Linked to Care			Retained in Care			HAART Prescription		
	Source	Means	Individual	Source	Means	Individual	Source	Means	Individual
AIDS (EFA): St. Louis, MI									
Washington AIDS Partnership (WAP): Washington, DC	EMR/EHR at clinic sites, lab reports and self-reports at CBOs, community health workers (CHW) report when CHWs attend visits with clients	Abstracted and interviewer administered	CHW	EMR/EHR at clinic sites, lab reports and self-reports at CBOs	Abstracted and interviewer administered	CHW	Client records, client self-report with prescription verification at CBOs	Abstracted and interviewer administered	CHW and state
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm only)	Medical Records	Data abstraction	Data Analyst	Medical Records	Data abstraction	Data Analyst	Medical Records + survey	Data abstraction + interviewer administered	Study coordinator and research assistant

Case studies: The case studies provide detailed descriptions of the program models as well as barriers and facilitators of implementation. This portion of the evaluation used an embedded case study design where subgrantees were embedded units of analysis within the larger program. Data were collected by JHU staff via one-on-one interviews. Interviews were semi-structured. We aimed to complete one case study for each SIF location, for a total of 12 case studies. We aimed to interview approximately two individuals at each sub-contracting organization—one individual who works at the administrative level (such as a supervisor) and one person who works at the service level (such as a peer). Interviews were conducted either over the phone or in person depending on sub-grantee location. Interviews are tape recorded and transcribed. Below is a table outlining by subgrantee the number of interviews conducted, the organizations interviewed, the interview dates:

Table 6: SIF subgrantee, number of interviews, organizations interviewed and interview dates for qualitative data collection

SIF subgrantee	Number of interviews	Organizations interviewed	Interview dates
ActionAIDS	Admin / Service: 3 Admin: 1 Service: 1	ActionAIDS COMHAR Gaudenzia Pathways to Housing	April – May 2015
AIDS Action Committee	Admin: 6 Service: 6	AAC Fenway PACT/JRI BIDMC ICH	February – March 2014
AIDS Foundation Chicago	Admin: 5 Service: 4	AFC MATEC Chicago House Mercy Care Program	July 2012 – October 2012
Amida Care	Admin: 4 Service: 4	Amida Care Housing Works Help/PSI Harlem United	June 2013 – July 2013
AIDS Project Los Angeles	Admin: 5 Service: 6	APLA DHSP MCA Clinic THE Clinic Rand Schrader Northeast Valley	December – January 2014
Christie’s Place	Admin: 4 Service: 2	Christie’s Place AVRC MCAP NCHS	May – June 2012
The Damien Center	Admin:2 Service:7	The Damien Center Brothers United Women in Motion Indiana Latino Institute Community North Hospital Bellflower Life Care	July – August 2015
Effort for AIDS	Admin: 3 Service: 3	Washington University Infectious Disease Clinic Washington University BEACON Team St. Louis Effort for AIDS	April 2014
Louisiana Public Health	Admin:6	Louisiana Public Health	June – August 2015

SIF subgrantee	Number of interviews	Organizations interviewed	Interview dates
Institute	Service:2	Institute Capitol Area Reentry Program CrescentCare Women with a Vision Louisiana State Health Department	
Medical AIDS Outreach	Admin: 4 Service: 5	MAO-Montgomery MAO-Selma MAO-Dothan AIDS Action Coalition Selma AIR	September – October 2014
University of Alabama	Admin: 2 Service:2	Birmingham AIDS Outreach University of Alabama at Birmingham	January – February 2016
Washington AIDS Partnership	Admin: 6 Service: 5	Washington AIDS Partnership Whitman-Walker Health Unity Health Care Chartered Health Plan Women’s Collective Institute for Public Health Innovation Family Medical Counseling Services	October – November 2012

Case study data were collected using a semi-structured interview guide. The interview guide included questions and probes about the program models, barriers to implementing the program, as well as factors that facilitated implementation of the program. Some example case study questions included: “What have been your biggest barriers to doing this work?”; “What successful strategies has [your organization] used to overcome these barriers?” and “Can you describe any unsuccessful strategies [your organization] tried?”

BA₂C RCT impact study: The impact assessment took place at the University of Alabama at Birmingham’s 1917 Clinic. Participants were randomized to either a standard-of-care arm or an intervention arm that provided strengths-based case management and motivational interviewing from community social workers. A component of the implementation evaluation is embedded within the RCT impact study. Specifically, the study assessed differences between the intervention and comparison arm in linkage to care and retention in care. Measures used to assess linkage and retention in care for the RCT were identical to those described above in Table 4. HIV primary care visit information was abstracted from 1917 Clinic’s medical records by the study’s data analyst. Additionally, we attempted to obtain releases of information from participants who elect to attend HIV primary care at a location other than the UAB 1917 Clinic. (Further details about data collection are outlined below in the Impact Study section.)

The randomized control trial enrolled 170 participants (87 in the intervention arm and 83 in the control arm).

Analysis methods

Please find below a description of the analysis method for the implementation evaluation by research question.

Implementation Evaluation:

Q11. *How many clients were served by SIF?* Count of number of enrolled participants.

Q12. *How many clients were linked to care?* Count of number of participants with verification of a visit for HIV medical care with a provider with prescribing privileges.

Q13. *Are participants in UAB's BA₂C intervention arm more likely to be linked to care than participants in the standard-of-care arm?* (UAB only) We answered this question using unconditional univariate odds ratios with a 95% confidence interval. (See Q1 for additional information on our analysis plan for assessing associations.)

Q14. *How many clients were retained in care?* Count of number of participants with two visits at least two months apart in the past twelve months.

Q15. *Are participants in UAB's BA₂C intervention arm more likely to be retained in care than participants in the standard-of-care arm?* (UAB only) We answered this question using unconditional univariate odds ratios with a 95% confidence interval. (See Q1 for additional information on our analysis plan for assessing associations.)

Q16. *How many clients have a current prescription for HAART?* Count of number of participants with a current prescription for HAART.

Q17-20. *How have sub-grantee sites implemented the following program models/strategies: peer navigation, community health workers, care coordination, motivational interviewing?* (case studies)

Qualitative data were transcribed verbatim. We used directed content analysis to analyze our data. Our interview guide included open-ended questions as well as probes to explore participants' experiences with predetermined categories such as collaboration, barriers, and relationships. Initially, we read through all transcripts without coding to allow for immersion. We then simultaneously coded the data and made notes of additional themes not captured in the initial coding schema. Our initial coding schema was created based on predefined research questions, the research literature, and our interview guide. The data were coded by the PI in this study (Dr. Maulsby) and five PhD student research assistants. Throughout the coding process, the team met regularly (weekly to bi-monthly) to discuss any discrepancies between coders as well as to discuss themes that emerged throughout the coding process. We discussed themes at both the site level and across sites. Codes were further defined and re-classified based on these discussions and resolution of coding discrepancies.

Findings

Monitoring of patient-level data: The implementation evaluation of SIF gathers data on enrollment, linkage to care, and retention in care. Findings are below in Table 7.

The percentage of participants linked to care within 30 days varies across sites from 28% in Indianapolis, Indiana and Birmingham, Alabama to 100% in Los Angeles, California and Montgomery, Alabama. Across the cohort, 59% (2,779/4,704)⁷ of participants were linked to care within 30 days of enrollment and 86% (4022/4704) of participants were linked to care during the program. The majority of subgrantees reported HIV retention in care percentages above 75% at twelve months. For BA₂C, as part of the additional

⁷ UAB control excluded from the numerator and denominator (n=83).

analyses of the data from the RCT, we also assessed retention in HIV care at 12 months with missing as failure (rather than missing=missing, which is presented below in Table 7). When missing was considered failure we found the 62.7% of the control arm were retained in care at 12 months (52/83) compared to 59.8% (52/87) of the intervention arm.

Across the cohort, 63% of participants (1570/2490) had current HAART prescriptions twelve months after enrollment. Two subgrantees (Los Angeles and Indianapolis) were not able to contribute to portions of this part of the implementation evaluation due to challenges in gaining access to data on HAART.

Table 7: Linkage, retention, and HAART use among SIF participants by grantee

Lead organization and location	# participants served	Linked to care within 30 days % (n/d)	Linked to care (without 30 days' restriction) % (n/d)	Retained in care (at twelve months) % (n/d)	HAART prescription (at twelve months) % (n/d)
ActionAIDS, Philadelphia	78	83% (65/78)	97% (76/78)	82% (40/49)	92% (45/49)
AIDS Action Committee, Boston, MA	342	31% (106/342)	82% (279/342)	85% (180/211)	68% (144/211)*
AIDS Foundation Chicago (AFC), Chicago, IL	639	57% (366/639)*	69% (440/639)*	45% (150/334)*	59% (198/334)*
Amida Care: New York, NY	833	53% (440/833)	87% (722/833)	73% (506/690)	51% (349/690)
AIDS Project Los Angeles (APLA): APLA arm	245	100% (245/245)	100% (245/245)	65% (128/197)*	63% (125/197)*
AIDS Project Los Angeles (APLA): DHSP arm	82	83% (68/82)	95% (78/82)	92% (44/48)	Not available ⁸
Christie s Place (CP): San Diego, CA	226	91% (205/226)	93% (210/226)	74% (119/161)*	69% (111/161)*
Damien Center: Indianapolis, IN	149	28% (41/149)*	79% (118/149)*	85% (79/93)*	Not available
Louisiana Public Health Institute (LPHI): Baton Rouge, LA ⁹	144	40%	83% (120/144)	60% (45/75)*	36% (27/75)*

⁸ DHSP collected data on HAART use at baseline only.

⁹ Louisiana gets their visit and lab from state partners. There is a considerable delay in getting this data, usually several months. This delay is anticipated and results in their clinic and lab data looking artificially low.

Lead organization and location	# participants served	Linked to care within 30 days % (n/d)	Linked to care (without 30 days' restriction) % (n/d)	Retained in care (at twelve months) % (n/d)	HAART prescription (at twelve months) % (n/d)
		(57/144)			
Medical AIDS Outreach (MAO), Montgomery, AL	244	100% (244/244)	100% (244/244)	95% (179/189)	96% (181/189)
St. Louis Effort for AIDS: St. Louis, MI	322	45% (144/322)*	89% (286/322)	90% (191/213)	73% (156/213)*
Washington AIDS Partnership (WAP): Washington, DC	1313	59% (774/1313)	86% (1124/1313)	70% (216/310)	57% (178/310)*
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm only)	87	28% (24/87)	93% (81/87)	85% (52/61)	92% (56/61)
University of Alabama (UAB): Birmingham, AL (control arm only)	83	24% (20/83)	92% (76/83)	90% (52/58)	90% (52/58)
TOTAL (excluding UAB control arm)	4704	59% (2779/4704)	86% (4022/4704)	73% (1929/2631)	63% (1570/2490)

*Greater than 10% missing. Interpret with caution.

Case studies:¹⁰

The case studies qualitatively assessed barriers and facilitators of program implementation. The sections below highlight cross-subgrantee findings. The accompanying report, "Social Innovations Fund Case Studies: Experiences with Linkage and Retention in HIV Care across Twelve Subgrantees and their Partners," provides a more detailed site-level analysis of program implementation, including a description of program models.

Barriers to implementing linkage and retention in care programs

Four themes that emerged across the SIF programs as barriers to program implementation were the intensity of client needs, recruiting and retaining participants, staffing and administrative hurdles, and challenges related to working with multiple partner organizations. These cross-cutting themes are discussed in more detail below.

Theme 1: Intensity of client needs

Across all 12 SIF subgrantees, the intensity of client needs posed a formidable barrier to program implementation. SIF participants had complex, interrelated needs that needed to be addressed before participants' health care could become a priority. Specifically, untreated mental illness and substance

¹⁰ Detailed descriptions of the sub-grantee program models and sub-grantee level findings are included in the accompanying report, Social Innovations Fund Case Studies: Experiences with Linkage and Retention in HIV Care across Twelve Subgrantees and their Partners

use were HIV comorbidities that were universally mentioned as unmet needs that prevented participants from successful re-engaging in care. All subgrantees described a lack of stable, affordable housing. They explained that lack of housing posed the greatest barrier to linkage and retention in care. Subgrantees also found a severe dearth of access to resources and services to address the housing, mental health, and substance use needs of their clients. Additional needs that were also frequently highlighted by subgrantees were employment, transportation, and dental care needs.

To address clients' needs, most SIF programs referred their participants to high-quality social services programs with which their staff had an ongoing relationship. These programs were sometimes housed within the lead SIF agency or a partner agency; other times, these programs were external to the SIF network. SIF implementers had a deep knowledge of the program being referred to and a strong relationship with the individuals who provided social services, which led to a smooth referral process. Some SIF subgrantees referred directly to social services while others worked through existing case management programs. Regardless of the strategy used, however, program implementers emphasized severe shortages of services, especially for housing, mental health, substance use, and dental services.

Theme 2: Recruitment and retention

Most SIF subgrantees faced challenges with participant recruitment. The challenges varied considerably depending on the recruitment strategy used. All implementers reported difficulties in communication with potential participants, enrolled participants, or other agencies working with PLWH. Many participants were geographically unstable, and subgrantees found it challenging to locate participants with out-of-date addresses and phone numbers. As a result, contact records, from sources such as medical records and case management records, were often outdated. Many subgrantees described locating participants as a time intensive and burdensome process with low yield. Successful participant recruitment and retention relied on reliable, ongoing communication between and within partner agencies about participants. Some agencies faced barriers to receiving and sharing participant-level information with health care providers, community based organizations, health departments, and social organizations because of Health Insurance Portability Accountability Act (HIPAA) restraints. Other subgrantees, such as Amida Care, faced challenges with intra-agency communication systems that were not optimal. Subgrantees working with incarcerated populations faced unique communication challenges as their program participants transitioned out of jail or prison: incarcerated individuals often did not know their residence immediately following release and also lacked access to a stable phone number.

Program implementers adopted a range of diverse and creative strategies to reach clients and indicated that it was important that programs have the flexibility to try a variety of approaches. Subgrantees facing challenges reaching participants on out-of-care lists made course corrections and relied more heavily on recruitment and referrals through partner organizations, and other avenues, such as a call-in hotline. Email and social media, such as Facebook, also emerged as a successful way to keep in contact with participants, even those with many basic needs. One of the most important strategies for retaining participants was the quality of relationships with A2C staff.

Theme 3: Staffing and administrative challenges

The majority of subgrantees faced several challenges related to staffing. Many programs experienced high staff turnover. Turnover among staff who had direct participant contact, such as navigators and community health workers, was viewed as particularly problematic for linkage and retention in care programs. Respondents described that successful linkage and retention in HIV care relied heavily on

having strong rapport with participants, as well as strong relationships within the community. This cadre also needed intense, ongoing job training. Building necessary skills and relationships took time and commitment. Building relationships, in particular, compounded challenges when transitioning in new staff. A closely related theme was a high level of burnout among staff who worked directly with clients. While a small number of interviewees attributed this to an unsupportive work environment, others explained that staff burnout was a result of the demanding and highly personal nature of the work, particularly for peers. Peers, who were usually PLWH, often had similar background to participants and shared their own stories when relating with and motivating participants to engage in HIV medical care. Program implementers created opportunities, such as peer meetings and all program staff meetings, for direct service staff to share their experiences, lessons learned, and to problem solve challenges in program implementation.

