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Navigation programs for people living with HIV/AIDS who experience homelessness: considerations for assessing performance and costs

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BOSTON UNIVERSITY
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Dissertation

**NAVIGATION PROGRAMS FOR PEOPLE LIVING
WITH HIV/AIDS WHO EXPERIENCE HOMELESSNESS:
CONSIDERATIONS FOR ASSESSING PERFORMANCE AND COSTS**

by

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ABSTRACT

Despite the advances in antiretroviral therapy (ART) a disproportionate number of people living with HIV (PLWH) remain limited in their access and use of health care and treatment, including racial/ethnic minorities, persons with mental health and substance use disorders and persons experiencing homelessness or unstable housing. Patient navigation programs have emerged as a potential effective and efficient use of resources to reach and engage these vulnerable populations as part of the HIV service delivery system.

This dissertation contains three chapters that aim to identify and assess the performance and mechanisms for navigation programs working with PLWH who experience homelessness and co-occurring substance use and mental health disorders. Study 1, *Developing a Reliable and Valid Composite Measure of Effectiveness for HIV Navigation Programs for PLWH who are homeless/unstably housed*, describes the development of a multidimensional outcome measure to assess the performance of navigation programs for this population. The composite measure was comprised of seven indicator variables: linkage to care, retention in care and adherence to treatment, patient

experience of care, physical and mental health related quality of life and housing stability. Using multivariate analyses, a 3 item measure of retention, adherence, and housing stability was found to have high goodness of fit and strong predictive association with viral suppression.

Study 2, *Classifying Components of HIV Navigation Programs for PLWH who are homeless/unstably housed*, used a latent-class analysis to identify common patterns of activities, modalities of communication, location of work, and staff composition among highest utilizers of services. Results showed that types of activities, work setting and modality of contact were significantly associated with increased retention in care. No difference in activity, staffing patterns, work setting or modality of communication of navigation programs were found on viral suppression rates.

Study 3, *An Economic Evaluation of HIV Navigation Programs Working with PLWH who are Homeless/Unstably housed* assessed costs and net benefits of these navigation programs overall and in subpopulations. Cost utility and net benefit analyses performed indicated that navigation programs for PLWH who are homeless/unstably housed are a potential efficient investment of resources at various willingness-to-pay thresholds.

Navigation programs provide a myriad of services for PLWH who are homeless/unstably housed and must be flexible in their approach to address the multiple medical and psychosocial needs of this population. The results of this dissertation provide information for improving the design, measuring performance and costs and benefits of

navigation programs as part of the HIV service delivery system for PLWH who experience homelessness.

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List of Abbreviations

ART	Antiretroviral therapy
CC/PN programs	Care coordination and patient navigation programs
CUA	Cost Utility Analysis
HRSA	Health Resources & Services Administration
HUD	US Department of Housing & Urban Development
IAPAC	International Association of Physicians in AIDS Care
ICM	Intensive Case Management
IOM	Institute of Medicine
LCA	Latent Class Analysis
NAS	National HIV/AIDS Strategy
PLWH	People living with HIV/AIDS
PPACA	Patient Protection & Affordable Care Act
QALY(s)	Quality-adjusted life year (s)
RWHAP	Ryan White HIV/AIDS Program
SPNS	Special Projects of National Significance
WTP	Willingness-to-pay

CHAPTER 1: Introduction

In the U.S., an estimated 1.2 million people are currently living with HIV/AIDS (PLWH) and 50,000 new infections occur each year.¹ Current recommendations call for all people living with HIV (PLWH) to initiate highly active antiretroviral therapy (ART) regardless of viral load and CD4 count, and at-risk individuals be provided PrEP (ART for pre-exposure prophylaxis) to prevent HIV transmission.² The estimated cost-savings to do this would be \$338,400 if all PLWH presented early and remained in care.³ However a disproportionate number of PLWH are from communities that have historically been limited in their access and use of health care and treatment, including racial/ethnic minorities, persons with mental health and substance use disorders and persons experiencing homelessness or unstable housing.^{1,4} Finding strategies to reach these populations with life-saving ART can reduce mortality and morbidity, improve the quality of life of PLWH and reduce medical costs to society.

People who are homeless or unstably housed are one of the most vulnerable populations at risk for having and living with HIV. Although only 0.4% of the general population is HIV positive, the percentage climbs to 3.4% for people who are homeless.⁵ PLWH who are homeless/unstably housed are more likely to delay entering care, more likely to have poorer access to HIV care, less likely to receive optimal antiretroviral therapy and less likely to adhere to therapy.⁶⁻⁷ Recent national data from the Ryan White Programs found that PLWH who were unstably housed were twice as likely to have a detectable viral load compared to PLWH with stable housing.⁸

One potential strategy to improve health and housing outcomes for this vulnerable

population is the use of care coordinators and patient navigators (CC/PN)[†] as part of the care team. In cancer care, navigators provide specific tasks as part of the care team including both patient related tasks (appointment reminder, service accompaniment) and network related tasks (coordination and communication with other providers, updating and maintaining chart data).⁹⁻¹⁰ In HIV programs, the role of the navigator is not as clearly defined although there is emerging evidence that navigators assist with facilitating the linkages to HIV care and treatment for those who are newly diagnosed and provide continued support for PLWH to stay in care.

This chapter will present a summary of the literature and the conceptual framework for my dissertation. The subsequent three chapters are separate studies aimed at evaluating the cost and effectiveness of patient navigation programs in enhancing care and treatment for PLWH who experience homelessness. The first study, *Developing a reliable and valid composite measure of effectiveness for HIV navigation programs* aims to enhance the current measures available to capture the effectiveness of HIV navigation programs working with populations facing multiple co-morbidities and barriers to care. The paper describes the development of a multidimensional outcome measure to assess the performance of patient navigation programs with PLWH who experience homelessness. The composite measure is derived from outcomes in accordance with the

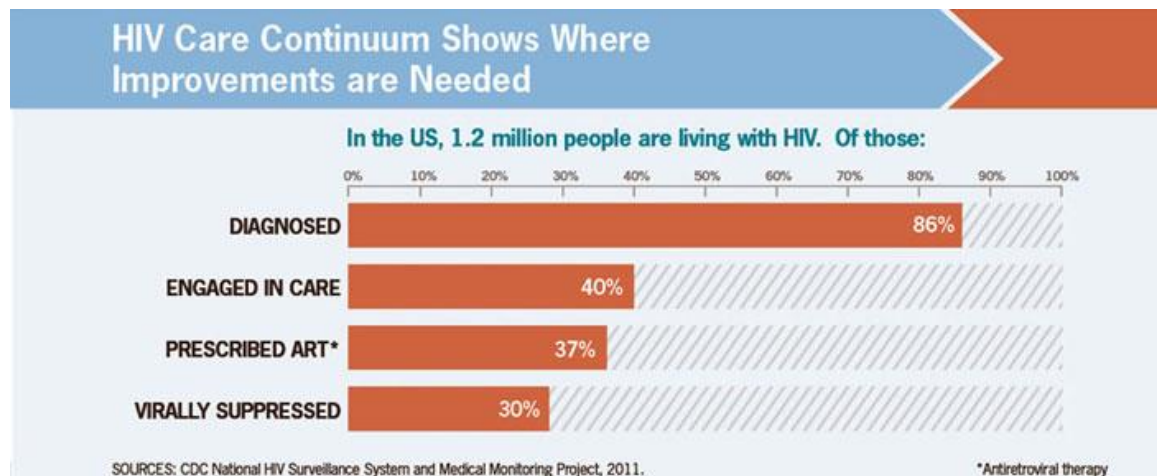
[†] For this dissertation I will be using the term CC/PN to represent the use of a care coordinator, a patient navigator, peer navigator or other support worker. The role was designed to be part of the HIV care team and support services in addition to the traditional care team that would reduce barriers to care and create a seamless system of care for the patient. In each case they are in addition to the HIV case managers and housing case managers and other health care members of the team.

2015 National HIV/AIDS Strategy for the U.S. The second study, *Classifying Components of HIV Navigation Programs for PLWH who are homeless/ unstably housed*, builds upon current evidence about the role of patient navigators in improving access to care for vulnerable HIV populations. It uses a latent class analysis to identify the key activities, staffing patterns modalities and settings that HIV patient navigators carry out their work with the PLWH who experience homelessness. Finally the third study, *An Economic Evaluation of HIV navigation programs working with PLWH who are homeless/unstably housed* aims to broaden the current knowledge base about cost-effectiveness of the components of patient navigation programs. It assesses costs and net benefits of navigation programs, and identifies specific patient and program characteristics that contribute to improved benefits.

Patient Navigation in Achieving the HIV Continuum of Care for PLWH Who Are Homeless

The National AIDS Strategy (NAS) first implemented in 2010 and then revised in 2015 set forth funding and program activities that aim to increase the rates at which PLWH are able to achieve a continuum of care: diagnosed, linked to medical care, retained in medical care, prescribed antiretroviral therapy and finally virally suppressed. (Figure 1-1)

Figure 1-1: The HIV Care Continuum



Source: www.hiv.gov

The NAS goals focus on this continuum of care and include: 1) Reduction in disparities in HIV care 2) Increased prevention and 3) Increased access and retention in care and treatment. The strategy focuses on populations where the HIV epidemic is increasing: racial/ethnic minorities, persons with high risk behaviors, those who inject drugs, young men who have sex with men, and homeless/unstably housed populations. To achieve these goals, the NAS calls for increased support for community level

strategies to reach these vulnerable populations and allocate resources through federal agencies such as the US Department of Health and Human Services (DHHS) and Housing and Urban Development (HUD) for distribution of those funds. A specific indicator was also established to reduce the percentage of persons in HIV medical care who are homeless to no more than 5%.¹¹ CC/PN programs are one type of community approach to achieve this continuum of care but little is known about the mechanisms and effectiveness of this model of service delivery and treatment for PLWH who are homeless/unstably housed.

Additionally, there is little known in the literature about the cost-effectiveness of CC/PN programs in engaging PLWH in care and treatment and specifically with hard to reach populations such as people who experience homelessness or are unstably housed. Current analyses focus on the cost per client for improving retention in care as a simple measure of the costs, without balanced assessment of the value of the intervention.¹²⁻¹³ Yet HIV navigation programs may result in additional measures of effectiveness that have important policy implications for the organization of health service systems.¹⁴ The Patient Protection and Affordable Care act of 2010 (PPACA) in addition to expanding health insurance coverage, created new initiatives to fund the use of community and non-clinician models of care, such as HIV navigation programs, to help meet the increase in demand for health services and improve the quality of care by reducing barriers from fragmented service systems.¹⁵⁻¹⁶ More research and information are needed about how investments in this health care workforce can improve the efficiency of the health service system and improve health outcomes of the populations being served.

Individual, provider and system level factors associated with HIV and homelessness

Data from the national Ryan White Program (RWHAP) indicate over 16% of PLWH have temporary or unstable housing situations.^{8, 17} However, the rates of homelessness among PLWH actually may be higher since this statistic represents PLWH who are known to care because of RWHAP. In addition, PLWH who are part of the RWHAP may also have better health outcomes compared to those with other types of coverage or no access to care.¹⁷ Thus, focusing resources on homeless/unstably housed populations is warranted from a population health perspective. Lower rates of viral suppression can lead to a greater risk for HIV transmission. In addition to lower rates of viral suppression, homelessness increases the risk of death among PLWH, with only 65% surviving five years compared with 81% of housed PLWH.¹⁸ These poorer health outcomes in homeless/unstably housed populations are inextricably linked to other co-morbidities, such as inadequately treated or untreated substance use and mental health conditions.¹⁹⁻²⁰ A systematic review of housing status, medical care and health outcomes for PLWH found that poor housing status was independently associated with poor health outcomes, controlling for individual and care system factors.²¹

There is some evidence that *obtaining housing* can contribute to better health outcomes for PLWH. Those who obtained supportive housing or had stable housing had improved CD4 counts, better functional health status, and a lower risk of death.²¹⁻²³ Stable housing has also been shown to help homeless individuals with detectable viral loads achieve viral suppression within a median of 3.9 months.²³ Evidence is also

emerging of an association between stable housing and virological suppression and engagement in health care.^{21,24-25} In studies of non-HIV homeless populations, Housing First programs, which provide permanent housing with support services, has been associated with a reduction in illicit drug and alcohol use, a decline in the severity of drug addiction, and an improvement in mental health.²⁶⁻²⁷ These studies suggest that interventions that improve housing stability may address the syndemic of unstable housing, HIV, addiction, and mental illness which is crucial to meeting the NAS goals of improving health outcomes and reducing disparities for PLWH.

However, these positive health outcomes are elusive since PLWH who experience homelessness face a myriad of systemic barriers to care, including a fragmented health service system and inadequate insurance coverage for primary HIV care and behavioral health services. Although integration of health services improves HIV treatment outcomes,²⁸⁻³⁸ these services are often provided by different types of clinicians and usually in different clinical settings. This in turn makes it difficult for people whose lives are complicated by homelessness to simultaneously access all types of care. One study of PLWH with co-occurring mental illness and substance use disorders found that only 33% received concurrent mental health and addiction treatment services, 26% received only mental health services, 15% received addiction treatment, and 26% received no services.³⁶

Even if these systemic barriers are addressed, PLWH who are homeless may experience provider-based barriers to care, including reluctance to treat patients with co-occurring substance use and mental health disorders due to inexperience and perceptions

of patient's poor adherence to treatment or beliefs that treatment will lead to increased HIV risk behaviors and transmission.³⁷ One study of experienced North American prescribers indicated they would withhold ART to PLWH if they were actively using drugs.³⁸

Efforts to reduce these system- and provider- related barriers to care have included co-location of HIV primary care with mental health and addiction services and having an interdisciplinary team approach that includes transportation, case management, mental health care, and medication-assisted therapies to reduce substance use. There is evidence that these strategies help to retain PLWH in primary medical care and treatment and are recommended strategies for improving HIV treatment outcomes by the International Association of Physicians in AIDS Care (IAPAC).³⁹ Yet more information is needed to identify the key aspects of these models of care and their relative and marginal effectiveness in improving health and housing outcomes for homeless/unstably housed PLWH.

Navigation programs, the HIV care system and homeless populations

In the last decade, patient navigation programs have been an evolving strategy in HIV programs to outreach, engage and retain people living with HIV who traditionally were marginalized from the care system.⁴⁰⁻⁴⁷ Data from the HRSA Outreach Initiative of 4 navigation-like interventions showed improvement in retention in care from 64% at baseline to 87% and 79% post 6 and 12 months follow-up.⁴⁰ Qualitative studies have shown similar promise of navigators reaching women of color and persons being released from jail in facilitating linkages to medical care.⁴³⁻⁴⁶

There is emerging evidence on the effectiveness of CC/PN programs, what navigators do, and how their roles differ from other members of the care team.⁴⁸ There is little standardization in the staffing pattern, qualifications and training of the person serving as a navigator. Many studies employ navigators who share cultural characteristics with the communities they serve. These navigators tend to be lay health workers as peers or para professionals.⁴⁸ One of their main roles has been to identify unmet needs and reduce barriers to care by connecting clients to resources for medical care and other social services.⁴⁰⁻⁴⁷ Other critical roles also have been to coach and support communication with providers and accompany clients to appointments and conduct health education sessions.⁴³⁻⁴⁶ Peer navigation has also been shown to play a role in providing emotional support to a client and fulfilling a need for an affiliation with a social network.⁴⁹

Navigators have ranged from peers and paraprofessionals with little formal training in social work or case management to highly trained nurses and social workers.⁴⁰⁻⁴⁹ Most navigation programs are based in clinics or hospitals, but in some cases a navigator may work across several agencies and often is trained to apply principles of strengths-based and motivational interviewing techniques to motivate their clients to healthy behaviors and actions.

There is emerging evidence the HIV patient navigation programs can achieve the outcomes of the HIV care continuum, such as linkage and retention in care.^{41, 42, 50} A national study of 3 care coordination/navigation programs to link and re-engage newly diagnosed and out of care PLWH achieved 88% linkage to care and 69% retention in

care.⁴⁷ In intensive peer navigation and education was also found to reduce gaps in care for PLWH who were out of care but also stably housed.⁵¹ Recent trials have found null effects of navigation programs on treatment adherence or viral suppression⁵¹⁻⁵² but peer and community health worker programs in HIV have been found to be efficacious with adherence to treatment in the United States especially if they lasted a minimum of 24 weeks and up to 48 weeks with emphasis on medication management.⁵³⁻⁵⁵

For PLWH who are homeless/unstably housed there is limited evidence of the role of CC/PN programs and their impact on housing or health outcomes. In studies of homeless populations including those living with HIV, interventions have focused on providing intensive case management services to obtain and maintain permanent supportive housing. These programs employ “housing first” strategies and provide housing assistance along with intensive supportive services through a case manager, regardless of the person’s housing history or substance use or mental health conditions.⁵⁶⁻⁵⁷ Housing case management included assistance with applying for benefits, obtaining government identification, negotiating with landlords, learning life skills, and organizing medical appointments.⁵⁸⁻⁶² In some cases the case manager was a social worker and in other studies the professional credentials are not clearly identified. Study results are mixed with respect to substantial improvements in health outcomes such as viral suppression, physical and mental health functioning and retention in care.⁵⁸⁻⁶² However, none of these studies test specifically the role of supportive services versus obtaining housing. Thus it is difficult to tease out the main effects resulting in particular housing stability and health outcomes.

Cost effectiveness of HIV and navigation programs

Most of the economic evaluations in HIV have focused on cost-effectiveness of therapeutic regimens and risk reduction strategies to avert future HIV cases but there is emerging evidence about the economic impact of interventions to link retain HIV-positive individuals in care and treatment.⁶³⁻⁶⁵ Most studies are not specific to homeless populations but do focus on other vulnerable populations. However, two cost analyses have focused on homeless with HIV or other chronic conditions who received intensive case management (ICM) interventions and housing assistance.⁶³⁻⁶⁴ Both studies found housing assistance with ICM to be cost-effective or cost saving with respect to avoidable health care costs such as excess emergency room visits or hospitalizations and averted HIV infections.⁶³⁻⁶⁴ Basu et al.⁶³ in an analysis of an intervention of housing assistance and case management to PLWH who were homeless estimated a cost-savings of approximately \$6,622 compared to usual care. Holtgrave et al.⁶³ in examining the cost effectiveness of similar housing and case management intervention found an estimated a cost-per quality of life year saved to be \$62,493 which compares favorably to other well-accepted medical and public health services using the standard threshold of \$100,000 willingness to pay for effective interventions.

However, there are challenges with these cost studies. A recent review of the costs and cost effectiveness of community services for HIV prevention and treatment in the last two decades, found that studies used retrospective costs and did not break down costs into relevant consistent components and few were disaggregated by the characteristics of the individuals using services.⁶⁶ A further challenge is the limitation in

lack of standardization of costing methods both in terms of estimating relevant unit costs and estimating cost per outcome achieved or service per unit time. Previous studies use micro costing techniques to estimate the average cost per client, include both payer related costs (personnel, materials, service costs per unit (medical, legal, housing) and client costs (transportation, child care, time spent in receipt of services). However these cost studies did not stratify across characteristics of individuals but more broadly for person who were both living with HIV and experience unstable housing. These studies calculated standard cost effectiveness measures of cost utility (CUA) using quality life adjusted years, which have been criticized for being biased toward age and disability status and not considering a person's willingness to pay for care.

Economic evaluations of strategies to link and retain HIV positive patients in care are beginning to emerge. One study of six clinic sites that used a Retention Care Coordinator plus education compared to an education alone group and a standard of care group resulted in a cost per client retained in care of \$393.¹² Another study of a case management intervention to link recently release PLWH from jail found a mean cost to link to care to be \$4,219 the cost to viral suppression was \$8,432 and the cost savings for quality adjusted life year was \$72, 285 deeming it cost effective from a societal cost perspective.¹³ Other linkage to care programs using similar navigation like interventions found monthly cost ranged from \$97 to \$536 per client from a payer perspective.⁶⁵ The challenge with these studies is the heterogeneity in the programs and populations served; the variation in the length of intervention, the roles of staff and the documentation and activity in staff tasks for linkage to care, and no evaluation of the types of tasks that were

particularly cost effective.

In summary, while there is emerging evidence of the impact of housing status and health outcomes, there is a need to better understand the mechanism and identify the key components of intervention such as CC/PN programs that contribute to the cost and effectiveness of implementing these interventions, especially for PLWH who are homeless. Identifying the role of these actors in improving housing and health outcomes and the services provided as part of the care team, can help to improve the delivery and efficiency of health services.

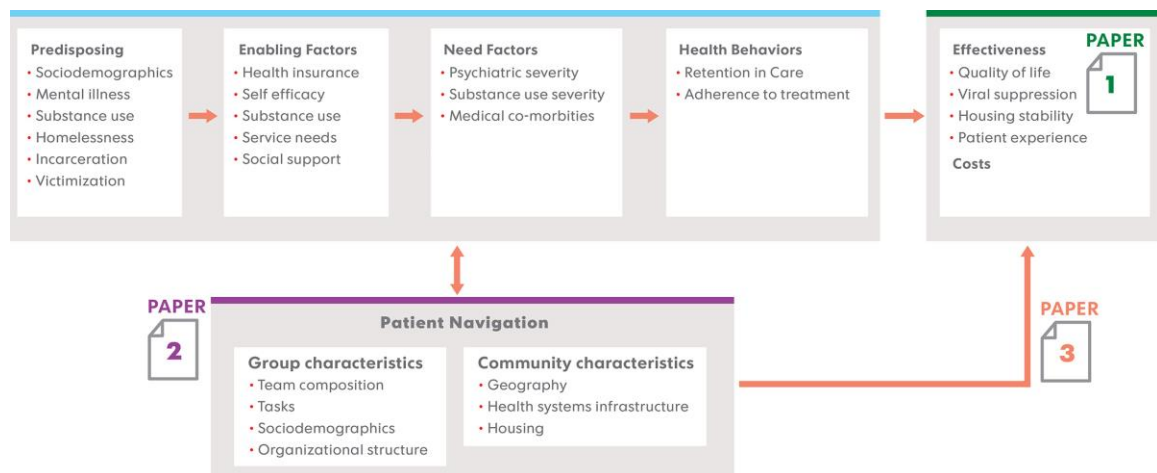
Conceptual Model

My dissertation uses a conceptual framework that incorporates elements of Gelberg's *Behavioral Model for Vulnerable Populations* for examining the access and use of the health and housing services, and Mittler's *The Engaging Consumers in Health Care in Communities (EHC)* framework.⁶⁷⁻⁶⁸ Gelberg's model adapts Andersen's Access to Health Care Utilization model to tailor predisposing factors such as mental illness and substance use, homelessness status and history of incarceration; and enabling factors such as level of social support, food security, stigma and self-efficacy and understand the impact on health service utilization, adherence to treatment and health outcomes such as viral suppression. Mittler's framework adopts the socio-ecological framework to look at individual, group and community level factors affecting consumer engagement in health care and their impact health status, well-being and costs.

My dissertation integrates these two frameworks to examine individual (Gelberg), group and community (Mittler) factors associated with HIV navigation programs that

impact access and use of HIV and other support services on health outcomes and the associated costs. The costs and effectiveness of HIV navigation programs may be driven by *individual characteristics*, such as severity of mental illness and substance use risk, incarceration history, level of unmet or length of time homeless/unstably housed. Some of the CC/PN factors to be explored include: *group characteristics* such as services provided to clients, tasks performed as part of the health and housing care team, and the team composition with whom patient navigator/care coordinators collaborate to address client needs and education and skills of the CC/PN; and *community characteristics* in which the CC/PNs operate such as the geographical setting, and the health system and housing infrastructure in the community. Figure 1-2 provides a visual representation of the proposed framework.

Figure 1-2: Determinants of the Effectiveness of HIV Navigation Programs for homeless/unstably housed People living with HIV



Using this framework my dissertation explores CC/PN programs in improving health outcomes among PLWH who are homeless with co-occurring mental health and substance use disorders. Three studies assess performance, specific characteristics of components of the navigation programs and costs and benefits.

Study one: Developing a reliable and valid composite measure of effectiveness for HIV patient navigation programs

Purpose: This study has two aims: 1) to develop a multidimensional outcome measure to assess the effectiveness of patient navigation programs that could capture the breadth and depth of HIV patient navigation programs working with PLWH who are homeless; and 2) evaluate the validity and reliability of this composite measure

Methods: A formative approach using *a priori* indicator variables established by the National HIV/AIDS strategy based on recommendations from measures across several federal agencies, including the U.S. Department of Health and Human Services, U.S. Department of Housing and Urban Development, U.S. Interagency Council on Homelessness, and the Institute of Medicine. These measures for program effectiveness include: linkage to care, retention in care, adherence to care, health related quality of life, patient experience of care and housing stability. Correlation procedures were used to test potential biases of each indicator variable in the summary measure and test for collinearity between indicator variables. Exploratory factor analyses were performed to test the viability of the composite measure. Predictive validity was tested with viral suppression. Sensitivity analyses were performed to assess the robustness of the measure and identify the best fit of the measure in predicting viral suppression.

Study two: *Classifying components of HIV navigation programs for PLWH who are homeless/unstably housed*

Purpose: HIV patient navigation programs have been used for certain discrete tasks in time-limited setting across a diverse group of PLWH. However, there are very few studies that examine the types of activities settings, staff composition and modalities that work with PLWH. This paper has three aims: 1) to characterize and classify the components of patient navigation programs working with PLWH who are homeless; and 2) to identify if certain aspects of patient navigation programs are associated with specific populations; and 3) assess which aspects of patient navigation programs resulted in improved health outcomes of retention in care and viral suppression.

