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Outcomes of Directly Observed Therapy in People Living with HIV Who Experience Homelessness and Substance Use Disorder

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Elaine Marieb College of Nursing, University of Massachusetts, Amherst 4/23/2023

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Abstract

Background: Antiretroviral directly observed therapy, in which nurses or other allied health professionals provide patients with daily medication, is an evidence-based solution for viral load suppression in people living with HIV who experience homelessness. Purpose: This quality improvement project aimed to assess the outcomes of antiretroviral directly observed therapy at one urban clinic caring for people living with human immunodeficiency virus who experience homelessness and substance use disorder. Methods: Data was collected from the electronic health record for the antiretroviral directly observed therapy patient cohort (n = 33); 10 of them were surveyed. Fisher exact tests determined nonrandom associations between viral suppression and all other categorical variables. Survey answers were mapped to the modified Andersen's Behavioral Model domains and subcategories. Results: Seventy-three percent of program patients were virally suppressed after participating in the program; 42% were virally undetectable. The relationship between viral suppression and date of most recent primary care provider visit was significant (p = 0.01). Eighty percent of surveyed patient participants reported that they liked the program, and 70% said that taking ART makes them feel better. Eighty percent of patients described their health as "Fair" or "Poor" before initiating treatment with the program, while 90% of patients reported their own health as being "good", "very good", or "excellent" after participating. Conclusion: Results suggest that when nurse-led teams actively engage PLWH, viral suppression, and consequent undetectability, is more likely. Clear implications for practice include continuing nurse navigation to promote viral suppression.

Keywords: human immunodeficiency virus, acquired immune deficiency syndrome, homeless, antiretroviral therapy, directly observed therapy, substance use disorder

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Outcomes of Directly Observed Therapy in People Living with HIV who Experience Homelessness and Substance Use Disorder

People living with human immunodeficiency virus (PLWH; HIV) require a daily regimen of antiretroviral medication (ART) to lower their HIV viral load. As HIV has no cure to date, the goal of ART is to suppress the viral load to the point of being "undetectable", or the level at which the virus can neither be further transmitted nor cause the patient harm (HIV.gov, 2022). For PLWH with comorbid substance use disorders (SUD) who are also people experiencing homelessness (PEH), daily medication adherence can be a serious challenge (Pan et al., 2020). Antiretroviral directly observed therapy (ART-DOT), a program in which nurses or other allied health professionals provide ART directly to the patient daily, is an evidence-based solution for medication adherence and consequent viral load reduction/suppression in PLWH who are also PEH with SUDs (HIV.gov, n.d.). This Doctor of Nursing Practice (DNP) project aimed to assess the outcomes of an ART-DOT program at one urban clinic (the Center) caring for people living with HIV who are also PEH with SUDs.

Background

Healthcare providers working with PLWH seek to decrease new infections in the community, improve health outcomes, and reduce health disparities by suppressing patients' HIV-1 viral loads with ART (Holtzman et al., 2015). These goals can be challenging, as typical HIV treatment requires a daily medication regimen of ART, frequent laboratory testing, and the close care of comorbidities and disease progression. However, these goals can be downright daunting in PLWH, who are also PEH with SUDs. Poor self-management of treatment in this population is indicated by high rates of unsuppressed viral loads, non-adherence to medication regimens, missed laboratory and health care visits, lack of access to transportation, loss of

belongings, the effects of SUDs and other comorbidities, and other economic and social determinants of health associated with homelessness (Aquino et al., 2021). Evidence suggests that ART-DOT may serve as an effective strategy to engage and retain PLWH and decrease viral loads for PLWH who are also PEH (Howell et al., 2018 & Gaur et al., 2010).

DOT was initially designed as a tuberculosis (TB) treatment program. In recent years, modified versions have been used as a bridge to incorporate therapeutic treatment of other chronic illnesses. One such bridge was described in a 2018 study across four regions in South Africa. It was found that patients who received home-based DOT for TB had higher rates of counseling and prevention for HIV (Howell et al., 2018). Similarly, a DOT program designed exclusively for the treatment of HIV with ART has been attempted previously, providing a base of evidence for this project. This study, by Gaur et al. in 2010, was done across four cities in the United States and described ART-DOT for nonadherent youth. 100% of participants in the study reported that they would recommend DOT to a friend, and most said that DOT helped motivate them to take their ART, suggesting satisfaction and efficacy (Gaur et al., 2010).

Review of the Literature

Before conducting this project, two separate literature reviews were performed to understand the landscape around HIV treatment in primary care for PEH. The search terms used for the first review (Search 1) in October 2021 were: acquired human immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV); homelessness or homeless persons or houseless or housing; and primary care or primary health care or primary healthcare or general practice. Search parameters included full-text, scholarly, peer-reviewed articles from academic journals in English that were published between 2011 and 2021.

The initial search produced 567 records from 21 databases. 299 duplicates were removed. 187 records were removed by filtering the articles by subject, specifically, HIV. With 82 records remaining, seven were excluded for having a title or description about a disease other than HIV or if the studies were performed outside of the US/Canada, leaving 75 records.

Abstracts were then reviewed, and 23 were removed for not relating directly to primary care (i.e., nutrition, counseling, housing-only programs). Two records were removed, as they were considered preliminary studies. Two more were removed, because they did not specify that the patients were experiencing homelessness. This left 48 articles.

All 48 full articles were reviewed, and 30 were removed due to a primary focus on aspects other than HIV and primary care, such as case management, housing, and economics. This left 18 records to be used for this review for Search 1.

In recent years, among PEH in the community of focus, HIV has been replaced by drug overdose as the primary cause of mortality (Baggett et al., 2013). As such, a second review of literature (Search 2) was conducted through the same library database, using the same search terms as Search 1, but also including "substance use disorder or substance abuse or drugs or addiction".

Search 2, conducted approximately six months after Search 1, in March 2022, used the same search terms as Search 1, but also included substance use disorders or SUD. It was limited to peer-reviewed scholarly articles in full digital text published between 2017 and 2022 in English. The search produced 163 records across 19 databases. Eighty duplicate records were removed, and the remaining 83 articles were reviewed for the appropriate subject matter. Seven were conducted outside the US and Canada and were removed. Forty articles were removed for irrelevant titles, leaving 36. Upon reviewing each of the 36 abstracts, 13 records were removed

for irrelevance or lack of comprehensive subject matter. Upon reviewing each of the remaining 23 records, 18 were found to meet the criteria for the search. Five of the 18 records were exact duplicates of articles used in the first search and were removed. This left 13 records to be used for this review for Search 2.

Record Characteristics

Of the 18 studies from Search 1, five used qualitative methods, two used mixed-methods, and the remaining 11 were quantitative studies (Table 1). The studies predominantly used selective sampling based on location (i.e., homeless shelter in urban setting) or retrospective chart reviews. The subjects typically were adults over the age of 18, previously diagnosed with HIV, without permanent housing, and typically in urban areas. The subjects tended to be people of heterosexual orientation and racial and/or ethnic minorities (Holtzman et al., 2015). Some studies were targeted more directly at certain demographics, as in Jemmott et al. (2019) which focused specifically on young African American males and their mothers, Greene et al. (2018) which focused on PLWH over 50 years old, and Hanrahan et al. (2011) which discussed people with HIV and mental illness. The latter is the only article that presented specific case studies. Asamsama et al. (2019), n = 706, had the largest cohort of subjects. Each article had a robust reference list, ranging from 15 (Hanrahan et al., 2011) studies to 40 (Holtzman et al., 2015).

Table 1Search 1 Methods

Qualitative	Mixed-Methods	Quantitative
1. Greene et al., 2018 2. Norberg et al., 2019 3. Pecoraro et al., 2013 4. Remien et al., 2015 5. Tofighi et al., 2019	1. Hanrahan et al., 2011 2. Holtzman et al., 2015	1. Aquino et al., 2021 2. Asamsama et al., 2017 3. Brody et al., 2021 4. Cabral et al., 2018 5. Fuster & Gelberg, 2019 6. Honer et al., 2017 7. Jemmott et al., 2019 8. Marx et al., 2011 9. Parker et al., 2014 10. Smith & Badowski, 2021 11. Walley et al., 2015

Regarding research design, only two of the studies reviewed in Search 1 were randomized controlled trials (Jemmott et al., 2019; Hanrahan et al., 2011). In three studies, Brody et al. (2021), Asamsama et al. (2019), and Marx et al. (2011) used secondary analysis. One study used a narrative review (Smith & Badowski, 2021), and two were longitudinal studies (Cabral et al., 2018; Honer et al., 2017). One systematic review (Norberg et al., 2019) and three original research studies (Pecoraro et al., 2013; Remien et al., 2015; Tofighi et al., 2019). The remaining studies used surveys or mixed methods approaches.