While all subgrantees that used peer models saw peers as vital to engaging participants, several reported challenges around recruiting and training peers. Peers handled significant responsibility across a wide variety of areas and finding individuals with the unique and varied skillset needed was challenging. Respondents reported a need to conduct ongoing, supportive training in areas such as program implementation, data collection, professional conduct, and maintaining professional boundaries with participants. Both direct service staff and supervisory staff reported that a close working relationship between direct service staff and their supervisors was critical for addressing some of the challenges faced by peers.

A related administrative challenge was the burden of data collection, data management, and meeting reporting requirements. Several subgrantees indicated that their program faced challenges meeting the reporting requirements of various funders, including SIF match funders and other federal funders. Respondents reported frustration over data collection systems and processes that were time intensive, duplicative, and incompatible across partner agencies. A few subgrantees reported that expectations or methods for data collection were not clear and changed midway through the program without explanation. To address these challenges, grantees adapted their data collection systems (for example by switching from paper to electronic systems), provided additional training and supervision of staff, and developed creative ways to provide time for data related activities (such as designated meetings for data entry and management).

Theme 4: Partnerships

Although partnerships between implementing partners were seen as critical to successfully linking and retaining clients in care, significant time and effort was needed to harmonize these relationships. Through the Access to Care initiative, very different organizations had the opportunity to work together towards a common goal—and at times these differences were challenging. Respondents indicated that they needed to overcome cultural differences between organizations. Initially, some HIV medical providers were reluctant to work with direct service staff. There were also differences in the administrative cultures of organizations. While some partners were quite nimble, others faced considerable bureaucracy. Several sites reported challenges in obtaining buy-in from other local agencies that focused on PLWH. This barrier was explained as a result of a scarcity of resources, which fueled competition for clients and heightened concern over duplication of services.

The primary strategy used to address these challenges was open communication to quell concerns and to build mutual understanding in an effort to develop even stronger working relationships across organizations.

Table 8: Cross-cutting barriers to program implementations

Theme	Illustrative quote
1. Intensity of client needs	<p><i>...they re just trying to maintain life, and so when you get to a point where you don't know where you're staying that night, you don't know if you'll be safe where you're staying wherever you can find, if you'll be eating, that takes precedence over 'Am I going to go to my doctor today? Did I get my script filled on time?' And then also you have other issues coming into play, trauma, maladaptive coping skills like substance abuse that leads to addiction. All of that works as barriers against linkage to care and continuity of care." (Louisiana)</i></p>
2. Recruitment and retention challenges	<p><i>One of the first barriers, I think, has just been trying to locate clients that are considered lost to care. Sometimes locator information at the clinic was poor and we tried out basically every other method available to us and we still were not able to find patients in the field, clients that have been lost to care. So that's been a huge barrier to the program. I think more than 30 percent of the clients that we've been trying to locate we've just not been able to find at all. And so I think that's been a lesson learned for our program." (Los Angeles)</i></p>
3. Staffing and administrative challenges	<p><i>We don t want them [peers] to do straight up counseling with their supervisor, but they need an outlet and a regular one in order to survive doing the work because it is really demanding. A good supervisor can help a peer with is even though the line's a little more blurry for a peer than for a traditional staff person, we still need them to maintain some boundaries on a professional level and for their own well-being. So being able to develop a really trusting relationship with a clinically trained supervisor I think is important to help anticipate what's going to happen in this relationship." (St. Louis)</i></p>
4. Harmonizing partnerships	<p><i>Originally, it was challenging or interesting in terms of getting the peer as a respected member of the team amongst medical providers, and I will say that she has, partially because of who she is, but she's been incredibly successful in establishing herself as a professional, and that has impacted the way in which the medical providers even see other peer navigators at [organization name] within the community, and I believe that it's positively impacted how well respected they are." (San Diego)</i></p>

Cross-cutting facilitators to implementing linkage and retention in care programs

Three themes emerged as factors that facilitated SIF program implementation were strong relationships with partner organizations; the flexible and innovative nature of the SIF programs; and the expertise, dedication, and passion of staff. These factors are described in detail below.

Theme 1: Strong partnerships with organizations with expertise in a range of areas

Across all sites, respondents reported that having strong partnerships with agencies that provided expertise in a range of areas was critical to program success. Specifically, subgrantees indicated the importance of having strong relationships with organizations providing social services and HIV primary care. For programs where the lead agency did not provide wraparound services, it was necessary to partner with organizations providing these services to meet the needs of participants. In particular,

housing, and mental health and substance use treatment was needed. Having strong partnerships with medical providers was also critically important, and many subgrantees recommended basing their staff at medical providers' offices as a way to strengthen these relationships. For example, one subgrantee had co-located case management, peer navigation, HIV primary care, and pharmacy services. Another subgrantee lauded working with small HIV primary care providers because small HIV primary care providers were viewed as having a keen grasp of community needs. A related theme was the importance of partnering with organizations that had expertise working with specific populations, including lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) individuals and racial minorities who face unique challenges related to immigration or multiple forms of stigma.

Strong relationships with organizations providing social services and with HIV primary care providers were useful for identifying potential participants and provided the benefit of a "warm" handoff. Because of these partnerships, SIF subgrantees were able to better serve their SIF clients—care was provided more quickly, a greater variety of services were provided to participants, and follow-up with clients who missed appointments was more achievable. In addition, strong relationships with HIV medical providers facilitated timely data collection and reporting for tracking participant health status and for meeting evaluation requirements.

Respondents reported that having strong relationships at the onset of the project, having staff dedicated to building and maintaining relationships, and frequent communication between partners facilitated the building of strong partnerships. Specifically, respondents recommended open communication from the onset of the program (even as early as the proposal writing stage) and maintaining strong communication through regular (e.g., monthly) partner meetings. During these meetings, subgrantees reported focusing on topics such as strategizing to address challenges, sharing lessons learned, handling issues related to caseloads (such as size, complexity, and specific cases), trainings, supporting staff, and building new relationships with organizations. Several respondents also reported that a lead agency that was established and well-respected within the community was helpful for building partnerships.

Theme 2: Innovative and flexible program models

Several respondents indicated that innovations unique to their interventions facilitated success. These innovations were methodological as well as programmatic. For example, in Philadelphia, ActionAIDS developed an Acuity Scale that they used to assess participant vulnerability. The scale was developed over 18 months with staff from partner organizations. The Acuity Scale's scoring system was used to determine clients' needs and to tailor the intervention to the participant. Louisiana's SIF program used process mapping to identify bottlenecks, improve efficiency, and identify optimal opportunities for meeting with participants within the jail. In Washington, DC, the SIF program worked with the University of the District of Columbia to develop an eight-month training for community health outreach workers, and in St. Louis, an emergency stabilization fund granted program participants access to a remedy for unexpected expenses. This fund helped BEACON participants to eliminate barriers outside the scope of many other funding streams, such as Ryan White Funding.

Trial and error are inherent to the iterative processes of program innovation. Respondents described the flexible nature of the SIF programs as being important for quick programmatic course corrections. Respondents indicated the utility of being able to adapt program strategies. This flexible approach facilitated the acknowledgment of implementation challenges and provided subgrantees with the opportunity to adapt program strategies accordingly, resulting in strong SIF program models.

Theme 3: Characteristics of staff

Across all respondents, the passion and dedication of staff were universally recognized as being instrumental to program success. In particular, respondents lauded the connections between direct service staff and the individuals served by the program. Respondents noted the importance of hiring staff with whom the SIF program participants could relate. Peers were recognized for their unique ability to build trust and rapport with clients and to serve as role models in ways that other cadre of staff (such as nurses and case managers) was not. Supervisors of direct service staff played an important role by providing support, guidance, and supervision to direct service staff. Having clearly defined roles and responsibilities (for example between case management and direct services staff) helped to ensure fluid, seamless, and team-oriented relationships among staff.

Table 9: Cross-cutting facilitators of program implementation

Theme	Illustrative quote
1. Strong partnerships with organizations with expertise in a range of areas	<i>I think what has worked best for us...relationship, relationship, relationship. The old kind of old boys' network that we talked about years ago. Things that happen in the back room. I think that [Organization D colleague] has worked really hard at developing very strong relationships with some of our key referral sources...we've got a few that we can really kind of count on and rely on. And she's just really worked hard at developing a trusting relationship with them, being incredibly reliable. They can count on her, when they call we will return the phone call, we will be there. We get information back to them so there's a nice kind of collaborative process that goes on..." (Chicago)</i>
2. Characteristics of staff	<i>You know most times people make that first initial appointment, sometimes they don't, but sometimes they make that first initial appointment and then make a decision not to go back to the doctor 'I'm not going to deal with this right now.' But some form of magic takes place in the comfort that [linkage specialist] is able to offer to these people." (Indianapolis)</i>
3. Innovative and flexible program models	<i>The creation of the acuity vulnerability scale under our ASSIST program is now is being used across the board, both in our general prison program, and our agency program, in our CARE Coach model. Everybody who is incarcerated and we get a referral for, has an acuity vulnerability done on them from the intake on, and then every six months after that. So that is huge, that's one huge impact. It's really helped us to look at where our clients are. You know we talk programmatically, we're going to meet clients where we are, but how do we know where they are if we don't gauge it, and we don't continue to gauge it? So, that's been a really, it's something that, you know, has changed the way that we do things." (Philadelphia)</i>

BA₂C randomized control trial: We observed that intervention arm participants were more likely to be linked to care, although these results were not statistically significant. Retention in care at T2 was more likely for participants in the control arm, although these results were also not statistically significant. These results may be explained by the nature of the intervention which provided intensive support for

individuals for the first six months of study enrollment, thus potentially providing impact on initial linkage to care. Once the intensive phase of the intervention was complete, participants may have had more barriers to sustaining retention in medical care.

Table 10: Linkage and retention in care among UAB Birmingham Access to Care (BA2C) participants

Patient characteristics, n (%) or median (IQR)	Intervention		Control		OR (95% CI)	p-value
	n/N (%)		n/N (%)			
Linked to care within 30 days of contact	24/87	27.6%	20/83	24.1%	1.2 (0.6-2.4)	0.6
Linked to care without 30-day parameter	81/87	93.1%	76/83	91.6%	1.2 (0.4-3.9)	0.7
Retained in care at T2 ¹¹	52/61	85.3%	52/55	94.6%	0.3 (0.1-1.3)	0.1

Lessons learned

The implementation evaluation suggests that SIF grantees are successfully implementing HIV linkage and retention in care programs. 4,704 participants are enrolled in the evaluation (with additional clients being served through the program but not enrolled in evaluation).

Monitoring of patient-level data: One of the key lessons learned through this initiative is the very high degree of effort that is required to engage people living with HIV who have fallen out of care back into care, particularly when they are experiencing multiple competing priorities such as homelessness or unstable housing, mental health issues, substance abuse, histories of trauma, other medical concerns, and employment and transportation challenges, among others. Many of our subgrantees proposed very high enrollment numbers in their initial proposals for funding and, even with subsequent reductions in enrollment goals upon funding award, have found that more effort than originally anticipated has been required to connect people with multiple barriers to care into HIV care. Accordingly, actual enrollment has been lower than initially projected. Fifty-nine percent of these participants were linked to care within thirty days of enrollment and 86% were linked to care at some point following enrollment. Across the entire cohort, among those with twelve-month data, 73% were retained in care and 63% had a current HAART prescription. Nationally among the 1.2 million estimated PLWH, the CDC estimates that 40% are engaged in care¹² and 37% are prescribed HAART (1).

Case studies: The case studies assessed and analyzed barriers and facilitators of program implementation. Across sites, several cross-cutting barriers emerged. Universally, the high level of participant need was a barrier to implementing linkage and retention in care programs. Staff reported a high acuity of unmet needs among participants and a dearth of local resources (such as housing programs) to address these needs. The most frequently mentioned needs among individuals interviewed were housing and services for mental health issues and substance use. Staff reported a range of strategies to help participants address these needs (including referrals to partner agencies and

¹¹ Denominator limited to all participants with a HIV medical visit with a provider with prescribing privileges in the past year.

¹² Engaged in care defined by the CDC as having a HIV medical care visit during the Medical Monitoring Project's sampling period of Jan-April 2011.

helping participants to navigate social services). Having close relationships with partner organizations was seen as a vital to making sure that participant needs could be addressed.

Recruitment and retention of program participants was another cross-cutting challenge to program implementation. Contact details of potential and enrolled participants were often out of date. Participants were highly transient, and this complicated locating participants for enrollment and services. Again, partnerships with community-based agencies that provided social services was an important strategy used to identify potential participants through referrals into the program and to keep in contact with existing participants.

Staffing and administrative challenges also posed barriers to program implementation, in particular high staff turnover, a need for a frequent staff training, and difficulty finding individuals with the unique qualifications needed to successfully provide direct linkage and retention in care services. While strong partnerships with a diverse set of organizations was seen as a necessary element for successful program implementation, it also brought with it challenges. The most commonly mentioned challenges in this area were cultural differences between organizational partners and competition between agencies for funding and participants.

In addition to strong partnerships, another facilitator of program implementation was the unique innovations of the SIF programs (such as ActionAIDS's Acuity Scale, WAP's CHW training, and St. Louis's emergency stabilization fund). Finally, the dedication and passion of the staff were universally recognized as being instrumental to program success. In particular, peers were lauded for their unique ability to relate with participants, build rapport, and act as positive role models.

BA₂C Randomized Control Trial (RCT): Many of the lessons learned from the RCT mirror those of other SIF projects. Once out of care participants were identified and located, achieving re-engagement in, or linkage to, care within 30 days is extremely difficult, even for participants in the intervention arm who received additional support through a community social worker. Again, we believe that this is primarily due to the extraordinary challenges in daily life that many in this population face. Anecdotally, we often spoke of "life chaos" as a reason that many participants were not immediately re-engaged; however, even our conceptualization of "life chaos" did not include the extreme socio-economic and psychological barriers faced by individuals living in poverty, often in the remotest of locations. However, when given time and consistent support, the most vulnerable individuals can be located, re-engaged, and, ultimately, retained in HIV medical care.

Outcome Evaluation

Level of evidence, outcome evaluation

The monitoring of patient-level data in the outcome evaluation has low internal validity and low to moderate external validity. This portion of the national evaluation used a pre-/post-test design, and therefore is subject to threats to internal validity. Pre-/post test designs are subject to all seven of the primary threats of internal validity (history, maturation, statistical regression, selection bias, experimental mortality, instrumentation and testing). This is primarily due to the fact that a pre-/post test design is nonexperimental and does not include a randomized control group (or other design features) to address these threats. In addition, this portion of the national evaluation used purposive sampling, which weakens external validity. However, it was conducted in a variety of settings and locations across the United States with diverse target populations. Similar findings across subgrantees

could suggest a higher level of generalizability. The case studies were qualitative and were conducted in a way as to achieve high to moderate validity including an analysis of disconfirming or deviant cases and respondent validation (2).

Study design and procedures

Three methods will be employed to conduct the outcome evaluation: monitoring of patient-level data, economic analysis, and monitoring sub-grantee networks.

Monitoring of patient-level data: The national evaluation of SIF gathered data on three outcome measures: mean CD4, mean viral load, and percent suppressed viral load. Baseline data were collected at enrollment or soon thereafter. Therefore, baseline measures aimed to represent clients' health status prior to exposure to the program. Follow-up data were collected twelve months following enrollment.