Methods: A latent class analysis is used to identify the key activities, staffing patterns modalities and settings that CC/PN programs implement their work with the priority study population. A multinomial regression analysis was performed to examine associations of the classes with patient characteristics and also outcomes of viral suppression.

Study 3: *An economic evaluation of HIV navigation programs for PLWH who are homeless/unstably housed.*

Purpose: The final paper examines the costs and benefits associated with the patient navigation programs for PLWH who are homeless. The study had two aims: 1) to assess the cost and cost utility of these programs and 2) perform a net benefit analysis to identify specific patient and program characteristics associated with the CC/PN programs.

Methods: Costs were calculated as average cost per patient at the program level for participants served in the 12-month program. A sub-sample of participants (n=542) with outcome data was used to calculate the cost per quality-adjusted life years and net benefit analysis applying regression techniques to identify associated patient and program characteristics.

Data for this dissertation are from a longitudinal dataset of a national multisite study of nine demonstration projects aimed at building a medical home for multiply diagnosed HIV –positive homeless/unstably housed populations.⁶⁹ The Health Resources and Services Administration (HRSA) through its Special Project of National Significance (SPNS) funded nine demonstration sites across the country to implement CC/PN programs as part of a care team with a goal of creating a networked system of care and medical home aimed at improving retention in HIV care, viral suppression and housing stability. The project period was from September 2012-August 2017. The nine sites provided services to 1,338 PLWH who were homeless or unstably housed with co-occurring psychiatric or substance use disorders. Among this population 909 individuals consented and participated in a prospective study to evaluate the impact of the CC/PN programs from September 2013-February 2017. Table 1-1 describes the 909 participants. Eight sites were located in urban settings in Oregon, California, Texas, Florida and Connecticut. One site was funded in rural North Carolina. Boston University School of Public Health served as the Evaluation and Technical Assistance Center (ETAC) to provide technical support with interventions and oversee and implement the national evaluation study. (See Appendix 1 for more detail)

Table 1-1: Characteristics of study participants (n=909)

Pre-disposing factors	
Gender	
Male	75.1%
Female	20.5%
Transgender or Other identified	4.4%
Race/ethnicity	
African-American/Black	45.2 %
Hispanic	19.4%
White	27.8%
Other (including multiracial)	7.5%
Age in years (mean, SD)	(43.0, 10.6)
Under 30 years	16.5%
31-54	70.4%
55 +	13.1 %
Education	
Less than high school	31.4%
High school	33.3%
Beyond high school	35.3%
Housing status	
Unstable	84.4%
Temporary	15.6%
Number of years homeless/unstably housed (mean, (SD))	8.5 (0.43)
Recent Incarceration (jail/prison past 12 months)	41%
Trauma history	
Ever physical injury, harm	43.9%
Ever sexually assaulted	40.4%
Enabling resources	
Mean social support score (SD)	11.2, (5.2)
Mean Self-efficacy score (SD)	
Getting information	8.6 (2.3)
Obtaining Help	5.7 (2.4)
Communicating with Physician	8.7,(2.1)
No insurance	36.3%
Food insecurity	58.6%
Mean number of unmet needs (SD)	3.6, (2.3)
Mean number of barriers to care (SD)	3.4, (3.3)
Need factors	
Substance Use Risk Level (moderate or high)	
Alcohol	43.3%
Cannabis	63.9%
Cocaine	52.2%
Opiates	21.5%
Amphetamines	35.8%
Depressive systems, CESD score (mean, SD)	14.7, (6.8)
CESD score ≥ 10 (mild-severe clinical depressive symptoms)	74.7%
Health status	
Virally suppressed prior to enrollment (n=770)	48.4%
Physical-composite score for health related quality of life (PCS)	37.9 (12.3)
Mental-composite score for health related quality of life (MCS)	34.8 (12.9)
Time living with HIV in years (mean, SD)	11 (8.8)

Chapter 2: Developing a Reliable and Valid Composite Measure of Effectiveness for HIV Patient Navigation Programs

Background

Over the past decade, HIV intervention research has focused on outcomes using a collection of singular measures related to achieving the HIV continuum of care for people living with HIV/AIDS (PLWH). These single measures include whether individuals: are diagnosed with HIV, linked to care, engaged or retained in care, prescribed antiretroviral therapy, and have achieved viral suppression. These measures are the cornerstone for the implementation of the National AIDS Strategy (NAS) for the United States with four goals for 2020: 1) Reduce new HIV infections, 2) Increase access to care and improve health outcomes for people living with HIV, 3) Reduce HIV-related disparities and health inequities, and 4) Achieve a more coordinated national response to the HIV/AIDS epidemic.^{1,2} The NAS calls for greater investment in community level interventions, such as care coordination and patient navigation (CC/PN) and stronger coordination of federal resources to achieve these goals. The result has been a wave of time-limited interventions that focus on unidimensional outcomes for specific populations in high-risk groups (young Black and Latino men who have sex with men, women of color, recently released PLWH from jails and prisons) aimed at improved linkage to care following diagnosis, retention in care for PLWH at risk of falling out of care, or improved antiretroviral therapy uptake. Recent systematic reviews and studies of community-based programs have shown promising evidence of success in meeting these outcomes but achieving viral suppression remains elusive.³⁻⁶

Patient navigation interventions are designed to be patient-centered and aimed at reducing barriers to care in the health service system, thus improving timely entry and receipt of care for vulnerable populations. These interventions employ a navigator, who often shares a similar cultural identity as the patient population being served, and as part of the health care team can work across health and social systems to address medical and non-medical needs of the patient.⁷ Patient navigation interventions work with many vulnerable population groups and key tasks for navigators in HIV care include service coordination, appointment reminders, education and provision of health information, providing practical support such as food, links to referrals, and accompaniment to medical and social service appointments.^{3-6, 8-9}

However, there are a number of limitations to using these single measures to assess performance of patient navigation interventions. One challenge is the lack of standard performance measures for each component of the HIV continuum of care. Funders for HIV population health programs developed programs independently.¹⁰⁻¹¹ One goal of the NAS was to develop a coordinated response of federal resources to fight the epidemic, and this prompted a need for standard measures to monitor quality and outcomes of HIV programs. The NAS, Institute of Medicine (IOM) and US Department of Health and Human Services currently have guidelines and recommendations for performance measures related to linkage and retention in care.¹⁰⁻¹¹

National consensus across federal agencies defines linkage to care as attendance at an initial HIV outpatient medical care visit with a prescribing provider within 3 months of diagnosis.¹⁰⁻¹¹ However, in many state and local jurisdictions the time frame may be

shorter (up to 30 days) and the evidence is lacking to define an optimal period for linkage to care for all persons diagnosed with HIV.¹²

Operationalizing retention in care is more complex. Measures may be based on “missed” or “kept” visits. Current recommendations include and quantify at least one measure based on “kept visits and one based on missed visits”.^{13, page 5} Furthermore, there is no consensus on a standard measure for adherence to antiretroviral therapy (ART). Studies use a range of data collection measures from patient self-report scales to more objective measures such as pharmacy refills, pill counts or electronic device monitoring devices depending on whether it is for clinical or research purposes.¹⁴ In addition, there is emerging evidence that these individual adherence measures are correlated.

A second challenge is that the use of multiple unidimensional outcomes can result in contradictory information which may obscure the true impact of the CC/PN intervention. Studies have shown mixed results, with more positive trends in improvements for linkage and retention compared to treatment adherence and viral suppression.^{3-6, 14-17} Part of this challenge could be attributed to variations in study design, outcomes, length of time of the intervention, the population served, and the scope and practice of the intervention staff (peer vs. non peer).^{3-6, 15-17} For example, a CC/PN intervention may carry out appointment reminders that support retention in care and address barriers to taking medications such as obtaining prescription refills. However, there is no current evidence that CC/PN programs have led to a significant effect on viral suppression.

A third challenge is the validity of the single outcome measure for the scope of

practice and populations served through the CC/PN model. The HIV continuum of care measures are only one approach to assessing the effectiveness of CC/PN program for PLWH who are from communities traditionally not reached by the health care system. There is evidence that peer and near-peer navigators improve physical- and mental- health related quality of life for PLWH over time (baseline to 12 months).⁸ In addition to health care utilization and health care outcomes, CC/PN programs may be instrumental in addressing basic needs, such as obtaining food or housing, which can affect health outcomes. A recent qualitative study found that in working with PLWH who are homeless, patient navigators secured stable housing in addition to reminders and accompaniment to HIV appointments and treatment adherence support.¹⁸ Thus these interventions may be effective in obtaining housing and addressing other social and non-medical needs that influence health behaviors and outcomes. The current standard performance measures only focus on unidimensional medical outcomes and not on broader multidimensional social needs.

To address these challenges and understand the impact of these interventions, a composite measure with multidimensional outcomes could be an improved strategy to assess the effectiveness of CC/PN interventions. A composite measure is a combination of two or more individual measures that results in a single score that can provide a useful summary of performance.¹⁹ Recent literature has examined composite measures that capture multidimensional attributes in assessing physician performance across facilities,²⁰⁻²¹ and its application could be applied to other staff members of the health care workforce. Composite measures often are used in several non-health-related fields,

including food security, to compare outcomes across countries.²² The benefits of a composite measure include integrating and standardizing complex information to facilitate comparison across individuals, organizations and communities. These measures are more easily interpretable for decision making and public dissemination compared to a variety of indicators that may tell different stories.¹⁹⁻²⁵ Given the challenge of lack of standardization of individual measures in HIV care, a composite measure may address some of the challenges associated with assessing CC/PN outcomes.

The purpose of this study is to develop and test a composite measure for the effectiveness of patient navigation programs among PLWH who also experience substance use and mental health disorders and are unstably housed/homeless. CC/PNs, as members of the care team, are working to both engage and retain PLWH in HIV care and obtain other services such as adequate housing. In terms of the HIV care continuum for homeless populations, CC/PNs may be involved in a range of activities with a client from linkage to adherence support to finding and maintaining housing. A composite measure may improve the reliability and validity of the effectiveness of CC/PN programs with patient outcomes across the health care system. A composite measure can provide a more easily interpretable single summary of the performance of CC/PN interventions in achieving the HIV continuum of care and changes over time. Thus, the composite measure can help program directors track the CC/PN performance and identify opportunities for addressing service gaps and training opportunities to improve service delivery or organizational systems that need to be strengthened to support CC/PN programs.

The specific aims of this study are two-fold: 1) to describe the selection of variables for operationalizing the composite measure, and 2) to evaluate the reliability of this composite measure and its predictive validity with viral suppression. The goal is to obtain an alternative measure of performance for the role of the CC/PN in the health care system that could improve the quality of health care services and enhance the role of the CC/PN as a sustainable member of the healthcare workforce.

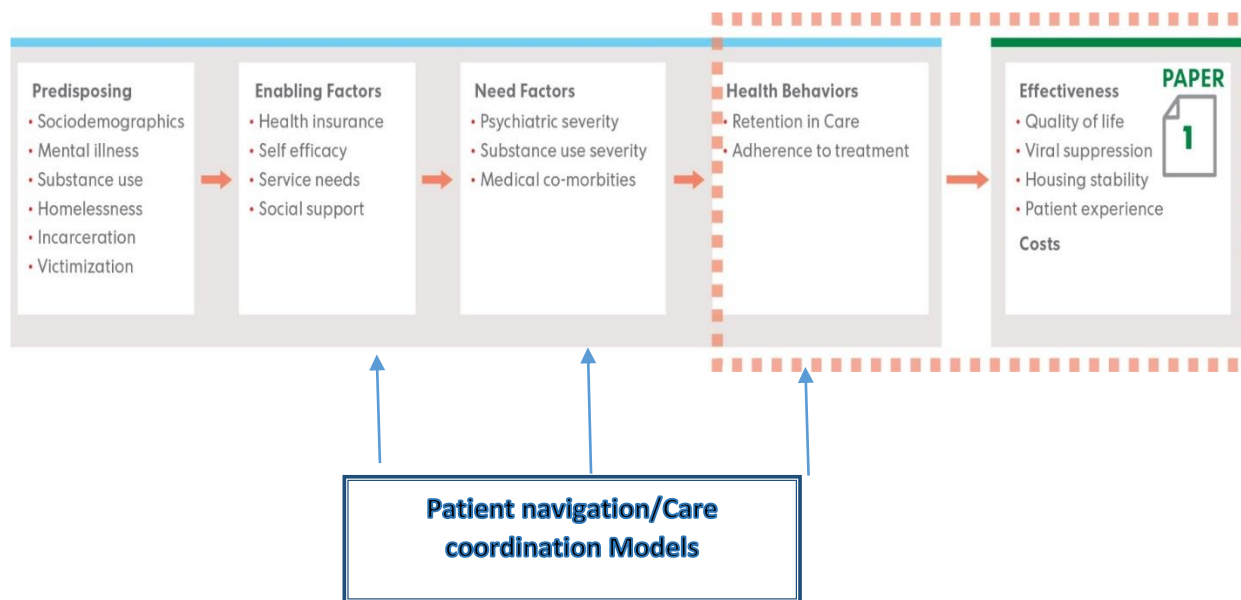
Methods

Theoretical framework

The theoretical framework for this composite measure is adapted from Gelberg's *Behavioral Model for Vulnerable Populations* in accordance with the primary outcomes for the NAS.²⁶ Drawing from the conceptual framework in Chapter 1, the aim of CC/PN interventions is to improve the access and use of health care services, reduce barriers to care and achieve health outcomes such as viral suppression, quality of life and patient experience. Figure 2-1 outlines the framework for where patient navigation programs are designed to work and how to define their outcome. The CC/PN in their work aim to increase access to enabling resources and reduce barriers to care such as transportation, provide connection to basic need services such as food insecurity and housing, and connect people to necessary care, such as mental health and substance use treatment for those with high risk need. Thus, assessing the performance of CC/PN, a composite measure could capture the impact on health behaviors (retention, linkage and adherence) and health outcomes (specifically quality of life and patient experience of care). Since the study population also includes individuals who are homeless and housing status has been

found to be associated with health status and outcomes,²⁷ an additional relevant indicator is housing stability. The assumption is that improvements in each of these indicators correspond to improved viral suppression.

Figure 2-1: Framework for Assessing the Effectiveness of Patient Navigation/Care Coordination Models



Study design and population

Data were collected from a longitudinal study of the impact of patient navigation interventions on the HIV continuum of care and housing stability. (See Appendix 1 for details) PLWH were recruited from nine participating sites across the United States operating in urban and rural areas. All sites were health care settings including federally qualified health centers (2), public health department clinics (3), and community outpatient HIV programs (1) or outpatient HIV clinics affiliated with hospital systems (3). Eight sites were located in urban areas: San Francisco, Los Angeles County and San Diego, CA; Houston and Dallas, Texas, Jacksonville, FL; New Haven, CT; and Portland OR. One site was located in rural North Carolina. Participant eligibility included: 1) being 18 years of age, 2) HIV-positive 3) a pre-existing or screened for a substance use disorder or mental health disorder and 4) determined to be unstably housed or homeless as defined by the Department of Housing and Urban Development for chronic homelessness. [28]. This study included a subsample of participants (n=472) who were enrolled in the study and had data collected from interviews and medical chart review at baseline and then post 12 months. The time period for data collection was from September 2013-February 2017. The Institutional Review Board at Boston University Medical Center approved this study.

Development of the composite measure

A formative approach was used to develop the composite measure in capturing different dimensions of CC/PN performance. Each specific measure has a particular meaning and definition. In addition, the intervention focuses on improving each

individual measure which in turn impacts the composite measure.²⁴ This approach assumes that the composite measure does not have an underlying construct. As specific individual measures are added or removed the meaning of the composite measure will change as the composite measure does not exist independently of the empirical measure. For this study, the composite measure includes 7 indicator variables that CC/PN models have been shown to influence health and housing outcomes for PLWH who are homeless/unstably housed: 1) linkage to care, 2) retention in care, 3) adherence to treatment, quality of life (measured as 4) physical health functioning and 5) mental health functioning), and housing stability. Since the overall goals of the study were to build a medical home for PLWH who experience homelessness, a seventh indicator of patient experience of care since this is one of the key outcomes for patient-centered medical home models. Thus, each indicator variable represents a different dimension of potential CC/PN performance. Another key assumption is that the individual measures are not correlated with each other. For example, a person may be retained in care but not necessarily adherent to their treatment.

The seven indicator variables for the composite measure were selected based on the goals of CC/PN program to achieve the HIV care continuum in accordance with the (NAS) improvements in linkage and retention in care and adherence to treatment. Housing stability was included as an indicator variable since there is evidence that housing status is a significant factor on medical care utilization among HIV populations.²⁸ Thus the ability of the CC/PN program to assist a person who is experiencing homelessness to find and obtain stable housing can be an indicator of the

program's success and impact health outcomes. The measures were selected based on the NAS goals and future research that is needed to understand the impact of community interventions to achieve the HIV care continuum.²⁹ The definition and approach for measuring each individual indicator is described as follows:

Linkage to care was defined as a person who had at least one primary care visit with a prescribing health care provider within 90 days of enrollment. For the composite measure the variable is dichotomous as linked (1) versus non-linked (0) to care. All data were collected from medical chart review.

Retention in care was defined as a person who had at least two HIV primary medical visits with a prescribing provider at least 90 days apart in the 12- month period post baseline. For the composite measure the variable was coded to a dichotomous variable as retained (1) versus not retained (0). All data were collected from medical chart review as described in the introduction.

Adherence to treatment was collected via self-report using a three item scale consisting of: *days taken* (how many days did you miss at least one dose of any of your [drug name]?); *frequency* (in the last 30 days how often did you take the medications in the way you were supposed to? scored on a Likert scale 1=Never, 6=Always); and *rating* (how good of a job did you do at taking your[drug name] in the way you were supposed to? (scored on a Likert scale 1=Very poor, 6=Excellent).³⁰ In this study sample, the Cronbach's alpha for this measure was 0.88 and 0.86, at baseline and 12 months respectively. This scale was selected because it was shown to have good reliability and validity in a sample of low-income patients at an HIV urban clinic and was validated with

electronic drug monitoring, seen as the gold standard for assessing adherence in an HIV population. Item responses for the three items were linearly transformed to a 0-100 scale with zero being the worst adherence and 100 the best.³⁰ A summary score was calculated of the mean for the three individual items. The continuous measure was then re-coded to a categorical variable using a cut-off of 95% or greater to define adherence to treatment, a conservative approach to assessing adherence.³¹⁻³² The variable was coded as non-adherent (below 95%) or adherent (95% or above). For the composite measure, change in adherence was calculated as a dichotomous variable: (0) stayed or became non-adherent or (1) stayed or became adherent.

Quality of life: Physical and Mental Health functioning (PCS & MCS): To assess physical and mental health related quality of life, a 12-item continuous measure (Veterans SF-12) was collected via self-report. This measure is based on the SF-8 and examines 8 concepts including physical functioning and role limitation due to bodily pain, general health perceptions of energy/vitality, social functioning and role limitation due to emotional problems or mental health. Each item is scored on a 5-point Likert scale as 1=all of the time, 2=most of the time, 3=some of the time, 4=little of the time, 5=none of the time. To generate the physical composite summary (PCS) and mental composite summary (MCS) scores, a four-step procedure is used. Step one involves recoding individual items so higher item value indicates better health. Step two creates indicator variables for all but one response choice category and 47 variables are created. In Step 3 weighting of each of the 47 indicator variables is performed, and aggregate scores are generated for PCS and MCS. In Step 4 a summary score is calculated to set to a mean of

50 and standard deviation of 10 for the US general population as in the SF-12.³³⁻³⁵ In this analysis, the continuous mean scores from baseline and 12-month follow-up were then re-coded into quintiles, with the three lowest quintiles representing “poor functioning” compared to the top two quintiles representing “higher functioning” based on the distribution of the scores in the sample for this population. Participant scores were calculated to assess the change in physical or mental health functioning between baseline and 12 months and then recoded to a dichotomous measure for the composite measure: (0) stayed or became poor functioning (in lower three quintiles) or (1) stayed or became higher functioning (top two quintiles).

Table 2-1: Distribution of PCS & MCS Scores at Baseline & 12-month Follow-up (n=472)

	PCS- baseline	PCS-12 month	MCS baseline	MCS 12-month
Mean (S)	37.2 (12.3)	39.8 (11.8)	35.6 (12.8)	40.3 (12.5)
Group				
Quintile 1	15.9	17.8	13.8	18.1
Quintile 2	25.7	20.8	23.8	30.4
Quintile 3	34.3	38.7	31.9	37.3
Quintile 4	42.0	45.2	38.9	43.3
Quintile 5	49.1	50.6	47.1	51.6

Patient experience of care was measured using a validated 33 item measure tested in homeless veteran populations with four dimensions: patient-clinician relationship, cooperation among clinicians, access and coordination, and homeless-specific needs.³⁶ For people who are homeless, their experience with primary care may be different because of priority concerns and needs. Each item across the domains is scored on 4-point Likert scale of 1=strongly disagree to 4=strongly agree. A measure of patient experience is important for understanding the patient-centered care and in building a

medical home. In this study, the measure was adapted to assess the impact of the CC/PN interventions on patient experience of care with their identified primary care provider.

The summary continuous score was recoded as a dichotomous variable with individuals who had an “unfavorable experience of care” in the lowest tertile and those with a “favorable experience of care” in the top two tertiles across all sites. For the composite measure, change in patient experience from baseline to 12 months was dichotomized as (0) care remained or became unfavorable and (1) care remained or became favorable.

Table 2-2: Distribution of Patient Experience Scores Baseline to 12-month Follow-up (FU)

	Overall		Access		Cooperation		Relationship		Homeless needs	
	Baseline	FU	Baseline	FU	Baseline	FU	Baseline	FU	Baseline	FU
Mean (S)	3.08 (.44)	3.05 (.36)	3.0 (.37)	3.1 (.37)	2.9 (.52)	2.8 (.59)	3.1 (.40)	3.1 (.39)	3.0 (.44)	3.1 (.44)
Group										
Tertile 1	2.4	2.5	2.5	2.5	2.0	1.6	2.5	2.3	2.3	2.3
Tertile 2	2.9	2.9	2.8	2.9	2.6	2.6	3.0	3.0	3.0	3.0
Tertile 3	3.1	3.2	3.0	3.0	3.0	3.0	3.3	3.2	3.0	3.0

Housing stability was measured as an index consisting of three domains: 1) type of housing, 2) tenure in a current place and 3) number of places stayed within a six-month time frame. The index was developed to capture more dimensions of factors that are associated with housing stability based on qualitative studies with homeless youth.³⁷

Most measures of housing status are binary and characterize a person as homeless or not at a given point in time. This index was hypothesized to assess if CC/PN programs could affect not only the type of housing a person resides, but also the tenure in that place and number of moves. For this study, the index was created from self-report interview data collected at baseline and 12-months follow-up. The three domains included:

- a) *Type of housing*, defined as: stable: own/rent apartment with or without subsidy; temporary housing: including persons who are doubling up or staying with friends and family, staying in a motel/hotel paid by friend or self with no lease; transitional housing or residential treatment; living in a controlled environment: such as jail/prison; inpatient substance use facility, mental health facility and/or a hospital; or homeless: staying in a shelter, street, park, public place, car, abandoned building or hotel/motel paid for by an agency. This variable dichotomized to those who had a stable dwelling (1) vs unstable (0) (homeless, temporary or in a controlled environment) at 12 months.
- b) *Tenure in a current place*: defined as 1=one week or less, 2=more than one week but less than one month; 3= one-three months, 4=more than three months but less than one year, and 5=one year or longer. This variable was then dichotomized to 0= less than three months as unstable and 1=more than three months as stable.
- c) *Number of places stayed*: examined the differences in the total number of places stayed between baseline and 12 months. This was dichotomized to increased in number of places or stayed the same as baseline (0) indicating lesser stability vs. decreased number of places stayed indicating greater stability (1). All individual items were calculated to examine change in stability between baseline and 12-months and categorized at 3 levels for the composite measure: became unstable or homeless (0), slight improvement if gained in two of the three dimensions (1); and finally greater stability if improved in all three areas (2).

In addition to assuming that the overall composite measure does not have an

underlying construct, a second assumption was that each individual variable was equally weighted in the composite measure. Correlation procedures were used to test potential biases of each indicator variable in the summary effectiveness measure and for collinearity between indicator variables.

In constructing the composite measure, steps were taken to address missing data across the indicator variables. A single imputation method was employed using the mean and standard deviation by site. Site was selected as the conditional variable that would account for missing data at random for each indicator variable.³⁰ Sixty-two (n=62) participants had missing composite scores which is less than 10% of the overall sample. Three variables contributed to the missing data representing: adherence scores, health-related quality of life (PCS, MCS scores) and patient experience of care. Missing data on patient experience and health-related quality of life scores were due to being lost to follow up at 12 months. Fewer than 15% of the participants were lost to follow up. Among participants with missing adherence scores, 53 were classified as “non adherent” since, according to their chart review, they were non-newly diagnosed, had been prescribed antiretroviral therapy in the past 6 months and had a detectable viral load. The other 9 participants were classified as adherent since their lab report at baseline indicated they were virally suppressed both at baseline and post 12 months enrolled in the intervention.

The composite score was calculated using an all-or-none approach by summing all seven indicators variables for a total score of 0-8. Lower scores (below the mean) indicate less effectiveness of the CC/PN interventions and higher scores (above the mean)

indicate greater effectiveness

Statistical analysis

To assess the validity and reliability of the composite measure a multi-step statistical process was implemented. Inter-item correlations (ICCs) and bivariate associations were conducted to assess potential collinearity between the composite score and individual items. An exploratory factor analysis was performed to identify any potential latent constructs. This allowed for testing the assumption of the all-or-nothing approach and appropriate weighting of indicators for each measure in the composite score. As a second step, factor analysis and item reliability analysis were performed to identify any underlying constructs and viability of the composite measure and test the assumption of the formative approach for constructing a composite measure.