Key Findings from the Literature

The records from both searches were categorized by content, as described in Table 2 in alphabetical order.

Table 2
Search 1 and 2 Study Subgroups

Patients and Care Providers Experiences	Engagement Among Patients	Sociodemographic Risk
 Green et al., 2018 Honer et al., 2017 Norberg et al., 2019 Wolfe et al., 2021 	1. Aquino et al., 2021 2. Asamsama et al., 2017 3. Brody et al., 2021 4. Cabral et al., 2018 5. Dombrowski et al., 2019 6. Fuster & Gelberg, 2019 7. Glynn et al., 2021 8. Grief & Miller, 2017 9. Holtzman et al., 2015 10. Jemmott et al., 2019 11. Smith & Badowski, 2021	1. Cassimatis et al., 2021 2. Hanrahan et al., 2011 3. Jones et al., 2020 4. Klimas et al., 2018 5. Lee et al., 2020 6. Marx et al., 2011 7. Pan et al., 2020 8. Parker et al., 2014 9. Pecoraro et al., 2013 10. Remien et al., 2015 11. Salters et al., 2021
	12. Thompson et al., 2017	12. Stoner et al., 2019 13. Walley et al., 2015 14. Wu et al., 2022

In the Patients and Care Providers Experiences study subgroup from Search 1, researchers investigated the personal experiences of PLWH, along with the experiences of their healthcare providers (Norberg et al., 2019), how providers feel about the care models in place for older PLWH (Greene et al., 2018), and clinical effectiveness for healthcare delivery in multimorbid HIV (Honer et al., 2017). In Search 2, the only article that fell into this category was from Wolfe et al. (2021), which described how including community health workers in service delivery can aid in addressing social determinants of health that co-occur in PLWH who also have SUDs.

In the Engagement Among Patients study subgroup from Search 1, researchers asked questions about how to engage with PLWH who are homeless when engagement and retention options are severely limited (in these cases, specifically during a global pandemic) (Brody et al.,

2021; Smith & Badowski, 2021). In the clinical setting, this can involve engaging patients in housing options, nurse and peer navigation programs, case management, and working to break down barriers to seeking HIV care (like Opioid Use Disorder) for PEH (Aquino et al., 2021; Asamsama et al., 2017; Cabral et al., 2018; Fuster & Gelberg, 2019; Tofighi et al., 2019). This also includes community engagement, such as mothers helping to engage adolescent sons and enhance peer intervention (Jemmott et al., 2019) (Table 2). In Search 2, some specific recommendations for engagement included using trauma-informed models of HIV care (Glynn et al., 2021), brief interventions for SUDs (Thompson et al., 2017), and a wide variety of health care delivery interventions, including walk-in interventions, targeted counseling and education, multi-service locations, and community-based outreach programs (Dombrowski et al., 2019; Grief & Miller, 2017).

The Sociodemographic Risk study subgroup from Search 1 detailed sociodemographic risks and other factors potentially associated with primary care and the barriers in place for this population to receive treatment. For example, one study focused on how substance use and psychiatric disorders contributed to patients with HIV not returning to primary care after a caring relationship had already been established (Pecoraro et al., 2013). In another study, researchers described the use of sociodemographic data in operationalizing HIV primary care patient retention (Marx et al., 2011). Differences in chronic health conditions, high risk behaviors (Parker et al., 2014), preexisting conditions (Walley et al., 2015), system, social, and individual barriers (Remien et al., 2015), along with clinical and social characteristics (Hanrahan et al., 2011) were examined as well. In Search 2, though the focus of the search was on people who have SUDs, only three of the articles focused on this aspect as the primary sociodemographic risk (Klimas et al., 2018; Salters et al., 2021; Wu et al., 2021). The remainder focused on sexual

risk behaviors (Lee et al., 2019; Pan et al., 2020; Stoner et al., 2019), race (Lee et al., 2019), psychiatric disorders (Jones et al., 2020), and pregnancy (Cassimatis et al., 2021).

Synthesis of the Literature

Across the three groupings, several predominant themes emerged from both searches, including stable housing and patient care, nurse navigation, provider relationships, and patients' needs.

Stable Housing and Patient Care

The first is the theme of stable housing and its role in patient care. Fuster and Gelberg (2019) found that, perhaps, the key facilitator for engaging these patients in primary care is being sheltered. In fact, even sleeping in a shelter the night before an appointment, as opposed to a space not typically used for human sleeping accommodations (henceforth referred to in this paper as the "street"), increases the likelihood of attending primary care clinic (Fuster and Gelberg, 2019). Without an address, it can be challenging for patients to access care, affecting both their motivation and their ability to engage. Accommodating a practice for homelessness allows for a higher-rated quality of patient care. (Remien et al., 2015, Wu et al., 2021). Similarly, homelessness contributes directly to poor treatment adherence and, therefore, a lack of viral suppression (Aquino et al., 2021; Cabral et al., 2018; Cassimatis et al., 2021; Pan et al., 2020). In fact, stably-housed patients at baseline have a tendency toward improved retention in care – with or without peer support (Cabral et al., 2018). While the conflict between housing instability and treatment can be mediated by peer support to some degree, this is not a fool-proof concept, and other methods must also be engaged. This is especially true for the most vulnerable, i.e., women, minorities, men who have sex with men, and people engaging in transactional sex. (Lee et al., 2020; Stoner et al., 2019).

Nurse Navigation

Another major theme in the literature is the importance of case management and nurse navigation. Connecting and retaining patients in primary care is essential in maintaining the continuity of HIV care (Aquino et al., 2021). Some argue that case management should perhaps be considered a requirement to achieve excellent outcomes in connecting PLWH to treatment (Aquino et al., 2021). Community health worker service delivery and/or case management improves with patients being sheltered and, as one might expect, is more associated with client satisfaction (Wolfe et al., 2021). A similar concept to case management is nurse navigation – a concept that has been poorly defined in the literature but essentially stands as a catch-all term for a nurse who provides a patient with case management, outreach, and systems collaboration (Asamsama et al., 2017). When a nurse navigator supports patients, they are more likely to achieve viral suppression and attend clinic visits. Professional navigators are more likely to assist in positive continuity of care for HIV management, showing most success when their activities address intended outcomes specific to a certain population (which may provide an excellent, directed model for widespread application) (Aquino et al., 2021; Asamsama et al., 2017; Hanrahan et al., 2011). For this paper, navigation and case management will be used interchangeably.

Similarly, consistency in these case-manager-patient relationships allows for health and recovery, as nurse case managers assist patients in understanding their behaviors and learn to participate in self-care (Hanrahan et al., 2011). To retain patients in care, nurse case managers and providers need to have, at minimum, biannual or quarterly interactions (Holtzman et al., 2015). Unfortunately, ART medication adherence requires daily action and can create confusion and amplify stigma. Having frequent support and visits from primary care staff/case

management can improve adherence, as these visits may help patients develop personal reminder strategies (Norberg et al., 2019). These types of hands-on case management strategies can help to destignatize HIV care and promote understanding among the population – especially if the provider is able to provide holistic, empathetic care with the utmost respect (Norberg et al., 2019).

Provider Relationships

The next theme relates to the care providers' relationships with patients. First and foremost, providers must show PLWH respect and empathy. However, while invaluable, these traits are not always enough to satisfy patients, many of whom wish to view their providers as experts in their care (Greene et al., 2018). They want to know that they will be provided with primary care tailored to them regardless of demographics. One way providers can tailor their care to have increased contact with their patients while decreasing the stigma associated with coming into the clinic is via telehealth (Smith & Badowski, 2021; Brody et al, 2021). Telehealth provides care for those who cannot come to the clinic, privacy for those who do not want to come, and flexibility for those with complicated schedules and transport options (Smith & Badowski, 2021). While it should be noted that this can be difficult in shelters or on the street where privacy is limited, it does, at the very least, increase patients' options when obtaining care. To combat some of these difficulties, providers are beginning to recognize telehealth as the future of medicine for pandemics (dual pandemics of COVID-19 and HIV are an excellent casein-point). However, providers recognize that telehealth on its own is insufficient without case management (Brody et al., 2021).