Outcome data were collected using a variety of methods and sources (Table 11). The majority of outcome data were extracted from medical records, including existing electronic databases, or from paper records. If staff were not familiar with the databases or data collection at the start of the project, they received training in timely and complete data extraction techniques and continued to receive on-going support as needed. Data were collected, monitored, and cleaned on an on-going basis by the subgrantees. Subgrantees reported aggregated data to JHU every six months via standardized excel spreadsheets (data shells) that included a series of monitoring data checks. JHU checked the data shells for data inconsistencies and analyzed the aggregate data for monitoring and evaluation purposes.

Table 11: Outcomes data sources by subgrantee

Lead organization and location	Source for outcome data	Outcome data collection method	Individual responsible for outcome data collection
ActionAIDS, Philadelphia	CareWARE	Interviewer administered or data extraction from medical record	Care coach or care outreach specialist
AIDS Action Committee, Boston, MA	Clinics & case management assessment (clients turn in lab reports to CM, CM enter into ETO. Or self report (esp. at baseline)	Data extraction and interviewer administered	Case manager
AIDS Foundation Chicago (AFC), Chicago, IL	Client medical record; survey	Data extraction, interviewer administered	Regional care coordinators
Amida Care: New York, NY	Lab data & MET client Survey	Extraction and interviewer administered	Program manager, case manager, peers
AIDS Project Los Angeles (APLA): Los Angeles, CA	Lab slips or fax medical release to consent to individual clinics	Data extraction	Peer navigator
Christie s Place (CP): San Diego, CA	Lab slips/ management reports	Data extraction	Peer navigator
Damien Center: Indianapolis, IN	CAREWare or CaseManager database	Data extraction	Dir quality assurance
Louisiana Public Health Institute (LPHI): Baton	Surveillance data	Data extraction from state surveillance data	OPH Data Management / Analysis manager

Lead organization and location	Source for outcome data	Outcome data collection method	Individual responsible for outcome data collection
Rouge, LA			
Medical AIDS Outreach (MAO), Montgomery, AL	CareWare	Data extraction	Registered nurse/social worker
St. Louis Effort for AIDS: St. Louis, MI	SCOUT and state surveillance database	Data extraction	Lead navigator and state
Washington AIDS Partnership (WAP): Washington, DC	Client records and state surveillance database	Extracted and interviewer administered	CHW and state
University of Alabama at Birmingham (UAB): Birmingham, AL	Medical records	Data extraction	Study coordinator

Table 12 below outlines study retention (monitoring of patient-level data) by subgrantee. The national evaluation monitors attrition using an ‘enrollment schematic’ form that asks subgrantees to indicate the total number of participants enrolled and the total number of participants with follow-up data. Of the total 4,787, enrolled 4,346 were eligible for twelve-month follow-up data collection. Of those eligible, data have been collected on 2,689 (62%). Among those without twelve-month data collected (2,098), 21% (441) have not been enrolled in the program long enough to reach twelve months, and the remaining 79% (1,657) are lost to the evaluation.

Table 12: Retention at twelve months by subgrantee

Lead organization and location	# enrolled	# 12-month follow-up completed ¹³	# not eligible for 12-month follow-up	# without 12-month follow-up data (% of total enrolled)
ActionAIDS, Philadelphia	78	49	5	24 (31)
AIDS Action Committee, Boston, MA	342	211	46	85 (25)
AIDS Foundation Chicago (AFC), Chicago, IL	639	334	96	209 (33)
Amida Care: New York, NY	833	690	36	107 (13)
AIDS Project Los Angeles (APLA): Los Angeles, CA (APLA)	245	197	0	48 (20)
AIDS Project Los Angeles (APLA): Los Angeles, CA (DHSP)	82	48	7	27 (33)
Christie s Place (CP): San Diego, CA	226	161	2	63 (28)

¹³ Subgrantee data came from multiple sources. The n for the follow-up data at 12 months indicates that a participant had a follow-up data point from any source. For example, a participant with lab data at 12 months but no survey data at 12 months was counted in the table above as having follow-up data at 12 months.

Lead organization and location	# enrolled	# 12-month follow-up completed ¹³	# not eligible for 12-month follow-up	# without 12-month follow-up data (% of total enrolled)
Damien Center: Indianapolis, IN	149	93	10	46 (34)
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	144	75	7	62 (43)
Medical AIDS Outreach (MAO), Montgomery, AL	244	189	0	55 (23)
St. Louis Effort for AIDS: St. Louis, MI	322	213	41	68 (21)
Washington AIDS Partnership (WAP): Washington, DC ¹⁴	1313	310	191	812 (62)
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm)	87	61	0	26 (30)
University of Alabama at Birmingham (UAB): Birmingham, AL	83	58	0	25 (30)
Total	4,787	2,689	441	1,657 (35)

Currently, JHU lacks complete follow-up data on approximately 44% of the sample; as a result, these individuals were excluded from analyses that require follow-up data, such as assessment of trends in health outcomes at baseline and twelve months. This exclusion could introduce bias, as the participants who were retained could be systematically different from those who are not. This bias is a threat to internal validity. Further analyses of missing data are addressed below in the analysis section.

Subgrantees faced a variety of challenges in collecting complete data, especially complete follow-up data and complete clinic/lab data. Several grantees have described challenges in getting follow-up data from clients primarily due to the transient nature of the participant population. In addition, subgrantees reported challenges or significant delays in getting clinical data from partners, including medical provider's offices and health departments. Increased communication, strengthening of partnerships, and formalizing relationships through MOUs helped to address some of these challenges.

We conducted power analyses for detecting a difference in mean CD4 from baseline to twelve months. At alpha .05, a sample size of 22 per group would give us a power of .80. All subgrantees have follow-up data on more than 22 individuals.

¹⁴ Washington AIDS Partnership faced considerable challenges in the first years of the program with follow-up data collection. As a result, twelve-month data will not be available for a substantial proportion of their participants (62%). A new evaluator for Washington, DC was hired in 2013 and the majority of the initial challenges faced by this subgrantee have been addressed

Economic analysis: The national evaluation included a cost analysis and a threshold analysis. The cost analysis estimated the cost of delivering the program locally. The cost analysis was conducted from the payer perspective as well as from the societal perspective. The cost analysis from the societal perspective included the payer costs plus the costs to the client (such as costs for travel, time and dependent care), while the cost from the payer perspective did not include costs to the client and only include cost to the implementing agency. The threshold analyses calculated thresholds needed to make claims that programs are cost-saving or cost-effective.

JHU provided training to each subgrantee via webinar on how to conduct cost and threshold analyses. The trainings provided detailed information on how to conduct cost and threshold analyses and also provided step-by-step instructions on how to fill out a cost analysis spreadsheet tool developed by JHU. The MS excel spreadsheet includes five steps and embedded formulas. The first step specifies the timeframe for the analysis. The second step describes the program and how participants interact with the program. The third step gathers information on the number of participants served, the number of participant contacts, time participants spent in the program, and costs to the participant, such as travel and dependent care. Step 4 gathers information on cost to the subgrantees to implement the programs and captures information on costs associated with staff and personnel, as well as materials and consumables. Staff and personnel costs include salary for all individuals who spend time working on the project. Materials and consumables include costs such as rent, utilities, promotional materials, and office supplies. Step 5 captures the overhead rate to gather data on any items not addressed in Step 4.

In addition to the training, JHU also provided subgrantees with a protocol of line-by-line instructions for how to complete the cost spreadsheet as well as answers to frequently asked questions. Subgrantees were also provided with one-to-one technical assistance over the phone or via email to address any additional questions that arise while completing the cost analysis spread sheets.

To complete the spreadsheets, the subgrantees extracted data from accounting forms, budgets, and administrative records. To assess the thresholds, JHU used several parameters from the literature. “T” is the medical costs saved for each transmission averted. “W” the estimated price that society is willing to pay for a QALY and “was estimated to be 5.83 based on prior work by Holtgrave (3). “T” was estimated at \$330,000 USD based on work by Farnham (4) and “W” was estimated using the commonly utilized standard of \$100,000 USD per QALY saved (5-7). The cost-saving threshold was estimated using the formula C/T while the cost effectiveness threshold was estimated using the formula $C/(T+WQ)$.

Monitoring sub-contractor networks: The implementation evaluation of SIF included a network analysis. This portion of the evaluation gathered data on collaboration between sub-grantee organizations six months prior to the start of SIF and during SIF. These data were used to develop visual representations of sub-contractor networks and to calculate network density and average node degree. The network analysis used a retrospective pre/post design. An online survey was used to obtain retrospective and current network data on the relationships between organizations. Network analysis data were collected from approximately two individuals at each sub-contracting organization. We gathered data from one individual who worked at the administrative level (such as a supervisor) and one person who worked at the service level (such as a peer). JHU worked with subgrantees to identify the appropriate individuals to survey. JHU then emailed these individuals to ask them to complete the on-line survey. A link to the on-line survey was embedded in the email. The survey was developed using Qualtrics.

The network analysis calculates density and average node degree. These data were collected by asking “Does your organization collaborate with [insert name of organization] in the implementation of SIF” and “In the six months before SIF, did your organization work with any of the following organizations to link PLWH into HIV care and treatment?” Three sites (APLA, MAO, and UAB) did not participate in this portion of the evaluation because their networks included only two organizations; as a result, the utility of the findings are limited. In addition, data on pre-implementation measures of agency interconnectivity are not available from WAP due to a survey collection error. Table 13 below provides detail on the number of individuals surveyed, the organizations surveyed, and the survey dates for the network analysis.

Table 13: Number of individuals surveyed, organizations surveyed, and survey dates by subgrantee

SIF subgrantee	Number of individual surveys	Organizations surveyed	Survey dates
ActionAIDS	5	ActionAIDS COMHAR Gaudenzia Pathways to Housing	April – May 2015
AIDS Action Committee	12	AAC Fenway PACT/JRI BIDMC ICH	February – April 2014
AIDS Foundation Chicago	10	AFC MATEC Chicago House Mercy Care Program	March – November 2013
Amida Care	8	Amida Care Housing Works Help/PSI Harlem United	June – November 2013
AIDS Project Los Angeles (DHSP arm)	11	APLA DHSP MCA Clinic THE Clinic Rand Schrader Northeast Valley	December 2013 – April 2014
Christie’s Place	6	Christie’s Place AVRC MCAP NCHS	June – November 2013
The Damien Center	9	The Damien Center Brothers United Women in Motion Indiana Latino Institute Community North Hospital Bellflower Life Care	July – September 2015
Effort for AIDS	6	Washington University Infectious Disease Clinic Washington University BEACON Team St. Louis Effort for AIDS	March – May 2014
Louisiana Public Health Institute	5	Louisiana Public Health Institute Capitol Area Reentry Program	June – September 2015

SIF subgrantee	Number of individual surveys	Organizations surveyed	Survey dates
		CrescentCare Women with a Vision	
Washington AIDS Partnership	10	Washington AIDS Partnership Whitman-Walker Health Unity Health Care Chartered Health Plan Women's Collective Institute for Public Health Innovation Family Medical Counseling Services	February – November 2013

Analysis

Analytical methods are outlined below by research question:

Q2: *What is the trend in mean CD4 from baseline to 12 months among participants?* We calculated the mean for baseline and twelve months. T-tests were used to compare changes in mean CD4 from baseline to twelve months.

Q3: *What is the trend in mean viral load from baseline to 12 months among participants?* We calculated the mean for each follow-up time point. T-tests were used to compare changes in mean viral load from baseline to twelve months.

Q4: *What is the trend in % of clients reporting a suppressed viral load from baseline to 12 months among participants exposed to SIF?* We calculated percentages at baseline and twelve months.

Q6. *Compared to the network six months prior to SIF, has the subcontractor network increased in density?* We calculated density as the sum of ties divided by all possible ties at two time points (six months prior to the start of the program and at least one year after program implementation).

Q7. *Compared to the network six months prior to SIF, does the subcontractor network average node degree increase?* We calculated the average number of ties across nodes (organizations) at two time points (six months prior to the start of the program and at least one year from program implementation).

Q8. *What is the cost saving threshold for Access to Care? (cost analysis)* We calculated the total cost of each intervention and then divide the total cost of the intervention by lifetime cost of care and treatment (\$330,000)(4).

Q9. *What is the cost effectiveness threshold for Access to Care?* The cost effectiveness threshold is $C/(T+(W*Q))$ where C is the cost of the intervention, T is medical cost averted each time a HIV infection is prevented (\$330,000), Q is the number of quality adjusted life years (QALYs) saved for each HIV transmission averted, and W is the price society appears willing to pay to “buy” a QALY. For Q, we used 5.83 (3) and for W, we used \$100,000 as the societal cost per QALY saved (5, 7, 8).

Q10. *What is the cost per QALY saved by delivering services in each program area?* We used mathematical modeling to translate estimated transmission rates and observed program outcomes into an estimate the cost per QALYs saved. We used standard methods from the U.S. Panel on Cost-Effectiveness and Health (9, 10). The main formula for the analysis as $R=(C-AT)/AQ$ where R is the cost-utility ratio which can be interpreted as the net cost per QALY saved. C, the cost of the program, and T the medical cost averted by the prevention of a HIV infection are defined above in Q9. Q (or QALY) included both discounted QALYs saved through improvements in individual quality of life due to viral suppression (Q1) as well as QALYs saved through averted HIV transmissions (Q2). Based on the literature, the value for Q1 we used was 0.039 and the value we used for Q2 was 5.83 (3, 4). A is the number of transmission averted. To estimate A, we first estimated the number of individuals whose viral loads went from not suppressed to suppressed over the course of the project using the available data from study participants. We did this by limiting the data to individual with data at enrollment and twelve months. We then estimated the proportion who became virally suppressed and applied that proportion to all participants enrolled who were eligible for twelve-month follow-up. This estimate of the net number of individuals who became suppressed was then multiplied by 0.046, a constant based on the literature that estimates the transmission rate of an individual with an unsuppressed viral load who is aware of their HIV status (11). The return on investment was calculated using the formula $ROI=TA/C$.

Findings

Monitoring of patient-level data: Tables 14-16 below outline changes from baseline to twelve months in mean CD4, mean viral load and percent with a suppressed viral load. Analyses were limited to individuals with data at both baseline and twelve months to allow for testing of statistical differences. A paired T-test was used to assess differences in mean CD4 and mean viral load. All subgrantees saw increases in mean CD4 from baseline to twelve months among SIF participants. These changes were significant for participants enrolled in Boston, Chicago, New York, Los Angeles, San Diego, Indianapolis, Montgomery, St. Louis, Washington, DC, and Birmingham.

Table 14: Mean CD4 by site at baseline and twelve months (limited to those with data at both baseline and twelve months)

Lead organization and location	N	Baseline mean CD4 (SD)	Twelve month mean CD4 (SD)	p-value
ActionAIDS, Philadelphia	41	523 (338)	555 (292)	>.05
AIDS Action Committee, Boston, MA	124	463 (320)	547 (324)	<.05
AIDS Foundation Chicago (AFC), Chicago, IL	189 ¹⁵	456 (23)	528 (24)	<.05
Amida Care: New York, NY	342	514 (331)	548 (341)	<.05
AIDS Project Los Angeles (APLA): Los Angeles, CA (APLA arm)	183	527 (294)	559 (285)	<.05
AIDS Project Los Angeles (APLA): Los	19	503 (383)	772 (1,089)	>.05

¹⁵ 190 clients had CD4 data at both enrollment and 12 months. However, one outlier was removed.