For predictive validity, a two-step procedure was used with viral suppression as the outcome, defined as <200 ml/copies. First an unadjusted bivariate analysis was conducted of the composite effectiveness measure with viral suppression and adjusted logistic regression accounting for site differences to assess for the significance and strength of predicting viral suppression at 12 months. Sensitivity analyses were performed to assess the robustness of the measure in predicting viral suppression. Two criteria were used for this sensitivity analyses. In the first step, moderately strong inter-item correlations were considered. In the second step, the predictive strength of the indicators with viral suppression was assessed using a threshold of 1.5 adjusted odds ratio. The individual measures that met the criteria of each step were then developed into another composite measure of effectiveness. In total, two additional composite measures

were then tested (six indicator and three-indicator variables). The best fit models for the various effectiveness measures regressed on viral suppression were then compared using the c-statistics. Finally, confidence intervals for the c-statistics were bootstrapped using the percentile methods to address any possible non-normal distributions³¹ and to assess the stability of the models on viral suppression.

Results

Sample characteristics

Table 2-3 describes the study sample. The majority were male, racial/ethnic minorities, primarily Hispanic and African/American/Black, and between the ages of 31-54 years. The average length of time homeless was approximately 6 years with 15% self-reporting to be continuously homeless or in an unstable housing situation for the past year. Two-thirds had a high school diploma or higher education, and three-quarters described themselves as not working, with 15% being disabled or retired. Approximately 40% had experienced some type of physical (44%) or sexual trauma (41%) in their life, with 25% reporting sexual assault and 42% physical injury in the past 12 months. More than three-quarters had a history of incarceration. Approximately 72% scored 10 or higher on the Center for Epidemiologic Studies Depression Scale (CESD), indicating mild to severe depressive symptoms at the time of the baseline. One-third had a history of injection drug use with approximately 10% being active drug users, defined as having used drugs in the past 3 months.

For health status, 9% were newly diagnosed with HIV within the past 6 months

and 27.8% were virally suppressed prior to enrollment in the intervention. The mean physical and mental health functioning scores were 36.9 and 37.7 respectively, approximately 1.5 standard deviations below the general population. The majority of the sample (85%) reported seeing a health care provider for their HIV outside of the emergency department in the past 12 months.

Table 2-3: Socio-demographic and Health Status Characteristics (n=472)

Predisposing Factors		N (%)
Age in years		
	30 years or younger	65 (13.7%)
	31-54	327 (69.4%)
	55 or older	80 (16.9%)
Gender		
	Male	343 (72.7%)
	Female	103 (21.8%)
	Transgender or Other	26 (5.5%)
Race/Ethnicity		
	Hispanic	100 (21.2%)
	Non-Hispanic White	113 (23.9%)
	Non-Hispanic Black	227 (48.1%)
	Other	32 (6.8%)
Education		
	Less than high school	157 (33.3%)
	High school	143 (30.3%)
	More than high school	172 (36.2%)
Length of time homeless in years, mean (SD)		6.3 (8.4)
Incarceration history		
	Ever	368 (78.0%)
	Jail past year	134 (36.6%)
Sexually assaulted		
	Ever	212 (44.9%)
	Past 12 months	119 (25.4%)
Physically assaulted		
	Ever	196 (40.9%)
	Past 12 months	197 (41.6%)
Enabling Factors		
Employment status		
	Working	50 (10.6%)
	Not working	345 (73.0%)
	Disabled/Retired	77 (16.4%)
No insurance		165 (37.8%)
Run out of money for basic necessities		
	Daily	134 (28.4%)
	Weekly	89 (18.9%)
Has a Case Manager		
	Yes	324 (89.3%)
	No	95 (10.7%)
Tenure in most recent place		
	One week or less	33.0%
	More than one week, less than one month	19.2%
	One-three months	20.2%
	More than three months	12.6%
	One year or longer	14.9%

Number of unmet needs mean, (SD)	3.4(2.1)
Number of barriers mean (SD)	3.2 (2.1)
Social support score mean, (SD)	11.4 (5.3)
Self-efficacy score (not confident (1) – confident (10))	
Communicating with provider	8.7 (2.1)
Getting information about resources	8.6 (2.4)
Obtaining help	5.7 (2.5)
Food insecurity	263 (55.7%)
Need factors	
Alcohol risk severity	
Low	280 (59.3%)
Medium	123 (26.1%)
High	69 (14.6%)
Amphetamines risk severity	
Low	315 (66.7%)
Medium	124 (26.3%)
High	33 (7.0%)
Cocaine risk severity	
Low	233 (49.4%)
Medium	194 (41.4%)
High	45 (9.5%)
Opioids risk severity	
Low	376 (79.7%)
Medium	84 (17.8%)
High	12 (2.5%)
Tobacco risk severity	
Low	91(19.3%)
Medium	272 (57.6%)
High	109 (23.1%)
Length of time living with HIV in years, mean (SD)	11.9 (8.8)
Injection drug use	
past 3 months	47 (10.1%)
Ever	107 (23.1%)
CESD >10 (moderate depressive symptoms)	348 (73.9%)
Health behaviors	
Newly diagnosed with HIV (in past 6 months)	58 (12.3%)
Last seen a health care provider in past 12 months	
Yes	400 (84.8%)
No	72 (15.2%)
Physical health functioning (PCS)	36.9 (12.4)
Mental health functioning (MCS)	37.7 (13.7)
Virally suppressed	27.8%

Care Coordination/Patient Navigation performance indicators

Individual performance indicators for the CC/PN interventions are presented in Table 2-4. Linkage-to-care rates were 79.8% post three months of enrollment and 88.6% were retained in care at 12 months. Forty percent (40.4%) improved or stayed adherent to treatment using the 95% cut-off for adherence value. Thirty-five (35%) percent had a favorable experience with the primary care provider after 12 months. For mental health functioning, 40% improved or stayed higher functioning, with similar results for physical health functioning. Two-thirds (64.5%) experienced a slight improvement in stability in at least two domains (tenure, type of housing or reduced number of moves) and 14.5% reported improvement in all three domains. The mean effectiveness score was 3.45 (1.4), indicating improvements in at least three of the seven indicator variables. As a scale, the weak indicators showed weak reliability with a Cronbach's alpha of 0.26. Exploratory factor analysis revealed no underlying single construct. (Supplementary materials)

Table 2-4: Descriptive Statistics of patient navigator performance during the 12-Month Observation Period (n=472)

Linkage to care, post 3 months enrollment	
Not linked	80 (16.9%)
Linked to care	392 (83.1%)
Retention in care 2 HIV primary medical care appts >90 days in 12 months	
Not retained	11.4%
Retained	88.6%
Adherence to treatment (95% threshold)	
Became or stayed non-adherent	229 (67.6%)
Improved or stayed adherent	153 (32.4%)
Patient experience	
Poor or continued to have an unfavorable experience	261 (65.0%)
Improved or continued favorable experience	145 (35.0%)
Mental health functioning (MCS)	
Remained poor or decreased functioning (lower 3 quintile	282 (59.9%)
Improved or stayed higher functioning (top 2 quintiles)	189 (40.0%)
Physical health functioning (PCS)	
Remained poor or decreased functioning	283 (60.2%)
Improved or stayed higher functioning	188 (39.8%)
Housing stability	
Lesser stability (unstable in type of housing, tenure, and increased number of moves)	98 (20.8%)
Slight improvement in stability (positive change in at least 2 domains (type, tenure or moves)	306 (64.8%)
Greater stability (improved in more stable type of housing, longer tenure and few moves)	68 (14.5%)
Effectiveness score (summary of 7 indicators) (mean, SD)	
0	1 (0.2%)
1	18 (3.8%)
2	41 (8.7%)
3	108 (22.9%)
4	130 (27.1%)
5	94 (19.9%)
6	57 (12.1%)
7	21 (4.4%)
8	2 (0.4%)

† Those with missing data were classified as non-adherent”

Table 2-5 shows that inter-item correlations between each individual item were weak and non-significant ($p > .05$). Linkage and retention were significant but weakly correlated ($r = 0.105$, $p < 0.029$). The distribution of the individual correlations with the composite measure indicated equal weighting, ranging from 0.281 (linkage) to 0.539 (adherence). Bivariate analyses show statistically significant association between effectiveness scores and viral suppression at 12 months. (See Table 2-6) Individuals with higher effectiveness scores were significantly more likely to be virally suppressed (mean score greater than 3) compared to those with lower effectiveness scores (below mean score) (54% vs 46%, $p < .001$ Fisher's exact test).

Table 2-5: Inter-item Correlations of Individual Indicators and the Effectiveness Scores (n=472)

	Effective score	Linkage	Retention	Adherence	Patient Experience	PCS	MCS	Housing stability
Effectiveness score (new)	1.000	.281 <.0001	.379 <.0001	.539 <.0001	.399 <.0001	.501 <.0001	.462 <.0001	.467 <.0001
Linkage		1.000	.105 .029	.035 .497	.078 .106	.013 .909	.013 .789	.036 .455
Retention		.105 .029	1.000	.097 .065	.031 .524	.048 .331	.124 .010	.022 .641
Adherence		.035 .497	.097 .065	1.000	.085 .105	.100 .056	.105 .045	.159 .003
Patient experience		.078 .106	.031 .524	.085 .105	1.000	.145 .003	.021 .653	.014 .769
PCS		.013 .789	.048 .331	.100 .056	.145 .003	1.000	.138 .004	.058 .229
MCS		.013 .789	.124 .010	.105 .045	.021 .653	.138 .004	1.000	-.006 .890
Housing stability		.036 .455	.022 .641	.159 .003	.014 .769	.058 .229	-.006 .890	1.000

Table 2-6 Distributions of Effectiveness Score with Viral Load: 7 Items

Effectiveness score	Virally Suppression	
	Yes	No
0	-	1.7%
1	2.9%	11.8%
2	17.5%	27.7%
3	25.0%	29.4%
4	26.7%	16.0%
5	16.3%	7.6%
6	10.8%	5.0%
7	0.84%	0.42%
8	0.42%	-
Total	66.8%	33.2%

*Adjusted for sites

Tables 2-7 & 2-8 show the results of each individual indicator compared to the full model with viral suppression adjusted by site. Improvements in four indicators (retention in care, change in adherence, change in mental health function and housing stability) significantly increased the odds of viral suppression at 12 months and moderate goodness of fit in c-statistics (0.60 for linkage-to-care to 0.66 for retention in care).

(Table 2-7)

In comparison, the adjusted model with all seven indicators only improvements in retention and adherence to treatment had significantly increased the odds of viral suppression, but the model had an increased predictive ability with viral suppression and improved fit statistics ($c=0.726$) (Table 2-8). Similarly, the composite measure had significant odds of predicting increased viral suppression (AOR: 1.5, (95% CI 1.3, 1.8)) and goodness of fit ($c=.703$).

Table 2-7: Bivariate Logistic Regression of Individual Indicators with Viral Suppression (n=472)

	Virally suppressed up to 12 months post enrollment		AOR (95% CI)	c-statistic
	β (SE)	p		
Linked within 90 days	.1084 (.2831)	.7018	1.1 (.640,1.941)	.605
Retention in care	1.479 (.3134)	<.0001	4.4 (2.291,8.414)	.661
Change in adherence to treatment (n=342)	1.13 (.2815)	<.0001	3.1 (1.8,5.4)	.678
Change in patient experience (n=357)	.3812 (.2350)	.1048	1.5 (.924,2.3)	.616
Change in physical health functioning (n=412)	.3290 (.2270)	.1473	1.4 (.891,2.2)	.617
Change in mental health functioning (n=412)	.5681 (.2278)	.012	1.8 (1.1,2.8)	.629
Housing stability (N=421)	.4513 (.1881)	.0164	1.570 (1.086, 2.271)	.637

****all indicators are calculated as change scores between baseline-12 month post intervention & adjusted for sites included**

Table 2-8: Multivariate Logistic Regression Analyses of Individual Indicators and Effectiveness Score with Viral Suppression (n=472)

	β (SE)	AOR (95% CI)	c-statistic
			0.726
Linkage	-.093(.3626)	.911 (.45,1.8)	
Retention	1.2(.3657)*	3.3 (1.6,6.8)	
Adherence	.9423 (.297)**	2.6 (1.4,4.5)	
Patient experience	.1416(.2734)	1.2 (.67,1.9)	
Physical health (PCS)	.0910(.2631)	1.1 (.65,1.8)	
Mental health (MCS)	.2375 (.2607)	1.3 (.76,2.1)	
Housing stability	.4180 (.2234)	1.5 (.98,2.3)	
Effectiveness score	0.417 (0.9)	1.5 (1.3,1.8)	0.703

All indicators are calculated as change scores between baseline-12 month post intervention & adjusted for sites

*p<.001, **p<.05

Sensitivity analysis

Table 2-9 shows the results of the sensitivity analyses for the composite measure. Two models were developed: 1) a six-item measure removing the linkage indicator variable due to significant correlation with retention and poor predictive power with viral suppression; and 2) a three-item measure consisting of retention, adherence and housing stability with the threshold of 1.5 times in the increased odds of viral suppression. The mean score for the six-item composite was 3.33 (1.3) and 2.14 (0.88) for the three-item measure. Similar patterns of distributions of scores by viral suppression for both models were found when compared with the seven indicator model. Individuals with higher scores were significantly more likely to be virally suppressed compared to individuals with lower effectiveness scores. (Tables 2-10a and 2-10b)

Table 2-9: Distribution of Six item & Three Item Effectiveness Scores (n=472)

Effectiveness score (summary of six indicators-no linkage) mean (SD)	3.33 (1.3)	Cum%
0	.66%	6.6%
1	5.9%	28.3%
2	21.7%	57.2%
3	28.9%	80.2%
4	23.0%	94.0%
5	13.8%	99.3%
6	5.3%	100%
7	.66%	
Effectiveness score (summary three indicators (retention, adherence, housing stability) mean (SD)	2.14 (.88)	
0	1.9%	22.0%
1	20.1%	62.9%
2	40.9%	93.3%
3	30.4%	100%
4	6.7%	

Table 2-10a Distributions of Effectiveness Score with Viral Load: Six Items (no linkage indicator) (n=472)

Effectiveness score	Viral Suppression	
	Yes	No
0	0%	1.5%
1	3.5%	16.4%
2	21.9%	29.1%
3	27.5%	29.1%
4	25.1%	14.9%
5	15.7%	13.5%
6	5.9%	2.9%
7	0.35%	0.75%
Total	68.2%	31.8%

Table 2-10b Distributions of Effectiveness Score with Viral Load: Three Items (Retention, Adherence and Housing stability) (n=472)

Effectiveness score	Viral Suppression	
	Yes	No
0	.7%	4.5%
1	15.3%	34.3%
2	43.2%	41.0%
3	34.8%	14.9%
4	5.9%	5.2%
Total	68.2%	31.8%

Table 2-11 shows the comparison across the three models of the composite measure and their adjusted odds ratios and goodness of fit with viral suppression at 12 months. The seven-indicator composite measure had an overall c-statistic of 0.703 (Bootstrap 95% CI 0.67, 0.78) but the three-variable composite had greater predictive ability for viral suppression. (AOR =2.0 (1.6, 2.7), c=.711 Bootstrap CI 95% 0.68, 0.79).

Table 2-11: Association of Model Effectiveness Measures with Viral Suppression (N=472)

Effectiveness scores	Virally suppressed up to 12 months post enrollment			
	β (SE)	p	AOR (95%CI)	c-statistic (Bootstrap 95% CI)
Model 1- 7 indicators	.4173 (.0914)	<.0001	1.53 (1.29,1.82)	.703 (0.67,0.78)
Model 2 6 indicators (no linkage)	.4675 (.0928)	<.0001	1.6 (1.3, 1.9)	.705 (0.67,0.79)
Model 3 (retention, adherence, housing stability)	.7247 (.1410)	<.0001	2.0 (1.6, 2.7)	.711 (0.68,0.79)

****all indicators are calculated as change scores between baseline-12 month post intervention & adjusted for sites**

Discussion

The purpose of this study was to develop and test a composite measure to assess the performance of CC/PNs as members of the health care team for improving outcomes for PLWH who are homeless/unstably housed. The findings from this study suggest a minimum of three key indicator variables: retention in care, adherence to treatment and housing stability, was the best indicator evaluating the effectiveness of CC/PN programs. In addition, this measure was predictive of viral suppression for PLWH who are homeless/unstably housed. Recent studies have called for a greater need for standardized measures related to the HIV continuum of care to better understand and set performance targets for domestic HIV programs, including suggestions to develop pay-for-performance programs.³² To my knowledge this is the first study that attempts to develop a composite measure of the performance of CC/PN interventions with respect to key health and housing outcomes.

One of the strengths of using a composite measure is that as a member of the care team the CC/PN is performing multiple tasks that can lead to multiple outcomes on the HIV continuum of care and therefore, one measure can assess several components at once. These tasks include linking newly diagnosed to their first primary care appointment or re-engaging patients who have missed medical appointments; supporting patients at risk for falling out of the care or missing treatment due to homelessness or mental health disorders by connecting them to housing or support services that keep them in care and following up with medical care. The composite measure captures the breadth and depth of the impact of CC/PN tasks by including other non-medical outcomes such as housing stability.

Surprisingly, patient experience and physical health-related quality of life were not significant items in the composite measure. For patient experience, it could be that the average scores were generally high for all domains, and in the overall score and there was very little change in scores between baseline and follow-up except in the area of cooperation among providers. It could be that CC/PN programs were unable to affect system changes that could facilitate better collaboration among providers for an individual, despite the individual attention of the CC/PN devoted to the person.

Another benefit of the composite measure is its feasibility in collecting information that is relevant and useful by programs for assessing performance of HIV care and treatment programs. Attendance at HIV primary care visits, prescription of antiretroviral therapy, and laboratory testing (CD4 and viral load) are required performance measures for HIV care and treatment programs endorsed by the National

Quality Forum and the Health Resources & Services Administration who manages the Ryan White Program which provides necessary affordable care and treatment to over 50% of the approximately 1.2 million people known to be living with HIV/AIDS in the US.⁴⁰ Housing stability is a new measure developed in this study and gathers information from existing program assessments used by housing providers to assess individual housing needs. This composite measure builds upon and uses existing data that are easily gathered and interpreted by clinicians and program directors. In addition, the measure incorporates and further refines the impact of CC/PN interventions on other non-health outcomes, such as housing stability, that can impact the health of lower income and vulnerable populations.

The composite measure may be useful to policy makers and program directors as a summary indicator that CC/PNs are making improvements in a number of outcomes for PLWH who are homeless/unstably housed. For example, since the three variable measure is scored on a scale of 0-4, programs that score below 2 indicate potential service gaps or areas to strengthen organizational and individual systems through additional training or supervision for CC/PN staff to support patient engagement in treatment or housing stability.

Another strength to the measure is its development with a study sample representing people who experience homelessness from a variety of health care service delivery systems. The navigators worked in a range of sites from large hospitals to federal qualified health centers in both urban and rural settings. The final models were adjusted for site when testing for predictive validity with viral suppression. Thus,

reducing potential bias due to site differences in the navigation programs.

There are several limitations to the measure. First, it was developed using *a priori* selected list of variables for the study. Five measures included in the composite measure (adherence to treatment, health-related quality of life, and patient experience of care) were self-reported and thus may be biased due to social desirability with reporting the data. Two indicator variables: linkage to care and retention in care were gathered from medical record review and thus may reduce the bias especially for its use in predicting viral suppression, since the measures were based on appointment attendance in the specified measurement year. Second, the composite measure was derived assuming an all-or-nothing approach of objective outcomes based on national performance measures. While the measure may provide a CC/PN program with information about which indicator variable(s) need more focused attention, could not assess within the individual indicator which item may need to be strengthened. For example—for adherence to treatment if an individual score a “0” for nonadherence, the score does not differentiate if nonadherence was the result of missing doses due to poor understanding of the health care provider’s instruction, choosing not take medications as prescribed, or limited access to obtain a prescription. Future research could test specific items under each of the indicator variables to gain more specific information about CC/PN effectiveness.

Second, the composite measure was developed in an observational study of a convenience sample of people living with HIV/AIDS who experience homelessness, substance use and mental health disorders. Thus, the results may not be generalizable to the wider HIV community or homeless populations. Third, the development of the

composite measure assumed an equal weighting of each indicator variable in the overall score. It may be that some navigations programs emphasized housing stability or adherence to treatment based on consumers preferences or acuity of need. Additional validation studies using techniques such as the Delphi procedure with experts in HIV care and housing would further test this assumption and contribute to validity of the composite measure.

Fourth, the time frame used for the composite was based on a 12- month period and the changes in each indicator from the baseline periods. Tests were not performed to assess if the measure would yield similar results and have predictive validity with viral load in the longer term such as 18 or 24 months. In addition, some participants may not have received the CC/PN intervention for the entire 12-month period. The length of time for each participant was not accounted for in the calculation of the composite measure changes. Some participants may have received more intervention encounters with a navigator. Further research is warranted to examine if the composite measure is sensitive to changes in the intensity of service delivery by the CC/PN programs.

Fifth, the effectiveness score was developed based on the study sample of participants with complete data at baseline and 12-months follow-up which only represented approximately half the individuals enrolled at baseline. As a result the effectiveness score may be affected by selection bias since it is based on participants who were more likely to remain in the study. An attrition analysis is further warranted to assess for significant differences in characteristics between those who were lost to follow up at 12 months to identify and those with follow-up data that could impact the reliability

and validity of the effectiveness score.

Finally models were adjusted for any site clustering when assessing individual change of the indicator variables and in testing models with viral suppression. It could be that the composite measure is driven by some specific navigation program that is masked through adjustment for clustering. Across the nine sites there was variation in the staffing patterns and patient populations which might have resulted in different modalities and services provided. Some sites used team-based approaches and others used solo navigators. Chapter 3 in this dissertation will examine variation in CC/PN programs by various organizational and community factors. Further studies are needed to examine if variation in navigator programs components are associated with the effectiveness score.

This composite measure represents a first step in understanding and capturing the impact of the navigators' work to help PLWH achieve viral suppression. This measure could serve as a tool for assessing and strengthening navigator program performance and tailoring their work with specific high-risk patients in a clinic. In conclusion, this study demonstrates a composite measure consisting of a minimum of three indicator variables of retention, adherence and housing stability can provide insight to navigator performance over time.

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**Supplemental Analyses: Reliability & Content Validity of Composite measure
Model 1:**

	Cronbach α	Cronbach α if item deleted
7 items	.261	
Linkage to care		.256
Retention in care		.202
Adherence to treatment		.163
Patient experience cat		.274
PCS		.222
MCS		.224
Housing stability		.276

Model 2:

	Cronbach α	Cronbach α if item deleted
6 items	.256	
Retention in care		.204
Adherence to treatment		.144
Patient experience cat		.275
PCS		.198
MCS		.227
Housing stability		.277

Model 3:

	Cronbach α	Cronbach α if item deleted
3 items	.191	
Retention in care		.277
Adherence to treatment		-.01
Housing stability		.128

Exploratory Factor Analysis—yield no underlying latent constructs in any of the 3 models (data not shown)

Chapter 3: Classifying Components of HIV Navigation Programs for PLWH who are homeless/unstably housed

Introduction

In the past decade, patient navigation has emerged as a strategy to reduce barriers to HIV medical care and increase access to and utilization of health care, with the ultimate goal of improving viral suppression rates for PLWH. HIV patient navigation programs were developed in response to improve access to and utilization of HIV care and treatment for “hard-to-reach populations” who were most likely to fall between the gaps of the continuum of care.¹⁻⁸ Growing evidence shows that navigation models are effective in linking people who are newly diagnosed, re-engaging individuals who are lost to care, and retaining PWLH in care.⁹⁻¹⁰

Despite this growing evidence, very few studies have examined the specific components of patient navigation programs and their contributions to HIV-related outcomes and the HIV workforce. Part of the limited evidence may be attributed to the lack of clear definition of patient navigator roles vis-à-vis other members of the HIV care team. For example, the Ryan White HIV/AIDS Program (RWHAP) as the payer of last resort for PLWH who are uninsured or underinsured requires a percentage of its funds to be used to pay for medical case management. RWHAP defines medical case management (including treatment adherence) as “a range of client-centered services that link clients with health care, psychosocial, and other services provided by trained professionals, including both medically credentialed and other health care staff.”¹¹ Traditionally

medical case managers have been clinic-based staff. As the epidemic shifted to harder-to-reach populations, HIV care providers needed to develop new strategies to reach communities hardest hit by the epidemic, putting strain on the traditional medical case management system where larger caseloads made it challenging for staff to meet all the needs of PLWH with multiple competing needs.¹² Some of these new strategies included focusing on community-level interventions such as navigation programs which could address the intensive individual needs and move across service systems, thus reducing barriers to care.

Current literature of HIV navigation programs shows variation across selected components. These components include staffing patterns, location of service provision, modality of service delivery, types of activities and length of time of the intervention. Staffing patterns for programs show mixed results depending on the type of staff and the population served. Peer navigation shows some promising results with linkage to care and retention in care for PLWH who are newly diagnosed or re-engage in care after prolonged absence,^{9-10, 13} but other studies found null effects on linkage to primary care and viral suppression for PLWH at the time of hospital discharge.¹⁴⁻¹⁵ Some studies have also shown positive effects on adherence to treatment in the short term up to 6 months, but no evidence to date on viral suppression rates.¹³⁻¹⁵ More research is needed to assess the effectiveness of types of patient navigation programs on the HIV care continuum outcomes.