Patients' Needs

The final theme focuses on patients and their needs. These patients are commonly lost to primary care due to substance and alcohol use, unstable housing, psychiatric disorders, incarceration, and difficulties related to HIV itself like stigma and difficulty following intensive medication regimens (Pecoraro et al., 2013; Thompson et al., 2017). These patients may be even more vulnerable due to co-occurring psychiatric disorders, including anxiety, depression, psychosis, and PTSD – of which the latter two have been proven to predict decreased ART adherence (Glynn et al., 2021, Jones et al., 2020). Treatment programs incorporating onsite care for behavioral health and substance use disorders in primary care clinics can serve as a potential strategy to engage patients in care. Given that, in some areas, opioid overdose is now the primary cause of mortality among underserved PLWH, it must be urgently addressed at the primary care level (Salters et al., 2021). Though controversial, one study suggested that heroinassisted treatment may help decrease morbidity and mortality in these cohorts (Klimas et al., 2018). It is not just opiating that is causing the problems. In fact, patients with a SUD (especially crack cocaine) are about one-half as likely to be retained in care as those without SUD (Parker et al., 2014; Marx et al., 2011). With the incorporation of peer and family support for these patients (with or without psychiatric diagnoses), high-risk behavior can be reduced while retention in care can be improved (Marx et al., 2011; Tofighi et al., 2019; Jemmott et al., 2019).

Beyond psychiatric disorders, given their immunocompromised state, PLWH/PEH with SUD are also more susceptible to other comorbidities, including tuberculosis, hepatitis B and C, syphilis, and a host of other diseases (Grief & Miller, 2017). They are frequently also more vulnerable given their social determinants of health, as a large percentage of the population belongs to racial or ethnic minority groups, has decreased health literacy, and faces infestations,

the elements, and overcrowding that can make them more susceptible to disease (Grief & Miller, 2017).

Summary of the Literature Review

To reiterate, it has been not easy to engage and retain PLWH who experience homelessness and SUD in primary care (Howell et al., 2018 & Gaur et al., 2010). This review provides insight into how providers and systems can engage and retain patients in care by recognizing barriers (including housing instability, social determinants of health, and difficult-to-follow ART regimens) and guiding to navigate those barriers. This is an exciting change from more antiquated approaches to medicine that might have inadvertently placed blame on the patient for treatment nonadherence.

The literature shows that to support PLWH and PEH, interventions are required both at the provider and at the community/systems level. For example, at the community level, family intervention and support reduced condomless sex and decreased the risk for HIV among adolescent males (Jemmott et al., 2019). As specialty and primary care become increasingly integrated for complex illnesses at the systems level, barriers to care for these patients will begin to decrease. Meanwhile, providers need to have a high level of understanding around HIV, homelessness, and other key topics, along with the ability to connect patients with other clinical specialties/experts (Greene et al., 2018).

The reviewed studies provide insight into the difficulties that PLWH and PEH experience when it comes to linkage to and retention in care and medication adherence (Holtzman et al., 2015). Despite these difficulties, the promise of interventions like nurse navigation, especially under the constructs of an existing theory like Andersen's Behavioral Model (ABM) which has been modified specifically for HIV care (to be discussed in further detail at a later point in this

paper), created an excellent opportunity for this ART-DOT program evaluation (Asamsama et al., 2017; Holtzman et al., 2015).

Unfortunately, most of these studies focus primarily on individual components of retention, as opposed to communities and policies that may play a more significant role than the patient-provider relationship itself (Marx et al., 2011). Except for one study, which focused on patients over fifty, it is important to note that much of the patient population studied included predominantly young, heterosexual males and thus may not be as applicable to a wide range of demographic determinants.

Regardless of the limitations, the primary take-away from this review is the importance of providing support for PLWH and PEH through a multi-faceted approach. Case management and nurse navigation promote treatment adherence, recognizing that adherence improves when patients experience a trusting relationship with their care team. Additionally, stable housing has been shown to be one of the best indicators of treatment and care engagement among PLWH. In summary, when PLWH are properly housed and actively engaged by nurse-led teams, they are more likely to become virally suppressed.

Theoretical Framework

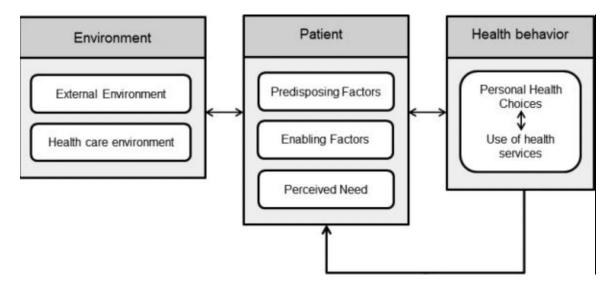
While conducting the literature review, the modified Andersen's Behavioral Model (mABM) stood out as an appropriate theoretical framework that could be used to guide this project (Figure 1, Figure 2) (Holtzman et al., 2015). Holtzman et al. (2015) modified the ABM by mapping barriers and facilitators that are specific to HIV care retention and medication adherence. The original ABM helps explain determinants of health – both individual and contextual - dividing them into factors that predispose (such as age, sex, education, beliefs), enable (finances, transportation, health insurance), or suggest need (symptoms, community

health, one's own view of wellness) (Babitsch et al., 2012). By adapting the more specific-to-HIV mABM to this project, a framework for piecing together the various social determinants of health affecting patients involved with the ART-DOT program emerged.

The DNP student used the mABM from Holtzman et al. as a framework to assess the environmental, individual/patient, and health behaviors that impact ART-DOT and how the program is accessed (Holtzman et al., 2015; Travers et al., 2020). Figure 1 shows Andersen's model, adapted for ART. Figure 2 then expands on Figure 1, by showing barriers and facilitators mapped to the model. The DNP student used these barriers and facilitators as a guide in designing the project to evaluate efficacy of the ART-DOT program.

Figure 1

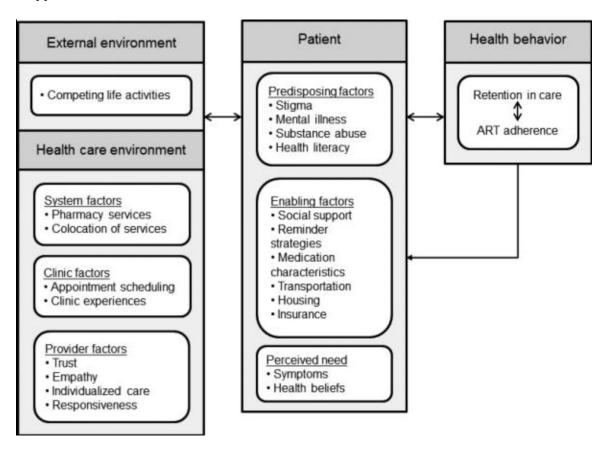
Diagram of Andersen's Behavioral Model Adapted for ART Adherence



Note. Image taken from Holtzman et al., 2015. Screenshot included with permission from Holtzman, C. (personal communication, March 9, 2023).

Figure 2

Mapped Barriers and Facilitators to Retention and Adherence



Note. Image taken from Holtzman et al., 2015. Screenshot included with permission from Holtzman, C. (personal communication, March 9, 2023).

Purpose of the Project and Objectives

After completing the literature review and determining a theoretical framework to understand the DNP project, a project purpose and objectives were outlined. The project aimed to assess the outcomes of an ART-DOT program at one urban clinic caring for PLWH who experience homelessness and SUD. Based on the purpose of this project, measurable objectives, and expected outcomes were identified.

1. Evaluate the ART-DOT program with electronic health record (EHR) data from 33 patients currently or previously enrolled in ART-DOT at the Center.

- a. Review EHRs of 33 ART-DOT patients to obtain most recent HIV-1 viral load and determine whether enrolment in the ART-DOT program was associated with suppressed viral load and/or viral undetectability (viral suppression: <200 copies HIV per milliliter of blood; viral undetectability: undetectable).
- b. Review EHRs of 33 ART-DOT patients to obtain and assess data that may have a significant impact on viral load and HIV wellness including: CD4 count, dates of recent primary care team visits, and demographics to consider whether outside factors may contribute to the success or failure of ART-DOT.
- 2. Evaluate the ART-DOT program through the patient perspective.
 - a. Conduct patient surveys using a sample of ten of the 33 patients reviewed in chart review (see Appendix F).

The expected outcomes for this DNP project were:

- Viral load of persons in the ART-DOT program would be comparable to the recommended level of viral suppression of <200 in at least 50% of the patient cohort.
- 2. Discovery of other variables, both as indicated in the EHR and in patient surveys that have nonrandom associations with HIV and suppressed (or unsuppressed) viral load.
- 3. At least 80% of patients would report satisfaction with the ART-DOT program.

Methods

The Framework for Program Evaluation in Public Health was used as outlined by the Center for Disease Control and Prevention (1999) to plan this project (Figure 3). Before beginning the project, stakeholders at the Center were engaged. The DNP student interviewed all ART-DOT providers at the Center and asked for feedback and recommendations on project design. From there, each project step was executed, keeping the CDC standards in mind (as

shown in Figure 3), precisely: utility, feasibility, propriety, and accuracy. The remaining steps are found in the remainder of the paper (i.e., Describe the Program is found in the following three sections).