Lead organization and location	N	Baseline mean CD4 (SD)	Twelve month mean CD4 (SD)	p-value
Angeles, CA (DHSP arm)				
Christie s Place (CP): San Diego, CA	104	515 (288)	574 (303)	<.05
Damien Center: Indianapolis, IN	46	379 (245)	508 (281)	<.05
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	39	437 (335)	469 (346)	>.05
Medical AIDS Outreach (MAO), Montgomery, AL	153	527 (314)	591 (306)	<.05
St. Louis Effort for AIDS: St. Louis, MI	167	295 (255)	427 (269)	<.05
Washington AIDS Partnership (WAP): Washington, DC	192	395 (253)	521 (310)	<.05
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm)	53	580 (365)	635 (385)	<.05
University of Alabama at Birmingham (UAB): Birmingham, AL (control arm)	49	584 (366)	638 (387)	<.05

As outlined in Table 14, subgrantees saw reductions in viral load among participants from baseline to twelve months. These reductions are significant in the following program locations: Chicago, Los Angeles, Indianapolis, Montgomery, St. Louis, and Washington, DC.

Table 15: Mean viral load by site at baseline and twelve months (limited to those with data at both baseline and twelve months)

Lead organization and location	N	Baseline mean viral load	Twelve month mean viral load	p-value
ActionAIDS, Philadelphia	31	12,157 (32,889)	6,293 (22,420)	>.05
AIDS Action Committee, Boston, MA	108	59,222 (398,940)	6,062 (33,440)	>.05
AIDS Foundation Chicago (AFC), Chicago, IL	165 ¹⁶	48,403 (11,781)	19,972 (6,501)	<.05
Amida Care: New York, NY	420	25,671 (185,370)	9,734 (41,561)	>.05
AIDS Project Los Angeles (APLA): Los Angeles, CA (APLA arm)	183	123,665 (925,383)	21,534 (105,988)	>.05

¹⁶ 166 clients had viral load data at both enrollment and 12 months. However, one outlier was removed.

Lead organization and location	N	Baseline mean viral load	Twelve month mean viral load	p-value
AIDS Project Los Angeles (APLA): Los Angeles, CA (DHSP arm)	34	90,037 (203,572)	4,017 (12,722)	<.05
Christie s Place (CP): San Diego, CA	91	6,287 (36,972)	1,539 (5,712)	>.05
Damien Center: Indianapolis, IN	51	81,953 (187,119)	15,446 (51,800)	<.05
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	52	119,857 (477,918)	23,586 (65,243)	>.05
Medical AIDS Outreach (MAO), Montgomery, AL	185	11,120 (51,782)	564 (3,796)	<.05
St. Louis Effort for AIDS: St. Louis, MO	169	304,440 (1,119,948)	19,446 (74,191)	<.05
Washington AIDS Partnership (WAP): Washington, DC	189	36,213 (138,168)	5,095 (15,584)	<.05
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm)	57	19,728 (72,891)	6,167 (17,869)	>.05
University of Alabama at Birmingham (UAB): Birmingham, AL (control arm)	51	20,312 (73,989)	6,395 (18,159)	>.05

Across all subgrantees, we see an increase in percent suppressed viral load among participants with data available at baseline and twelve months. Confidence limits do not overlap in Boston, Chicago, New York, Los Angeles, Indianapolis, Montgomery, St. Louis, and Washington, DC.

Table 16: Viral suppression by site at baseline and twelve months (limited to those with data at both baseline and twelve months)

Lead organization and location	N	Baseline % viral suppression	Twelve month % viral suppression	Confidence interval overlap ¹⁷
ActionAIDS, Philadelphia	31	58% (18/31)	77% (24/31)	Yes
AIDS Action Committee, Boston, MA	108	61% (66/108)	83% (90/108)	No
AIDS Foundation Chicago (AFC), Chicago, IL	166	53% (88/166)	68% (113/166)	No

¹⁷ 95% Confidence intervals were computed by modified Wald method.

Lead organization and location	N	Baseline % viral suppression	Twelve month % viral suppression	Confidence interval overlap¹⁷
Amida Care: New York, NY ¹⁸	441	66% (291/441)	76% (334/441)	No
AIDS Project Los Angeles (APLA): Los Angeles, CA (APLA arm)	183	51% (94/183)	67% (122/183)	No
AIDS Project Los Angeles (APLA): Los Angeles, CA (DSPH arm)	34	44% (15/34)	74% (25/34)	Yes
Christie s Place (CP): San Diego, CA	91	73% (66/91)	85% (77/91)	Yes
Damien Center: Indianapolis, IN	51	20% (10/51)	75% (38/51)	No
Louisiana Public Health Institute (LPHI): Baton Rouge, LA	52	52% (27/52)	60%(31/52)	Yes
Medical AIDS Outreach (MAO), Montgomery, AL	185	80% (148/185)	94% (174/185)	No
St. Louis Effort for AIDS: St. Louis, MI	169	11% (18/169)	76% (128/169)	No
Washington AIDS Partnership (WAP): Washington, DC	189	49% (92/189)	78% (148/189)	No
University of Alabama at Birmingham (UAB): Birmingham, AL (intervention arm)	57	79% (45/57)	79% (45/57)	Yes
University of Alabama at Birmingham (UAB): Birmingham, AL (control arm)	51	75% (38/51)	76% (39/51)	Yes

To better understand missingness on our primary outcome of interest, viral suppression, we compared the demographic characteristics of participants with viral load data available at enrollment and twelve months to participants without those data available. Across all subgrantees, differences emerged. These differences are significant with regards to age, race and gender. Biases in attrition are important to understand when interpreting the outcomes from the SIF program.

¹⁸ For Amida Care, undetectable VL and Suppressed VL has a larger N because in the survey, clients who do not remember a precise number of VL were provided an option to answer if VL was undetectable or not.

Table 17: characteristics of individuals with data on viral suppression at baseline and 12 months

Had viral load data at both baseline and 12 months?		All Sites N=4377		
		Yes n (%)	No n (%)	P-value*
TOTAL		1519 (35)	2858 (65)	
Age	≤ 24 years	97 (6)	257 (9)	<0.05
	25 – 39 years	501 (33)	959 (34)	
	40 years and above	920 (61)	1622 (57)	
	Missing	1 (0)	20 (1)	
Race	Black, non-Hispanic	1044 (69)	2095 (73)	<0.05
	White, non-Hispanic	164 (11)	290 (10)	
	Hispanic	231 (15)	312 (11)	
	Other	72 (5)	111 (4)	
	Missing	8 (1)	50 (2)	
Gender	Male	949 (62)	1656 (58)	<0.05
	Female	534 (35)	1072 (38)	
	Transgender	35 (2)	105 (4)	
	Other	0 (0)	1 (0)	
	Missing	1 (0)	24 (1)	
Education ¹⁹	Less than High School	411 (31)	903 (32)	>0.05
	High School diploma or equivalent	495 (37)	992 (35)	
	Some college or technical school	294 (22)	602 (22)	
	College or higher education	119 (9)	207 (7)	
	Other	0 (0)	1 (0)	
	Missing	15 (1)	94 (3)	
Viral suppression (<200 copies/ml) at baseline	Yes	1163 (77)	1136 (40)	>0.05
	No	278 (18)	317 (11)	
	Missing	78 (5)	1400 (49)	

*Chi-Square. Missing values excluded from Chi-Square analyses.

¹⁹ One site (Medical AIDS Outreach) does not collect data on education.

Economic analysis: Table 18 presents the findings from the cost threshold analyses. Program costs are presented from both the payer perspective and the societal perspective. The table below displays overall costs as well as the costs per client. The payer costs ranged from \$102,313.65 over six months to \$382,551.29 over twelve months. The per client payer costs varied widely, ranging from \$1088.44 to \$7,428.94. The societal costs ranged from \$104,288.12 over six months to \$391,467.06 over twelve months. The per client societal costs ranged from \$1,109.45 to \$7,602.54. Table 18 displays the cost-saving thresholds and the cost-effectiveness thresholds from the societal perspective. The cost-saving thresholds ranged from 0.32 to 1.19, and the cost-effectiveness thresholds ranged from 0.11 to 0.43. As discussed with CNCS program officer Parita Patel, the sensitivity analyses for the cost-utility analysis are on-going and final cost utility results will be completed in by July 1.

Table 18: Payer and societal program costs – overall and per client

Lead agency name	Analysis time period (months)	Payer		Societal	
		Overall (\$)	Per client (\$)	Overall (\$)	Per client (\$)
ActionAIDS	12	276,049.22	4,678.80	291,689.90	4,943.90
AIDS Action Committee	6	295,035.90	2,565.53	330,465.98	2,873.62
AIDS Foundation Chicago	6	377,375.62	5,169.53	385,318.85	5,278.33
AIDS Project Los Angeles	6	128,389.03	2,292.66	139,962.83	2,499.34
Division of HIV and STD Programs	6	170,865.69	7,428.94	174,858.49	7,602.54
Amida Care	6	333,308.67	2,687.97	363,068.67	2,927.97
Christie’s Place	6	266,882.00	5,446.57	290,478.79	5,928.14
The Damien Center	12	342,155.05	4,562.07	364,991.71	4,866.56
St. Louis Effort for AIDS	12	382,551.29	3,787.64	391,467.06	3,875.91
Louisiana Public Health Institute	6	105,692.42	2,935.90	107,749.82	2,993.05
Medical AIDS Outreach	6	102,313.65	1,088.44	104,288.12	1,109.45
University of Alabama / Birmingham AIDS Outreach	9	173,311.47	2,586.74	185,698.43	2,771.62

Table 19: Cost-saving and cost-effective thresholds, by program

Site name	Cost-saving	Cost effective
	threshold	threshold
	C / T	C / (T + WQ)
ActionAIDS	0.88	0.32
AIDS Action Committee	1.00	0.36
AIDS Foundation Chicago	1.17	0.42
AIDS Project Los Angeles	0.39	0.14
Division of HIV and STD Programs	0.52	0.19
Amida Care	1.10	0.40
Christie s Place	0.88	0.32
The Damien Center	1.04	0.37
St. Louis Effort for AIDS	1.19	0.43
Louisiana Public Health Institute	0.33	0.12
Medical AIDS Outreach	0.32	0.11
University of Alabama / Birmingham AIDS	0.56	0.20

C: the cost of the intervention; T: lifetime total cost of treatment (\$330,000); Q: number of QALYs saved from each averted infection (5.83); W: the societally accepted cost per QALY (\$100,000). Cost thresholds are calculated from the societal perspective (e.g., using the societal costs) with the exception of AIDS Project Los Angeles and The Damien Center, which are from the payer perspective.

Monitoring sub-contractor networks: Table 20 below highlights the findings from the network analysis. The network analysis assessed changes in interagency collaboration by looking at network density and average node degree six months prior to the implementation of SIF and then during the implementation of SIF. Network density is the proportion of all reported connections out of all possible connections between organizations. Across all sites but two we saw increases in network density. For Christie’s Place, network density decreased from 1.00 to 0.75. This decrease can be explained by a change in partnership that occurred midway through the program. Similarly, we saw increases in node degree, or the average number of connections per organization in the network, across all organizations except for Christie’s Place and APLA’s DHSP arm. This decrease can also be explained by changes in composition of the network during the implementation of the project. Visual depictions of the pre- and peri-implementation SIF networks are displayed in the accompanying report, “Social Innovation Fund Case Studies: Experiences with Linkage and Retention in Care across Twelve Grantees and their Partners.”

Table 20: Network density and average node degree, by program

Site name	Network Density		Average Node Degree	
	Pre	Peri	Pre	Peri
ActionAIDS	0.50	0.70	2.0	2.8
AIDS Action Committee	0.45	0.60	1.8	2.4
AIDS Foundation Chicago	0.45	0.90	1.8	3.6
Division of HIV and STD Programs	0.70	0.60	3.3	2.8
Amida Care	0.50	0.83	1.5	2.5
Christie s Place	1.00	0.75	3.0	2.5
The Damien Center	0.26	0.64	1.6	3.9
St. Louis Effort for AIDS	0.50	1.00	1.0	2.0
Louisiana Public Health Institute	0.33	0.67	1.0	2.0
Washington AIDS Partnership	NA	0.86	NA	6.0

Lessons learned

Across all subgrantees, mean CD4, mean viral load, and percent viral suppression trended in the hypothesized direction. For several sites (see tables 14-16 above) these trends are statistically significant. All subgrantees participated in the national evaluation, though some subgrantees faced significant challenges around data collection and reporting. Several grantees described challenges in getting clinical data from medical providers' offices, as well as connecting with clients for follow-up data collection. Sites developed systems (e.g., contracts with providers) to gain access to these data, sought the help of program staff accompanying clients to appointments, and asked clients to sign release forms that eased access to these data.

The cost analysis found that program costs varied considerably, which is expected given the differences in program location, model, and population served. Cost per client from the societal perspective ranged from \$1,109.45 per client to \$5,928.14. Cost-saving thresholds ranged from .32 to 1.19, indicating that to be cost-saving the programs would need to avert from just over one to less than 1 HIV infection (during the timeframe of the analysis.) To be cost-effective, the programs would need to avert fewer than one HIV infection. These cost-saving and cost-effective thresholds appear quite achievable and compare favorably to cost analyses of other retention in care programs (12, 13).

The network analysis found increases in density and average node degree across the SIF network. These findings suggest increases in interagency collaboration. It appears that targeted linkage and retention in care programs may increase collaboration among diverse organizations (public health departments, AIDS service organizations, social service organizations, and HIV primary care providers) serving people living with HIV. Programs such as A2C that are working with highly underserved populations must address participant needs and barriers to HIV care (such as homelessness, unemployment, food insecurity, mental health challenges, substance use, and dental services) as part of providing HIV linkage and retention services. Often meeting such a range of client needs is beyond the scope of a single organization. Increased collaboration and interaction between agencies has the potential to provide enhanced and streamlined services to PLWH with a high acuity of need without building a new infrastructure. Thus, strong network collaboration among a variety of diverse organizations, such as the networks demonstrated by A2C, might help to provide timely and efficient "wrap around services" to PLWH in locations where "one-stop-shop" services are not yet available or are over taxed.

Impact Evaluation

The impact evaluation includes two components: (1) an RCT impact study; and (2) comparisons of local treatment continuums of care.

Level of evidence, impact evaluation

The evaluation of SIF meets a "moderate" level of evidence. The RCT impact study used a randomized control design. This type of design should account for most threats to internal validity. The study could not draw a random sample from a sampling frame as a traditional sampling frame was not available. Given this limitation, the study cannot make broad claims about generalizability. Thus, the external validity of the RCT impact study is moderate to low. However, to the best of our knowledge, there is nothing unique about the setting and location for the RCT impact study (the 1917 Clinic in Birmingham, Alabama) that would cause the study findings to not be applicable in similar settings and locations, such as Southern cities in the United States. In addition, the RCT impact study tested the effect of an

evidence-based intervention and thus the study findings are contributing to a growing body of evidence to support the use of intensive case management and motivational interviewing.

The all-subgrantee and grantee-specific continuums of care used data gathered from purposive samples. This limits generalizability and external validity. However, comparative continuums of care from all grantees provides a valuable contribution to the understanding what linkage to care looks like for PLWH who are out of care across various settings (for example, urban vs. rural) and with diverse populations (for example, MSM and people under 40).