In other studies of navigation programs, the navigation staff are case managers, nurses, or social workers who in addition to working one-on-one with individuals are also

working across service systems. The ARTAS model is a social worker led strength-based case management intervention that was found to be effective in linking newly diagnosed individuals into care within 90 days of diagnosis compared to those PLWH who received a standard referral to medical care. However not all newly diagnosed PLWH were successfully linked especially those with active substance use disorders.¹⁶ Similarly, in a randomized study of the patient navigation programs using professionally trained staff (nurses, social workers) with or without financial incentives for PLWH with active substance use at hospital discharge found no difference in viral suppression rates with those patients who received standard referral at discharge.¹⁷

Despite the increasing evidence and adoption into HIV service delivery, challenges remain for patient navigation programs being integrated into and sustained as part of the HIV workforce. One challenge is the lack of clear definition and scope of practice for this role within the HIV care team. There are no current systematic reviews of patient navigation programs for people living with chronic illness on health outcomes and no consensus or standards for patient navigation programs in the health care system.¹⁸ In the HIV care system, patient navigators have provided a broad spectrum of services as a member of the care team to support linkage, engagement, retention and viral suppression for PLWH.¹⁹⁻²³ Patient navigation has been described under the umbrella of “a type of care coordination which also includes other care team roles, such as case management, peer education/navigation/support, outreach, and/or community health worker”.^{1, pg. 15} This lack of a clear function and role of patient navigators and other community health workers as part of the care team can create confusion especially with

respect to more traditional models of medical case management which have been a cornerstone of HIV services.

Another distinction of HIV patient navigation from traditional HIV case management programs is their design as a “time-limited intervention” which often varies depending on the patient population being served. In some studies, patient navigators focus on timely entry to primary care for persons being released from jail¹⁹⁻²¹ or being discharged from the hospital.¹⁷ In each case, the function of the navigator is focused on a specified number of patient contacts, in-person or via telephone, with the goal of linking to primary care within a specified time frame such as 30 or 90 days of post release or discharge. In other programs, patient navigators may play a support role to medical case managers to target persons who are newly diagnosed or out of care to ensure a person is linked and retained in care. In these programs, patient navigators may work for a period of up to six or twelve months.²⁻¹⁶ Their roles include making reminder phone calls about upcoming medical appointments, providing health education topics, and connecting a person to resources to address immediate non-medical needs. Within the specified intervention period, the goal is to make a linkage to another health care team member, usually the case manager, who provides longer-term support with medical care and social services as prescribed.

Finally, other elements of navigation programs that vary in studies are the mode of communication (phone vs. in-person contact), team composition for navigation services (peer, nurse or social worker) and the settings in which navigators work (within the community, clinic setting or both). Lessons from the cancer field show that more

information is needed to understand if patient navigators working alone versus as part of a team are more effective.²² Few studies have examined staffing patterns and inclusion of peers vs. near-peers vs. clinician. In cancer care, one recent study found that differences in program models were observed by navigator type, populations served and poverty level of the community.²⁴ Programs that worked in high-poverty communities were more likely to engage lay navigators and be located in community health centers or agencies with religious affiliations.²⁵ More information is needed about these components of patient navigation programs and linking these components to improving HIV health outcomes. This information may contribute to replicating and, in the long run, developing a payment model to ensure that a patient navigator or equivalent is a sustained member of the HIV workforce.

For PLWH who experience homelessness, there is limited information about the scope of practice for patient navigation programs. In a qualitative study with clinic and partner agency staff charged with building a medical home for PLWH who experience homelessness and other co-morbidities, patient navigators had a broad spectrum of roles and tasks. This included client tracking and outreach for those who fell out of care, scheduling and completing medical and social service appointments, developing and following through on comprehensive care plans, forging critical relationships with providers both within and outside of health care systems, providing holistic support to increase patient self-management, and assisting in achieving housing stability.²⁶ The findings indicate that for homeless populations navigation programs may need a broader scope and longer time of service delivery to impact health outcomes. More information

about the types of activities performed by patient navigators as part of the health care team would be beneficial to reduce duplicative efforts with other HIV care team members, such as case managers and to improve integration of patient navigators and other types of community health workers into the HIV workforce.

Furthermore, there is little known about the effectiveness of patient navigation programs within specific subgroups of homeless populations. It is well known that length of time homeless is a predisposing factor that impacts health care utilization and health outcomes for people who are homeless.²⁷ However, little is known about the effectiveness of interventions with persons who are newly homeless compared to those who are chronically homeless. In addition, current studies examining the impact of patient navigation have shown limited effectiveness on outcomes for PLWH who have behavioral health disorders such as high levels of anxiety, depression and illicit drug use.^{17, 28-31} There is some promising evidence that peer navigation may help improve general physical health, mental health and quality of life among African Americans who have serious mental health disorders and are homeless.³²

In summary, more research is needed to identify the components of patient navigation programs that are effective in serving PLWH who are homeless, if certain components of patient navigation programs work more effectively with sub-groups, and the effectiveness of patient navigation programs on achieving the HIV care continuum for PLWH who are homeless. In trying to address these gaps in the research, this study has three aims: 1) to describe and develop a classification of patient navigation program components for PLWH who are homeless: 2) to identify patient navigation components

that may be more likely to be received by subgroups of PLWH who are homeless, and 3) examine the components of navigation programs that contribute to retention in care and viral suppression. The information may be used for identifying methodologies to enhance the HIV workforce and create cost-effective methodologies for HIV prevention and care.

The specific research questions are:

1. What are the underlying components (types of activities, team composition, location of activities and modalities of encounters) of patient navigation models for working with people living with HIV/AIDS who are homeless/unstably housed?
2. Are these components of patient navigation models different across characteristics of the populations including number of years homeless, severity of mental health status and level of unmet need of people who are homeless/unstably housed?
3. Do certain components of patient navigation models predict retention in care or viral suppression?

Methods

This study is part of a larger national multisite intervention that used navigation programs to provide intensive services at the individual level and work across the service system to build a medical home for PLWH who experience homelessness, substance use or mental health disorders. Participants were enrolled from September 2013-February 2016 with the expectation that navigators would follow the participants for a minimum of

six months post baseline. Eligibility criteria for the study included: 1) being at least 18 years of age and living with HIV/AIDS, 2) meeting criteria of being literally homeless (staying in a shelter, public park or space in the streets or abandoned buildings) or unstably housed (moved at least twice in the past 60 days and having no signed lease or mortgage) or fleeing domestic violence, and 3) screening positive for a mental health or substance use disorder. Across the nine sites, one of the common elements for building a medical home was having a dedicated staff member or members who were part of an HIV medical team. The navigator role and job description were designed to address barriers to care and unmet needs for services, including health care, housing, behavioral health to support the existing health care team in improving linkage, retention in care, and adherence to treatment and to obtain stable housing for this patient population. The navigation programs used a single dedicated staff member or a team of members to deliver care in the clinic and out in the community. These staff members had a variety of titles, including “patient navigator”, “network navigators”, “and service linkage workers,” “case managers,” “care navigators,” “peer navigators” and “care coordinators.” The background and training of the staff member in the position varied and could be a peer (person living with HIV/AIDS), or a bachelor’s level or master level professional who was not HIV-positive. At some sites, the staff member was a licensed social worker working solo or a nurse or specialized case manager paired with a peer. The main goal of each intervention was to create a seamless system of care so a PLWH who was homeless could access HIV primary care, behavioral health, housing and other support services. For purposes and clarity of this study, the term “patient navigation” is used to refer to the

intervention staff working on building the medical home since this was the “new” role added to the existing HIV care team of the physician, medical case manager and behavioral health therapist. Further description of the role of these patient navigation interventions in building the medical home has been previously published.²⁶ Further details of the overall study are available in Appendix A. The Institutional Review Board at Boston University Medical Center approved this study.

For all staff participating in the navigation intervention, a comprehensive common 16-hour training program was provided that focused on principles of trauma-informed care, motivational interviewing techniques to provide engagement and adherence to treatment, harm reduction and strategies for de-escalating clients in crises, establishing boundaries and self-care, and advocating for clients that are challenging to house. In addition, staff participated in bimonthly, one-hour training programs sponsored by the national technical assistance and evaluation center as well as local trainings offered at the sites. Topics focused on strategies to address participant needs to attain appropriate health care, behavioral health treatment and housing. Each staff member was supervised by a senior staff member and all intervention staff regularly received clinical supervision which could be monthly or bimonthly and delivered in a group setting or on an individual basis.

Theoretical Framework

The analysis for this study was driven by Mittler’s *Engaging Consumers in Health Care in Communities (EHC)* framework as described in chapter 1. Mittler’s framework adopts the individually focused Transtheoretical Behavior Change model and

the multilevel socio-ecological model to examine individual-, group- and community-level characteristics that affect consumer engagement in health care and impact health status, well-being and costs.³³ The navigation programs across the nine sites represented *group characteristics* that could influence individual level of engagement in HIV care and treatment. These characteristics included: activities performed as part of the health and housing care team, the staff type and team composition of the intervention, and the setting in which services were delivered (in a medical clinic or in the community) and the modality in which services are delivered to the participant (face-to-face vs. telephone). Finally *community* characteristics in which the navigation program operates, such as the geographical setting, and the organization health system and housing infrastructure, were also considered in developing a classification.

Data Collection Methods

Data were collected from encounter forms completed by staff members who were part of the intervention program. The form was developed initially with expert review from the sites and based on a review of the literature on the role of care coordinators, outreach workers, navigators and peers in building a medical home for PLWH. Each staff member completed a form after an encounter with the client or with a provider on behalf of the client (*“collateral contact”*). Staff also recorded attempts to reach clients but these data are not included in this study. Information collected included: *staff type*; *location of the encounter*, *duration* of the encounter per day, *type of contact* (face to face, group, telephone, email, text, social network, and collateral); and *activity of the encounter*. The activity of the encounter encompassed eight categories:

i. finding/outreaching to clients, ii. client needs assessments, iii. health care-related, iv. mental health and substance use related, v. housing related, vi. social services (arranging transportation), vii. educational and emotional support and viii. employment and other practical support. Across these eight activity domains 43 tasks were identified. The form also included space for documenting detail case notes with the client and other tasks that might occur that could not fit into one of the prescribed 43 tasks. Appendix B shows the intervention encounter form used to collect these data.

Eleven variables describe the organization and community characteristics of the programs including: having a mobile medical unit, national certification as a medical home, access to behavioral health prescriber, co-location of mental health and substance use treatment, access to residential substance use treatment, housing resources available (access to emergency housing and accessing housing units available), direct transportation for clients, and provision of clinical supervision for staff. These variables were derived from in-depth interviews with staff about the key characteristics for building a coordinated system of care and medical home for homeless population and factors that could affect patient health and housing outcomes.

Statistical Analyses

To develop the classification of the navigation programs, four components of the encounters were selected for analyses that represent the group characteristics of the navigation programs in accordance with the theoretical model: *staff type, location of the encounter, content of the encounter (activity) and the type of the encounter (modality).*

These components were also combined with 11 variables representing the organizational

and community characteristics of the operating environment of the navigation programs. Univariate statistics were run to assess the distribution of encounters per person for each characteristic. (See Tables 3-1 and 3-2). A series of binary indicator variables were created for each of the four components: *Activity*: (6) described as (i.) health care, (ii.) mental health or substance use treatment, (iii.) housing, (iv.) social services, (v.) education and emotional support and (vi.) employment and other practical support; *staff type* (4) clinician, case manager, peer and navigator; *location of encounters*: (3) medical setting (including health clinic, hospital or residential treatment or some other skilled nursing or rehabilitation center); offsite community setting (in the streets, on mobile van, client's house, other public place); and a fixed community setting that provides no health care services such as an outreach program office or other social service agency; and finally the *modality* of communication for the encounter (4) in-person, collateral (meetings with other medical or service providers on behalf of the client), telephone and text.

To create the binary indicators, a step-wise procedure was used. First all encounters were summarized across participants by each component. The number of encounters were then ranked by quartiles to obtain the frequency of encounter for each variable in the domain. Each binary indicator variable was then coded as "1" (frequency in lowest three quartiles) or "2" (frequency for encounters in the top quartile). This coding was applied for each variable in the four domains so that the classification of the patient navigation programs would be based up the highest frequency of encounters for this population.

Organization and community characteristics were created as a binary variable: 1=no, not an active feature of the organizational model and 2=yes, is a characteristic of the organization model. Organizational and community characteristics were developed from data gathered via interviews with site program staff on their approaches for building a medical home for PLWH who are homeless. Organizations were classified as having the characteristic if the feature was present for the entire life of the intervention and resources were allocated to the cost of the element. For example, an organization would receive a “yes” if intervention staff regularly received supervision and there was evidence in the cost expenditures for a licensed clinician to provide the service.

Latent Class Analysis (LCA) was used to identify and classify the navigation programs for the highest utilizers. LCA is a technique used to estimate a single “latent” variable that explains the association between observed variables and groups or subtypes of individuals or cases. Each class has a conditional probability of group membership for each individual.³⁴⁻³⁶ LCA has been used in previous studies to identify groups of individuals who are at highest risk for HIV infection,³⁷ examine housing trajectories for diverse homeless populations³⁸ and identify individuals who could be successful with housing first programs and substance use treatment services.³⁸⁻⁴¹ At a program level, LCA has also been used to classify substance use treatment facilities and the types of services offered when treating patients with co-occurring substance use and mental disorders.⁴²

In this analysis, LCA was used to derive the key elements of navigation programs using observed patterns of encounters provided to PLWH who are homeless. LCA models with two to nine classes for each domain were compared using model fit statistics

including G-squared (G^2), Akaike Information Criterion (AIC) (Akaike, 1983) and Bayesian Information Criterion (BIC). A maximum of nine classes could be considered since this was the maximum number of participating sites. The smallest relative AIC and BIC values were considered to be better fit models. The entropy value of 0.7 was used as a cut-off to assess the extent to which classes were distinct and accurately classify individuals across program components. The maximum-probability assignment rule was used to assign individuals to the latent class in which they had the highest posterior probability of membership. A cut-off point of 0.4 was used for group assignment.^{34-35, 43}

For the second research question, multinomial logistic regression was performed to examine associations of the classes for each domain with patient characteristics. Co-variables were selected based on findings in the literature about factors that affect health care utilization and outcomes for persons who are homeless and the efficacy of patient navigation programs with sub-group populations. Co-variables selected were length of time homeless, the level of unmet need, and severity of mental health, measured by their score on The Center for Epidemiologic Studies-Depression (CES-D) scale.^{27-32, 44} Each co-variate was added separately to the model. The largest class membership was set as the reference group for each model.

Finally, as part of my third research question, a final multinomial logistic regression was performed to assess the association of each class of the domains for patient navigation with retention in care and viral suppression. All data analyses were performed in SAS v9.4.⁴⁵

Results

Table 3-1 provides summary statistics for the encounters between patient navigators and participants. There were 885 participants with completed encounters recorded for the study and a total of 38,760 encounters across all study participants. Twenty-four participants were excluded after completing a baseline survey due to failure to have any encounters with a navigator. Encounters with missing data fields were also removed from analysis. These participants were also lost to follow up for all other aspects of the study. Participants worked with navigators for an average of 19 months and had on average 154 encounters over the course of their participation in the intervention. Health-related activities (mean=107) (accompaniment to medical appointments, assisting with medications, scheduling appointments) and housing-related services (mean=88.2) (finding housing, completing housing paper work, meeting with landlords) were the most common activities completed with clients. Encounters were conducted most commonly in a medical setting (15.9), followed by those at a community or non-medical organization. In-person encounters with clients were on average more frequent compared to encounters by text or by telephone. Navigators also spent time working with other providers, and an average of 120 encounters per person were collateral contacts occurring on behalf of a client to coordinate services between navigation staff and service providers. With respect to the type of staff who performed the encounters, navigators (bachelor or master's level) had an average of 111 encounters per participant followed by a peer (mean=13.2), clinician (nurse or licensed social worker) (mean=8.4) and finally case managers (both medical and housing case managers (mean=2.3).

Table 3- 1 Summary Statistics of Client Encounters (N=885 participants)

Variable	Mean, SD
No. Encounters/person	154 (247)
No. Activities/person	358 (651)
Average duration/person	3.3 hrs/month (4.7)
Average months in intervention	19.9 (9.2)
<12 months	15.0%
12-18 months	35.7%
19-24 months	20.2%
25-36 months	20.3%
>36 months	8.8%
Content of encounters	
Health care related	107. 1 (215)
Housing related	88.2 (194)
Education & Emotional support	57.4 (134)
Social services	35.7 (76.1)
Mental Health or Substance use treatment services	28.7 (52)
Employment	4.8 (7.6)
Mode of encounter	
Face-to-face	138.1(198.9)
Collateral	119.7 (296)
Telephone	96.5 (273)
Text	2.3 (7.3)
Location of encounters	
Offsite (streets, public space, client house)	5.6 (9.9)
Fixed community (non-medical setting, community setting)	6.9 (13.4)
Medical setting (clinic, hospital)	15.9 (27.1)
Residential treatment	0.4 (1.5)
Staff encounters performed by	
Navigator	111.1 (240.9)
Clinician	8.4 (44.3)
Case manager	2.1 (5.3)
Peer navigator	13.2 (29.9)

Table 3-2 describes the organizational and community characteristics in which the navigation programs conducted their work. Approximately 27% of participants received services through a mobile medical unit, and 60% of participants received services by staff as part a facility that was certified by national standards to be a medical home. A majority of participants (71%) received services related to mental health care and substance use treatment from a prescribing provider. One-third of participants received services in organizational and community settings at a residential treatment facility, and

one-third of the patient navigation programs had staff that could provide medication-assisted therapy as part of the intervention model. One-third of participants had direct access and a formal partnership with a housing agency who had vouchers or access to housing units including HOPWA and HUD assistance. One-third of participants had access to emergency housing as needed. All the patient navigation programs provided some form of transportation assistance, with one-third able to have staff directly provide transportation to reach a medical or social service appointment. Approximately 70% of the participants received services where clinical supervision was formally and consistently provided to staff as part of the program model.

Table 3-2: Program Model Characteristics Across Nine Sites (n=885)

Characteristic	%
Mobile medical home (clinical and navigator type staff)	26.8%
Certified Patient medical home (by JACHO or NCQA standards)	60.0%
Access to a behavior health prescribing practitioner	71.3%
Mental health counseling on site	71.3%
Substance use treatment counseling on site	71.3%
Access to residential treatment for substance use	35.5%
Provided medication assisted therapy on site	37.6%
Housing partner with accessible units	30.9%
Emergency housing readily available (hotel/motel, non-shelter facility)	37.2%
Provide transport rides to clients for services	35.5%
Other transportation assistance (vouchers, subway bus passes)	70.9%
Clinical supervision provided	70.9%

Description of navigation programs and the components

As a first step a LCA was conducted with all 28 indicator variables, 17 from encounter components (activity, staff, modality and location) and 11 from the organizational and community characteristics). Results revealed no underlying pattern

across domains and organizational/community characteristics to identify a limited set of patient navigation programs. (Data not shown)

Given this finding, the analysis was revised to run a series of LCA procedures to identify patterns across each component of the navigation program, and limited to encounter data only. Tables 3-3a-d summarize the classification of patient navigation programs for each domain. Selection of the best class solution was based on comparing a fit statistics (AIC, BIC and entropy) and finding a balance for fit, parsimony, and substantive interpretability. Four separate analyses were examined with each domain (*activity, staffing patterns, modality and setting*) of the CC/PN model. Domains were analyzed separately since there were weak correlations among the four domains ($r=0.02-0.16$). Within each domain, the indicator variables had low correlations among each of the latent classes meeting the LCA assumption of local independence.

Activities: Four class solution

Table 3-3a shows the conditional probabilities of highest utilizers of the type of activity provided by the navigation model. Classes were labeled according to their patterns of item response probabilities. The “limited” class was the largest class with 64% and had the lowest probability of receiving intensive services across all the activity domains. This could be interpreted as the group who received a little bit or “light touch” of all services. The “comprehensive” class (18%) had a high probability of receiving an intense level of all the activities by the navigation intervention—in health care, housing, mental health, educational, social services, and employment support. The “non-medical” group (13%) had intensive services provided in all domains (housing-behavioral-social

services-employment) except for health care. The “health-education-employment” group was the smallest class (5%) receiving support for health care appointments, education and some employment and benefit activities. This group had a very low probability of health care-related support, such as reminders for appointment, accompaniment to appointments or referrals for other specialty health care (non-behavioral).

Table 3-3a Latent Class Membership by Navigation (n=885)

	Class 1 Comprehensive	Class 2 Limited	Class 3 Health- Education- Employment	Class 4 Non- Medical Services
Class membership probabilities: Gamma estimates (standard error)	0.1786 (.0138)	0.6359 (.0230)	0.0577 (.0172)	0.1278 (.0247)
Latent Class Prevalence				
Item response Probabilities (Rho estimates)				
Health care activities	0.9963	0.0256	0.9237	0.0230
Housing activities	0.9739	0.0331	0.0326	0.4126
Education activities (mentoring, harm reduction, disclosure, relationship-building)	0.6204	0.0401	0.4914	0.6499
Mental health and substance use treatment activities (accompaniment, referrals, follow up appointments)	0.9812	0.0148	0.2679	0.4307
Social Service activities (including transportation)	0.9630	0.0047	0.3221	0.4377
Employment and financial benefit (getting phones, getting benefits, legal documents)	0.4551	0.1125	0.7633	0.4209

Modality of contact: 2 class solution

A two-class solution for method of contact was selected as shown in Table 3b. The “Multi-modal” class (20.2%) had high probabilities of intense in-person contact, telephone and communication with other providers (collateral) contact with navigation staff. The second and largest class had high probability of receiving only telephone contact (79.8%).

Table 3-3b: Latent Class Membership of Modality of Contact

	Class 1 Multi-modal	Class 2 Telephone only
Class membership probabilities: Gamma estimates (standard error)	0.2023	0.7977
Latent Class Prevalence		
Item response Probabilities (Rho estimates)		
Face to face	0.9797	0.0671
Collateral	0.8541	0.0962
Telephone	0.6771	0.1425

Staff composition: 3 class solution

A three-class solution was selected for classifying the staff type for encounters performed with participants. (See Table 3-3c) The largest class consisted of a “navigator” only model at 56.2%. This group included staff who identified themselves as care coordinators, service –linkage workers, or network or patient navigators. The class “peer-case manager” represented participants who high probability of receiving services from medical case manager, housing case manager and a peer navigator or educator. (29.9%). The third class were participants who received services from a “peer-clinician” team (13.9%) which consisted of a peer navigator working with either a social worker, nurse practitioner or nurse.

Table 3-3c: Latent Class Membership by Staffing Pattern

	Class 1 Peer- clinician	Class 2 Peer-case manager	Class 3 Navigator only
Class membership probabilities: Gamma estimates (standard error)	0.1391 (0.0830)	0.2985 (0.1039)	0.5624 (0.0346)
Latent Class Prevalence			
Item response Probabilities (Rho estimates, standard errors)			
Navigator	0.0416	0.004	0.4332
Clinician	0.5985	0.001	0.0001
Case manager (include medical, housing & program director)	0.0010	0.7550	0.0003
Peer navigator	0.6059	0.4543	0.0453

Location of encounters: Three class solution

The setting in which individuals received services was best determined by a three-class solution. (See Table 3d) The “medical setting” was the largest class (62.2%) where individuals received encounters with the navigation programs at a clinic, hospital or health care setting, with a low probability of receiving services in the streets, at home or at a community non-medical setting. The “community setting” (22.6%) had a high probability of receiving services outside a clinic in the streets at a community site as a home visit for clients or community organization that was a non-medical site.” The smallest class was the “mixed setting” (15.2%) where services were received at a medical site and at the client’s home or in the streets.

Table 3-3d: Latent Class Membership by Location of Encounter

	Class 1 Community	Class 2 Medical	Class 3 Mixed
Class membership probabilities: Gamma estimates	0.2256	0.6220	0.1524
Latent Class Prevalence			
Item response Probabilities (Rho estimates, standard errors)			
Offsite (streets, client home, public place)	0.4407	0.0117	0.8432
Fixed community (other community office, nonmedical)	0.8433	0.0162	0.2585
Medical setting	0.0206	0.1876	0.8343

Do patient navigation model characteristics vary across patient risk factors?

Based on findings from the literature about the effectiveness of patient navigation across patient sub-groups and factors associated with health outcomes for people who experience homelessness, three variables were selected as risk factor predictors to assess association with latent class membership for each domain.²⁷⁻³¹ These variables included: number of years homeless, depression score and unmet need. Table 3-4 describes the results of the logistic regression. The number of years experiencing homelessness was a

significant predictor of latent class membership for some components of patient navigation. Persons who were homeless for a longer period of time were slightly more likely to be seen by a peer-clinician [odds ratio 1.10 (95%CI 1.05, 1.14)] or peer-case manager team [odds ratio 1.08 (95% CI, 1.04, 1.12)] in the field compared to a navigator only. Greater length of time homeless was also associated with being seen outside the medical setting and with higher odds of receiving targeted services for health-education and practical support or non-medical services and with lower odds of receiving comprehensive services. Participants with higher unmet needs had slightly greater odds of seeing a team of peer/clinician [odds ratio 1.13, (95% CI, 1.0,1.2)] or peer-case manager. Severity of depression was not a significant predictor of class membership across any domain.