Figure 3

Framework for Program Evaluation in Public Health



Note: Program Performance and Evaluation Office. (1999). Framework for program evaluation in public health. *Centers for Disease Control and Prevention*. https://www.cdc.gov/evaluation/index.htm

Project Site and Population

The site of this evaluation was an urban clinic in the Northeast (the Center) that provides integrated primary care services to more than 11,000 individuals annually who experience homelessness. The Center operates over 30 sites, including shelters, day centers, street and van outreach programs, and motels (citation redacted for privacy). Patients enrolled at the Center

receive care regardless of "race, color, religion, gender, gender identity, sexual orientation, age, disability, veteran status, military service, national origin, immigration status, genetic information, or marital status" (citation redacted for privacy). The Center's focus on delivering high-quality, equitable healthcare is known to have saved countless lives (citation redacted for privacy).

This project took place in the urban Center and in the outdoor area around the Center, where PEH frequently gather. Typically, this area hosts between 100 and 500 persons who may be outside during the day. Outreach workers from the Center, the Department of Health, and various housing services and shelters are typically outside in this area during the day. This allowed for ease in surveying ART-DOT patients and enhanced safety, as the DNP student was never alone during data collection.

The ART-DOT Program

At the Center, when patients are diagnosed with HIV, they are referred to the "HIV Team" (team name changed for privacy), which seeks to provide them with "wrap-around services". Wrap-around services through the HIV Team include being paired with medical and housing case managers, access to nurses trained in HIV care, a primary care provider, and a licensed clinical social worker and psychiatrist.

In response to the chronic needs of PLWH in the area and to reduce community transmission of HIV, the HIV Team formed an "outreach team" in December 2018. The goal was to get the required daily ART directly into the hands of PLWH, who are also PEH with SUDs. This outreach team was based, in part, on the work of the late Dr. Paul Farmer, an advocate for medical justice for socio-economically disadvantaged PLWH. During his life, Dr. Farmer wrote extensively on the topic of "accompaniment", which "means being present on a

journey with someone and committing to help them stay well" (Harvard, 2011). The outreach team was designed to "accompany" the panel of high-risk PLWH as a commitment to their wellness and to the wellness of other high risk community members.

In January 2019, just one month after the formation of the outreach team, there was a "cluster outbreak", in which six individuals in the homeless community were diagnosed with HIV. Five of those six were included in the first panel of the newly formed outreach team to control the outbreak. Those patients were given medical and psychosocial support and the option to take daily ART-DOT. Daily contact was made by the outreach team, with the goal that a HIV Team staff member could provide the most vulnerable patients with connection to and retention in care. This impromptu program involved outreach team members walking and driving the streets in search of specific individuals and ensuring that everyone on the panel could take daily ART if they were willing. Later that year, to promote equity and inclusion, three additional individuals were included on the ART-DOT panel who had been previously diagnosed with HIV, including two monolingual Spanish speakers and a black transgender woman.

Despite the impressive efforts of the outreach team and their ART-DOT attempts, by 2021 there were 170 new HIV diagnoses in the surrounding homeless community. The ART-DOT program/outreach team and the HIV Team continued to add the most vulnerable patients to their panel in hopes of minimizing the outbreak. Individuals most at risk, including individuals who experienced chronic street homelessness, psychiatric disorders, substance use disorders, and those with detectable viral loads, were considered for ART-DOT rather than traditional clinic-based management.

As of April 2022, the HIV Team patient panel consisted of 349 patients, 151 of whom were virally suppressed, or 43.27%.

Criteria for Project Inclusion

Between inception of the ART-DOT program in December 2018 and a finalized list created in June 2022, there were 41 patients ever included on the panel. Of the 41 patients, 33 were eligible for inclusion in the project. Inclusion criteria were as follows: age 18 or older, not virally suppressed before beginning ART-DOT, chronic experience with street homelessness, at least one psychiatric disorder listed in the EHR (ICD 10 codes F01 – F10.99, F19.959 – F99.99) and at least one chronic substance use disorder listed in the EHR (ICD 10 codes F11 – F19.9).

All patients enrolled in ART-DOT since the program's inception who met the above criteria were included in the chart review portion of this project. The nine patients deemed eligible are as follows: six who passed away, one who became restricted from the Center's services, and two who did not have a documented SUD. This resulted in the inclusion of 33 patient participants rather than 41.

Measurement

Data for this project was collected from two sources: the EHR of 33 patients and patient surveys with ten of those 33. While the primary measure of interest was most recent viral load, other measures were added to the EHR list of measures and patient survey questions to collect relevant data frequently tracked by and of interest to the HIV Team (HIV Team key indicators, etc.).

The DNP student developed a list of 23 health measures with recommendations from HIV Team staff, to be extracted from the EHR on behalf of the 33 ART-DOT patients. This list included the most recent viral load, dates of most recent primary care team visits (nurse and primary care doctor, separately), most recent CD4 count, demographics, comorbidities, immigration status, recent incarceration history, date of HIV diagnosis, and type of HIV

medication most recently prescribed. The DNP student extracted this deidentified data from the EHR using a secure computer and stored for analysis on a secure, password-protected internal server.

Additionally, a patient survey was developed with 47 multiple choice questions (with the option for patients to add verbal details to each answer if desired) and two open-ended questions to be carried out in a verbal dialogue format. Questions were developed, keeping the domains of the mABM framework in mind. For example, the question "During the past month, how often would you say you have injected non-prescribed drugs" was associated with the mABM "Patient" domain and category of "Predisposing factors: Substance use" (see Figure 2) (Holtzman et al., 2015). The survey answers were entered into an Excel spreadsheet in real time and stored on a secure, password-protected internal server.

Data Collection Procedures

Data collection began in October 2022 and was completed in November 2022. Analysis occurred once data was collected in November 2022 (see Appendix D for the timeline table).

Chart Reviews

EHR chart reviews were conducted for n=33 patients enrolled in the ART DOT program since its inception who met the criteria for this project. Objective data was collected from the EHR using the list of 23 measures described in the Measurement section above and was entered into a secure spreadsheet using a pre-determined drop-down menu created with the Excel Data Validation tool (see Appendix E).

Identifiable information was viewed only by the DNP student, and all recorded information was de-identified, and saved to a secure, password-protect internal server, known as the P-drive, in a folder to which only the DNP student has access.

Patient Surveys

The following are the actualization steps that were used for the patient survey portion of this project:

- 1. Participants were contacted by a HIV Team outreach staff member over the phone or in person, who invited the patient to participate in a survey with the DNP student.
- The outreach staff member introduced the DNP student (if the survey was to occur in person) or informed them that the DNP student would call on a secure line over the phone.
- 3. Using the template found in Appendix F, the DNP student asked the patient participant if they would be willing to participate in a brief survey. If they agreed to participate and the survey was to be conducted in person, they were invited to a private room. If the survey was performed over the phone, the DNP student conducted the survey from a private office.
- 4. The patient was presented with an IRB-approved consent form and was informed that they could stop the survey at any time, could decline to answer any questions, would receive some form of compensation regardless, and that participation would in no way impact their care with the HIV Team.
- 5. Once the consent form was signed or verbally agreed to, the survey occurred. The DNP student recorded answers in an excel spreadsheet with curated drop-down answers but allowed the patients to add verbal details and free-typed qualitative answers when the participant provided them. Three interviews were completed in person and seven were completed over the phone.

6. Upon survey completion, the patient participant was provided with compensation. All participants fully completed the survey and were compensated with a \$25.00 gift card. Three were given their gift cards in person by the DNP student, two were given their gift cards in person by a HIV Team staff member, and five were given their gift cards through the mail.

To conduct the patient surveys, a list of the 33 ART-DOT patients was generated to display a random order. The DNP student or HIV Team staff member made one attempt to contact each person on the randomly ordered list. If the patient declined or could not be contacted, the next person on the list was contacted, and so-on, until ten patients had been surveyed. See Appendix A for the script that was used to recruit patients.

No HIV positive status or other private health information or specific conditions of patients were discussed prior to survey initiation. Each survey took 15 to 30 minutes to complete. Nine surveys were conducted on 11/11/2022, and one was conducted on 11/14/2022. Eight surveys were conducted in English, and two surveys were conducted in Spanish. See Appendix F for the survey questions both in English and in Spanish.

Data Analysis

EHR

All quantitative answers from EHR chart reviews were entered into pivot tables using Excel spreadsheets. Descriptive statistics, specifically frequency, and percentage, were used to describe the data.

First, viral load levels were compared with acceptable levels of viral suppression, or <200, and categorized as not virally suppressed or virally unsuppressed. The virally suppressed group was further categorized into detectable and undetectable viral loads.