Impact evaluation design

BA₂C RCT impact study: The impact assessment took place at the University of Alabama at Birmingham's (UAB's) 1917 Clinic. The study used a randomized control group design. This study design was chosen because it controls for most threats to internal validity. Study participants were 1917 Clinic patients who met one of three definitions of out of care (failing to have a visit with a health care provider for twelve months, having multiple no-show primary care visits in the last twelve months, or having gaps in continuous care of greater than six months in the past twelve months). To recruit RCT participants, a list of participants who are out of care that included contact information was routinely generated (quarterly) by the 1917 Clinic. Individuals on this list were recruited, consented, and then randomized to an intervention or standard-of-care arm. Thus, the unit of randomization was the individual. Study staff used an iPad application designed by UAB Information Technology (IT) staff in collaboration with the subgrantee's biostatistician to randomly assign participants to intervention or standard-of-care condition. Research staff hired exclusively to recruit and enroll participants into this study facilitated the randomization process. All research staff (research assistants and research technicians) received extensive training in study protocols, including the randomization process. At conclusion of the baseline assessment battery, research staff had the option to "submit" the participant's responses to assessment instruments and proceed to randomization. The simple click of a "Randomization" button that appeared in the iPad application informed the research staff of which study arm the participant was assigned. Random assignment to study groups was predetermined using SAS programming and included in the study iPad application. The SAS program used a block randomization approach in which the first 250 participants are randomly assigned to one of the two study arms. An additional command included the next 100 participants, assuring more evenly distributed assignment to both study groups. Only the study biostatistician and the IT development staff had access to this randomization schedule prior to participant randomization. Ideally, the randomization yields a balance for all covariates (measured and unmeasured). For measured covariates, we assessed statistical equivalence by testing if individuals in the intervention and standard-of-care arm were similar at baseline on a range of demographic and health-related characteristics, including age, gender, race, retention, median CD4, and median viral load, as well as CD4 and viral load categorically. The intervention and control arms of the study were statistically equivalent for all covariates except for median number of days from first seropositive test.

Table 21: Baseline socio-demographic and clinical characteristics of participants enrolled in Birmingham Access to Care (BA₂C)

Characteristic	Intervention arm n=87	Control arm n=83	p-value	Total n=170
Age (years), mean(SD)	44.4 (10.9)	41.8 (10.5)	0.11 ^a	43.1 (10.8)
Race, n (%)			0.44 ^{b,c}	
White	19 (21.8)	13 (15.7)		32 (18.8)
Black	64 (73.6)	68 (81.9)		132 (77.7)
Other	4 (4.6)	2 (2.4)		6 (3.5)
Sex, n (%)			0.75 ^{b,d}	
Female	30 (33.5)	27 (32.5)		57 (33.5)
Male	57 (65.5)	55 (66.3)		112 (65.9)
Transgender (M-F)	1 (1.2)	0 (0.0)		1 (0.6)
CD4 count (cells/uL), ^e median (min, max)	483 (257–778)	552 (393–865)	0.33 ^f	531 (315–819)
CD4 count (cells/uL), n (%)			0.89 ^g	
≤ 200	13 (16.9)	13 (16.1)		26 (16.5)
> 200	64 (83.1)	68 (84.0)		132 (83.5)
Viral Load (IU/mL), ^e median (min, max)	19 (19–851)	19 (19–4060)	0.93 ^f	19 (19–1690)
Viral Load (IU/mL), n (%)			0.87 ^g	
≤ 200	57 (69.5)	56 (68.3)		113 (68.9)
> 200	25 (30.5)	26 (31.7)		51 (31.1)
Seropositivity (days), ^e median (min, max)	4464 (2052–7225)	2995 (1283–5233)	<0.01 ^{f*}	3585 (1609–6530)
Retention, n (%)			0.70 ^g	
Yes	54 (65.1)	59 (67.8)		113 (66.5)
No	29 (34.9)	28 (32.2)		57 (33.5)

*Statistically significant at 0.05 level.

Max=maximum; Min=minimum; SD=standard deviation.

Missing data: CD4, n=12 (Intervention=10, Control=2); Viral load, n=6 (Intervention=5, Control=1);

Seropositivity, n=4 (Intervention=5, Control=1).

^aCalculated by unpaired t-test.

^bFisher's exact test.

^cAfter excluding the 'Other' category, the p-value was 0.27 (chi-square test for two proportions).

^dAfter excluding the "Transgender" category, the p-value was 0.83 (chi-square test for two proportions).

^eAs the variable was skewed, median (range) is reported.

^fWilcoxon rank-sum test (non-parametric test).

^gChi-square test for two proportions.

We did not use any matching prior to randomization. Enrollment into the RCT concluded in February 2015 and the last participant provided follow-up data in December 2015 (the beginning of the 12-month follow-up window).

The standard-of-care arm received a passive referral. The passive referral included a brochure that informed the individual about the availability of HIV care and ancillary services at the 1917 Clinic and at the community partner site, Birmingham AIDS Outreach. The intervention arm received strengths-based case management and motivational interviewing from community social workers in 10–12 evidence-informed sessions in a time-limited manner (within six months of enrollment).

The design of the impact study assured protection against diffusion of program activities into the standard-of-care arm. Clear measures were taken to differentiate study controls from individuals assigned to the intervention. For example, study controls never have contact with the intervention staff (community social workers). At baseline, study controls were provided standard of care passive referrals for local HIV treatment and supportive services, including a flyer with contact information for both the HIV primary care clinic and AIDS service organization collaborating on this project. All study participants complete the same assessment battery at baseline, 6-month, and 12-month. Completed survey assessments of intervention arm participants have informed the individuals' participation in the intervention; completed survey assessments for study controls are maintained for use study reporting and analysis only. Additionally, all participants receive lab tests at baseline and at 12 months to assess their CD4 cell count and their viral load.

For control participants, these laboratory tests took place at an external provider in the participants' community. For intervention participants, these tests occurred at the new clinic orientation visit as routine care for new clinic patients or in conjunction with another community HIV clinic that the intervention participant elects to attend. As the study intervention primarily consists of the assistance provided by the community social worker and ultimate re-engagement into HIV primary care, we assured that study controls were prevented from interaction with intervention staff, and we monitored control participants' involvement with HIV primary care within the UAB system via system-wide medical records. Community social workers were trained to complete intervention dosage data forms that document the type of interaction completed, date, amount of time, and resolution of the interaction, as well as the unique study identification number of the specific participant. From these data, we were able to confirm any documented interaction between the intervention team and study controls. Differences between program participants and comparison group members in terms of access to program components and delivery of services were likewise be monitored through this documentation. All data for this research were collected using project-specific iPads and iPad applications develop specifically for this study. Paper documents were available and were used only in cases which use of the iPads was limited (e.g., areas with limited wireless access, times when the equipment is not functioning, etc.).

Fidelity to the program design described above was assured and evaluated through a number of activities. First, all aspects of the RCT were manualized; each project staff member—project director(s), community social workers, research assistants, and community outreach workers—received intensive project orientation training that included role plays, problem-solving exercises, and introduction to study outcomes. Additionally, new staff members also received individualized project orientation. Second, the project director(s) and project evaluator conducted audits of staff activities, paperwork, and understanding to prevent drift. Third, regularly scheduled team meetings, led by project director(s), were held. During these meetings, the team addressed implementation issues, such as linkage to care and retention in care among RCT participants, on an on-going basis. Finally, we convened monthly

“leadership” meetings that include study investigators, the project evaluator, project directors, and fiscal agent (among others) and during which implementation research questions were addressed, as well as issues relating to project sustainability and results dissemination.

Comparison of local treatment continuums of care: To improve our understanding of the unmet HIV care and treatment needs for individuals living with HIV, researchers have recently constructed continuums of care. The care and treatment continuum of care includes being HIV infected, diagnosed HIV positive, linked to HIV care, retained in HIV care, on ART, and having an undetectable viral load. The continuums of care estimate the number of PLWH in each category and allow researchers to estimate the percentage of PLWH who are linked to care and the percentage of PLWH who have suppressed viral load.

We used client-level data to create all-subgrantee and subgrantee-specific continuums of care to show the number of SIF participants who are enrolled, are linked to care, are retained in care, are on ART, and have a suppressed viral load.

Measures

Randomized control trial: The primary outcome measure for this study is viral suppression, which is defined as a viral load less than 200. Data on viral suppression are gathered at baseline and at 12 months through a blood draw. Lab results are facilitated as part of study protocol or are collected as the participant’s routine care at their primary care provider appointment. For study labs, participants are transported to the UAB Clinical Research Unit (not affiliated with the 1917 Clinic) for blood draw; results are forwarded to the study coordinator. For labs collected as routine care (e.g., during hospitalization or a primary care provider visit), study staff abstract lab results from the participant’s electronic medical record. All labwork is processed through the UAB Hospital Laboratories. UAB laboratories uses the Roche COBAS AmplePrep/COBAS TaqMan HIV-1 RNA v.2.0 to ascertain viral load.

Comparison of local treatment continuums of care: the SIF evaluation developed an all subgrantee continuum of care (as well as subgrantee specific continuums of care). We aim to juxtapose the all subgrantee continuum of care to the CDC’s national continuum of care. However, because SIF and the CDC are using different measures for the development of the continuum of care, direct comparisons may not be appropriate. Despite this, we feel that discussing the SIF continuum of care within the context of the CDC continuum of care is important for understanding our findings. Table 22 below outlines the measures used by JHU to form their continuum of care and the measures used by the CDC to create their continuum of care.

Table 22: Continuum of care measures

CDC variable	CDC calculation	SIF variable	SIF definition
HIV diagnosed	# PLWH from CDC HIV Surveillance	Enrolled in SIF	# PLWH enrolled in SIF
Linked to care	# PLWH linked to care calculated as 77% of HIV diagnosed based on a meta-analysis by Marks (2010) that averaged % linked to care at 4,6 & 12 months & Torian (2011)	Linked to care	# PLWH with one visit with a medical care provider with prescribing privileges within a HIV care setting
Retained in Care	# of PLWH retained in care calculated as 51% of HIV diagnosed based on Marks (2010) (averaged 2 visits 6 mo.; 2 visits 12 mo.; 3 visits 12 mo.), Hall (2011), Tripathi (2011)	Retained in care	# PLWH who reported two visits at least two months apart in the past 12 months (at 12 months follow-up)
On ART	# on ART calculated as 88% of retained in care based on the medical monitoring project	On ART	# of PLWH with a ART prescription (at 6 or 12 months follow-up)
Suppressed viral load	# with a suppressed viral load calculated as number on ART times 88.8% based on the medical monitoring project. Suppressed viral load defined as ≤ 200 copies/mL	# with suppressed viral load	Defined as ≤ 200 copies/mL (at 6 or 12 months follow-up)

Data collection activities

Potential study participants were identified using in-reach strategies that generate a list of PLWH who are out of care at the 1917 Clinic. All study participants were assigned a unique study identification number upon enrollment. All contacts (both for the intervention by the community social workers and for the research and follow-up) were documented using this unique number. Hence, at any given time, we could report a wealth of information regarding the projects interface with study participants (e.g., date and nature of contact). A local standard operating procedure was established to delineate the extent of efforts to initially contact potential participants for recruitment. This system included formal scripts which were used on initial and follow-up telephone calls with the potential participant, an emergency contact, a case manager, and a medical provider. The system provided direction about how many telephone calls to make, when to make them, when to send a recruitment letter, and how to send the letter (certified mail). The formal recruitment plan allowed attempts at initial contact for up to one year should an individual continue to be lost to follow-up. An on-site evaluation team worked closely with the project staff—as well as the lead evaluation team at JHU—throughout the course of the study; regular meetings were scheduled to discuss recruitment, retention, tracking, and other potentially

problematic issues. Standard reporting periods were established for providing up-to-date information to the lead evaluation team. Community outreach workers (COWs) were integral to project retention. Two COWs were hired for this project specifically to provide on-going communication with all study participants. COWs followed a standardized system for contacting study participants by telephone and letter after they have been enrolled and completed baseline activities. Additionally, the COWs were charged with providing transportation—a common barrier to retention in research studies at this site—to and from research study visits such as follow-up interviews (not intervention activities). Efforts to retain all participants in the study for its entirety were maintained until the study period ends. All study data were entered into the iPad application that was developed for use solely in this project. This single system of data collection provided all collected data to the local project evaluator in real time; this allowed for random reviews of data collection activities.

At initial contact and prior to baseline activities, we attempted to collect general demographic information on all potential study participants (using a standardized form). Individuals were asked if they were currently receiving HIV primary care and the date of their last appointment. For potential participants whose information could not be confirmed in the system-wide UAB medical record, we asked individuals to provide us with the name of their most recent HIV primary care provider. After the participant provided informed consent to participate in the study, all data were collected and entered into an iPad application developed by the IT team at UAB specifically for this research. Additionally, study participants' CD4 and viral load laboratory tests were either abstracted from the medical record (for intervention arm participants), received from external providers, or captured through study-specific labs collected at baseline and 12-months. Medical record abstraction was used to obtain all participants' HIV primary care appointment information during the study period. Locator information was collected on all study participants at baseline and regularly updated at study visits or other study contacts (e.g., telephone) in order to assist research staff in maintaining contact with participants and optimizing retention in the study. The information collected prior to enrollment and all baseline data was consistent between individuals in both study arms. All information collected prior to study enrollment and during baseline activities (and follow-up interviews) was collected by research staff (research assistants, research technicians, and/or research interns) during initial telephone contacts and semi-structured face-to-face interviews. This same research staff was responsible for any necessary medical record abstractions, as well. We concluded enrollment at this site in February 2015, and 170 individuals were entered into the study and, therefore, have participated in all baseline activities. Enrollment activities were completed in December 2015.

Immediately following completion of all baseline measures, the research staff facilitated the randomization process. Intervention participants were introduced to the community social worker and completed an initial session and were introduced to the community health outreach worker, who was responsible for maintaining contact with the participant throughout the study period. Intervention/Dosage data were collected beginning with this initial session with the community social worker. Control participants immediately received passive referral to the local HIV clinic and ancillary services will be introduced to the COW.

Participant demographic information was collected using a standard Patient Screening Form that had been used successfully by the site in other clinical trials. Specifically, this form included information regarding patient age, race, gender, ethnicity, education, annual income, and insurance status. All other

study measures were standardized and had been tested for reliability and validity for adult clinic populations. The local evaluation team was very familiar with each instrument and had extensively conducted and published research with similar data. All study staff who accessed data via electronic medical records at UAB participated in mandated training for use of the system. The local UAB staff completed all required trainings to access the electronic medical records systems. All study staff (at both the UAB and Birmingham AIDS Outreach sites) were adequately trained in use of the study-specific iPad application.

Sample retention and missing data

Randomized control trial: As a primary output for this study was retention in care, attrition was critically evaluated. Herein lays the difficulty with missing data—poor engagement in care (or missing data) was, at least, an element of the study. Hence, missing data were not a nuisance; it was a major focus of the study. Additionally, linkage to and retention in care have been extensively studied at the UAB subgrantee site. For these studies, the subgrantee used three different strategies to account for missing data. For this analysis, one of these strategies was actually used—We considered missing data as missing (missing=missing). We plan to investigate a second strategy to consider missing data as failure (missing=failure). Results from this second strategy are complete for retention in care at 12 as discussed above in the implementation evaluation findings section of this report.