Table 3-4: Participant Characteristics Associated with Navigation Components

Patient navigation component	Homeless years*	Depression scores	Unmet needs*
Activity	OR	OR	OR
Comprehensive	0.87(0.83,0.92)	1.04(0.67,1.6)	0.86 (0.79,0.94)
Health-Education-Employment	1.06 (1.03,1.08)	0.85 (0.51,1.4)	1.09 (0.93,1.3)
Non-medical	1.0 (.07,1.04)	3.04 (0.67,13.9)	0.90(.80,1.0)
Limited	Ref	Ref	Ref
Mode of encounter			
Multi-modal (In person-collateral-telephone)	0.80	1.3	0.85
Telephone only	Ref	Ref	Ref
Location of encounters			
Community	1.00	0.84	0.77
Mixed setting	1.03	1.7	1.00
Medical setting	Ref	Ref	Ref
Staff			
Peer-clinician team	1.10 (1.05,1.14)	0.71 (0.40,1.3)	1.13 (1.0,1.2)
Case manager-peer	1.08 (1.04,1.12)	0.74 (0.49,1.1)	1.0 (0.04,1.09)
Navigator only	Ref	Ref	Ref

Association of program components with retention in care and viral suppression

The final analysis examined class membership for navigation programs and its association with viral suppression and retention in care. Table 3-5 describes the associations of each navigation component associated with the health outcomes. Class membership for activity, mode and setting of patient navigation was significant for retention in care but not for staffing patterns. No significant associations were found between class membership and viral suppression across all domains. Participants who received “limited” activities had significantly lower rates of retention in care (70.3%) compared to the groups that received “comprehensive” (80.4%) or “health-education-employment support” (98%) or “non-medical services” (79.8%). Participants who received multimodal contact had higher rates of retention (82.6%) compared to those who received only telephone contact (72.9%), and participants seen only in the medical setting

Table 3-5: Navigation Components by HIV Outcomes

	% Participants Retained in care 2 visits 90 days apart post 12 month period (n=847)	% Participants Virally suppressed 12 months post enrollment (n=738)
Activity		
Comprehensive	80.4% *	68.8%
Limited	70.3% *	70.1%
Health-Education-Employment	98.0% *	68.8%
Non-medical	79.8% *	75.9%
Modality		
In person-collateral-telephone	82.6% *	67.5%
Telephone only	72.9% *	71.2%
Setting		
Community	83.8% *	76.5%
Medical setting	66.6% *	70.2%
Mixed setting	92.3% *	64.2%
Staff composition		
Navigator only	72.6%	70.3%
Peer-clinician team	81.1%	62.1%
Case manager-peer	77.2%	73.3%

*p<.05

had lower rates of retention in care (66.6%) compared to those participants who had encounters both in the community (83.8%) or in combination of community and medical settings (92.3%). While not significant, the navigation programs with peer-clinician team members had the higher rates (81.1%) of retention in care compared to peer-case manager teams (77.2%) or navigator only (72.6%).

In multinomial logistic regression receiving high intensity of non-medical support services (housing-behavioral health-social services-employment) had significantly highest odds of being retained in care [AOR=20.7, 95% CI 2.8,151.3] compared to the group receiving “comprehensive” activities [AOR=1.73 ,95% CI (1.1, 2.7)]. Participants in the “health-education-employment support group” also had higher odds of being retained in care compared to the limited group (AOR=1.67, 95% CI (.98, 2.8)], but this was not significant. Patients seen in the community as well as medical setting are twice as likely to be retained in care. (Tables 3-6, 3-7)

While class membership was not significantly associated with viral suppression there was some suggestive evidence of positive and clinically relevant findings for this population. Those who were in the health-education-employment group had higher rates of viral suppression [AOR=1.3, 95% CI .78, 2.3] compared to those who received limited activities. Even though this result was not significant it suggests that activities such as talking about disclosure, education on HIV treatment, coaching on communication with providers and reducing substance use may help contribute to viral suppression. Participants who received patient navigation services in the community had increased odds of being virally suppressed [AOR=1.4, 95% CI (0.91, 2.10)] rates

compared to those who received services in the medical setting only, but these rates were not significant. Finally, those seen by the peer-case manager team had increased odds of being virally suppressed [1.16, 95% CI (0.81, 1.6)] by the 12-month period compared to the navigator only and peer-clinician team. However, none of these findings was significant. (Tables 3-6 and 3-7)

Table 3-6: Multivariate Logistic Regression of Navigation Program Characteristics with Retention in Care (n=847)

	β (SE)	p	AOR (95% CI)	c-statistic
Activity				
Comprehensive	0.55 (0.22)	0.01	1.73 (1.1,2.7)	0.59
Health-Education-Employment	0.48 (0.26)	0.054	1.67 (.98,2.8)	
Non-medical services	3.03 (1.01)	0.003	20.7 (2.8,151.3)	
Limited	Ref		Ref	
Mode				
Multi-modal (In person-collateral-telephone)	0.56 (0.21)	0.009	1.76 (1.1,2.7)	0.54
Telephone only	Ref	Ref	Ref	
Setting				
Community setting	0.95 (0.22)	<.001	2.6 (1.7,4.0)	0.64
Mixed setting	1.78 (0.32)	<.001	5.9 (3.1,11.3)	
Medical setting	Ref		Ref	
Staff Composition				
Peer-clinician team	0.48 (0.31)	0.12	1.6 (.876,2.9)	0.54
Case manager-peer	0.24 (0.17)	0.17	1.3 (0.90,1.8)	
Navigator only	Ref	Ref	Ref	

Table 3-7: Multivariate Logistic Regression of Navigation Program Characteristics with Viral Suppression 12-Months Post Enrollment (n=738)

	β (SE)	p	AOR (95% CI)	c-statistic
Activity				
Comprehensive	-0.06 (0.20)	0.77	0.942(0.62,1.4)	0.52
Health-Education-Employment	0.29 (0.27)	0.27	1.3 (0.78,2.3)	
Non-medical	-0.064 (0.32)	0.84	0.94 (0.49,1.78)	
Limited	Ref		Ref	
Modality				0.51
Multi-modal (In person-collateral-telephone)	-0.17 (0.29)	0.36	0.89 (0.58,1.2)	
Telephone only	Ref			
Setting				0.55
Community setting	0.32 (0.21)	0.12	1.4 (0.91,2.1)	
Mixed setting	-0.27 (0.20)	0.18	.76 (0.509,1.1)	
Medical setting	Ref	Ref	Ref	
Staff composition				0.53
Peer-clinician team	-0.36 (0.27)	0.41	0.694 (0.40,1.12)	
Case manager-peer	0.15 (0.18)	0.18	1.16 (.81,1.6)	
Navigator only	Ref		Ref	

****Most recent viral test in the post 12-month period**

Discussion

In this study, findings show that navigation programs vary in tasks/activity level, staffing patterns, settings in which services are performed, and the modality of encounter between staff-client for PLWH who are homeless/unstably housed. Participants received a range in types of activities within navigation programs, with some receiving services from a comprehensive set of services while other participants utilized more focused activities, such as housing, behavioral health or employment and educational support activities. Staffing composition varied, with a group of participants that received services primarily from one navigator assigned to a client (bachelor's or master's level person), and another receiving services from a peer-clinician or peer-case manager team. The settings in which patient navigation programs deliver their services to PLWH who are homeless also varied, with results showing that working beyond the clinic walls and in the community is a critical component.

The data did not reveal any clustering of the navigation programs across the domains (team composition with activities by modality or setting) to determine a specific set of navigation models for health service delivery to PLWH who are homeless. However, the findings do suggest that there are distinct service categories within program components that are important to consider for engaging PLWH who are homeless.

Furthermore, these patterns varied depending on the individual risk factors. The results showed that PLWH who are more recently homeless may receive a comprehensive set of services ranging from health care, behavioral health services, housing and social services compared to more chronically homeless who were more likely to use non-health related services such as housing, social and employment services with greater frequency. While there were no differences among navigation programs in providing services to clients with varying levels of depression, the study results suggest that staffing composition for navigation programs differ depending on client level of unmet needs. Participants with higher level of unmet needs were slightly more likely to receive greater frequency of contact from navigation programs that used a team composition with peers and case managers or clinicians compared to those who work with a solo navigator.

In this study, types of activities, location of work and modality of contact of navigation programs were associated with better retention in care for PLWH who are homeless. Participants who received intensive, comprehensive activities ranging from health and non-health care services had higher odds of being retained in care compared to those that had “limited” service. Navigation programs that spent time with participants

out in their communities, including home visits or providing care in public spaces and the streets, were more likely to retain PLWH who are homeless in HIV care than programs that were more clinic based. Persons who are unstably housed require navigators to spend a significant portion of their time working directly with the person to provide support and connection to services, but also networking with other providers on behalf of the client. These findings are similar to other qualitative studies with persons leaving jail or those who were out of care which found navigators play a unique role in system coordination as part of the care team compared to other team members.²⁰⁻²³ This study builds upon those findings and provides evidence that this role is as essential as providing the individual (one-on-one) support services.

No differences were found in staffing patterns for navigation programs associated with retention in care. Navigation programs that had team approaches with peers and clinicians or case managers were as effective as navigators alone. These findings suggest that *the role of a navigator* and its functions alone are important for reaching a homeless population rather than the composition of the team in delivering services. Having a team member or members who is able to build the trusting relationship and has the flexibility to work with a person who is experiencing homelessness in a variety of settings and across providers, perform multiple tasks, and has knowledge about both health and non-health services is critical. The traditional HIV health care approach of physician, nurse, social worker and case manager in the clinic is not sufficient to address all the complex needs of PLWH who are homeless. There is some suggestive evidence that peers as part of the care team when working directly with a case manager or clinician may have a

complimentary role that supports a client to engage and stay in care, especially for the chronically homeless and those with greater unmet needs.

Similar to other studies of navigation programs, we found no difference in activity, staffing patterns, settings or modality of communication of patient navigation programs on viral suppression rates.⁹⁻¹⁵ One reason for this null finding may be related to other priority needs such as obtaining food, housing and employment rather than taking medications as prescribed. While many navigators reported helping to obtain prescriptions and educating about treatment (as part of health-education-employment class) not all navigators in this program performed directly observed therapy which could facilitate adherence to treatment. In addition, while the navigation programs were able to engage and retain people in care and support them to attend medical appointments, navigators could not control if health care providers prescribed treatment for the persons who were homeless. Other studies have shown that health care providers may be reluctant to prescribe treatment if a PLWH is homeless or unstably housed, actively using illicit drugs or suffering from mental health disorders.⁴⁶ Also, personal choice to not take medications cannot be ruled out. Given the multiple co-morbidities, level of trauma experienced and multiple competing needs of our population, taking HIV medications to stay virally suppressed may not be the priority, especially if a person feels healthy and is not experiencing an acute illness, compared to other needs such as obtaining food and being in a safe place.

This study contributes to the literature by providing information about the breadth and depth of the work of navigation programs when serving PLWH who experience

homelessness. Most studies of HIV navigation programs emphasize a time limited and/or discrete set of activities to be carried out in a medical setting.⁹⁻¹³ Other studies have described the importance of peer navigator and near-peer navigators in retaining vulnerable populations in care such as women of color and young MSM but do not show a link between which activities or modality of communication between staff and client are critical for improving health outcomes.⁹ Other studies have shown that telephone-based care coordination programs are effective in retaining PLWH in care who missed appointments but these studies were carried out in clinic settings and were not effective with persons who had at least one unmet need or used illicit drugs.²⁷

The findings of this study also provide evidence of the level of effort required by navigation programs when working across the health and housing systems and the role in improving patient outcomes. In this study a substantial amount of effort (on average 154 contacts per client, with 120 contacts with service providers) by the staff providing navigation support was spent communicating and coordinating activities with other providers on behalf of a client. Previous studies have examined a dose threshold of encounters to reduce gaps in care.^{3, 10} This study builds upon the current knowledge by providing information for navigation programs who wish to engage PLWH who are homeless. The findings demonstrate the importance of system-level strategies to bring and coordinate the services of providers from health, housing and other social service sectors together. In addition, having a dedicated staff member or team to be the point of contact and share information is essential for PLWH who have multiple service needs and reduces barriers as a result of fragmented services.

This study also demonstrates that navigation programs must be adaptive in their approach to the scope of services for PLWH who are experiencing unstable housing situations. For some individuals, the priority may be on finding employment or obtaining educational support related to living with HIV that can lead to a more stable housing situation and continued engagement with their health care. For others who are chronically homeless, services that focus on housing and mental health may be the first priority to be addressed by patient navigator rather than addressing employment or health care needs. Critical tasks for navigators include 1) collecting information about health care, mental health, and substance use treatment needs, 2) developing a comprehensive care plan with the patient based on their level of acuity and 3) prioritizing appropriate referrals based on the level acuity for PLWH who are homeless. Using traditional programs of retention in care programs that focus on telephone reminders for missed visits and weekly educational sessions may not be effective with this population even if phones are accessible and provided to the individual.

Limitations

Despite monthly monitoring reports and annual site visits to ensure staff encounters were entered into the electronic data system, there may be an underreporting of staff encounters with clients. Research staff conducted annual audits, and automatic cleaning reports which tracked encounters entered by staff and for each client across the sites were shared monthly with each site for quality assurance purposes. Audit processes included a random selection and review of the data for 10% of the site study sample. During the audits, research staff compared encounter data to the chart and progress notes

in electronic health records at the sites. In cases where information either from the progress note was not included in the encounter form or a missing encounter form was not entered for a progress note, discrepancies were shared with the site staff who later resolved and updated the multisite data system.

In addition, the encounter forms may not have captured all the tasks and amount of time spent with client or providers on behalf of clients. The form also did not capture the administrative time spent on tasks, such as completing charts or documentation of work. This study only describes the structure and process of navigation programs during the intervention period. Some of the tasks and the setting and timing in which they occur may have a greater impact on outcomes. In addition, the study did not tease out which tasks are critical for each team member nor the specific tasks under each activity domain, such as care planning versus housing needs assessment and its link to the retention in care and viral suppression. Future research studies are warranted to address these aspects of the navigation model.

Implications

In a recent update on the NAS goals, data showed that efforts to reduce homelessness among PLWH who are engaged in care were increasing from 7.9% in 2013 to 9% in 2014. These increased rates in homelessness in turn increase the risk for poorer health outcomes in the future.[†] For PLWH who are homeless, traditional medical home approaches of providing integrated services within a brick and mortar clinic are proving

[†] (US Department of Health & Human Services “Reducing Homelessness among PLWH to reach our goals: A Listening Session” September 25, 2017 www.hiv.gov Last accessed September 25, 2017).

to be insufficient for retaining people who are at risk of homelessness or living in unstable housing situations. This study found that navigation programs that incorporate mobile services out in the community and have staff who use multi-modal strategies to work with clients are key components to improve health care access and utilization for this population. For individuals who are chronically homeless or have a higher number of unmet needs using a team-based model of care that may be more effective, but additional research is needed. Having a peer-clinician or peer-case manager team who can make immediate referrals to health and behavioral health care and follow through with the client on attending or accompanying to appointments is an important process for improving access to and use of care and treatment.

In this study, navigation programs that focus activities on medical as well as non-medical services (i.e. behavioral health, housing and employment) and educational support activities did have a significant impact on retention in care. Thus, having a team member or members who can facilitate referrals to other providers, or including a clinician who can directly offer counseling or prescribe medications on demand to clients may be the critical link in a chain for reducing the barriers creating by a fragmented services system especially between housing, behavioral health and medical care systems. While team composition (navigator alone vs team models of peers-clinician or case managers) was not significantly associated with better HIV outcomes, the findings highlight the importance of the navigator role for the health care team. Future studies are needed to examine the mechanism of the various navigation staff roles in the engagement and viral suppression process. This study identified the staff composition for navigation

programs working with this populations.

Navigation programs that work with homeless multiply diagnosed populations require a breadth and depth of training on topics to support not only HIV care, but mental health disorders, substance use treatment options including counseling and medication-assisted therapy, and knowledge about housing assistance and available resources. In addition, being trauma informed and supporting people to address the lifelong impact of trauma is another area to help reduce the barriers to care.

Future research of navigation programs with PLWH who are homeless/unstably housed could further explore the level of intensity of navigation services in reducing unmet need and level of acuity of PLWH over time. This study found some suggestive evidence of associations between types of activities, location of services delivered or modality of contact and participant characteristics of homeless chronicity and level of unmet needs. These findings highlight the importance of assessing the level of acuity and unmet need of this population and tailoring the staff efforts and tasks accordingly. At the time of the study, there was no standardized tool to assess patient acuity and the systematic process for assigning patients to navigation caseloads. Future studies could develop and test a common set of indicators to assess the level of acuity and unmet need, and then examine the time and dose of navigation programs that work with homeless populations.

In conclusion, the findings from this study highlight the diversity in activity, staffing pattern, modality of contact and location of work performed within CC/PN programs that work with PLWH who are homeless. The study suggests that there are

core components in CC/PN that can improve retention in care. However, these should be tailored to the level of acuity and unmet need of the person.

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Chapter 4: An Economic Evaluation of HIV Navigation Programs

Working with PLWH Who Are Homeless/Unstably Housed

Introduction

Over the last decade of the HIV epidemic, a growing body of evidence has emerged to identify effective interventions to improve linkage and retention in care and adherence to treatment for people living with HIV/AIDS (PLWH) in the US.¹ Recent research has called for greater application and the adaption of the health care delivery system to use community-based strategies such as community health workers, peers, patient navigators to connect people to needed support services that reduce barriers to care and achieve the goals of the HIV care continuum.² These strategies can play a critical role in increased global and US commitment of resources to end the HIV/AIDS epidemic, especially for marginalized communities hit hardest by the epidemic. Evidence of support for these community strategies has been mentioned in the United Nations AIDS Program (UNAIDS) 90-90-90 Initiative, a bold initiative that 90% of all people living with HIV/AIDS will know their HIV status, 90% will receive antiretroviral treatment and 90% will be virally suppressed by the year 2020.³ Similar goals have been developed in the United States starting with the National AIDS Strategy (NAS) first drafted in 2010 and recently updated to achieve a goal of reaching viral suppression among 80% of PLWH in the US.⁴

In the past five years there has been an increasing shift to examining the *efficiency* of these community-based interventions, especially in an effort to address the trend of

rising health care costs. One identified challenge to achieving the NAS's HIV care continuum goals is the US health care financing system with its emphasis on payment for medical services and inadequate reimbursement for support services that achieve linkage and retention in care.² Adequate reimbursement is needed for strategies that promote linkage and retention in care and adherence to treatment.^{2, 5}

The Ryan White HIV/AIDS Program (RWHAP), a federal program directly funded by Congress and administered by the US Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau, fills this gap by serving as the payer of last resort for PLWH who are uninsured or underinsured and cannot afford to pay for HIV care and treatment. Eligible recipients are states, selected cities and geographic areas with high HIV incidence and prevalence, and medical providers. However, currently the RWHAP reaches only about half of the 1.2 million people living with HIV in the US.⁶ Furthermore, federal mandates allow RWHAP recipients to spend only 25% of awarded dollars on support services, such as linkage to care and psychosocial activities, while 75% of funds must be allocated to core medical services such as provision of medical care by a prescribing provider and antiretroviral therapy. Thus, the benefits of the RWHAP program may not reach the most vulnerable populations who are not engaged in primary care and treatment. With state and local budgets facing fiscal restraints, it is important to understand the cost and effectiveness of various linkage, retention and adherence strategies to make appropriate decisions in the allocation of resources for reaching vulnerable populations such as people who experience homelessness.

Economic evaluation for linkage and retention programs for PLWH

There is emerging literature on economic evaluations of programs for linking and engaging PLWH into care and treatment. The studies vary in their methodologies with respect to measuring costs and utility and in the approach to assessing cost effectiveness of the interventions. Study designs included a *cost analysis*, a calculation of the cost from administrative records of an additional linkage or retention service compared to the standard of care or a *cost-utility* or *cost-savings* analysis, a form of cost-effectiveness analysis, in a cost-utility analysis, costs are directly collected and calculated from the intervention, and the utility metric is a quality-adjusted life year (QALY), derived from the literature and an outcome of the program. *Cost-savings* studies estimate the number of future HIV infections averted, thus saving on future treatment costs attributed to the program intervention. In both cost-savings and cost-utility analyses, the calculated values are then compared to a standard economic threshold for expenditure of resources. In addition to the variation in methodologies, cost-effectiveness studies also vary in the population groups for the interventions with respect to demographics, health status or social risk factors. Finally, while most of the programs studied are time limited there may be variation in the length of time or no limit established.

The Antiretroviral and Access to Treatment Study (ARTAS), a brief case management intervention to link persons newly diagnosed with HIV medical care within 90 days of diagnosis, estimated the cost per client as \$600 to \$1200 (2002 US Dollars \$800-\$1600 in 2016 US Dollars) for the intervention. Costs included the salary of case management staff, transportation costs, rent, overhead and other program costs. Persons

newly diagnosed with HIV who received up to 5 contacts with case managers were 1.17 times more likely to be linked to care in 90 days, compared to the standard of care group who received a passive referral to care.⁷ The intervention was not effective with persons with substance use.

Kim et al. (2015)⁸ conducted a cost and threshold analysis to estimate potential cost effectiveness and cost-savings of five linkage-to-care programs across the United States.⁸ The “Positive Charge” programs were based in 5 geographically diverse areas including New York, Chicago, Louisiana, North Carolina and San Francisco. The projects served a diverse group of vulnerable populations including young men who have sex with men (MSM), persons released from incarceration, low-income members of a Medicaid managed care population, and newly diagnosed and out-of-care PLWH. Program duration ranged from three to nine months across sites. Some site interventions were time limited and other sites had ongoing activities. Costs were calculated from both a provider perspective which included staff/personnel, materials and other consumables, and a societal perspective (transportation incurred going to and from the program and child care cost). Data were gathered from administrative records. Cost savings were calculated as C (total program cost) / T (medical cost averted) and cost effectiveness was estimated as cost per quality-adjusted life year (QALY) saved and compared to standard benchmark for willingness-to-pay thresholds. Average per client costs ranged from \$517-\$3,218 from a payer perspective and \$524-\$3,270 from a client perspective. The cost-savings threshold ranged from 0.15-1.1 for number of HIV transmission averted, and cost per QALY saved ranged from 0.48-3.71. These findings were determined to be

achievable with respect to cost savings and cost effectiveness within the willingness-to-pay (WTP) thresholds. Thus authors concluded the programs may be a potential efficient use of public health resources.⁸

Jain et al. (2016)⁹ conducted a cost-utility analysis of three linkage and re-engagement programs in the United States. The study collected and calculated the total cost of program implementation from three urban sites. The utility metric, quality-adjusted life years (QALYs) was calculated as the sum of 1) the net number of individuals participating in the program intervention who were virally suppressed and 2) the number of infections averted using values from the literature for individual who are newly suppressed. The study found that the cost-utility ratio for each program ranged from \$4,439 to \$137,271 a highly cost-effective ratio when compared to the WHO CHOICE threshold of \$159,429 for US GDP in 2013.⁹ The authors concluded that linkage-to-care programs similar to Positive Charge may be cost-effective, have a potential societal benefit and are a productive and efficient use of public health funds.^{9, 10}

Spaulding et al. (2013)¹¹ conducted a cost-effectiveness analysis of an enhanced linkage intervention using care coordinators to connect PLWH who were released from jail or prison at six months post enrollment. The analysis used an HIV transmission-rate model to estimate the number of secondary HIV infections prevented during each six-month interval by the linkage program for a period of ten years. Sensitivity analysis performed included varying the following elements: 1) the linkage ratio by 10% to the

base case scenario[†] 2) the analytic time frame for model infections averted from 5 to 15 years, and 3) the attrition rate 13.5% to 22.5% being lost to care in the 6-month follow-up interval. The results found the mean cost of clients linked to care within 90 days of release from incarceration was \$4,219, and \$4,670 for sustained linkage per client, and viral suppression was \$8,432. Compared to the standard of care the cost per QALY saved was \$72,285, suggesting the intervention was cost effective from the societal perspective using a willingness-to-pay threshold of \$100,000. However, the intervention was not effective when examining outcomes in a time frame of less than five years suggesting that the linkage interventions are worthwhile investments in longer-term scenarios. This study also used comparison values from the literature that were not focused on PLWH who were incarcerated and thus may overestimate the cost-effectiveness ratio.¹¹

Fewer studies have examined the costs and cost effectiveness of retention-in-care programs for people living with HIV and specifically in marginalized populations. Shresthra et al. (2015)¹² estimated the additional cost of using retention care coordinators to provide enhanced personal contact compared to a standard of care. The care coordinators were clinic-based in six academically affiliated HIV clinics in large urban areas. The intervention included telephone contact (appointment reminders) and in-person health education sessions in the clinic. The patient population included persons who had missed one or more scheduled visits in the past twelve months or patients who failed to attend clinic in two consecutive six-month periods over twelve months, and had

[†] In the ARTAS study patients who received a case management intervention were 1.3 times more likely to be linked to care compared to the standard referral. In the Enhanced linkage program—the model varied linkage ratio from 1.17 to 1.43 times.

not been incarcerated or hospitalized as a reason for missing a previous visit. Costs were collected using a micro costing technique to account for fixed and variable labor and non-labor costs attributable to the enhanced contact intervention. Fixed costs include project meetings, supervision, general administration, travel for training, utilities, durable goods such as computers, and office space. Variable costs included staff time with patients and office supplies. Cost data were collected from a provider perspective as a one-month period and then annualized. Labor costs were estimated based on staff time spent on intervention activities multiplied by wage and fringe rates paid. Outcome measures included annual costs, cost per patient, and cost per additional patient retained in care beyond the standard of care. The results showed an average cost per client for the intervention to be \$393, and the estimated cost per additional client retained in care was \$3,834 compared to the standard referral group.¹²

Maulsby et al. (2017)¹³ conducted an economic analysis estimating the costs and effects thresholds for seven retention in care (RIC) programs funded throughout the US. The programs were located in six urban sites and one rural site. Program components were diverse, ranging from use of additional workforce such as health navigators, peers or community health workers to link to social services to address needs, use of smartphone applications, use of housing and payee services, provision of wrap-around services and transportation services. Program interventions ranged from six to sixteen months. The target populations focused on people who were hard to retain in HIV care including transgendered persons, persons who are homeless or unstably housed, racial/ethnic minorities and persons with active substance use or who have experienced

trauma. A cost analysis included total societal program costs and cost per client in a 12-month period. Cost savings were derived as a ratio of total program costs per year to the discounted lifetime cost for HIV care (C/T). Effects were estimated as the number of HIV infections averted per year to reach the cost-savings threshold of C/T. This cost-saving threshold ratio was then used to estimate the number of transmissions prevented per 100 participants. Total program costs ranged from \$47,919 to \$423,913 per year or \$146 to \$2,752 per person. Cost-savings thresholds were estimated at 1.18 or less, which translated to programs being cost-saving if they averted 1-2 HIV transmissions per year.¹³

Cost analysis of programs for persons living with HIV/AIDS who are homeless

Fewer studies have specifically focused on cost effectiveness of interventions for persons who are chronically homeless with multiple co-morbid conditions. Basu et al. (2012)¹⁴ examined the cost savings of a Housing First intervention that provided housing and case management to patients being discharged from the hospital into respite care and then additional follow-up when the person was subsequently transitioned to stable housing. Costs were assessed for medical, legal, housing and social services; enrolled patients included persons with a broad spectrum of homelessness (minimum 30 days) and co-morbid conditions. The authors found a potential overall cost savings of \$6,307 per person. Cost savings varied depending on the patient population, with higher rates at \$9,809 per chronically homeless person and \$6,622 per person who was homeless and HIV-positive compared to those who received usual care at hospital discharge. The study demonstrated the potential benefit of integrating housing and case management in the

health care delivery service system.¹⁴

Only one study to date has examined the cost utility of supportive housing programs specifically for PLWH who experience homelessness. The Housing and Health Study examined the cost utility of a supportive housing intervention (HOPWA assistance with a case manager) in three urban cities (Baltimore, Chicago, and Los Angeles). Cost utility was measured by the cost per quality of life years saved calculated as the number of HIV infections averted due to viral suppression and the improved quality of life measured by reduced stress. The intervention was assessed as being favorably cost-effective at \$62,493 in comparison to other medical and public health services at society's willingness to pay of \$100,000.¹⁰

In summary, there is emerging evidence that linkage and retention in care programs may be cost-effective for vulnerable HIV populations including newly diagnosed, low income and those at risk of disengaging from care. In addition there is some evidence that housing assistance with support services is cost-effective especially for individuals, including PLWH who are homeless and being released from the hospital. Current economic evaluations of linkage and retention programs apply a variety of methods to including cost-savings thresholds (cost per case of HIV infection averted) to cost utility (cost per quality-adjusted life year gained) to assess the potential efficiency of the program.