Second, all other variables (i.e., race, gender, etc.) were put into pivot tables to compare with viral suppression. Fisher exact tests were then used to determine whether there were any nonrandom associations between viral suppression and all other categorical variables.

Patient Surveys

Similarly, all quantitative answers from patient surveys were entered into pivot tables using Excel spreadsheets. Again, descriptive statistics (frequency and percentage) were used to describe the data. Because data was deidentified, answers were not compared with the patients' individual viral loads.

Both quantitative and qualitative survey answers were mapped to the mABM domains and subcategories to ensure that all questions/answers were relevant to the framework of the project.

Qualitative survey data from the two open-ended questions and any additional verbal detail that participants provided was reviewed for themes. This was done with both Microsoft Excel and Word, by mapping phrases to the mABM domains, including factors associated with the external and healthcare environment, patient behaviors, and health behaviors as well as to each domain's subcategories.

Ethical Considerations/Protection of Human Subjects

The University of Massachusetts, Amherst (UMass) Internal Review Board (IRB) approval was obtained prior to initiating the DNP Project (see Appendix B). All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other guarantees, protects the privacy of patients' health information (Health and Human Services Department, 2013). Additionally, the DNP student followed the Standards of Care for practice in a primary care office (NIH, 2023). All information collected in this program

evaluation are aggregated, deidentified data from the project participants and do not include any patient identifiers. The DNP student received project approval through the University of Massachusetts (UMass) Institutional Review Board (IRB) and through the HIV Team Medical Director in September 2022.

The risk to patients participating in this project was no different from the risks to patients receiving standard ART-DOT care. No electronic files containing identifiable patient information were stored or retained except for consent forms signed by patients who were surveyed. These forms are kept on a secure server at the Center in a password-protected folder only accessible to the DNP student. They will be kept for five years and then destroyed.

Cost-Benefit Analysis

Individuals who are patients of the ART-DOT program and participated in the patient survey were compensated with a \$25.00 Visa gift card. This amount was determined to be appropriate based on typical incentives patients receive in other studies at the Center, with the help of the HIV Team Medical Director and the IRB. This funding was provided through a scholarship that the DNP student received from CVS Pharmacy and came at no cost to the Center. The DNP student has no conflicts of interest to report with CVS Pharmacy. See Appendix C for Cost Table.

Results

This project took place in an urban clinic in the Northeast and in the surrounding community in which PEH frequently gather. 33 PLWH who are PEH with SUDs were included in the chart review, and ten patients were recruited for patient surveys.

Patient Characteristics

Table 3

Patient characteristics, broken into demographics and health characteristics, are described below in Table 3 and Table 4, respectively, as a percentage of the total 33 patients for whom data was collected.

Patient Demographics from the EHR Chart Review

Variable		N	%
Condon Identita	Female	12	36%
Gender Identity	Male	21	64%
	18-30	4	12%
	31-40	12	36%
Age	41-50	12	36%
	51-60	5	15%
	Unknown	8	24%
	Black or African American	5	15%
Race	White	18	55%
	Multiracial	1	3%
	American Indian or Alaska Native	1	3%
	Unknown	1	3%
Ethnicity	Hispanic or Latino	14	42%
	Not Hispanic o Latino	18	55%
D: 1 G 1	English	24	73%
Primary Language Spoken	Spanish	9	27%
	Evidence of Past Incarceration	20	61%
Incarceration History	No Evidence of Past Incarceration	13	39%

Table 4

Patient Health Characteristics from the EHR Chart Review

Variable		N	%
	Depressive disorder or episodes, regardless of severity or remission	21	64%
	Post-traumatic stress disorder	16	48%
	Anxiety disorder	11	33%
	Mood disorder	3	9%
	Other mental disorder	3	9%
	Bipolar disorder	3	9%
Psychiatric Comorbidities	Attention deficit hyperactivity disorder	2	6%
	Adjustment disorder	2	6%
	Nightmare disorder	1	3%
	Psychoactive substance-induced psychotic disorder	1	3%
	Delusional Disorder	1	3%
	Depressive disorder in remission	1	3%
	Hepatitis C, acute or chronic	21	64%
Physical/Medical	Personal history of other infectious and parasitic diseases	8	24%
Comorbidities	Latent Tuberculosis	3	9%
	Hepatitis B, chronic	1	3%
	Syphilis	1	3%
	Opioid use or dependence regardless of remission	30	91%
	Nicotine or tobacco use or dependence	19	58%
Substance Use Disorder Comorbidities	Other stimulant use, abuse, or dependence regardless of remission	16	48%
	Cocaine use, abuse, or dependence regardless of remission	14	42%
	Other psychoactive substance use, abuse, or dependence	9	27%
	Opioid use or dependence in remission	8	24%

	Sedative, hypnotic, or anxyolytic abuse or dependence	6	18%
	Cannabis use or dependence regardless of remission	2	6%
	Cocaine use, abuse, or dependence in remission	1	3%
	Other stimulant use, abuse, or dependence in remission	1	3%
Alcohol Use Disorder	No	27	82%
Comorbidity	Yes	6	18%
Date of HIV Diagnosis	1991 - 2000	4	12%
	2001 - 2010	5	15%
	2011 - 2017	2	6%
	2018	3	9%
	2019	8	24%
	2020	6	18%
	2021	5	15%

EHR Review of Viral Load Status

EHR review determined that 73% of ART-DOT patients were virally suppressed, and 42% were undetectable as of their most recently reported lab value (see Table 5).

Table 5

Viral Undetectability vs. Suppression

		Viral Suppression		
	Virally Undetectable	No	Yes	Total
No		9	10	19
Yes			14	14
Total		9	24	33

Relevant data was compared with viral suppression (e.g., gender and viral suppression) to assess other factors that may have impacted viral load. Using Fisher Exact Tests, two categories

were found to be statistically significant: CD4 (p < 0.001) count and most recent primary care provider (PCP) visit (p = 0.01). CD4 count is, by definition, correlated directly with viral suppression, and therefore its statistical significance was not further discussed in this paper. See Table 6 for data comparing the most recent primary care visit with viral suppression.

Table 6 *Primary Care Provider Visit and Viral Suppression*

Date of Most Recent HIV Team	Viral Suppression			
Primary Care Provider Visit	No	Yes	Total	
2019	1		1	
2020	1		1	
2021	2	1	3	
2022	5	23	28	
Total	9	24	33	

Note. p = .013. Significant nonrandom association of recency of PCP visit with viral suppression.

Also notable, though not statistically significant, is data found in Table 7 of viral suppression compared with housing status, which shows that 13 of 24 (54%) virally suppressed patients are housed either in supportive housing or in housing without supportive services. This suggests that patients with stable housing may be more likely to experience viral suppression.

Table 7

Housing and Viral Suppression Viral Suppression **Housing Status** No Yes Total 3 3 Street 6 Shelter 1 2 3 Doubled Up 2 2 Transitional housing or Residential 2 3 1 treatment program Supportive housing 2 9 11 Housing with no supportive 2 6 8 services 9 Total 24 33

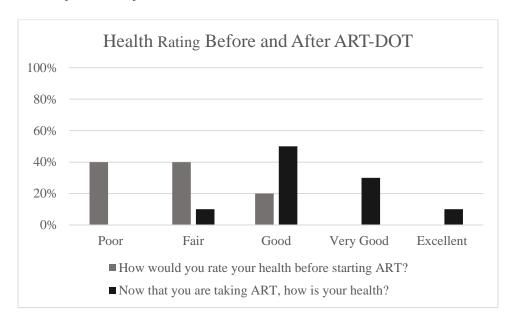
No other data was found to have potential nonrandom associations with viral suppression. Nonsignificant variables included: date of HIV diagnosis, psychiatric comorbidity, medical comorbidity, substance use disorder comorbidity, incarceration history, type of ART prescribed, gender identity, race, ethnicity, immigration status, and primary language status. Limitations in statistical significance are to be expected, given the small sample size used in this project. This project aimed to assess program outcomes - not to prove the correlation of categorical variables with viral suppression. Because these variables are of interest to the Center and potential relevance to this population's viral suppression, they were included in the chart review.

Patient Surveys

Data from patient surveys were not compared with viral suppression and were therefore not assessed for statistical significance. Instead, it was evaluated with descriptive statistics (frequency and percentage). Notable findings are as follows.

80% of surveyed patient participants reported that they like the ART-DOT program (20% did not answer specifically whether they do or do not like it), and 70% said that taking ART makes them feel better. 80% of patients described their health as "Fair" or "Poor" before initiating ART with the ART-DOT program. However, no patients reported their health as being "Poor" since initiating ART with the ART-DOT program. 90% of patients reported their own health as being "good" or better, and 40% described their health as "very good" or "excellent" since participating in the program (see Figure 4).