Comparison of local treatment continuums of care: As discussed above in the outcome evaluation section, subgrantees faced challenges in collecting follow-up data, which resulted in missing data at follow-up. This introduces bias as the individuals with follow-up data are most likely systematically different from those without follow-up data. When constructing the continuums of care, to be included in the final three bars (retention, HAART, viral suppression) a participant had to have follow-up data at either six or twelve months. Individuals without follow-up data were automatically coded as having a “no” response. For a study that focuses on retention in HIV care, missing visit, prescription, and lab data can be interpreted as an indicator of not being retained, on HAART or virally suppressed. However, this is a conservative approach and, as a result, our estimates for the continuums of care (see impact assessment section) are most likely underestimates. Our approach is conservative because it is also possible that these individuals with missing data were not out of care but rather were getting care at another facility. Subgrantees tried to rule out this possibility, for example by calling around to differ local clinics and by checking to see if participants were incarcerated, but they faced considerable challenges in gathering this information (such as the intensity of time it took to gather this information and HIPAA constraints).

Sample and supplemental power analysis

Randomized control trial: The proposed impact study does did not use a traditional sampling frame as national-, state-, or city-level lists of PLWH who are out of care are not available. This prohibits random sampling and the generalizability that random sampling affords. Therefore, the generalizability of study findings beyond patients who are out of care who attend the 1917 Clinic is unknown. However, there is nothing unique to the study setting, location, or population that would cause the study findings to not be more broadly applicable.

The target population for the study was PLWH in the Birmingham, Alabama area who were not engaged in HIV care and treatment services. It is unknown if the individuals who are out of care who attended

the 1917 Clinic are representative of PLWH who are out of care in Alabama or more broadly representative of PLWH who are out of care in Southern cities or in the U.S.

The randomized control trial enrolled 170 participants (87 in the intervention arm and 83 in the control arm). Assuming a reference proportion of 0.67, power of 0.80, and alpha of 0.05, the study has the power to assess a relative risk of 1.28.

Statistical analysis of impacts

BA₂C randomized control trial: Q1: *Are participants who receive the intervention more likely to have a suppressed viral load than individuals who receive standard of care?* Initial exploration of the data included descriptive statistics of the variables (BL, T1, T2) reporting frequencies and percentages for categorical variables and mean (standard deviation) or median (quartiles/range) for continuous variables; the distribution of the continuous variables was assessed using histogram and QQ plots. The research arms (intervention versus control) were compared with regard to the socio-demographic and clinical variables examining baseline (at enrollment) differences informing whether “randomization” has worked or not. Furthermore, the research arms were compared with regard to the following outcomes of interest: viral suppression at T2 (12 months), change in viral load (BL to T2), linked to care within 30 days or without 30-day parameter, and retained in care at T2 (12 months). Change in viral load from BL to T2 was examined by both as a continuous variable (copies/mL) and as a categorical variable (viral suppression at BL versus T2 within each arm). The differences were assessed comparing frequencies and percentages while association was examined using unconditional univariate odds ratio (OR) with 95% confidence interval (CI); for comparing viral load suppression at BL versus T2 within each arm, conditional ORs were reported owing to paired data. To maintain the original group allocation and minimizing confounding, “intention to treat” analysis was performed. This analysis is based only on “complete” data; sensitivity analysis and missing data imputation will be considered in future.

Comparison of local treatment continuums of care: Q5. *Compared to national and/or community-level statistics, does the program have a higher percentage of participants linked to care, retained in care, on HAART, and with a suppressed viral load?* We used client-level data to create across subgrantee and subgrantee-specific continuums of care of the number of SIF participants who: are enrolled, are linked to care, are retained in care, are on ART, and have a suppressed viral load. The all-subgrantee continuum of care are compared to national continuums of care developed by the CDC. The subgrantee-specific continuums of care are compared to continuums of care for each location where available.

Findings

Randomized control trial: We observed that intervention arm participants were more likely virally suppressed at T2 (12 months), although these results were not statistically significant. As discussed above, the results may be explained by the nature of the intervention which provided intensive support for individuals for the first six months of study enrollment, thus potentially providing impact on linkage to care. Once the intensive phase of the intervention was complete, participants may have had more barriers to sustaining retention in medical care and ultimately viral suppression.

Table 23: Viral suppression among UAB Birmingham Access to Care (BA2C) participants

Patient characteristics, n (%) or median (IQR)	Intervention		Control		OR (95% CI)	p-value
	n/N (%)		n/N (%)			
Viral suppression (≤ 200) at 12 months (T2)	46/58	79.3%	42/54	77.8%	1.1 (0.4-2.7)	0.8

Table 23a: Change in Viral Load from Baseline (BL) to 12-Months (T2) by Study Arm for UAB Birmingham Access to Care (BA2C) participants

Intervention Arm			
T2	Baseline		
	Not Suppressed	Suppressed	Total
Frequency			
Percent			
Row Pct			
Col Pct			
Not Suppressed	8	4	12
	14.04	7.02	21.05
	66.67	33.33	
	66.67	8.89	
Suppressed	4	41	45
	7.02	71.93	78.95
	8.89	91.11	
	33.33	91.11	
Total	12	45	57
	21.05	78.95	100.00
Frequency Missing = 30			

OR=1.00 (95% CI: 0.19 – 5.37); p=1.00

Table 23b: Change in Viral Load from Baseline (BL) to 12-Months (T2) by Study Arm for UAB Birmingham Access to Care (BA2C) participants

Control Arm			
T2	Baseline		
Frequency Percent Row Pct Col Pct	Not Suppressed	Suppressed	Total
Not Suppressed	9 17.65 75.00 69.23	3 5.88 25.00 7.89	12 23.53
Suppressed	4 7.84 10.26 30.77	35 68.63 89.74 92.11	39 76.47
Total	13 25.49	38 74.51	51 100.00
Frequency Missing = 32			

OR=1.33 (95% CI: 0.23 – 9.10); p=0.71

Comparison of local treatment continuums of care: Table 24 presents the continuum of care for each site and for the A2C program overall. Overall, among A2C program participants, 86% were linked to care, 69% were retained in care, 49% had a HAART prescription, and 62% were virally suppressed. (See Appendix 1 for links to the local cascades used in the table below). While direct comparisons with non SIF local continuums of care and the national continuum of care are not appropriate due to differences in methods, these non-SIF continuums of care do provide important context. The combined subgrantee SIF continuum of care exceeds the national continuum of care for each bar measured. The National HIV AIDS Strategy sets out ambitious targets of 85% linked to care within 30 days, 90% retained in care, and 80% virally suppressed. In order to achieve those goals, programs, such as those implemented by the SIF subgrantees that engage the most underserved populations, will be needed.

Table 24: HIV continuum of care among SIF participants by grantee

Location, lead agency and number of participants enrolled (n)		Linked to care % (n)	Retained in care % (n)	HAART prescription % (n)	Virally suppressed (<200 copies/ml) % (n)
Philadelphia, PA	A2C- ActionAIDS (78 clients served)	97% (76/78)	67% (52/78)	91% (71/78)	68% (53/78)*
	Local	80%	42%	Data not available	46%
Boston, MA	A2C- AIDS Action Committee (AAC) (342 clients served)	82% (279/342)	77% (265/342)	64% (220/342)*	69% (237/342)
	Local	75%	59%	Data not available	65%
Chicago, IL	A2C- AIDS Foundation Chicago (AFC) (639 clients served)	69% (440/639)*	48% (305/639)*	52% (334/639)*	52% (333/639)*
	Local	80%	54%	48%	40%
New York City, NY	A2C- Amida Care (833 clients served)	87% (722/833)	74% (619/833)	66% (551/833)	64% (536/833)*
	Local	73%	55%	51%	41%
Los Angeles, CA	A2C- AIDS Project Los Angeles (APLA): APLA arm (245 clients served)	100% (245/245)	76% (186/245)	71% (175/245)*	58% (141/245)
	Local	61%	51%	Data not available	50%
Los Angeles, CA	A2C- AIDS Project Los Angeles (APLA): DHSP arm (82 clients served)	95% (78/82)	84% (69/82)	Data not available	44% (36/82)
	Local	61%	51%	Data not available	50%
San Diego, CA	A2C- Christie s Place (226 clients served)	93% (210/226)	65% (147/226)*	66% (150/226)*	61% (137/226)*

Location, lead agency and number of participants enrolled (n)		Linked to care % (n)	Retained in care % (n)	HAART prescription % (n)	Virally suppressed (<200 copies/ml) % (n)
	Local	54%	32%	Data not available	31%
Indianapolis, IN	A2C- Damien Center (149 clients served)	79% (118/149)*	60% (89/149)*	Data not available	49% (73/149)*
	Local	76%	48%	48%	81%
Baton Rouge, LA ²⁰	A2C- Louisiana Public Health Institute (LPHI) (144 clients served)	83% (120/144)	69% (100/144)*	37% (53/144)*	53% (77/144)*
	Local	69%	54%	Data not available	49%
Montgomery, AL	A2C- Medical AIDS Outreach (MAO) (244 clients served)	100% (244/244)	88% (215/244)	90% (220/244)	96% (235/244)
	Local	82%	68%	Data not available	54%
St. Louis, MI	A2C- St. Louis Effort for AIDS (EFA) (322 clients served)	89% (286/322)	91% (293/322)	48% (156/322)*	65% (210/322)*
	Local	83%	53%	Data not available	54%
Washington, DC	A2C- Washington AIDS Partnership (WAP) (1313 clients served)	86% (1124/1313)	65% (857/1313)	Data not available	63% (823/1313)*
	Local	Percentage not available ²¹	89%	59% ²²	63%

²⁰ Louisiana gets their visit and lab data from state partners. There is a considerable delay in getting this data, usually several months. This delay is anticipated and results in their clinic and lab data looking artificially low.

²¹ The numerator was stated. 5,622 clients had one or more medical visits. No denominator was given. Total clients served (All HIV positives using any Ryan White care service from January 1- December 31, 2014) was not stated.

²² One provider was unable to submit date and therefore was not included in this metric.

Location, lead agency and number of participants enrolled (n)		Linked to care % (n)	Retained in care % (n)	HAART prescription % (n)	Virally suppressed (<200 copies/ml) % (n)
Birmingham, AL (intervention arm only)	A2C- University of Alabama at Birmingham (UAB) (87 clients served)	92% (80/87)	66% (57/87)*	64% (56/87)*	53% (46/87)*
	Local	74%	73%	Data not available	61%
Birmingham, AL (control arm only)	A2C- University of Alabama at Birmingham (UAB) (83 clients served)	93% (77/83)	69% (57/83)*	73% (61/83)*	51% (42/83)*
	Local	74%	73%	Data not available	61%
USA	A2C- all sites (4704 clients served) ²³	86% (4022/4704)	69% (3254/4704)*	63% (1986/3160) ^{24*}	62% (2937/4704)*
	National	80%	40%	37%	30%

*Greater than 10% missing. Interpret with caution.

Lessons Learned

BA₂C RCT impact study: The UAB/BAO team learned many valuable lessons throughout the implementation of the RCT. The greatest challenges were study recruitment and retention. The complexity of attempting to locate BA₂C target population was greater than expected. Waiting a full year to adjudicate whether a patient was “out of care” meant that the study team was likely never to be able to contact that patient. UAB adjusted their eligibility criteria as a result. They also expanded recruiting hours to include some weekend and after-hours calling. Both of these efforts met with success. In addition, UAB promoted the study on radio, social media, Craigslist, and Grindr. These efforts produced many inquiries, but few eligible enrollees. They also implemented in-hospital recruitment, identifying eligible patients admitted to UAB hospital and approaching those patients in the hospital. This effort was successful in securing the enrollment of a number of patients who they were previously unable to contact. In addition, communication and locating participants turned out to be more difficult expected. Great care, planning, and practice should be taken to ensure that timely and complete information can be shared quickly and easily between implementing organizations. UAB would recommend having sufficient staff committed to the project from the outset, in order to locate and

²³ The control arm for University of Alabama not included.

²⁴ This data does not include three sites- Damien Center, APLA_DHSP arm and Washington AIDS Partnership (WAP).

transport participants. In addition, the challenges met highlight the importance of retention as a public health practice. Our experience indicates that retaining participants is much easier than re-engaging out of care participants.

Finally, prior to the grant award, we recommend beginning detailed discussions about the regulations inherent in the grant award and implementation process. To help prevent contract complications, include AIDS United leadership, local entity decision-makers, local department leadership, and a financial representative from each of these, in these in-depth discussions.

Comparison of local treatment continuums of care: Most subgrantees' A2C continuums of care compared favorably to the corresponding geographically local continuums of care and surpassed their local continuums of care for all or most bars measured. In addition, the A2C all subgrantee continuum of care surpassed the national HIV continuum of care for all bars measured. However, it is very important to note that direct comparisons between non-A2C cascades and A2C cascades may not be appropriate due to differences in methods used to construct the cascades. Therefore, the non-A2C cascades should be used only to provide context and to better understand what gaps exist locally and how A2C programs might have served to address those gaps. In addition, one important lesson learned was that many sites struggled with getting data on whether or not participants had a current HAART prescription. This challenge was not anticipated given that HAART data can be reliably gotten from pharmacy records, medical record, and self-report (although with some limitation). For future programs, we would recommend either strengthening partnerships with pharmacies or relying on self-report data for HAART measures.

Summary and Conclusions from Evaluation Findings

This report presents findings from the national evaluation of the A2C program. Findings from the single-group assessment of participant health outcomes at baseline and 12 months suggest that A2C program participants successfully moved along the continuum of HIV care, as evidenced by significant increases over time in viral suppression. A2C subgrantee continuums of HIV care also compared favorably to location-specific HIV continuums of care. Additionally, the continuum of care for all A2C participants exceeded the national continuum of HIV care for all bars measured. However, it is important to note that while the RCT of one of the 12 A2C programs, BA₂C, saw increases in viral suppression from baseline to 12 months, these increases were not statistically significant.

At the network level, the evaluation of A2C assessed change in interagency collaboration as measured by network density and average node degree. Increases at most subgrantee locations in network density and average node degree suggest that interagency collaboration increased during the project. The findings also suggest that this collaboration was not simply due to the lead agency working with each implementing partner agency in a silo, but rather that collaboration increased between implementing partner agencies. Including at least one implementing partner agency was a mandate for the A2C program, and the evaluation suggests that, during A2C, collaboration between various types of organizations, including health departments, AIDS service organizations, HIV medical providers, and social service providers increased. All subgrantees acknowledged that the close partnerships with implementing partners was one of the key factors that helped their programs to succeed, especially when working with highly vulnerable populations with a high acuity of need. Other linkage and

retention-in-care programs might want to consider adopting a similar model to A2C of lead agency and a network of implementing partners.

The economic analysis of A2C assessed the cost of program delivery and estimated the cost-saving threshold, or the number of HIV infections each program would need to avert in order to be cost-saving. Program costs were estimated from the societal perspective, meaning that they took into consideration costs accrued by participants (such as costs related to transportation, lost wages, and dependent care). Six-month program costs ranged from \$104,288.12–\$385,318.85. A range in costs was expected given differences in program models, locations, and target audience served. As such, cost results from one A2C program should not be directly compared to cost from another A2C program. The cost-saving threshold for the A2C programs ranged from 1–2. These cost-saving thresholds indicate that the programs would need to avert from 1–2 HIV infections to be cost-saving. The A2C program thresholds are highly achievable and compare favorably with other, similar programs. (14) Overall, these findings suggest that HIV linkage and retention in care programs are an efficient use of resources.