However, there are a number of limitations to these studies that warrant additional research. One limitation is the diversity of the patient population within the intervention. Few studies have explored patient heterogeneity within homeless or HIV populations.⁸⁻¹⁴

Addressing patient heterogeneity in cost effectiveness analyses can result in more efficient use of health care resources by identifying specific subgroups where policy makers can make informed decisions about tradeoffs between equity and efficiency.¹⁵ Another limitation is that current studies include a broad definition of program components in terms of the activities, staffing patterns (community health workers vs peer vs health navigators) and length of time of the intervention to assess cost-effectiveness for achieving health outcomes.⁸⁻¹⁴ More specific information is needed about the types of tasks, staffing patterns, and methods of service delivery to make better conclusions about the efficiency of interventions.

To address this gap, this study is an economic evaluation of navigation programs for people living with HIV who experience homelessness or unstable housing. The study has two aims: (1) to conduct a cost utility analysis: the cost per quality-adjusted life years (QALYs) gained for participation in the programs, and (2) to assess the net monetary benefit associated with patient and program characteristics. The goal is that the findings from this study can assist policy makers and program directors with decisions to allocate resources for navigation programs for PLWH who are homeless and to improve the implementation for specific subgroups of the population.

Study Design and Scope

The study was designed based on guidelines from the Second Panel on Cost-Effectiveness in Health care and Medicine using both provider and societal perspectives.¹⁶⁻¹⁷ This study examined both the costs and effectiveness of the patient CC/PN programs for PLWH with mental health and substance use disorders who also

experience homelessness, funded through a five-year cooperative agreement with the Health Resources and Services Administration, HIV/AIDS Bureau, Special Programs of National Significance (HRSA/SPNS) from September 1, 2012 to August 31, 2017. The interventions were implemented at nine sites across the U.S., in eight urban and one rural setting and represented two federally qualified health centers, three county health department clinics, two large outpatient HIV clinics affiliated with large hospital and university systems, and two comprehensive HIV care programs. The intervention programs were designed to build a “medical home” for this vulnerable population. (See Appendix A)

Services included intensive contact with a patient navigator/care coordinator or navigation team who provided assistance with obtaining more stable housing and other basic needs, linkage and retention in medical care via appointment reminders or accompaniment, treatment adherence support, HIV education and support, and linkage to substance use and mental health treatment. For this study, services were restricted to 12 months, but on average participants received 19 months of services, with a range from 6 to 22 months. (See Chapter 3 for detailed descriptions of the intervention services provided by the navigation programs.)

Methods

Study participants

A total of 1,278 PLWH received navigation services in the HRSA/SPNS initiative across nine sites during the life of the program (September 2012-August 2017). This study included a subsample of 542 participants who had available data to assess cost

and effectiveness. This subsample of participants was enrolled in the intervention for at least 12 months, had documentation of encounters with navigation staff and consented to participate in a longitudinal study with data available on health outcomes. Table 4-1 below shows the housing status and demographics for both samples. In both samples a majority were literally homeless, male and identified as a racial/ethnic minority. The evaluation sample had higher proportions of persons who identified as literally homeless, female, racial/ethnic minorities and were fleeing domestic violence.

Table 4-1: Number and Demographics of HRSA/SPNS Participants Served vs Enrolled in the Study

	Total sample N=1,278	Evaluation sample N=542
Housing status		
Literally homeless	787 (61.5%)	438 (80.8%)
Unstably housed	475 (37.1%)	101 (11.6%)
Fleeing domestic violence	51 (4.0%)	71 (13.0%)
Gender		
Male	961 (75.1%)	343 (73.7%)
Female	266 (11.7%)	103 (21.8%)
Transgender/other	51 (4.0%)	26 (5.5%)
Race/ethnicity		
African-American/Black	605 (47.3%)	279 (51.5%)
Hispanic	213 (16.6%)	112 (20.7%)
White	573 (44.8%)	201 (24.4%)
Other	100 (7.8%)	82 (14.7%)

Data collection

Sites entered the number of clients served each month per year into a web-based portal along with demographic (race and gender) and housing status at the time of entry into the program. Individual-level data for effectiveness measures (quality of life, viral load and primary care visits) were collected via interviews and medical-chart review at

baseline and 12 months post enrollment on a subsample of participants (n=542). Costs were collected at the program level across each site. A standardized EXCEL spreadsheet with cost variables was provided to each site annually. (Appendix C) Data were collected from administrative and financial records using standard micro costing techniques including both fixed and variables costs.¹⁸ Data collection occurred at the closing of final financial reports to HRSA. This process was to ensure that all costs incurred in the previous fiscal year were accounted for in the administrative records. All data were submitted via a password-protected web-based portal to the multisite evaluation center. Training was provided to program and administrative staff at each site to enter data based on expenses reported to federal funders at the end of the fiscal period. One researcher worked with sites to resolve missing data and clarify expenses related to the intervention to ensure the accuracy of data and standardization of cost information across sites. The Institutional Review Board at Boston University Medical Center approved this study.

Measures: Costs

Costs included personnel *labor costs* for those involved in the delivery of the navigation programs including supervisor time, behavioral health and medical staff time, and patient navigator/care coordinator staff; *Materials/consumables* included communication costs (cell phones, housing assistance for clients) transportation costs for clients and staff; incentives and tangible reinforcements such as hygiene kits, food baskets for clients to come into the programs; and fixed costs such as overhead rates, computers and rents charges if not part of overhead rates.

This study only included costs associated with implementing the SPNS intervention. Other resources could be used by the sites to help support the intervention such as behavioral health or medical provider health time paid for by third party resources. However, these data were excluded because of the variability across sites to obtain accurate data from appropriate administrative departments. Attempts were also made to obtain actual medical treatment costs, including laboratory tests, patient visit costs applied by the health care center, however, data on costs or charges to third party were not available. Expenses related to the study procedures were also excluded from the analysis, since these costs may not be replicable to other agencies or be relevant for dissemination, spread, and sustainability.

Costs were annualized for the years 2013-2016 of the intervention. To account for regional differences across the intervention sites in terms of labor and other non-labor costs, all costs were wage and price adjusted to avoid any biases from one program in a specific region. First, labor cost data were adjusted by region using the Medicare Wage Index for medical services. Second, all costs were then expressed in 2016 dollars and further adjusted using the Bureau of Labor Statistics Consumer Price Index for Medical Services for ease of interpretation.¹⁹⁻²⁰

The next step was to calculate the average cost per client for the length of time in the intervention. This cost was a weighted average of the program costs from each year, based on the individual's time enrolled in the study. For example, for a person who was enrolled from December 2014 to December 2015, her/his average cost was based on a weighted average of the program costs for Years 3 and 4. This procedure was done so

all cost data for each individual was preferentially weighted to match his or her outcome data for retention, viral suppression and QALYs gained.

Measures: Utility/ Effectiveness

Primary outcomes were retention in care and viral suppression. Retention in care was measured using the Health Resources and Services Administration's (HRSA's) standard definition of two appointments at least 90 days apart in a 12-month period. Viral suppression rates based on the most recent viral load in the 12-month follow up period defined as <200 copies/mL post intervention enrollment. These outcomes were used to calculate (1) costs per client retained in care; (2) costs per client virally suppressed. Cost per client retained in care and cost per client virally suppressed were calculated based on the subsample of participants who were enrolled in a longitudinal study and had cost and outcome data up to 12 months (n=542).

The quality-adjusted life years gained (QALY) was used as the utility metric for the cost utility and net benefit analyses. The QALY is a measure that captures health gains from improved quality of life due to reduced morbidity and reduced mortality. It allows for comparisons across different disease interventions and population groups.²¹ QALYs were calculated using the VR-12 Health Related Quality of Life (QoL) measure collected at baseline and 12 months for each individual. Data were gathered from the Veterans Rand 12-item Health Survey (VR-12) to assess the domains of general health perceptions, physical functioning, role limitations due to physical and emotional problems, bodily pain, energy-fatigue, social functioning and mental health.²²⁻²⁸ Each item was measured on a five-point Likert scale from “none of the time” to “all of the

time.” The measure is adopted by the Veterans Health Administration and Medicare Health Outcomes Survey (HOS) sponsored by the Centers for Medicare and Medicaid Services. The twelve items are summarized into a physical composite summary score (PCS) and a mental composite summary score (MCS). The summary scores are set to a mean of 50 and standard deviation of 10 for the US general population. Scores were then converted to the VR-6D to assess the change in quality of life between baseline and 12-month follow-up. The VR-6D has been tested and shown to be comparable to other utility metrics, such as the SF-6, and is responsive to change across various disease conditions including diabetes, hypertension, cardiovascular disease chronic pulmonary conditions and stroke.²⁹⁻³⁰ Table 4-2 below summarizes the change in quality of life across the nine study sites (n=542).

Table 4-2: Baseline and 12-Month Follow-Up Average VR6D Across Sites (mean, SD)

Site	Baseline V6d	12M VR6Ds	Δ VR6D
PrismHealth NT, Dallas TX (n=58)	0.63 (0.13)	0.67 (0.10)	0.04 (0.08)
CommWell Health, NC (n=66)	0.60 (0.12)	0.66 (0.12)	0.06 (0.13)
Family Health Centers, San Diego (n=53)	0.66 (0.12)	0.63 (0.13)	0.03 (0.13)
Harris Health System, Houston, TX (n=82)	0.58 (0.14)	0.64 (0.13)	0.06 (0.14)
Multnomah County Health Dept, Portland, OR (n=59)	0.59 (0.12)	0.62 (0.14)	0.03 (0.13)
Pasadena Public Health Dept, Pasadena, CA (n=81)	0.60 (0.14)	0.63 (0.12)	0.03 (0.13)
San Francisco Dept of Public Health, San Francisco, CA (n=33)	0.55 (0.12)	0.65 (0.11)	0.09 (0.12)
UF Cares, Jacksonville FL (n=50)	0.59 (0.13)	0.65 (0.13)	0.07 (0.14)
Yale University, New Haven CT (n=60)	0.64 (0.13)	0.67 (0.14)	0.03 (0.14)
Multisite QoL	0.60 (0.13)	0.65 (0.13)	0.05 (0.13)

**No significant difference in changes in quality of life (VR6D) across sites (ANOVA $F=1.47$, $p=0.17$)*

This value was then used to calculate the QALY gained for a PLWH experiencing homelessness participating in the navigation program using the formula ³¹:

$$\text{QALY gained: } (\Delta\text{QoL})(1-e^{-rL}/r)$$

where ΔQoL is the change in health-related quality of life from baseline to 12 months of being in the program using the VR6D; r is the discount rate of 3%²¹ (standard rates in the literature for assessing future health benefits in current values)[†]; and L is the average life

[†] The discount rate is applied to calculate the current value of QALYs gained in the future from the intervention, and assumes that people prefer to receive benefits now rather than in the future.

expectancy of a person living with HIV who participates in the navigation program and is adherent to treatment. For a PLWH, the average life expectancy is up to 73 years if adherent to treatment.[†] L was estimated to be 28 additional years of life, given the average age of the sample population was 45 years. The value assumes a person received the benefits of staying adherent to treatment and becoming stably housed as a result of participating in the navigation program. No other co-morbidities were accounted for in calculating the QALY.

Methods: General statistical analyses

The economic evaluation of the SPNS intervention program included four components:

- 1) a cost per outcome (retention in care and viral suppression)
- 2) cost-utility analysis and estimated return on investment to compare findings to other published studies and similar interventions.
- 3) net monetary benefit analysis per participant of the SPNS intervention across all programs with the average cost per client per quality of life year gained and then compared to society's willingness to pay for an intervention based at \$50,000/QALY.
- 4) a multivariate regression analysis to assess for any patient or program model characteristics predicting improved net benefit. Net monetary benefit techniques

[†] Marcus JL et al. *Narrowing the gap in life expectancy for HIV+ compared with HIV-individuals*. Conference on Retroviruses and Opportunistic Infections (CROI), Boston, abstract 54, 2016

allows for control for any patient heterogeneity and identification of potential patient sub-groups that benefit from the intervention.³²⁻³⁶

Assumptions:

In conducting these analyses, a number of assumptions were made.

- 1) Quality of care and services delivered by intervention staff is held constant.

Service level is driven by the patient level of need and other characteristics

- 2) Preferences for working with the patient navigator are constant; all participants voluntarily and willingly participated in the intervention;

- 3) Participants who enroll in the intervention and are subject to lifetime treatment costs as calculated in the literature. Additional costs for treatment of co-morbidities, hospitalization or emergency room visits were not included in the model.

Methods: Cost-utility analysis

Using previous calculations for PLWH from the literature the cost-utility analysis for similar navigation programs was performed by using the formula^{9, 37-39}

$$CU = (C - AT) / AQ$$

The parameter *C* is the total implementation cost during the 3-year project time frame;[†] *A* is the number of HIV infections averted based on patients that are virally suppressed; *Q* is the sum of quality-adjusted life years gained from participation in the

[†] The parameter *A* was calculated based on the difference between participants who were virally suppressed at baseline follow up and those who were virally suppressed at 12-month follow up. This number was then multiplied by 0.046, which is the constant estimating the transmission rate of an individual with an unsuppressed viral load who is aware of their status.³⁰

program. This parameter was derived from the current study data of QALYs (Q1) gained across site by participants (0.05) in this sample and the number of QALYs saved through viral suppression (Q2) for each person who is newly suppressed (5.83) derived from the literature from participating in the program;³⁷⁻³⁹ and T is the cost of HIV treatment from the literature and valued at \$330,000 adjusted to 2016 dollars. This ratio was then compared to standard willingness to pay thresholds (WTP) of \$50,000 to determine their cost savings.

As part of this overall program analysis and to enhance comparisons to other interventions, a calculation on a return on investment scenario (ROI)⁹ was calculated as:

$$ROI = TA/C$$

T = Treatment cost in 2016 dollars

A = Utility metric net infections averted from persons who were virally detectable and became suppressed as a result of 12 months in the program intervention.

Methods: Net benefit analysis

The second aim of the study was to determine the net benefit associated with patient and program characteristics. In this analysis, the sample was limited to study participants who had completed baseline and 12-month follow-up data for quality of life years, viral suppression and retention in care (n=542). The net benefit calculation was performed using the formula

$$NMB: I * \Delta QALY_i - \Delta C^{32,34}$$

where I is the willingness-to-pay (WTP) threshold estimated on the literature, ΔC , the average cost for clients, was calculated based on the weighted average of the program

costs corresponding to the individual's time period in the study; $\Delta QALY_i$ is the quality of life year gained calculated for each individual's change in health-related quality of life from baseline to 12 months in the intervention period.

A decision rule using the WTP thresholds was employed to determine if the intervention is a worthwhile investment of resources based on cost per quality of life gained. Historically, \$50,000 per QALY was the decision rule since 1982 and was calculated based on the cost-effectiveness of investing in dialysis for end-stage renal disease. Since that time, \$50,000 has been used as the benchmark decision for undertaking an intervention. Recent studies argued for adjusting this value to account for inflation or based on a country's GDP.⁴⁰⁻⁴⁶ For sensitivity analyses, the WTP of \$50,000, \$100,000 and \$200,000 was used, based on literature values.

Assessing patient and program covariates with QALYs, costs and net benefit

Ordinary least squares regression techniques (OLS) were used to reduce the number of patient- and program-level predictors associated with costs, QALYs, and net monetary benefit. As a first step, individual and program characteristics were selected from Gelberg's and Mittler's framework for factors associated with access to and use of health care services and improved health status. (Chapter 1) Individual factors included: predisposing factors, such as socio-demographics (age, race, gender, years homeless, history of incarceration, substance use risk, depression risk, history of trauma, viral suppression); enabling factors (social support, food insecurity, number of barriers to care), need factors (total unmet need for services). Program characteristics were selected from the results of analyses in Study 3. These program components represented the

group and community factors (program characteristics including activities, delivery of intervention at the organization and community level; intervention staff composition, and method of delivery of service). Bivariate unadjusted analyses, including ANOVA, t-test and simple linear regression, were run to assess each individual and program predictors with net monetary benefit. Individual and program factors significant at $p=0.20$ were included in a final model. Regression diagnostics were performed to assess for any potential influence points on parameter estimates using a Cook's D threshold value of greater than $4/n$ to identify any such points. To assess potential collinearity between individual- and program-level predictors, the condition indices and the Variance Inflation Factor (VIF) were performed in the multivariate model with all predictors using a cut-off value of greater than 10.⁴⁷

The final multivariate model used a generalized estimated equation (GEE) to adjust for any between-site variations. The GEE model was selected over an OLS regression model to account for any biases due to site clustering of observations, and to calculate an average effect of my outcome of interest (costs, QALYs or net monetary benefit) as opposed to an individual-specific effect over time. GEE is a useful statistical technique if the correlation structures are unknown. GEE analysis assumes that responses are independent across sites but may be correlated within each site. The estimated parameters represent an unconditional average effect across all data sites. The coefficients are interpreted as population averages rather than a marginal impact on the response of an individual or observation. The advantage of using GEE is it can directly deal with the distributional skewness as well as the correlated nature of the data and is

particularly useful for estimating parameters when sample sizes are small.⁴⁸⁻⁵⁰

The GEE models were analyzed using within group correlation structures to reduce the likelihood of misspecification. Two models were run with varied correlations structure. The first model used the exchangeable (compound symmetry) correlation option which assumes all the variances and covariances for variables are equally correlated within groups and correlations are the same across groups. The second model assumed an independent correlation (variance components) where the variances are different and within group responses are uncorrelated. Both models were run to check for variations in the coefficients and standard errors. I used the rule of 10% change in the magnitude of the standard errors (SE) and (β) coefficients to determine if the GEE was robust for this analysis.

Finally, a one-way sensitivity analyses was performed using two approaches. First, quality-adjusted life years and net benefit were recalculated using shorter time frames for the expected benefit of navigation programs at one-, two- and five-year increments. Second, willingness to pay (WTP) thresholds were adjusted to assess the potential benefit of investing in navigation programs at varying decision rules. WTP threshold values of \$100,000 and \$200,000 were selected based on current values in the literature for assessing cost-effectiveness.⁴⁰⁻⁴⁶ All data analyses were performed in SAS v. 9.4.⁵¹

Results

The SPNS programs served a total of 1278 individuals at a total implementation cost of \$6,340, 484 for all nine sites for a three-year intervention period. Table 4-3 shows

the adjusted total program costs per site per year.

Table 4-3: Total Adjusted Costs for Nine sites

Site	Year 2 (Sept 2013-Aug 2014)	Year 3 (Sept 2014-Aug 2015)	Year 4 (Sept 2015-Aug 2016)
	Adjusted Total costs	Adjusted Total Costs	Adjusted Total Costs
PrismHealth NT, Dallas TX	\$ 571,939	\$363,062	\$304,273
CommWell Health, NC	\$173,495	\$249,365	\$261,412
Family Health Centers, San Diego	\$290,517	\$340,231	\$325,340
Harris Health System, Houston, TX	\$189,311	\$250,241	\$255,632
Multnomah County Health Dept, Portland, OR	\$368,370	\$178,883	\$174,066
Pasadena Public Health Dept, Pasadena, CA	\$173,544	\$183,705	\$146,019
San Francisco Dept of Public Health, San Francisco, CA	\$ 132,954	\$143,668	\$182,019
UF Cares, Jacksonville FL	\$208,637	\$151,753	\$115,410
Yale University, New Haven CT	\$281,614	\$238,769	\$176,247
Total	\$2,390,385	\$2,099,679	\$1,940,420

Table 4-4 shows the average costs and number of patients served across the nine sites per year. Sites served a total of 525 to 715 persons per year, with a range of 22 to 122 persons per site. The average costs per client per year ranged from \$2,713-\$4,553 across all sites with a range from \$1,254 to \$8,674 per site.

Table 4-4 Average Costs per Client per Site by Year

Site	Year 2 (Sept 2013-Aug 2014)		Year 3 (Sept 2014-Aug 2015)		Year 4 (Sept 2015-Aug 2016)	
	Clients served	Adjusted Average costs	Clients served	Adjusted Average Costs	Clients Served	Adjusted Average Costs
PrismHealth NT, Dallas TX	73	\$ 7,834.79	81	\$ 3,989.70	84	\$3,622
CommWell Health, NC	22	\$ 8,674.78	63	\$ 3,667.14	79	\$3,309
Family Health Centers, San Diego	106	\$ 2,740.74	92	\$ 1,753.77	77	\$4,225
Harris Health System, Houston, TX	78	\$ 2,427.07	122	\$ 1,331.07	122	\$2,095
Multnomah County Health Dept, Portland, OR	56	\$ 6,578.05	59	\$ 1,771.12	74	\$2,352
Pasadena Public health Dept, Pasadena, CA	47	\$ 3,692.43	78	\$ 1,954.31	74	\$1,973
San Francisco Dept of Public Health, San Francisco, CA	32	\$ 4,154.82	41	\$ 2,317.23	46	\$3,956
UF Cares, Jacksonville FL	83	\$ 2,513.71	78	\$ 1,167.33	92	\$1,254
Yale University, New Haven CT	28	\$ 10,057.65	61	\$ 3,511.31	67	\$2,630
Average Multisite Total Cost	525	\$ 4,553.11	675	\$ 3,110.64	715	\$2,713

Table 4-5 shows a cost analysis per person and per outcome for a 12-month intervention period (n=715). The time period September 2015-August 2016 was selected for the analysis because this represented a period when caseloads were at maximum capacity, enrollment into the intervention ceased, and staffing patterns were relatively

stable across the sites. (See Appendix Tables 4-1 through 4-3) Total costs for this period were \$1,940,420, with 77% of costs related to staff/personnel, 22.3% for materials (including expenses for tangible resources such as cell phones, emergency housing assistance client transportation costs), and approximately 8% for overhead costs. The number of PLWH who were retained in care (n=528) and virally suppressed (n=507) was calculated using the rates for retention in care (74%) and those who became virally suppressed (71%)¹ at 12 months post intervention for the overall study. The cost per client retained was \$3,668 and \$3,827 per viral suppression.