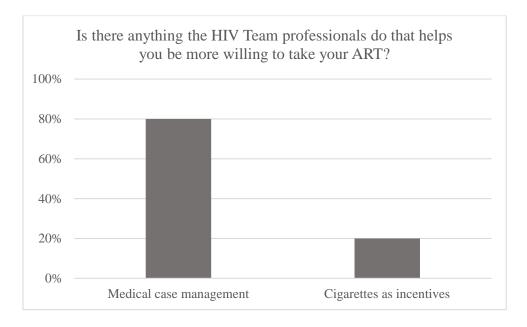
Figure 4Rate Health Before and After ART-DOT



80% of patients pointed to case management from the HIV Team professionals as being what helps them be more willing to take their ART (the remaining 20% referred to specific incentives provided by case managers) (see Figure 5). 50% said that the main way to help health programs improve the lives of people living with HIV in this community is with more/better outreach case management. Other recommendations included more/better community education, support groups, and more/better access to clean needles/syringes/other injection supplies.

Figure 5

How HIV Team Professionals Help with ART



70% of the cohort did not miss any ART doses over the last three days, and 40% did not miss any ART doses over the last month (see Figure 6). 50% of patients said that what helps them most to take ART on time is an established routine, followed by a support person (30%) and feeling well (20%) (see Figure 7). Patients gave reasons for not taking their medications as being illness (30%), pharmacy problems, (30%), substance use (30%), and forgetting (10%) (see Figure 8). 40% of patients stated that, in the past year, they have had problems accessing ART on time because they could not reach the Center. 100% of patients surveyed have a person in their life who can support them in their HIV diagnosis. 40% of them stated that this support person is a staff member of the HIV Team.

Figure 6

Missed ART Doses

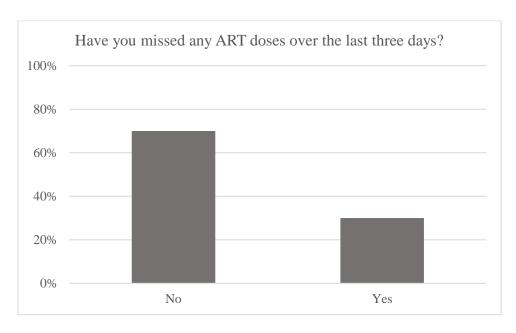


Figure 7

ART Reminder Strategies

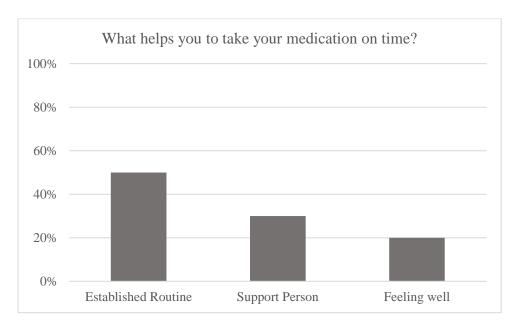
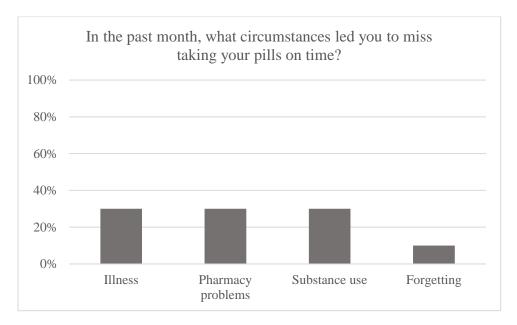


Figure 8

Reasons for Missing Doses



70% said they currently use illicit drugs. Of patients who inject drugs, 100% of them inject some form of opioid (either fentanyl or heroin), usually in conjunction with other drugs. In addition, of patients who inject drugs, all inject at least once a day, and 2/3 inject at least six times per day. 40% stopped using injection drugs since ART-DOT enrolment.

Qualitative Results

During the patient survey, patients could add verbal detail to any question to allow for a qualitative element. Additionally, questions 22 and 47 were open-ended. Question 22 was "Do you have any suggestions for ways that health programs can help improve the lives of people living with HIV in this community?" and question 47 was "Is there anything else that you would like to say about your diagnosis, HIV in this community, the HIV Team, ART, DOT, or any other topic we have discussed today?". Answers to questions 22 and 47 and any other relevant verbal details were reviewed for themes by mapping answers to the mABM (see Figure 2).

Environment

The environment domain is broken into external and health care. Of the external environment, several mentioned competing life activities, especially regarding the hustle of substance use. Of the healthcare environment, patients mentioned system, clinic, and provider factors. For system factors, patients discussed difficulties accessing their ART (when not in the ART-DOT program) because of pharmacy problems but appreciated that the center has an inhouse pharmacy and colocation of services, such that the Center serves as a one-stop for all their healthcare needs. For clinic factors, patients noted that, without DOT, it could be difficult to access ART and other care because the Center closes during the evenings and on weekends. For provider factors, patients spoke very highly of the HIV Team and of the trusting relationship held with the HIV Team Staff with phrases like "These people saved my life during these years" and "There's not one bad word I could say about anyone at [the Center] and especially at the HIV Team". Suggesting that HIV Team staff are empathetic, patients said, "they sincerely care about us" and "they're proud of me...they're out to help me... you can't find no other team like that but here." They also spoke of individualized care, saying "[My HIV Team PCP] is beside me a hundred percent and gives me advice constantly.", "If it wasn't for the HIV Team, I'd probably be dead.", and "I think [ART-DOT] is probably one of the best things that [the Center] has come up with.". They also spoke of the HIV Team's responsiveness, saying "If I have a problem, I call them and within ten minutes they call back and help with whatever. And that's the truth.".

Patient

In the patient domain, patients spoke of predisposing factors, enabling factors, and perceived needs. Patients had much to say about predisposing factors, which can be broken into stigma, mental illness, substance use, and health literacy. Several comments combined the

themes of stigma and health literacy, as shown by "I just wish people would know that it's not as bad as they think it is... you can be a big part of stopping it by telling people, 'Hey, I have it, and I'm healthy."". Patients also combined themes of mental illness and substance use comorbidities, stating gratitude for the HIV Team's work to help them achieve treatment beyond the ART. After speaking about a substance use disorder now in remission, one patient said "I love this place, because nowhere else in the US will you find something like the HIV Team that goes out on the street and brings meds. We just need more people doing the job you're doing."

Enabling factors include social support, reminder strategies, medication characteristics, transportation, housing, and insurance. Patient discussed social support with comments like "[I tell] close friends [about my HIV status]... just in case cause I get high so often. I'd be devastated if I gave anybody the bug even if it was by accident" and "It would be nice if we could...make something where maybe we can help people who are confused or are embarrassed by [HIV] or just depressed thinking their life is over. I would love to be some type of support to let people know that it's not the end of your life. It could be the beginning of your life." Patients discussed reminder strategies at length, referring to partners, schedules, and, primarily, the HIV Team. Of medication characteristics, two patients mentioned side effects making it difficult to take ART, and of transportation, one mentioned difficulty taking ART due to difficulty getting to the Center. A few patients spoke of housing, noting that the HIV Team guided them to achieve housing and that it is easier to take ART when housed. One patient mentioned insurance and that, after medications were stolen from the patient's backpack, they had to go on a different type of ART for the rest of the month because insurance would not cover a refill.

Perceived need includes symptoms and health beliefs. As discussed previously, during the quantitative portion of the survey, most patients said that taking ART helps them to feel

better. Regarding health beliefs, patients said, "HIV used to be the worst words to hear, but now it's like, ok I have it and I can move on from it."

Health Behavior

The health behavior domain is divided into retention in care and ART adherence. Several statements combined the two categories, with phrases like "I don't know anybody that's not hooked up with [the Center]...Just having nurses that give meds to people, it helps people" and "[HIV Team nurses] would come down and give [ART] to me. They're just wonderful. If I asked them to come here every day to take my meds, they really would" and "I just take one pill a day and I'm healthy." One patient gave a recommendation: "If they're out there and not taking their meds, have a nurse go look for them with their meds so they can start taking it."

Discussion

Expected Outcomes

This DNP project aimed to assess the outcomes of an ART-DOT program at one urban clinic caring for people living with HIV who are also PEH with SUDs. The program was evaluated with data from the EHR and patient surveys. Expected outcomes and actual outcomes are as follows.

The first expected outcome was that the viral load of persons in the ART-DOT program would be grossly comparable to the recommended level of <200 for at least 50% of patients. While all patients began ART-DOT with uncontrolled HIV viral loads, a remarkable 73% of patients were found to be virally suppressed with a viral load of <200 in their most recent lab draw. Still more impressive is that 42% of the cohort was found to be "undetectable", suggesting a viral load so low that the test cannot detect it. This is momentous, given that PLWH who are PEH are known to have an approximate average viral suppression rate of 32% (Land, 2018).