The implementation evaluation sought to document barriers and facilitators to program implementation in order to inform the implementation of future programs. Across all 12 subgrantees, several themes emerged. Common barriers to program implementation included: the intensity of client needs; recruiting and retaining participants; staffing and administrative hurdles; and challenges related to working with multiple partner organizations. The high level of need among individuals who are not engaged in HIV medical care has been documented previously, in particular the need for housing. (15) In addition, the literature corroborates administrative challenges to implementing HIV linkage and retention-in-care programs, particularly those which employ peers. (16, 17) The three themes that emerged as factors that facilitated SIF program implementation were strong relationships with partner organizations; the flexible and innovative nature of the SIF programs; and the expertise, dedication, and passion of staff. These findings support prior research which has documented the facilitating factors at the organizational level, such as a prior history of collaboration between implementing agencies, strong leadership, formalized relationships such as MOUs, and clearly defined staff and implementing partner roles. (17)

Human subjects protection

BA₂C RCT impact study: UAB was the lead agency for this study and served as the oversight investigator for all activities that involve human subjects. All UAB and Birmingham AIDS Outreach staff completed human subjects training required by the UAB Institutional Review Board (IRB). The original human subjects protocol was submitted to the UAB IRB for a full review in July 2013, and subsequently received approval. Annual investigator progress reports have been submitted as required. There have been no notable issues with the study's IRB approval.

JHU was a study partner but at no point did JHU collect or receive client-level data. JHU contacted the JHU IRB and explained JHU's role in the study as a technical advisor. JHU's IRB determined that JHU's role constitutes non-human subjects research.

Outcome and implementation evaluation: The Johns Hopkins IRB has determined the evaluation activities conducted by JHU to be non-human subjects research (including the work JHU does with regards to monitoring of participant-level outcomes, network analysis, case studies, and economic

analysis). At the local level, each subgrantee site applied for IRB approval to carry out their proposed evaluation activities, including collection of patient-level data for the national evaluation. Table 25 below outlines the date each subgrantee site obtained IRB approval, the final determination, and a brief overview of consent procedures.

Table 25: IRB approval, final determination, and consent procedures by grantee

Subgrantee	Date of IRB approval	Final determination	Consent procedures
ActionAIDS	4/1/2013	Project does not constitute human subject research and does not require IRB oversight	NA
AIDS Action Committee of Massachusetts	9/26/2011	Minimal risk study	At enrollment staff reviews consent form with participants who then sign and date. All case managers have completed Human Subject Training.
AIDS Foundation Chicago	9/2011	Human subjects research	At enrollment staff reviews consent form with participants who then sign and date.
AIDS Project Los Angeles	7/2012 CBO Arm (Los Angeles County Department of Public Health) 1/2013 Clinical Arm (University of Southern California (USC))	Human subjects research	At enrollment staff reviews informed consent, California Medical Bill of Rights, and the Medical Release forms with participants. Signed and dated consent is accepted for each document. All staff have been trained to conduct human subjects research and received certificates from USC and LA County Department of Public Health.
Amida Care	11/30/2011	Non-research	All data used for the national evaluation are de-identified.
Christie s Place	4/2011 9/11/2012	Human subjects research	At enrollment staff reviews consent form

Subgrantee	Date of IRB approval	Final determination	Consent procedures
	**this 2012 date was for a project revision		with participants who then sign and date.
Damien Center	6/26/2013	not necessary/not reviewable”	Informed Participation Agreement signed by client
Louisiana Public Health Institute	8/6/ 2013	Human subjects research	Consent signed by participant
Medical AIDS Outreach	9/19/2013	Human subjects research	Consent signed by participant
St. Louis Effort for AIDS	5/2012	Human subjects research	Consent waived because all data are de-identified
University of Alabama, Birmingham	8/27/2013	Human subjects research	Performed by Research Assistant prior to baseline activities; baseline activities are scheduled to occur in the community (at Birmingham AIDS Outreach)
Washington AIDS Partnership, Positive Pathways	6/17/2011	Exempt	All data received by evaluation staff are de-identified.

Timeline

BA₂C RCT impact study: UAB sent study progress reports to JHU and AU every six months, in June and December. The progress reports include information such as: changes to personnel or major duties of existing personnel, tasks completed and in progress, data collected, unforeseen problems that occurred, and a narrative of important events that occurred. Study enrollment began in August of 2013 and ran through January of 2015. Twelve-month follow-up data collection started in August 2014 and continued through February 2016.

Monitoring of patient-level data: Subgrantees reported data to JHU every six months in June and December of each year. The final data was submitted to JHU in December of 2015. JHU cleaned and conducted final analyses through May 2016.

Case studies and network analyses: Data were collected for the case studies and the network analyses approximately 18–24 months from the start of program implementation. There were two cohorts of SIF subgrantees, and thus there are varying dates on data collection for case studies based on when implementation began Table 5 above highlights the dates for data collection for the case studies.

Evaluator/subgrantee role and involvement

AIDS United and the JHU evaluation team have worked closely and collaboratively on the national evaluation of the SIF initiative. We participate jointly on calls with subgrantee sites following each data pull to discuss the evaluation process, any outstanding questions or issues, and next steps. AIDS United and JHU staff conducted two joint subgrantee site visits during 2014 and coordinate on communications and site visits whenever feasible. Additionally, we have collaborated closely on plans for the final year of SIF funding and timelines for ending enrollment into the evaluation and completing follow up data collection cycles.

Evaluation staff has remained consistent with Dr. Cathy Maulsby continuing to serve as the Principal Investigator (PI) on the national evaluation and Dr. David Holtgrave continuing to serve as the Co-PI. Blessing Enobun, MPH, has joined the Johns Hopkins evaluation team and has played an important role in communication with subgrantees on data collection and analysis. At University of Alabama at Birmingham, Dr. James Raper serves as the PI, with Drs. Mugavero and Batey serving as Co-PIs for the randomized control trial of BA₂C.

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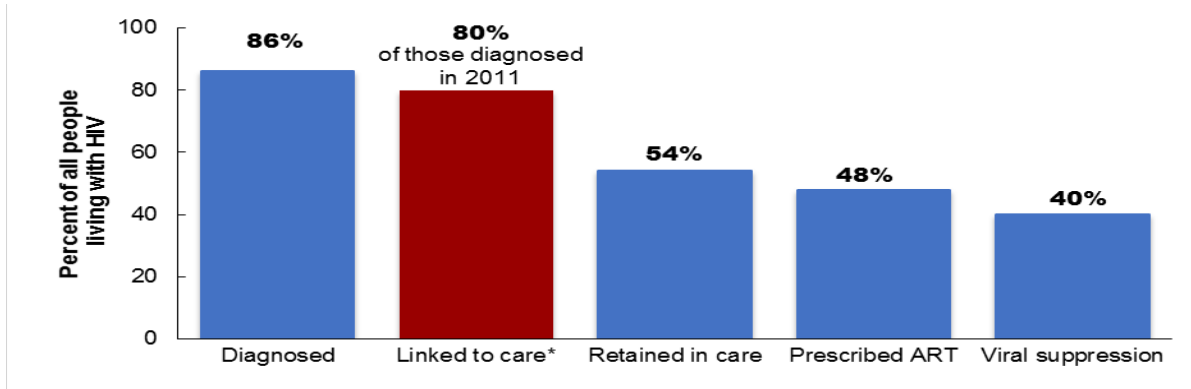
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Appendix 1: Local Cascades

Chicago:

http://www.cityofchicago.org/content/dam/city/depts/cdph/HIV_STI/2014HIVSTISurveillanceReport.pdf



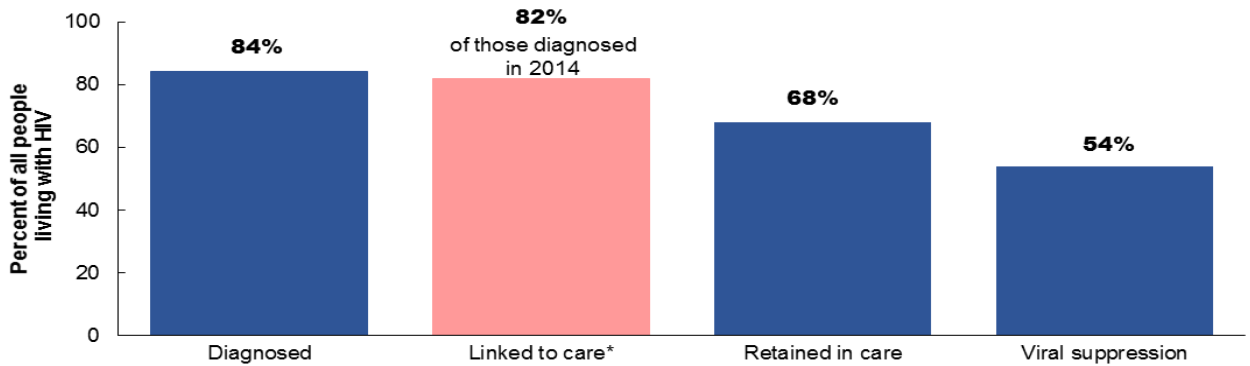
*Percent of persons ≥ 18 years of age with ≥ 1 CD4 or Viral Load or HIV-1 Genotype test reported within 3 months of HIV diagnosis among those diagnosed with HIV infection from 1/1/2011 to 12/31/2011.

Retained in care in care- Total weighted percent of HIV-infected adults who had at least one documented HIV medical care visit in 2011 and had a documented HIV viral load of undetectable or ≤ 200 copies/mL at most recent viral load test.

Alabama:

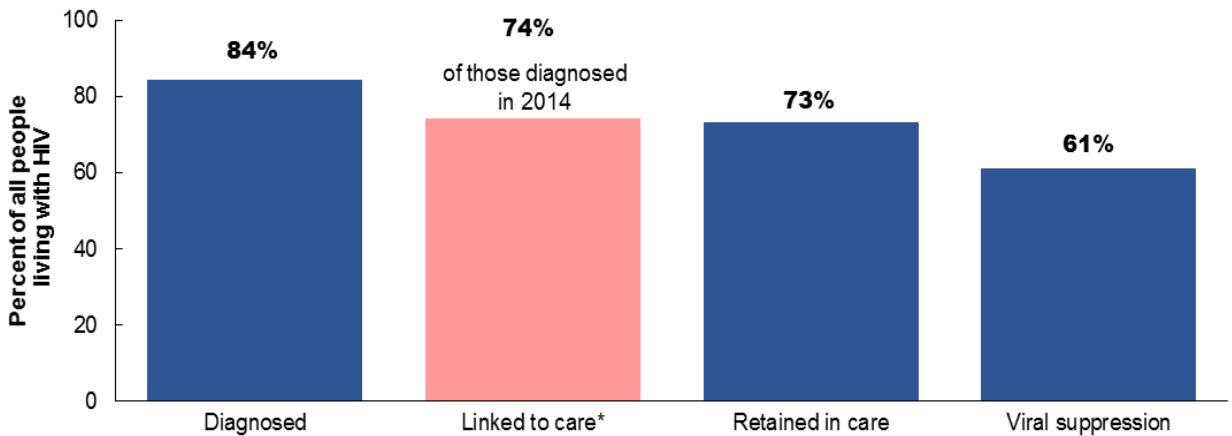
http://adph.org/aids/assets/TreatmentCascade_2014_Preliminary.pdf

Alabama-Public Health Area 8, includes Montgomery County among others.



*Calculated as the percentage of persons linked to care, evidenced by ≥ 1 CD4 and/or viral load test(s) within 90 days of diagnosis, among those newly diagnosed with HIV infection during 2014. Please note- HAART data not available.

Alabama-Public Health Area 4, includes Jefferson County among others.

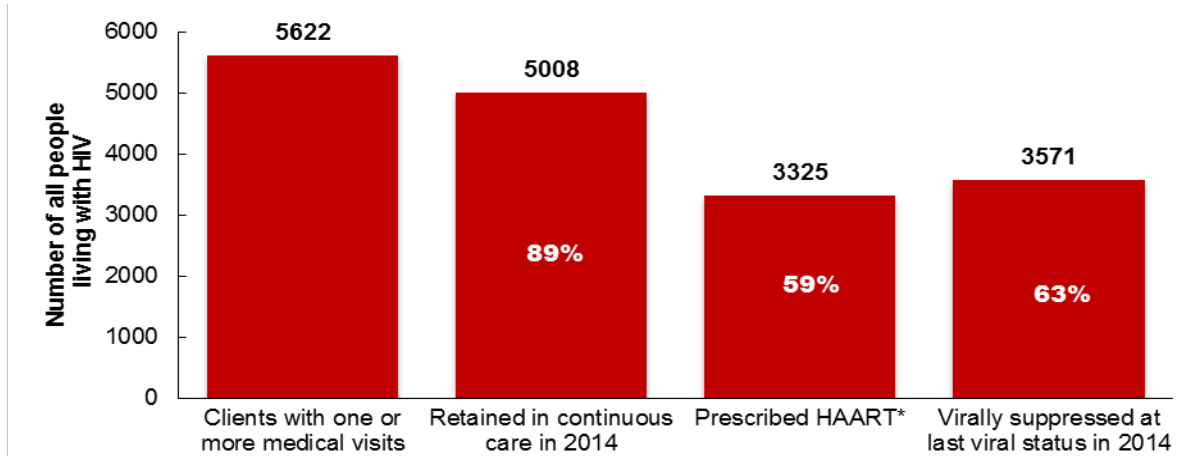


*Calculated as the percentage of persons linked to care, evidenced by ≥ 1 CD4 and/or viral load test(s) within 90 days of diagnosis, among those newly diagnosed with HIV infection during 2014. Please note- HAART data not available.

Washington, DC:

http://doh.dc.gov/sites/default/files/dc/sites/doh/page_content/attachments/HAHSTA%20HIV%20Care%20Dynamics%20supplement%20FINAL.pdf

2014 Care dynamics among Ryan White Clients

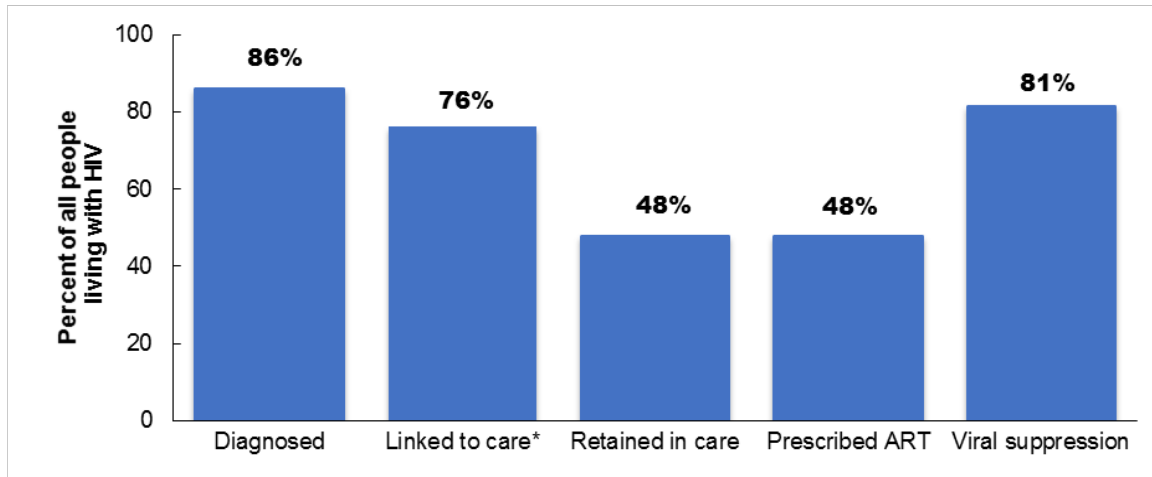


*One provider was unable to submit date and therefore was not included in this metric.