Table 4-5: Costs and Cost per Outcome of Navigation Programs in 12 Month Period

<i>Time frame for CC/PN intervention</i>		<i>All Programs</i>
		12 months (9/1/15-8/31/2016)
<i>Total clients served clients enrolled in program (range)</i>		715 (46-122)
<i>Total implementation costs</i>		\$1,940,420 (\$115,410-
	<i>% personnel</i>	\$325,340)
	<i>% materials</i>	\$1,508,861 (77%)
	<i>% fixed/overhead</i>	\$ 430,184 (22.3%)
		\$153,395 (7.9%)
<i>Number of clients retained in care (N)</i>		529
<i>Virally suppressed (N)</i>		507
<i>Per client costs</i>		
<i>Cost per client (C/#clients)</i>		\$2,713
<i>Cost per client retained in care</i>		\$3,668
<i>Cost per client with viral suppression</i>		\$3,827

¹ The retention and viral suppression rates are based on the sample of participants who were out of care or newly diagnosed at baseline and were able to achieve the retention and viral suppression in the post 12 observation period (n=334). Participants who were engaged in care or virally suppressed are excluded.

Cost-utility analysis

Table 4-6 shows the results of the cost-utility (cost-per-QALY) analysis for per person. Quality-adjusted life years was a sum of life years gained from improved quality of life ($Q1=0.05$) with persons becoming virally suppressed and derived from sample data; and life years saved based on cases averted from new infections ($Q2=5.83$) with values calculated from the literature.³⁷⁻³⁹ The number of new infections averted was calculated from the new cases of viral suppression, ($n=152$) in the 12-month time frame from the study data. The number of new cases of viral suppression were calculated as the sum of those who had a detectable viral load or were newly diagnosed at baseline but became virally suppressed by 12 months in the intervention in the entire three-year period of the study. The overall cost-utility was estimated to be \$11,150 per QALY gained. Return on investment was calculated as the number of infections averted times the treatment costs in 2016 dollars, divided by the overall cost of the SPNS program. This yielded a return on investment of \$0.41 on the dollar.

Table 4-6: Cost Utility and Return on Investment Across all Sites

	All Sites
Estimated full duration of implementation costs (C)	\$6,430,484
Treatment costs in 2016 dollars (T) (from the literature (\$330,000*488.086/423.810))	\$380,048
Infections Averted (A)	
Net number of individually virally suppressed at 12 months in SPNS initiative	152
Number of infections averted. (.046X 152)	7.0
Quality-of –life adjusted years saved (Q)	
QALYs (Q1) gained through improved health (.05 [†] X152)	7.6
QALYs saved through averted HIV infections (7.0 x 5.83 [‡])	40.8
Total QALYs saved (A*Q1 +A*Q2)	48.3
Cost Utility ratio [R = (C-AT)/AQ]	\$11,150
R=[6,430,484-(380048* 7.0)]/7.0*48.3= \$11,150	
Return on investment ROI = TA/C	\$0.41
ROI= \$380048*7.0/6,430,484=\$0.41	

[†] Estimated QALYs (0.05) from study data (n=542)

[‡] the constant (0.046) estimating the transmission rate of a person with an unsuppressed viral load but is aware of his or her status who aware of the HIV status from Hall et al. 2013³⁹

[‡]Estimated 5.33 QALYs saved per infection averted Jain et al. 2015⁹, Holtgrave et al. 2012,³⁷ and

[‡]Treatment costs for one HIV infection, Farnhum et al. 2013³⁸

Net monetary benefit analysis

To calculate the net monetary benefit, the sample was limited to those with baseline and follow-up health-related quality-of-life data to calculate the utility metric QALYs gained (n=542) and navigation services received for a 12-month period. Average costs per program per person were recalculated using a weighted average of costs over the three years to correspond to the participant's time in the intervention and the associated program costs. Table 4-7 shows the results of the net monetary benefit of the intervention across sites. The weighted average across the nine sites ranged from \$1,239-

\$4,189 per site and an average cost of \$2,586 across all sites. The QALYs gained across sites between baseline and 12 months ranged from 0.46-1.80 with an average cross-site of 0.97. There was no statistically significant difference in the QALYs gained across sites. ($F=1.47$, $p=0.17$). Average costs were significantly different across sites ($F=81.8$, $p<.05$)

Table 4-7: QALYs Gained, Average Weighted Cost and Net Benefit per Client per Site

Site	QALY gained	Average Cost (mean, SD) [†]	Net Monetary Benefit* (\$50k)
PrismHealth NT, Dallas TX (n=58)	0.73 (2.4)	\$4,189 (1,400)	\$32,156 (121370)
CommWell Health, NC (n=66)	1.19 (2.3)	\$3,932 (1107)	\$55,803 (114647)
Family Health Centers, San Diego (n=53)	0.54 (2.3)	\$1,721 (194)	\$25,146 (113,180)
Harris Health System, Houston, TX (n=82)	1.12 (2.7)	\$1,503 (391)	\$54,528 (133,998)
Multnomah County Health Dept, Portland, OR (n=59)	0.46 (2.4)	\$1,995 (1,183)	\$20,989 (118384)
Pasadena Public health Dept, Pasadena, CA (n=81)	0.71 (2.8)	\$2,179 (656)	\$33,349 (139738)
San Francisco Dept of Public Health, San Francisco, CA (n=33)	1.80 (2.3)	\$2,558 (690)	\$87,201 (115948)
UF Cares, Jacksonville FL (n=50)	1.38 (2.5)	\$1,239 (466)	\$67 584 (123949)
Yale University, New Haven CT (n=60)	0.65 (2.6)	\$4,069 (1,798)	\$28,659 (132073)
Multisite QALY	0.97 (2.4)	\$2,586 (1,489)	\$42,930 (126010)

Individual and program characteristics associated with costs, QALYs and net monetary benefit

Tables 4-8 and 4-9 show the unadjusted bivariate associations of individual and program characteristics associated with the net monetary benefits. A data reduction strategy using OLS was employed to select for key predictors in cost, QALYs and net monetary benefit. Depression risk scores, alcohol risk, cocaine risk, social support, total

barriers to care, race/ethnicity identity, and food insecurity were significant at $p=.20$ level and included in the final multivariate model. Race and incarceration were forced into the model because of their suggestive statistical effects. Among program characteristics, only types of activities provided and the modality of service delivery were included in the final model.

Table 4-8: Unadjusted Bivariate Associations of Patient Characteristics with Net Monetary Benefit at \$50,000 WTP (n=542)

Predictor	Net Monetary Benefit (WTP \$50,000)				
	B (SE)	F	p-value	INTERCEPT	R ²
Viral suppression Yes No	3262	0.08	0.77	45074	0.0002
Self-efficacy- obtaining information	-931.4	0.16	0.68	51294	0.0003
Self-efficacy-Communication with Provider	2764.82	0.00	0.97	43851	0.002
Gender Male (n=394) Female (n=120) Transgender (n=28)	-15,297 -43,946 ref	0.69	0.49	53435	0.003
Age	251.7	0.24	0.62	31807	0.0004
Race/ethnicity White (n=132) Non-white (n=410)	-13673	1.18	0.22	46260	0.002
No. years homeless (n=542)	-460.37	0.48	0.48	46226	0.009
CESD score	4939	41.9	<.0001	28570	0.07
Risk for opioid use Low (n=18) Moderate (n=90) High (n=434)	-32917 -32328 ref	0.59	0.58	74657	0.002
Risk for alcohol use Low (n=327) Moderate (n=139) High (n=76)	-26149 -29807 ref		0.20		
Risk for cocaine use Low vs high Moderate vs high	-19841 (17122) -33692 (19075)	1.79	0.17	66519	0.007

Risk for amphetamine use Low vs high Moderate vs high	1027 (20795) -4927 (22449)	0.11	0.89	43496	0.0004
Injection drug use No (n=353) Yes past 3 months (n=60) Yes, ever not 3 months (n=121)	8286 8548 Ref	0.20	0.81	37790	0.0007
History of incarceration Yes No	16769	1.56	0.21	46426	0.003
History of trauma Yes No	10121	0.84	0.35	46981	0.002
Social support	-1616.5	2.43	0.12	61174	0.004
No. unmet needs	-1577.3	0.44	0.49	48327	0.001
Total barriers to care	4045	5.52	0.02	30093	0.01
Food insecurity Yes (n=297) No (n=241)	-25090 (10852)	5.35	0.02	53224	0.01

Table 4-9: Unadjusted Bivariate Associations of Navigation Program Characteristics with Net Monetary Benefit

			Net Monetary benefit (WTP \$50,000)			
	Mean (SD)	β	F	p-value	Intercept	R ²
Activities						
Comprehensive N=110	28247 (109731)	-27804	2.56	0.05	56052	0.014
Health-Education-Employment N=37	89644 (124319)	33591				
Non-medical N=73	56052 (21542)	ref				
Limited N=320	38349 (131677)	-16702				
Modality						
Telephone (n=414)	47690 (129917)	ref	2.68	0.10	26996	0.005
Multi-modal (n=126)	26696 (112117)	-20994				
Setting						
Community (1) n=130	35996(127315)	-20865	0.81	0.44	56462	0.003
Medical (2) n=312	44699 (124808)	-14813				
Mixed (3)n=100	56462 (128276)	ref				
Staff						
Peer-clinician n=45	58864 (115797)	18639	0.43	0.64	40224	0.002
Peer-case manager n=170	43466 (130168)	3222				
Navigator n=325	40224 (125675)	ref				

Multivariate analysis of patient and program characteristics associated with QALYs, average cost and net benefit

Table 4-10 shows the multivariate analysis models for patient and program characteristics associated with net benefit. There was a difference of less than 10% in the magnitude of the coefficients, standard errors and p-values when assessing for the underlying correlation structure due to site clustering. For the final multivariate analysis, after adjusting for site and using an exchangeable correlation structure, persons with higher depression scores, program model activities and type of modality were significantly, positively associated with improved net benefit.

In general, the type of navigator activities was significant with net benefit improvement [(F=8.41, p=0.0016)]. Using comprehensive activities as the reference group, those who received limited or light touch of intervention had lower net benefits [B=-\$14236 (SE=31411), p=0.65], while those who received services related to health education and employment [B=\$43491 (SE=31075), p=0.18] and those who received housing and behavioral health [B=\$3425 (SE=41370), p=<0.93] had an increased level of net benefit.

The modality of encounter was also overall significantly associated with an increase in net benefit improvement [F=6.98, p=0.04] when adjusting for other patient and program characteristics. There was a lower net benefit associated with the participants with whom patient navigators used multiple modalities (direct in-person contacts, via telephone or working with partner agencies on behalf of clients) compared to the participants with whom telephone contact with patient navigators was the primary source of contact [B=-38726 (SE=14654), p=0.04].

A final multivariate model was run to examine patient and program characteristics associated with QALYs gained and average costs per person. Similar to models for net benefit, persons with more severe depressive symptoms were significantly associated with increased QALYs gained [B=0.005 (SE=0.005), p<0.001] as well as the modality of contact [B=0.04 p=0.04] with multimodal contact demonstrating a slight increase in QALY compared to telephone contact. No other individual characteristics were associated with improvements in QALYs.

Types of activities were significantly associated with average costs per person.

Compared to participants who received comprehensive services, those who received limited activities had lower costs [$\beta=-1325$ (44), $p<.009$], while those who received health-education-employment [$\beta=1041$ (570), $p<.08$] and non-medical services [$\beta=1609$ (498), $p<.005$] had slightly higher costs. Finally persons with higher food insecurity had significant lower average costs [$\beta=-124$ (48), $p<.001$]. A second model was run with a log transformation of costs to adjust for non-Gaussian distribution. Navigation activities remain significantly associated with costs. Persons with higher food insecurity had lower costs but the difference was not significant. (Results presented in Appendix Table 4-4)

Table 4-10: Multivariate Model of Patient and Program Characteristics Associated with Increased Net Monetary Benefit by Correlation Structure

	Net Monetary benefit (WTP \$50,000) Using exchangeable correlation (CS)) constant within group correlation		Net Monetary benefit (WTP \$50,000) Using Independence- (independent within group correlation)	
Factors/Variable	B (SE)	p-value	B (SE)	p-value
Intercept	-32937 (44975)		-32305 (48578)	
Activities				
Comprehensive	ref	0.0016	ref	0.005
Health-Education-	43491 (31075)	0.18	42691 (31429)	ref
Employment	3425(41370)	0.93	529 (42390)	0.19
Non-medical	-14236(31411)	0.65	-17774(32476)	0.99
Limited				0.59
Modality				
Multi-modal	-38726 (14654)	0.04	-38818 (15860)	0.05
Telephone	ref		ref	
Race/ethnicity				
Minority	16994(11016)	0.16	18171(11284)	0.14
History of incarceration	20945 (13898)	0.37	21059 (14154)	0.13
CESD score	4842 (481)	<.0001	4831 (475)	<.0001
Risk for alcohol use				
Low vs mod	-3546 (11590)	0.76	-3573(11672)	0.50
Low vs high	8569 (13007)	0.51	8941 (13100)	0.76
Risk for cocaine use				
Low vs mod	-23138 (13264)	0.10	-22664 (13185)	0.10
Low vs high	-15717 (25524)	0.54	-14876 (25788)	0.57
Social support	-544 (1277)	0.67	-498 (1292)	0.69
Barriers to care	876 (1809)	0.63	902 (1887)	0.63
Food insecurity	6348 (10181)	0.53	6455 (10393)	0.53

Table 4-11 Multivariate Analysis of Patient and Program Characteristics Associated with QALYs and Costs (n=542)

	QALYs		Average Cost	
	B (SE)	p-value	B (SE)	p-value
Intercept	-1.3		1493 (399)	
Activities				
Limited	-0.01 (0.02)	0.61	1325(444)	0.009
Health-Education-Employ.	0.43 (0.02)	0.16	1041(570)	0.08
Non-medical	0.004 (0.04)	0.91	1609 (498)	0.005
Comprehensive	ref		ref	ref
Modality				
Multi-modal	0.04 (0.01)	0.04	134 (193)	0.51
Telephone				
Race/ethnicity				
minority	0.017 (0.1)	0.15	-19.1 (72)	0.79
History of incarceration	0.02 (0.01)	0.11	-32.7 (62.6)	0.60
Depressive symptoms, (CES-D score)	0.005 (0.005))	<0.001	-14.5 (8.8)	0.10
Risk for alcohol use				
Mod v low	-0.03 (0.13)	0.76	80 (110)	0.48
High v low	0.008 (0.02)	0.51	34(138)	0.80
Risk for Cocaine use				
Mod v low	0.024(0.013)	0.09	92 (124)	0.47
High v low	-0.016 (0.02)	0.54	233 (246)	0.35
Social support	0.005 (0.001)	0.68	13.4 (11.6)	0.25
Barriers to care	0.009 (0.002)	0.61	40 (24)	0.09
Food insecurity	0.006 (0.01)	0.53	-124 (48)	0.01
AIC	605		8645	

Severity of depression was also associated with an increased net benefit on average [(B=\$4842 (SE=481), $p<.001$)]. Further analysis of the subgroups found that persons with more severe depressive symptoms (greater than 15 indicating moderately high level of depression) experienced a significantly improved net monetary benefit from participation in the intervention compared to individuals with lower depression scores (14 or below) ($F=13.5$, $p<.05$). However, these benefits would only be efficient at a greater than \$100,000 WTP. There was no difference in average costs per person and severity of depressive symptoms ($F=0.82$, $p=0.48$). However persons with higher depressive symptoms (CESD >15) had significant higher QALYs gained (mean=1.25) compared to those with mild or no depressive symptoms. (Table 4-11)

Table 4-12: Net Benefit Associated with Severity of Depressive Symptoms (n=542)

<i>CESD score</i>	<i>N</i>	<i>Net monetary benefit (mean, SD)</i>	<i>Average cost (mean, SD)</i>	<i>QALY (mean, SD)</i>
Group 1: 0-9	143	-1126.9620 (131,755)	\$2692 (1538)	0.03 (2.6)
Group 2: 10-14	130	30838.4394 (128,980)	\$2616 (1507)	0.67 (2.5)
Group 3: 15-19	132	60109.1704 (105,918)	\$2619 (1530)	1.25 (2.1)
Group 4: 20-30	136	85354.8890 (118,783)	\$2424 (1377)	1.75 (2.3)

*** $p<.05$**

Sensitivity analyses

One-way sensitivity analyses were performed to assess the robustness of findings for patient and navigation program characteristics with net benefit. Analyses were performed varying the expected benefits via QALYs from the participation in the programs and adjusting the willingness to pay thresholds in calculating net benefit. First QALYs and subsequent net benefits were recalculated to measure expected benefits at

one year, two years and five years post enrollment. QALYs gained averaged across all sites at 0.05, 0.09 and 0.21 at one, two and five year post enrollment. At one year post enrollment, the program had a negative net benefit at \$236 across all sites, but increased to \$1,956 at two years and to \$8,302 at five years. (Table 4-13)

The magnitude of net benefit also varied for each site. (Table 4-13a) Four sites had positive net benefits with the programs after one year post enrollment. Seven sites had positive benefits at two years post enrollment and by five years all sites had positive net benefits from the program.

At willingness-to-pay thresholds of \$100,000 and US GDP \$200,000 (Table 4-14) types of activities, modality of contact and severity of depressive symptoms were significantly associated with positive net benefit. Participants who received non-medical and health, education and employment services had increased benefit while those who received limited activities had lower net benefit compared to those who received comprehensive services. Multimodal contact had lower net benefit compared to telephone contact. Person with higher severity of depressive symptoms had improved net benefit. Substance use risk, food insecurity, number of barriers to care, history of incarceration status, and race/ethnicity were not significant associated with net benefits at other willingness to pay thresholds.

Table 4-13: Expected QALYs (SE) Gained at One, Two, and Five year post Enrollment (n=542)

Site	QALY Gained Lifetime	QALY 1 year	QALY 2 year	QALY 5 year
PrismHealth NT, Dallas TX (n=58)	0.73 (2.4)	0.04 (0.12)	0.07 (0.24)	0.17 (0.58)
CommWell Health, NC (n=66)	1.19 (2.3)	0.06 (0.11)	0.12 (0.22)	0.28 (0.55)
Family Health Centers, San Diego (n=53)	0.54 (2.3)	0.03 (0.12)	0.05 (0.22)	0.13 (0.54)
Harris Health System, Houston, TX (n=82)	1.12 (2.7)	0.06 (0.13)	0.11 (0.27)	0.27 (0.64)
Multnomah County Health Dept, Portland, OR (n=59)	0.46 (2.4)	0.02 (0.12)	0.04 (0.23)	0.11 (0.56)
Pasadena Public health Dept, Pasadena, CA (n=81)	0.71 (2.8)	0.04 (0.14)	0.07 (0.28)	0.17 (0.67)
San Francisco Dept of Public Health, San Francisco, CA (n=33)	1.80 (2.3)	0.09 (0.11)	0.18 (0.23)	0.42 (0.55)
UF Cares, Jacksonville FL (n=50)	1.38 (2.5)	0.07 (0.12)	0.13 (0.24)	0.33 (0.59)
Yale University, New Haven CT (n=60)	0.65 (2.6)	0.03 (0.13)	0.07 (0.26)	0.16 (0.63)
Multisite QALY	0.97 (2.4)	0.05 (0.13)	0.09 (0.25)	0.21 (0.60)

Table 4-13a: Net Benefits (NB) at One, Two and Five year post enrollment (n=542)

Site	NB 1-year	NB 2-year	NB 5-year
PrismHealth NT, Dallas TX (n=58)	\$-2313 (5838)	-\$561 (11646)	\$4,505 (28606)
CommWell Health, NC (n=66)	\$-848 (5964)	\$2030 (11442)	\$10,357 (27400)
Family Health Centers, San Diego (n=53)	\$333 (5839)	\$960 (11929)	\$4,706 (27070)
Harris Health System, Houston, TX (n=82)	\$1,389 (6878)	\$4,089 (13333)	\$11,900 (32016)
Multnomah County Health Dept, Portland, OR (n=59)	\$-809 (6332)	\$298 (11979)	\$3,502 (28431)
Pasadena Public health Dept, Pasadena, CA (n=81)	\$-344 (7160)	\$1,367 (13883)	\$6,320 (33367)
San Francisco Dept of Public Health, San Francisco, CA (n=33)	\$2,075 (6145)	\$6,401 (11,708)	\$18,914 (27842)
UF Cares, Jacksonville FL (n=50)	\$2,313 (6432)	\$5,630 (12396)	\$15,224 (29667)
Yale University, New Haven CT (n=60)	-\$2,379 (7430)	-\$802 (13677)	\$3,759 (31963)
Average multisite net benefit	-\$236 (6670)	\$1956 (2662)	\$8,302 (30176)

Table 4-14: Program and Patient Characteristics Associated with Net Benefit at One, Two and Five years Post Enrollment (n=542)

	Net Monetary Benefit 1 Post-Enrollment		Net Monetary Benefit 2 years Post- Enrollment		Net Monetary Benefit 5 years Post-Enrollment	
	B (SE)	p-value	B (SE)	p-value	B (SE)	p-value
Intercept	-6179 (2028)	0.02	-9688 (3803)	0.03	-1930	0.04
Activities Comprehensive Health-Education- Employment Non-medical Limited	ref	<0.001	ref	<0.001	0.0007	
	3253 (1487)	0.04	5679 (2801)	0.06	11593 (6762)	0.10
	-133 (1864)	0.94	44 (3683)	0.99	423 (9068)	0.96
	-61 (1558)	0.96	-649 (2838)	0.65	-2890 (6688)	0.67
Modality Multi-modal Telephone	-1893 (765)	0.04	-3786 (1362)	0.03	-9208 (3303)	
	ref		ref		Ref	0.03
Race/ethnicity minority	748 (521)	0.18	1603 (993)	0.14	4047 (2473)	0.14
History of incarceration	1167 (687)	0.09	2185(1313)	0.09	5098 (3154)	0.10
CES-D score	265 (28)	<.001	498 (52)	<.001	1171 (122)	<0.001
Risk for alcohol use Mod v low High v low	-228 (571)	0.69	-380 (1132)	0.74	-865 (2757)	0.76
	340 (720)	0.64	785 (1339)	0.56	2017 (3146)	0.53
Risk for Cocaine use Mod v low High v low	-1157 (815)	0.18	-2231 (1457)	0.14	-5437 (3279)	0.12
	-1050 (1454)	0.48	-1777 (2688)	0.51	-3896 (6244)	0.54
Social support	-64 (75)	0.38	-91 (139)	0.51	-159 (315)	0.61
Barriers to care	-2.6 (87)	0.97	42.6 (173)	0.80	173 (428)	0.68
Food insecurity	470 (487)	0.33	778 (968)	0.42	1648 (2367)	0.48
AIC	10612		11288		12191	

Table 4-15: Program and Patient Characteristics Associated with Net Benefit at \$100,000 and \$150,000 Willingness to pay thresholds

	Net Monetary benefit (WTP \$100,000)		Net Monetary benefit (WTP \$200,000)	
	B (SE)	p-value	B (SE)	p-value
Intercept	-63029		-1233234	
Activities		0.0018		
Comprehensive	ref	ref	ref	
Health-Education-	85513 (62315)	0.19	169592 (124790)	0.19
Employment	7603 (82857)	0.92	16017 (165819)	0.92
Non-medical	-28849 (62814)	0.65	-57997 (125613)	0.65
Limited				
Modality				
Multi-modal	-77523 (29435)	0.04	-155188 (58985)	
Telephone	ref		ref	0.04
Race/ethnicity				
minority	33923 (2212)	0.16	67762 (44324)	0.16
History of incarceration	41769 (27803)	0.13	83414 (55607)	0.13
CES-D score	9668 (965)	<.001	19322 (1933)	<0.001
Risk for alcohol use				
Mod v low	-7063 (23222)	0.76	34326 (51858)	0.76
High v low	17157 (25958)	0.51	-14095 (46485)	0.51
Risk for cocaine use				
Mod v low	-46436 (26409)	0.54	-93038 (52704)	0.09
High v low	-31315 (50884)	0.10	-62527 (101605)	0.54
Social support	-1053 (2543)	0.67	-2074 (5076)	0.68
Barriers to care	1797 (3616)	0.61	3639 (7230)	0.61
Food insecurity	12522 (20381)	0.53	24867 (40777)	0.54
AIC	14392		15110	

Discussion

The findings from this study show promising evidence that navigation programs for PLWH who are homeless are a productive allocation of resources. Using two approaches to assess the economic evaluation of the program, the navigation program overall had a cost utility of \$11,150 per QALY gained and the net monetary benefit at the individual level of \$42,930 per QALY gained over a course of lifetime, assuming a willingness-to-pay threshold of \$50,000. The return on investment (ROI) was estimated at \$0.41 on the dollar which is in the mid-range compared to other linkage and re-engagement programs where ROI was estimated between \$0.26 and \$0.92 on the dollar.⁹ The average cost per person for a 12-month time frame was \$2,713 and the cost per person retained in care was \$3,668 and \$3,827 per person virally suppressed. These results are comparable to other retention-in-care programs which estimated \$3,834-\$4,670 per additional client retained in care and lower than \$8,432 per client virally suppressed for PLWH exiting incarceration.¹¹⁻¹³ Moreover the results are also similar to other studies specific to providing housing and case management services to PLWH who are homeless.¹⁴

Sensitivity analysis showed that net benefit was dependent on the time frame for analysis. After one year of implementation, only four sites had positive net benefits but by five years all participating sites had positive net benefits. Given that there were no significant differences in QALYs gained per individual across sites at each period, it is likely that other individual and structural factors of the programs may be contributing to overall net benefit that were not measured. For example, the models run did not account

for specific number of contacts from the navigator per individual or availability of services, such as housing, mental health and substance use treatment that may have influenced the expected benefits and resulted in lower QALYs in the short run for some sites. In addition, differences in the average costs per person across sites may be attributed to this difference. It may be that for some sites the acuity level for their patients was much higher, thus allowing for smaller caseloads to improve outcomes. In Chapter 3, the study found that certain program components such as type of activities are associated with participant characteristics, such as homeless chronicity and level of unmet need. While the final net benefit models accounted for potential site clustering, future analyses should include other program and community characteristics such as case load size and receipt of housing and other support services.