PLWHs who are stably housed have an average viral suppression rate of 75% (Land, 2018). In other words, PLWH/PEH who participate in ART-DOT have nearly the same outcomes as PLWH who are stably housed. As one patient stated, "[The HIV Team is my primary support] since I became homeless until the last minute I became not homeless. Because of them my life is the way it is right now."

The second expected outcome was that the DNP would discover other variables, both as indicated in the EHR and as indicated in patient surveys, that have nonrandom associations with HIV and suppressed (or unsuppressed) viral load. The only variable with a potential nonrandom association with viral suppression was having a recent with HIV Team PCPs. This is important, because it shows that patients engaged and retained in primary care are more likely to be virally suppressed. The patient survey also confirmed this, as 80% of patients surveyed said that case management from HIV Team professionals helps them be more willing to take their ART. Importantly, this may be associated with 40% of patients no longer using injection drugs since engaging in ART-DOT. Patients engaged and retained in care may be more likely to reduce injection drug use.

Two notable, though nonsignificant, findings were the association of viral suppression with housing and, separately, with age. 54% of virally suppressed patients reported having stable housing – with or without supportive services. This echoes findings in the literature review suggesting that stable housing is associated with viral suppression. It was also found that no patients older than age 60 were included in the ART-DOT cohort. This is of utmost importance because the literature suggests that PEH have a life expectancy of 56 years for males and 52 years for females (Romaszko et al., 2017). As mentioned previously, six patients from the original cohort of 41 passed away before data for this project could be reported. This made the

project seem even more urgent, as the DNP student saw firsthand the vulnerability of PLWH who are PEH with SUDs.

The third expected outcome was that ART-DOT patients would report at least 80% satisfaction with the ART-DOT program. 80% of patients surveyed reported liking the program, and 20% did not respond whether they did or did not like it. Patients had, as one participant put it, "not one bad word to say...about the HIV Team". And, from another, "These people saved my life during these years, so I have no complaints or anything bad to say about them."

Theoretical Framework Connection

The literature review and theoretical framework, mABM, guided the creation of the project and the reporting of results. Both the EHR review and the patient survey was created with the domains of the mABM in mind. After mapping the qualitative data to the mABM, several key themes emerged. These key themes are reported here based on categories that had the most matched responses. These include individualized care, reminder strategies, stigma, ART adherence, and substance use. Each of these themes had a meaningful impact on how patients experience their HIV and their ability to achieve viral suppression with ART. Unsurprisingly; they are all themes described in the literature review as impacting viral suppression in PLWH who are PEH.

Limitations and Future Research

While the findings align with the expected outcomes, the project had several limitations. First, the sample size of 33 patients in the entire ART-DOT cohort (and ten who were interviewed) is too small to draw generalized conclusions. Future research with a larger sample of patients will ensure accuracy and may prove feasibility for other clinical settings.

Second, patients began receiving ART-DOT in January 2019, and this project is reported in April 2023. Future longitudinal research is indicated to gain long-term insight into how patients fare during and after the program. Indicators of interest include viral suppression, housing status, and connection and retention to primary care.

Third, this project was meaningfully limited by external factors that affected the ART-DOT program. Within three months of program initiation, the Center and the community were profoundly impacted by the COVID-19 Pandemic. This led to new difficulties for PLWH, who now had fewer places to go, were vulnerable to the Sars-CoV-2 virus, and whose care providers were forced to focus on other areas of infectious disease (Brody et al., 2021). PLWH, especially those with decreased CD4 counts, were particularly vulnerable to the severe effects of COVID-19 (Spinelli et al., 2022). In addition, during this project, the area around the Center where PEH typically stay (and where HIV Team outreach staff typically find their patients) was "swept" on multiple occasions. In these traumatic instances, the city would require PEH to move out of the area around the Center - typically without any notice. Usually, the city did not have another housing solution for the PEH, so they were required to leave the area where they have good access to care and support, go to somewhere else potentially less safe, and leave behind their belongings which were eventually destroyed by the city (Qi et al., 2022). This infraction on human rights severely inhibited the progress of the ART-DOT program, which, after each sweep, essentially had to start from the beginning – sending HIV Team outreach workers across the city to find patients from the cohort that needed to be taking ART.

Fourth, there are limitations with the patients themselves. The DNP student noted that it could often be challenging to engage and retain PEH in care, especially if they are engaging in

substance use. Several patients were in and out of the hospital, treatment facilities, and incarcerated during the project, making continuity of care more difficult to achieve.

Conclusions

The primary outcome of importance for this program evaluation is that a remarkable 73% of the ART-DOT cohort were virally suppressed, and 42% were found to be "undetectable. Patients engaged and retained in primary care were more likely to be virally suppressed, and 80% of patients surveyed said that case management from HIV Team professionals helped convince them to take their ART. The majority (54%) of virally suppressed patients had stable housing.

Six patients from the original cohort of 41 passed away before data for this project could be reported, making the project feel even more urgent, as the DNP student saw firsthand the vulnerability of PLWH who are PEH with SUDs.

The review of literature for this project provided insight into the importance of providing support for PLWH and PEH through a multi-faceted approach, including access to case management. Similarly, results from this DNP project suggest that when outreach teams actively engage PLWH who are PEH with SUDs, they are more likely to become virally suppressed and, subsequently, undetectable. Results from this project matched or exceeded expected outcomes, suggesting efficacy of the ART-DOT program at the Center.

This project, though limited, shows that ART-DOT can be an effective tool to achieve viral suppression for PLWH who are PEH with SUDs. Urban clinical settings with similar populations of PEH with HIV may benefit from instituting ART-DOT programs. This project lays a solid foundation for future research that can use evidence-based approaches to study ART-DOT and its long-term efficacy further.

References

- Aquino, G., Byrne, M., Dorsey, K., Siegel, M., Mitchell, O., Grant, S., Fox, A., Lum, G., Allston, A., Monroe, A., & Doshi, R. (2021). Examining retention in HIV care and HIV suppression on housing services intake at a Washington, DC community-based organization. *Journal of Community Health*, 46, 861-868. https://doi.org/10.1007/s10900-020-00959-w
- Asamsama O.H., Squires, L., Tessema, A., Rae, E., Hall, K., Williams, R., & Benator, D. (2017).

 HIV nurse navigation: Charting the course to improve engagement in care and HIV virologic suppression. *Journal of the International Association of Providers of AIDS Care*, 16(6), 603-607. https://doi.org/10.1177/2325957417732835
- Babitsch, B., Gohl, D. & von Lengerke, T. (2012). Re-visiting Andersen's behavioral model of health services use: A systematic review of studies from 1998—2011. *Psychosocial Medicine*, 9. https://doi.org/10.3205/psm000089.
- Baggett, T.P., Hwang, S.W., O'Connell, J.J., Porneala, B.C., Stringfellow, E.J., Orav, E.J., Singer, D.E., & Rigotti, N.A. (2013). Mortality among homeless adults in Boston shifts in causes of death over a 15-year period. *Jama Internal Medicine*, 173(3), 189-195.
- BHCHP. (2014). *Medicine that matters*. Boston Healthcare for the Homeless Program. https://www.bhchp.org/
- Brody, J.K., Rajabiun, S., Allen, H., Joslyn, S., & Baggett, T. (2021). Enhanced telehealth case management plus emergency financial assistance for homeless-experienced people living with HIV during the COVID-19 Pandemic. *American Journal of Public Health*, 111, 835-838. https://doi.org/10.2105/AJPH.2020.306152
- Cabral, H.J., Davis-Plourde, K., Sarango, M., Fox, J., Palmisano, J., & Rajabiun, S. (2018). Peer

- support and the HIV continuum of care: Results from a multi-site randomized clinical trial in three urban clinics in the United States. *AIDS and Behavior*, 22(8), 2627-2639. https://doi.org/ 10.1007/s10461-017-1999-8
- Cassimatis, I.R., Miller, E.S., Benes, L., Levesque, J., & Yee, L.M. (2021). Housing instability is associated with failure to achieve virologic control among pregnant individuals with HIV. *American Journal of Obstetrics & Gynecology MFM*, 3(5), 100406.

 https://doi.org/10.1016/j.ajogmf.2021.100406.
- Dombrowski, J.C., Galagan, S.R., Ramchandani, M., Dhanireddy, S., Harrington, R.D., & Moore, A. (2019). HIV care for patients with complex needs: A controlled evaluation of a walk-in, incentivized care model. *Open Forum Infectious Diseases*, 6(7), ofz294. https://doi.org/10.1093/ofid/ofz294
- Fuster, D., & Gelberg, L. (2019). Community screening, identification, and referral to primary care, for hepatitis C, B, and HIV among homeless persons in Los Angeles. *Journal of Community Health*, 44(6), 1044-1054. https://doi.org/10.1007/s10900-019-00679-w
- Gaur, A.H., Belzer, M., Britto, P., Garvie, P.A., Hu, C. Graham, B., Neely, M., McSherry, G., Spector, S.A., & Flynn, P.M. (2010). Directly observed therapy (DOT) for nonadherent HIV-infected youth: Lessons learned, challenges ahead. *AIDS Research and Human Retroviruses*, 26(9), 947-953. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957634/
- Glynn, T.R., Mendez, N.A., Jones, D.L., Dale, S.K., Carrico, A.W., Feaster, D.J., Rodriguez, A.E., & Safren, S.A. (2021). Trauma exposure, PTSD, and suboptimal HIV medication adherence among marginalized individuals connected to public HIV care in Miami.