Indianapolis:

<https://matecindiana.com/2015/04/13/april-13-2015-hiv-care-updates-for-the-indianapolis-carmel-metropolitan-statistical-area-hiv-continuum-of-care-measures-2014-vs-2013/>

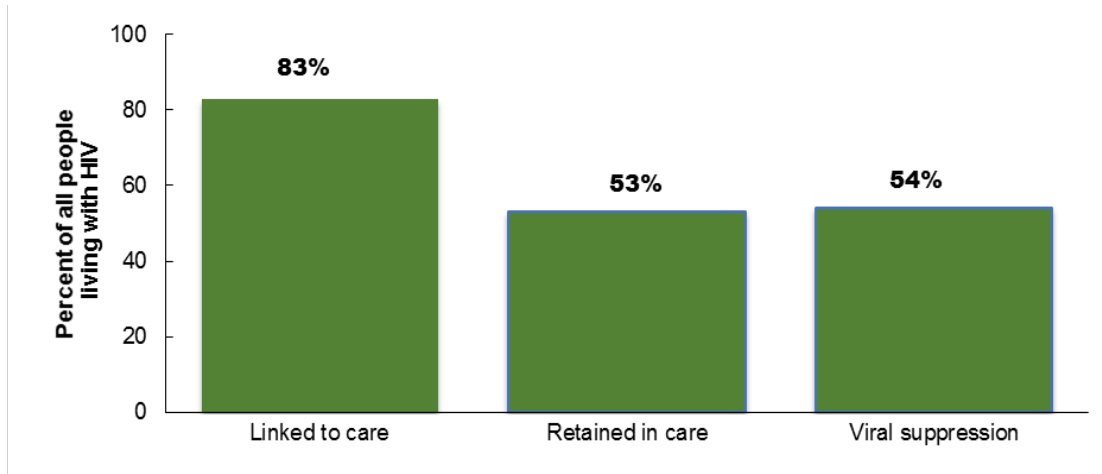
HAB Continuum of Care Measures among People Living with HIV/AIDS, Indianapolis-Carmel Metropolitan Statistical Area and U.S.: 2014



St. Louis:

<http://stlplanningcouncil.com/files/treatmentcascade2014.pdf>

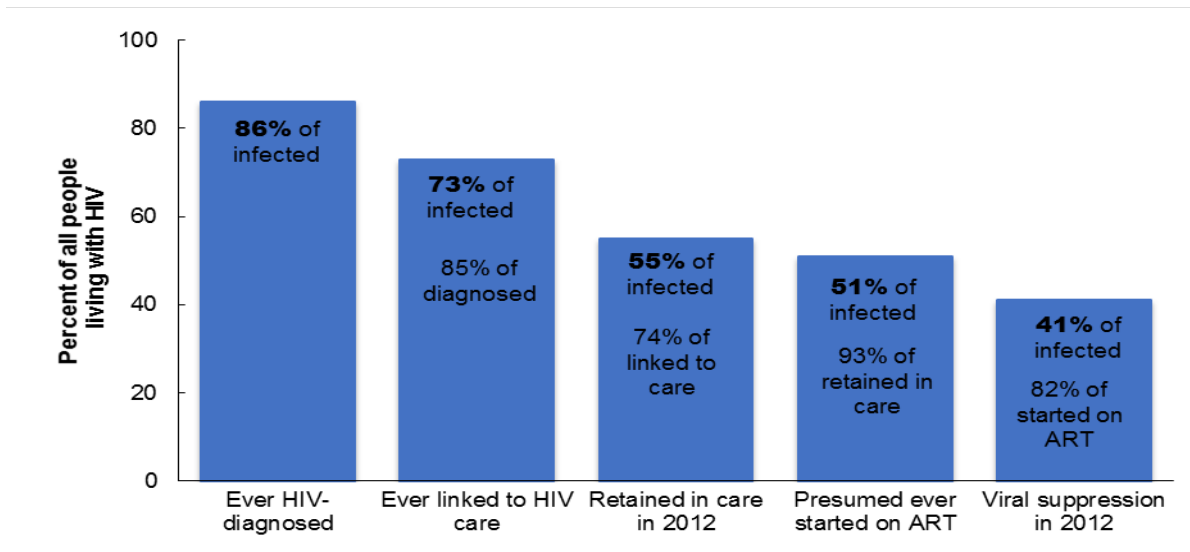
Engagement in HIV Care, St. Louis HIV Care Region, 2014 (Provisional)



*HAART data not available.

New York City:

https://www.health.ny.gov/diseases/aids/ending_the_epidemic/meetings/docs/ete_nycdohmf.pdf

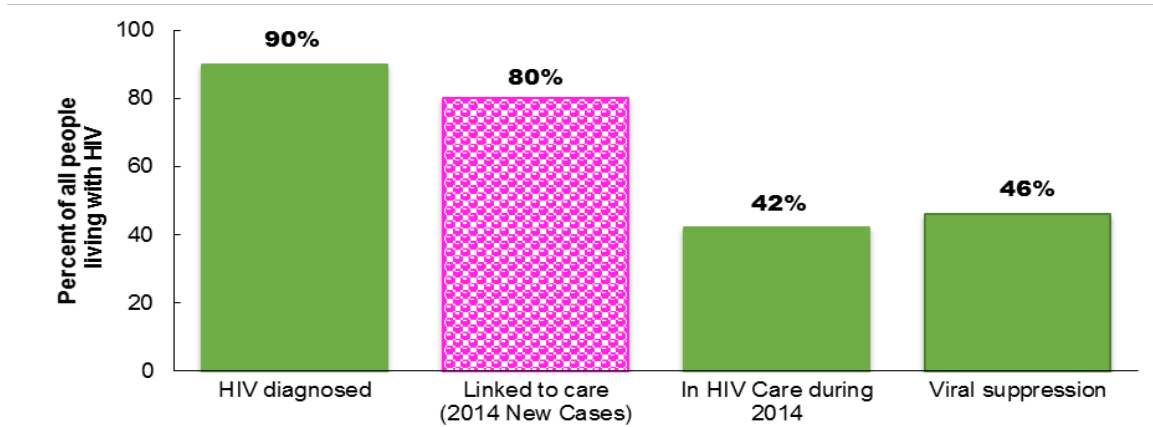


Engagement in HIV care

Philadelphia:

<http://www.phila.gov/health/pdfs/2014%20Surveillance%20Report%20Final.pdf>

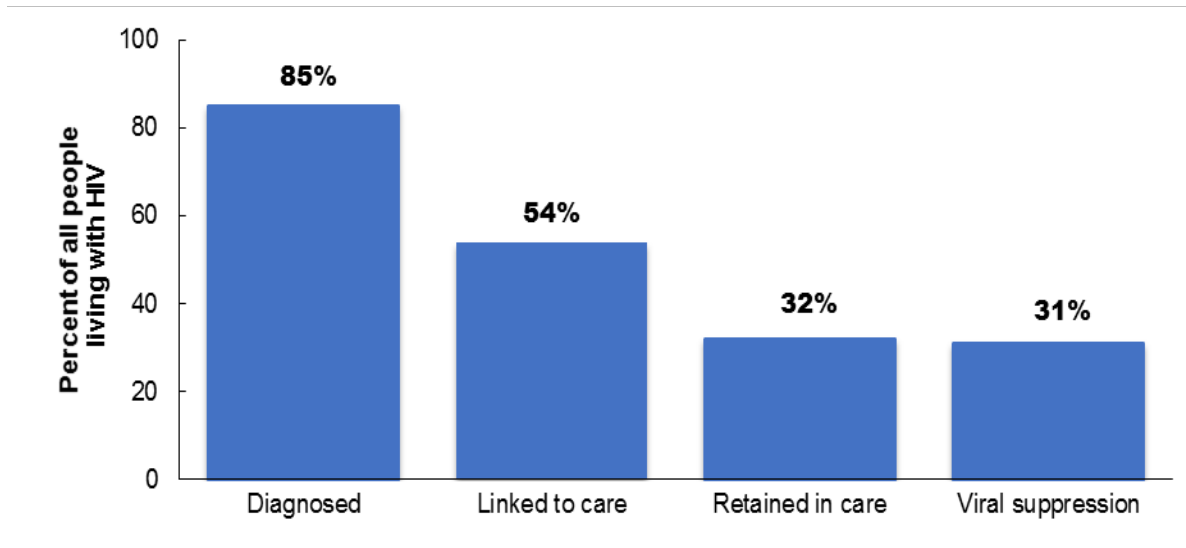
HIV Care Continuum Philadelphia, 2014



*An estimated 10% of those infected are unaware of their status Source: Philadelphia Department of Public Health, AIDS Activities Coordinating Office

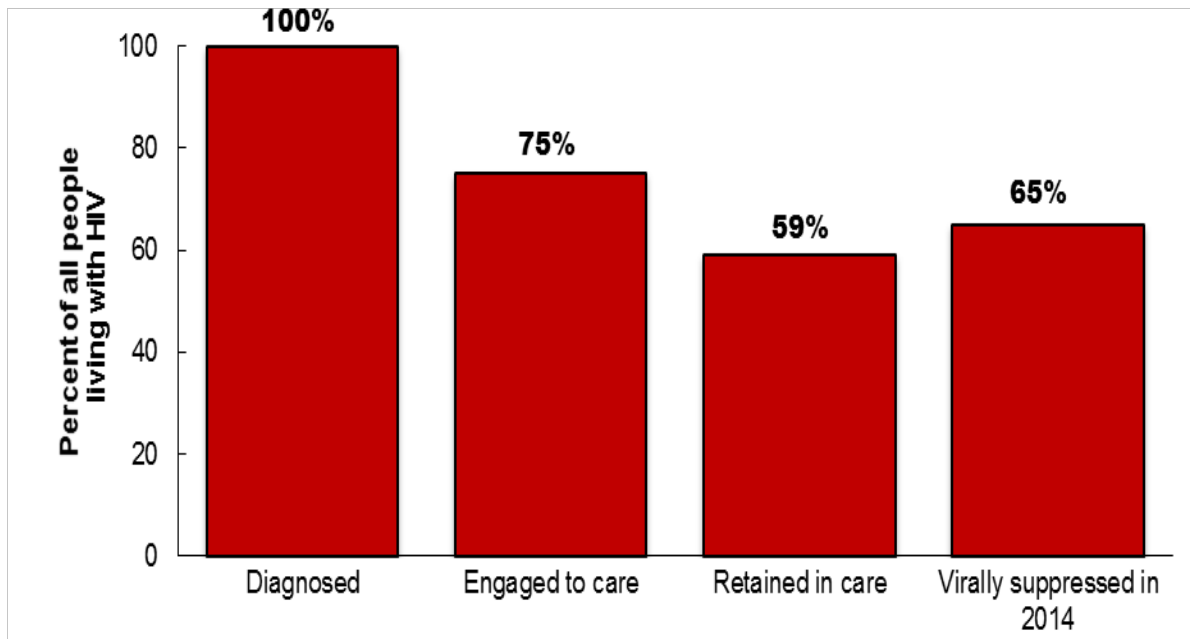
San Diego:

http://www.sandiegocounty.gov/hhsa/programs/phs/documents/STDMonthlyReport_Vol_6_Issue_1.pdf



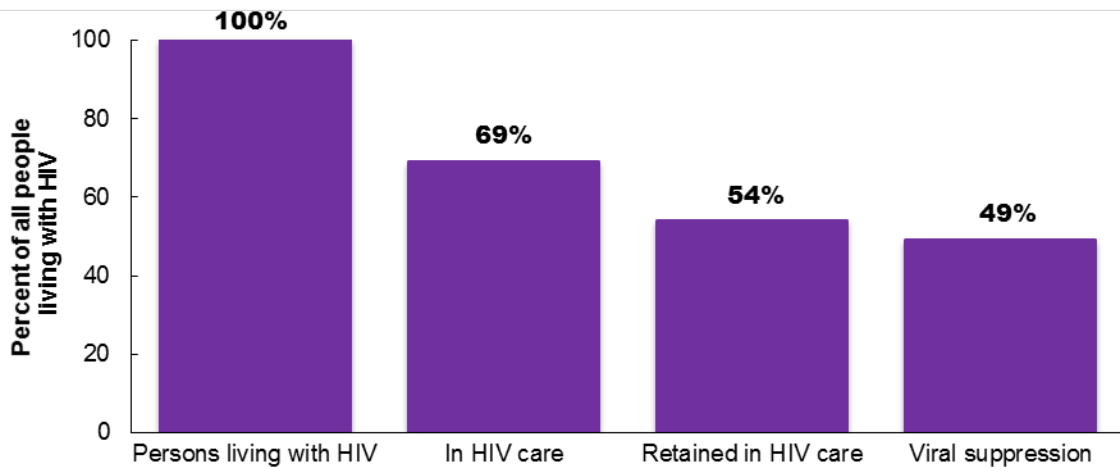
Boston:

<http://www.mass.gov/eohhs/docs/dph/aids/2016-profiles/hiv-care-continuum-factsheet.pdf>



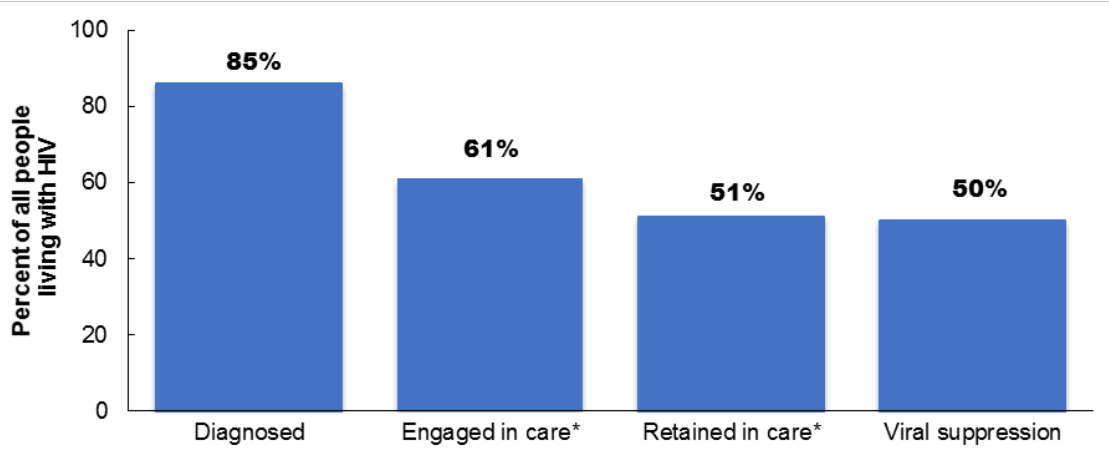
New Orleans:

<http://new.dhh.louisiana.gov/assets/oph/HIVSTD/hiv-aids/2015/2013 STD HIV Surveillance Report.pdf>



Los Angeles:

<http://publichealth.lacounty.gov/dhsp/Reports/HIV-STDsurveillanceReport2014.pdf>



*Engaged in care: ≥ 1 CD4/VL/Geno tests in 2013; retained in care: ≥ 2 CD4/VL/Geno tests at least 3 months apart in 2013.