The findings also contribute to the literature in identifying the individual and program characteristics associated with net benefit. Navigation programs were able to reach PLWH who are homeless with more severe depressive symptoms (CESD >15) with a greater potential net benefit at \$100,000 WTP threshold. Other studies have found higher costs for severely mentally ill persons who are homeless but argue that investment in resources is ethical and make a moral argument for society in caring for member who are less well off.⁵²⁻⁵³

Those who received a limited scope of activities or received services via telephone had a greater net benefit compared to participants who required multiple intensive face-to-face contact with service providers across systems. This finding also suggests that telephone contact may be an efficient mechanism for working with persons

who are homeless if given access to telephones. Several of the navigation programs spent time assisting PLWH with application for free cell phones. Studies among homeless veterans have found that access and use of a cell phone could be a potential strategy for improving engagement in care and disseminating health information that could improve health outcomes.⁵⁴⁻⁵⁶ This study was not able to tease out the effects and costs of navigation programs in supporting access to cell phone technologies. Further research in this area is warranted.

This study is also comparable to other cost-effectiveness studies that examine navigation programs in cancer care. Using a payer perspective, Shih et al. (2016) found that use of patient navigators was a cost-effective strategy to provide timely linkage and coordinated care for patients with lung cancer. The incremental cost was \$9,145 and QALY was equal to 0.47 with an incremental cost ratio of \$19,312/QALY.⁵⁷ This study's findings with the net benefit analysis, \$42,930 exceeds this utility metric but was still within the willingness-to-pay threshold of \$50,000. This study calculated net monetary benefit from individual-level data and was not based on literature estimates and thus may reflect the value of the intervention from the participant perspective. Furthermore the cost-utility analysis, was estimated at \$11,150 per QALY gained, which was similar to other cost utility analyses of community health worker interventions for diabetes care, which ranged from \$10,955-\$13,810 per QALY gained.⁵⁸⁻⁵⁹ Similar to other community studies, navigation programs maybe an efficient use of resources for improving linkage and retention in care and housing stability to reach a vulnerable population such as the homeless. This study adds to the role of community health worker as a potential cost-

effective strategy to the health care workforce.⁵⁸⁻⁶¹

One strength of this study is that the sites represented a diverse group of organizational settings from community health centers to large outpatient clinics affiliated with hospitals in both rural and urban areas. Thus the results have greater generalizability, given that currently navigation programs are adapted to work in a variety of settings and thus are more generalizable with respect to the way navigation programs are implemented in the health care system.

There are limitations to the study. The findings are tailored to a specific at-risk population with multiple co-morbidities including HIV, mental health and substance use disorders, and are not necessarily generalizable to navigation programs for PLWH or the homeless in general. A second limitation is that net benefit was calculated based on willingness to pay thresholds per QALY gained and previous WHO recommendations at two to three times the per capita of the US (\$172,000 2016).⁶² However controversy persists in the continued use of these thresholds, which some have argued are too easily attained and may not reflect society's true willingness to pay threshold.⁴⁰⁻⁴⁶ In addition, these benchmarks do not consider the true opportunity costs of new delivery programs or disease burden. They do not consider affordability or budget impact. Yet WTP often can serve as a guide to help determine which investments are reasonable.⁴⁶ In practice, WTP is a way of adding new favorable interventions without replacing any unfavorable ones (deemed greater than the WTP per QALY threshold), since in the US, policy makers do not explicitly face rigidly fixed budgets.⁴⁵⁻⁴⁶ This study attempted to address these limitations by using multiple thresholds based on a fixed-budget constraint of \$300,000

and in the specific context of the populations being served: people living with HIV who are homeless and with co-occurring mental health and substance use disorders.

This was an observational study, and the effectiveness measure was based on the QALYs gained prior to the intervention and up to 12 months post the intervention period. The QALYs were calculated based on potential lifetime benefits to a PLWH who experiences homelessness from the program and remains adherent to treatment. The QALYs may be overestimated since the calculations did not include other co-morbidities, such as mental illness and active substance use. For PLWH who are homeless and experience co-occurring mental health and substance use disorders, staying adherent to treatment may be challenging without additional support, even if a person becomes housed. Recent studies have found that improvements in mental health and reductions in illicit substance use are closely associated with transitions from homelessness which in turn can affect HIV treatment outcomes.⁶³

Finally, the data did not account for all the actual costs and potential benefits beyond QALYs, such as housing and savings from reduced emergency room visits and hospitalizations associated with the program. It was not feasible to establish an appropriate reference case, and thus the estimate of the costs and effects of an additional navigator or team of navigators as part of the HIV care team may be limited. For example, at the time of the study several sites were just migrating to electronic health record systems, and many sites were not able to collect reliable data related to emergency room use or hospitalizations prior to the intervention or post enrollment. Future research studies should establish as standard reference case in accordance with the guidelines set

forth in the Second Panel on Cost-Effectiveness in Health care and Medicine.

The effectiveness measures in this paper focused on individuals who were virally suppressed at 12 months and retained in care using the standard HRSA definition (two appointments at least 90 days apart in a 12-month period and most recent viral load).

QALYs were also calculated to enhance comparison with other health-related interventions and is a standard measure in economic evaluations of interventions. However, QALYs as a composite measure may not capture all the non-health related gains of the intervention such as housing stability and employment a participant was able to achieve due to services received from the program. The QALYs gained by the intervention in this study are comparable to other interventions for people living with HIV and other chronic diseases.^{8-10, 13, 64-65}

The analysis was calculated from both a provider and societal perspective. The latter perspective included transportation costs for the client. Caregiver or patient time for participating in the intervention was not included in the cost calculations. Other studies have shown that providing permanent supportive housing is a worthwhile investment for multiply diagnosed individuals who experience homelessness.⁶⁶⁻⁶⁹ However, these studies often do not detail the components of the intensive support provided by a case manager or navigator to obtain or maintain housing. This study details the costs that navigation programs can provide to support and maintain housing stability and health outcomes for chronically homeless persons. This information may be used by community health centers hospitals and public health officials and payers who want to estimate the benefit of investing in a navigation programs for PLWH who are homeless.

Policy Implications

Despite these limitations, this study provides further evidence for planning purposes on the costs for navigation programs to improve retention in care and achieve viral suppression among homeless populations. Costs were similar to other retention and linkage studies for PLWH. For state, local and federal programs seeking to reduce future HIV transmissions, providing support to PLWH who are homeless may have a beneficial public health impact.

In addition, for PLWH who also experience severe co-morbidities such as substance use and mental health disorders, navigation programs could be an efficient strategy to improve outcomes. The navigation programs provide connection to housing, mental health care and substance use treatment. This may be helpful in reducing duplication of services and overall net benefit for PLWH with greater severity of depression.

The Affordable Care Act has enabled states to expand insurance coverage to increase access and use of health care among previously uninsured or underinsured populations. However, for PLWH who are homeless, insurance coverage may not be enough, as there is a greater need for integrated care management to address the complex needs of food, housing, behavior health services and other basic needs.⁷⁰ Navigation programs could potentially assist to fulfill these needs. In the past couple of years, several states have begun to move towards establishing medical homes for PLWH, and designing and implementing reimbursement strategies for coordination and care management programs.⁷¹ For example, Wisconsin instituted Health Homes for PLWH

and Medicaid which reimburses a flat rate and payment of \$359 per year for comprehensive care assessments and updates to care plans as well as \$102 monthly case rate for care management services.⁷² New York is implementing care management strategies with guidelines to focus specifically on PLWH who are homeless with another chronic illness such as mental illness.⁷³ As states look to adopt programs that can reduce health care costs, community-level strategies such as navigation programs provide a potential cost-effective approach to providing the high quality of care and coordination of services needed by PLWH who are homeless to reach viral suppression.

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Chapter 5 Conclusion

In their 2008 article, Berwick et al. called for reforms in the US health care system that would achieve the “Triple AIM goals”: *improving individual experience of care, reducing the per capita costs of care for populations and improving the health of populations*. To achieve this goal, the authors described a need for an organization or “integrator” that accepts responsibility for these aims and that it must include the integration of medical and non-medical sectors.[†] The aim of this dissertation was to investigate in greater depth how navigation programs could achieve these Triple AIM goals in the context of providing care for PLWH who are unstably housed and experience substance use and mental health disorders.

Study one developed a composite measure that could be used to capture the effectiveness of CC/PN programs on health outcomes for PLWH who are homeless. I found that these CC/PN programs directly impact three domains: retention in care, adherence to treatment and housing stability. A composite measure with a minimum of these 3 indicators had good fit and predictive validity with viral suppression. CC/PN programs may also affect patient experience with their health care providers and health related quality of life, but these did not necessarily predict viral suppression. Further research is warranted to identify the specific items within each domain that navigation programs can directly impact.

The second study identified the specific tasks, modalities of communication,

[†] Berwick, D. M., Nolan, T. W., & Whittington, J. (2008). The triple aim: care, health, and cost. *Health Affairs*, 27(3), 759-769

location of services and staffing patterns of navigation programs for PLWH who are unstably housed. The findings indicated there was not a set of limited navigation models but the components were classified as into four key activities that navigators provided to PLWH who are homeless; staffing patterns included both team approaches (peer-clinician) or peer-case manager, and a solo navigator; modality of services provided were characterized as either multimodal working with providers (collateral) face to face or via telephone; and finally location of services can vary in the medical setting, out in the community or person's residence or in mixed settings both in the medical center and community settings. The findings can be useful in designing health care service delivery programs and systems that better address some of the most vulnerable populations of care. Furthermore, it can provide an understanding of the type of tasks that can be used to finance navigation programs. These could be incorporated into financing strategies and a clear scope of work and tasks for the medical team.

Finally my third study examined the costs of navigation programs in providing services to PLWH who are homeless. I found that the average cost per person per client was \$2,713 with an average cost to reach viral suppression at \$3,827. While I was unable to estimate cost-savings from the program, the return on investment of \$0.41 on the dollar and net benefit of \$42,830 demonstrate a potential worthwhile strategy for investing resources. Future studies that can directly compare and calculate costs to a usual care group and calculate cost-effectiveness are needed. However, this study shows that with modest investment of resources these programs can reach the most vulnerable populations.

Appendices

Appendix A: Study Design for Building a Medical Home for multiply diagnosed HIV positive homeless populations

Study Sample

The sample includes 909 participants who were enrolled from September 2013-February 2016 in the CC/PN interventions across the nine sites. Eligibility criteria included: 1) being homeless or unstably housed (in accordance with the HUD definition) and 2) having at least one co-occurring substance use or mental health disorder. The nine sites span three organizational settings: federally qualified health centers (2), city or county public health departments (3), hospital or university based hospital systems (2) and community based comprehensive HIV programs (2), one of which is affiliated at a university hospital. At the time of funding all nine sites provided comprehensive HIV medical and case management services funded by Ryan White programs. Four of the organizations established formal partnerships with the housing agency that provides rental assistance, voucher programs or support to find housing through private landlords. The other five programs established networks with external housing agencies to obtain housing assistance for their clients.

Intervention design

Each site created a new position and employed a care coordinator/navigator as part of the care team with the goal of achieving a networked system of care for the patient. This staff member was either employed by the clinic staff and worked directly with the care team or was hired by a housing partner agency that was contracted by the clinic. The qualifications of care coordinators/patient navigators ranged from master's level social workers to peer navigators across sites. The intervention was designed to provide a minimum level of service for 6 months and most had an average of 18 months of service. In addition to employing a new staff member to be part of the team and work directly with the priority population, the programs incorporated system and organizational level interventions to build a medical home that would also address behavioral health and housing needs of the patient and create a seamless system of care. Some examples of organizational level changes include using electronic health records or daily/weekly team huddles with medical, behavioral health and CC/PN staff to better communicate about patient medical and social service needs. On a system level sites are convening regular meeting with partner agencies that provide housing and behavioral health care or treatment to better link PLWH with services.

Data collection methods

The MedHEART study design is a non-experimental, longitudinal study of patients receiving services from a care coordinator/patient navigator. Data collection methods include: 1) interviews collected at baseline, and post 3, 6, 12 and 18 months via a REDCap electronic data system to minimize data entry error; and 2) medical chart abstraction for baseline then at 6 month intervals up to 24 months, and 3) an electronic intervention encounter form that is completed daily by intervention staff. Data collection

began in September 2013 with baseline enrollment closing in February 2016. Longitudinal data (a subset of participants will only have 12 months of data) will be collected through February 2017.

Measures

The primary outcome measures for the MedHEART study include: 1) retention in care, 2) viral suppression and 3) stable housing. The first two primary outcomes measures will be defined in accordance with the standard definitions set forth by HRSA. There is no standard definition for measuring stable housing and a proposed measure is one aspect to be examined in this proposal (see paper 1). The study was designed using Gelberg's framework as noted in the theoretical framework, and thus other measures include *predisposing factors* such as demographics, substance use, mental health status, exposure to trauma, and housing status; *enabling factors* include self-efficacy, social support, and competing service needs and barriers to care; other measures collected include health care utilization (medical and behavioral health) and adherence to treatment. Other outcomes measures of interest include patient experience of care and quality of life (physical and mental health functional) using validated scales that have been tested in either homeless or HIV populations. Table 1 below summarizes the primary measures and data collection methods for the overall study. These will also be the main variables to assess the individual characteristics that may contribute to cost-effectiveness of the CC/PN models.

A standard intervention encounter form was implemented across sites to document the type, location, duration and content of work with clients or on behalf of clients in working towards the goals of the intervention. CC/PNs also documented the work both directly conducted with clients, work with providers on behalf of clients, and activities and time spent finding clients or obtaining a service on behalf of a client.

For quality assurance, each site was sent a monthly report of all interview, chart and encounter data address inconsistencies and validate missing data fields. Annual audit visits were conducted by staff at the multisite evaluation center each year to assess the quality of the chart and intervention forms. During these visits study data were compared to documentation in chart records on a random selection of 10% of the site's sample.

Limitations of the overall study design

Since the intervention sites are all Ryan White funded clinics, the results may not be generalizable to PLWH who seek and obtain care in other health care settings. The sites are well-distributed geographically representing the northeast, southeast and southwest, northwest and western United States. Second with no direct comparison group, internal validity is also limited primarily due to potential selection bias. However, data collection does include multiple methods to improve reliability and validity and the multiple time points may limit the effects of some of the secular trends and maturation over time. As noted, another strength is that the sites represent regional variation for where CC/PN models are operating including serving both rural and urban populations.

Table A1: Measures for the HRSA Building a Medical Home Study by Gelberg's framework

Outcomes Measures	Definition	Data source	Data collection points
Viral suppression	Dichotomous lab value yes/no undetectable (<200 copies/ml)	Medical chart review (paper or Electronic health record)	Baseline, 6, 12, 18, 24 months
Quality of life	Physical and Mental health functioning VR-12	Patient self-report	Baseline, 6, 12, 18, month
Patient experience of care	A validated scale in homeless populations the 33 items measure has been tested in homeless vets (cite reliability)	Patient self-report	3 months, 12 months
Housing Stability	A composite measure to be developed based on 12 items: current type of housing, length of time homeless/unstably housed; reason because homeless; number of places stayed, length of time since own housing	Patient self-report	Baseline, 6, 12, 18, month
Health service utilization			
Retention in care	2 HIV primary care appointments at least 90 days apart in a 12 month period 4 month constancy: 1 primary care visit in each 4 month interval over a 12 month period	Medical chart review (paper or Electronic health record)	Baseline, 6, 12, 18 and 24 months
Adherence to treatment	Self-report four item scale number of days missed doses in past 30 days; perception of how good a job at taking medications; and perception of how often took medication as prescribed; (Wilson's adherence scale validation in press)	Patient self-report	Baseline, 6, 12, 18, month
Covariates			
Pre disposing factors			
Demographics	Age, gender, race/ethnicity, country of birth, education status, employment status, public assistance	Patient self-report	Baseline, 6, 12, 18, month
Housing status	A 12 items: current type of housing, length of time homeless/unstably housed; reason because homeless; number of places stayed, length of time since own housing	Patient self-report	
Incarceration history	Ever in prison or jail; history of incarceration in the last year	Patient self-report	
		Patient self-report	
Depression	Center for EESD	Patient self-report	Baseline, 6, 12, 18, month
Substance use	WHO Assist Scale	Patient self-report	Baseline, 6, 12, 18, month
Exposure to violence	History and current physical and sexual abuse	Patient self-report	Baseline, 6, 12, 18, month

Enabling factors			
Self-efficacy	Lorig's self-efficacy scale for persons with chronic conditions	Patient self-report	
Social support scale	5 item scale recommended by NIH/NIDA Data Harmonization for Vulnerable Populations	Patient self-report	Baseline, 6, 12, 18, month
Barriers to care & health beliefs	20 items Adapted from NIH/NIDA Data Harmonization for Vulnerable Populations	Patient self-report	Baseline, 6, 12, 18, month
Competing services needs	3 questions: Did you need service in past 6 months, did you attempt to get it, did you obtain the services	Patient self-report	Baseline, 6, 12, 18, month
Insurance and health care utilization	Insurance type, ER visits, hospitalization	Patient self-report	Baseline, 6, 12, 18, month
Evaluated & Perceived Need for health care			
Substance abuse treatment & mental health service utilization	Number of visits with a substance use treatment/mental health provider-external and internal	Medical chart review (paper or Electronic health record)	Baseline, 6, 12, 18, 24 months
Health care utilization	HIV primary care visits ER visits, hospitalization	Patient self-report medical chart review	Baseline, 6, 12, 18, month
Patient Navigation encounters	Definition	Data source	Data collection time points
Staff type	Navigator, Peer navigator, Service linkage worker, Care coordinator (not the housing or HIV case manager)	Intervention encounter form	Daily completion by staff
Location	Community, medical setting, streets, shelter, client home, residential treatment and other community setting		
Duration	In minutes		
Mode of communication	Face-to-face, phone, email, text, collateral, other		
Content	43 items across 8 domains: finding client, needs assessments, health care related activities, mental health or substance use related activities, housing, other social services, educational emotional support, employment and other practical support		

Appendix B: Intervention Encounter form for CC/PN Models

Intervention Encounter Form	
Date of Contact ____/____/____	Staff ID: _____
Client ID: _____	Site: _____
Encounter made:	Location of Encounter(s): Check all that apply
<input type="checkbox"/> Yes (with the client or for the client with other provider)	<input type="checkbox"/> Streets, parks, open space
<input type="checkbox"/> No	<input type="checkbox"/> Mobile van
If "No," why?	<input type="checkbox"/> Client house or apartment
<input type="checkbox"/> Unable to reach	<input type="checkbox"/> Client non-permanent residence (shelter, SRO)
<input type="checkbox"/> Cancelled/Rescheduled appointment	<input type="checkbox"/> Outreach program office
<input type="checkbox"/> No show	<input type="checkbox"/> Other social service agency
<input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Medical setting (clinic, hospital)
	<input type="checkbox"/> Residential treatment program
	<input type="checkbox"/> Correctional setting
	<input type="checkbox"/> Other community setting (Bar, Drop-In Ctr)
	<input type="checkbox"/> Other (specify): _____
Total Duration of Encounters: _____	<input type="checkbox"/> N/A (not face-to-face)

Type of Contact			
Face-to-face (Individual)	1	Social network site: Facebook, twitter	6
Group	2	Not face-to -face (finding)	7
Telephone	3	Other:	8
Email	4	Collateral (client not present)	9
Text message	5	Fax	10
		EMR	11

Encounter content:

Mark with a "✓" for each encounter that you had with a client in the course of one day. In the column to the right please enter the type and duration of the encounter using the codes above. For example if you took a client to a medical appointment that lasted 1 hour-enter "1" in the "Type" column and "d" in the "duration" column next to the content. Please mark all contacts for the entire day.

	Type	Duration (minutes)
1. Find client/Outreach		
2. Client needs assessment		
HEALTHCARE-RELATED ACTIVITIES		
3. Collect, update, and/or confirm information about HIV specific services for documentation purposes		
4. Collect, update, and/or confirm information about non-HIV medical services for documentation purposes		
5. Linking newly-diagnosed client to first HIV medical appointment		
6. Accompany client to a medical appointment		
7. Discuss medical appointments		
8. Assist with making appointment for health care		
9. Create or update client individualized care plans		

Appendix C: Cost analysis worksheet

Multi-Site Cost Analysis Data
Year 2: September 1, 2014 - August 31, 2014

Cost Item	Site 1		Site 2		Site 3		Site 4		Site 5		Site 6
	SPNS	Non-SPNS	SPNS	Non-SPNS	SPNS	Non-SPNS	SPNS	Non-SPNS	SPNS	Non-SPNS	
Personnel											
Care Coordinator/navigator											
Program Supervisor/Manager											
Case Manager (% FTE x salary)											
Program Director (% FTE x salary)											
Behavioral health provider (%FTE x salary)											
Medical provider (%FTE x salary)											
Other supervision support time											
Fringe benefits (if not included)											
Other visit cost											
Laboratory test (cost per test CD4 & VL per patient)											
Training costs (not provided by BU)											
a. Personnel costs											
b. Materials/supplies											
c. Travel											
d. Other direct costs (please describe in notes)											
Transportation for clients											
Transportation for staff											
Other direct costs											
Subcontract with Partner (housing)											
Housing costs (Emergency housing)											
Telecommunications											
a. Staff related											
b. Client related (cell phones)											
Materials/equipment supplies											
Overhead/indirect rate											
Total Cost per site											
1-Separate by type of staff: Psychiatrist, Psychologist, Uic Social Worker											
2-Separate by provider types NP, PA, physician; costs to third party payors											
3: Other costs built to visit (medical asst, jpn rn, clerk, include as staff time or total visit charge)											
4: Value of bus/subway passes; taxis											
5: Mileage/gasoline reimbursed to staff of client support											
6: Cost of medications, Food, child care, clothing, hygiene packs; NO study related incentives; etc											
7: Emergency housing											
8: Communications with clients including cell phone; also include staff cell phone costs											
9: Computers; programs for client monitoring/tracking services											
Data Sources:											
Site budgets (final approved from HRSA for SPNS grant)											
Site administrative billing/expenditure reports for Ryan White and other payors											

Appendix Table 4-1a Average case load per navigation staff (9/1/2013-8/31/2014)

Site	Number of Unique Clients Served	Number of Intervention Staff	Average Client Caseload per Staff
All Sites	299	46	6.5
AIDS Arms Inc.	36	4	9
CommWell Health	21	5	4.2
Family Health Centers of San Diego Inc.	21	4	5.3
Harris Health System	59	5	11.8
Multnomah County Health Department	29	5	5.8
Pasadena Public Health Department	40	4	10
San Francisco Department of Public Health	24	4	6
University of Florida - UF Cares	41	7	5.9
Yale University	28	8	3.5

Appendix Table 4-2a Average case load per navigation staff (9/1/2014-8/31/2015)

Site	Number of Unique Clients Served	Number of Intervention Staff	Average Client Caseload per Staff
All Sites	675	45	15
AIDS Arms Inc.	81	5	16.2
CommWell Health	63	6	10.5
Family Health Centers of San Diego Inc.	92	3	30.7
Harris Health System	122	7	17.4
Multnomah County Health Department	59	5	11.8
Pasadena Public Health Department	78	4	19.5
San Francisco Department of Public Health	41	4	10.3
University of Florida - UF Cares	78	6	13
Yale University	61	5	12.2

Appendix Table 4-3a Average case load per navigation staff (9/1/2015-8/31/2016)

Site	Number of Unique Clients Served	Number of Intervention Staff	Average Client Caseload per Staff
All Sites	715	43	16.6
AIDS Arms Inc.	84	5	16.8
CommWell Health	79	5	15.8
Family Health Centers of San Diego Inc.	77	4	19.3
Harris Health System	122	8	15.3
Multnomah County Health Department	74	5	14.8
Pasadena Public Health Department	74	3	24.7
San Francisco Department of Public Health	46	4	11.5
University of Florida - UF Cares	92	5	18.4
Yale University	67	4	16.8

Table 4-4 Comparison of Average cost and Log transformed costs associated patient and program characteristics

	Average Cost		Average cost (log transformed)	
	B (SE)	p-value	B (SE)	p-value
Intercept	1493 (399)		7.4 (0.16)	
Activities				
Limited	1325(444)	0.009	0.33 (0.08)	0.001
Health-Education-	1041(570)	0.08	0.23 (0.15)	0.16
Employ.	1609 (498)	0.005	0.40 (0.13)	0.007
Non-medical	ref		ref	Ref
Comprehensive				
Modality				
Multi-modal	134 (193)	0.51	0.12(0.6)	0.85
Telephone				
Race/ethnicity				
minority	-19.1 (72)	0.79	0.008 (0.02)	0.69
History of incarceration	-32.7 (62.6)	0.60	-0.12 (0.16)	0.46
CES-D score	-14.5 (8.8)	0.10	-0.004 (0.003)	0.11
Risk for alcohol use				
Mod v low	80 (110)	0.48	0.01 (0.04)	0.77
High v low	34(138)	0.80	-0.03 (0.06)	0.54
Cocaine				
Mod v low	92 (124)	0.47	0.01 (0.05)	0.76
High v low	233 (246)	0.35	0.74 (0.6)	0.27
Social support	13.4 (11.6)	0.25	0.004 (0.004)	0.36
Barriers to care	40 (24)	0.09	0.01 (0.009)	0.18
Food insecurity	-124 (48)	0.01	-0.03 (0.2)	0.13
AIC	8645		312	

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Curriculum Vitae