 **Journal of Behavioral Medicine, 44, 147-158. https://doi.org/10.1007/s10965-020-00191-

- Greene, M.L., Tan, J.Y., Weiser, S.D., Christopoulos, K., Shiels, M., O'Hollaren, A., Mureithi E., Meissner, L., Havlir, D., & Gandhi, M. (2018). Patient and provider perceptions of a comprehensive care program for HIV-positive adults over 50 years of age: The formation of the Golden Compass HIV and aging care program in San Francisco. *PLoS ONE*, 13(12), 1-19. https://doi.org/10.1371/journal.pone.0208486
- Grief, S.N. & Miller, J.P. (2017). Infectious disease issues in underserved populations. *Primary Care: Clinics in Office Practice*, 44(1), 67-96. https://doi.org/10.1016/j.pop.2016.09.011
- Hanrahan, N.P., Rolin-Kenny, D., Roman, J., Kumar, A., Aiken, L., & Blank, M. (2011).
 Promoting self-care management among persons with serious mental illness and HIV.
 Home Health Care Management & Practice, 23(6), 421-427.
 https://doi.org/10.1177/108482231
- Harvard. (2011, May 25). Paul Farmer: "Accompaniment" as policy. *Harvard Magazine*. https://www.harvardmagazine.com/2011/05/paul-farmer-accompaniment-as-policy
- Health and Human Services Department. (2013). Modifications to the HIPAA privacy, security, enforcement, and breach notification rules. *Federal Register: The Daily Journal of the United States Government*, 2013(01073), 5556-5702.
 - $\frac{https://www.federalregister.gov/documents/2013/01/25/2013-01073/modifications-to-the-hipaa-privacy-security-enforcement-and-breach-notification-rules-under-the}{}$
- HIV.gov. (n.d.). *HIV/AIDS glossary: Directly observed therapy*. US Department of Health and Human Services. https://clinicalinfo.hiv.gov/en/glossary/directly-observed-therapy-dot
- HIV.gov. (2022). *HIV treatment overview: Why is HIV treatment important?* US Department of Health and Human Services. https://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/hiv-treatment-overview/

- Holtzman, C., Shea, J.A., Glanz, K., Jacobs, L.M., Gross, R., Hines, J., Mounzzer K., Samuel, R., Metlay, J.P., & Yehia, B.R. (2015). Mapping patient-identified barriers and facilitators to retention in HIV care and antiretroviral therapy adherence to Andersen's Behavioral Model. *AIDS Care*, 27(7), 817-828.
 https://doi.org/10.1080/09540121.2015.1009362
- Honer, W.G., Cervantes-Larios, A., Jones, V.A., Vila-Rodriguez, F., Montaner, J.S., Tran, H.,
 Nham, J., Panenka, W.J., Lang, D.J., Thornton, A.E., Vertinsky, T., Barr, A.M.,
 Procyshyn, R.M., Smith, G.N., Buchanan, T., Krajden, M., Krausz, M., Macewan, G.W.,
 Gicas, K.M., Leonova, O., Langheimer, V., Rauscher, A., & Schultz, K. (2017). The
 hotel study—clinical and health service effectiveness in a cohort of homeless or
 marginally housed persons. *La Revue Canadienne Psychiatrie*, 62(7), 482-492.
 https://doi.org/10.1177/0706743717693781
- Howell, E.M., Kigozi, N.G., & Heunis, J.C. (2018). Community-based directly observed treatment for TB patients to improve HIV services: A cross-sectional study in a South African province. *BMC Health Services Research 18*, 255. https://doi.org/10.1186/s12913-018-3074-1.
- Jemmott, L.S., Jemmott, J.B., Chittamuru, D., & Icard, L.D. (2019). Effects of a sexual HIV risk reduction intervention for African American mothers and their adolescent sons: A randomized controlled trial. *Journal of Adolescent Health*, 65(5), 643-650. https://doi.org/10.1016/j.jadohealth.2019.05.017
- Jones, A.A., Gicas, K.M., Seyedin, S., Willi, T.S., Leonova, O., Vila-Rodriguez, F., Procyshyn, R.M., Smith, G.N., Schmitt, T.A., Vertinsky, T., Buchanan, T., Rauscher, A., Lang, D.J., MacEwan, W., Lima, V.D., Montaner, J.S.G., Panenka, W.J., Barr, A.M., Thornton,

- A.E., & Honer, W.G. (2020). Associations of substance use, psychosis, and mortality among people living in precarious housing or homelessness: A longitudinal community-based study in Vancouver, Canada. *Plos Medicine*, *17*(7), e1003172. https://doi.org/10.1371/journal.pmed.1003172.
- Klimas, J., Dong, H., Fairbairn, N., Socias, E., Barrios, R., Wood, E., Kerr, T., Montaner, J., & Milloy, M. (2018). Eligibility for heroin-assisted treatment (HAT) among people who inject opioids and are living with HIV in a Canadian setting. *Addiction Science & Clinical Practice*, 13(3). https://doi.org/10.1186/s13722-017-0104-y.
- Land, E. (2018, October 2). Homelessness linked to HIV infection and low rates of viral suppression. *San Francisco AIDS Foundation*, para. 7.
- Lee, J.S., Safren, S.A., Bainter, S.A., Rodriguez-Diaz, C.E., Horvath, K.J., & Blashill, A.J. (2020). Examining a syndemics network among latino men who have sex with men.

 *International Journal of Behavioral Medicine, 27, 39-51. https://doi.org/10.1007/s12529-019-09831-1
- Marx, K.A., Malka, E.S., Ravishankar, J., & Schwartz, R.M. (2011). Measurement of retention in care among adults infected with HIV in an urban clinic. *AIDS Care*, 23(10), 1298-1304. http://dx.doi.org/10.1080/09540121.2011.555942
- NIH. (2023). Clinical practice guidelines. *National Center for Complementary and Integrative*Health: Resources for Health Care Providers.

 https://www.nccih.nih.gov/health/providers/clinicalpractice
- Norberg, A., Nelson, J., Holly, C., Jewell, S.T., Lieggi, M., & Salmond, S. (2019). Experiences of HIV-infected adults and healthcare providers with healthcare delivery practices that influence engagement in US primary healthcare settings: A qualitative systematic review.

- Database of Systematic Reviews & Implementation Reports, 17(6), 1154-1228. https://doi.org/10.11124/JBISRIR-2017-003756.
- Pan, Y., Metsch, L.R., Wang, W., Philbin, M., Kyle, T.L., Gooden, L.K., & Feaster, D.J. (2020).

 The relationship between housing status and substance use and sexual risk behaviors among people currently seeking or receiving services in substance use disorder treatment programs. *The Journal of Primary Prevention*, *41*, 363-382.

 Https://doi.org/10.1007/s10935-020-00597-x
- Parker, R., & Dykema, S. (2014). Differences in risk behaviors, care utilization, and comorbidities in homeless persons based on HIV status. Journal of the Association of Nurses in AIDS Care, 25(3), 214-223. https://doi.org/10.1016/j.jana.2013.06.004.
- Pecoraro, A., Royer-Malvestuto, C., Rosenwasser, B., Moore, K., Howell, A., Ma, M., & Woddy, G.E. (2013). Factors contributing to dropping out from and returning to HIV treatment in an inner-city primary care HIV clinic in the United States. *AIDS Care*, 25(11), 1399-1406. http://dx.doi.org/10.1080/09540121.2013.772273
- Program Performance and Evaluation Office. (1999). Framework for program evaluation in public health. *Centers for Disease Control and Prevention*.

 https://www.cdc.gov/evaluation/index.htm
- Qi, D., Abri, K., Mukherjee, R., Rosenwohl-Mack, A., Khoeur, L., Barnard, L., & Knight, K. (2022). Health impact of street sweeps from the perspective of healthcare providers.

 **Journal of General internal Medicine, 37, 3707-3714.
- Remien, R.H., Bauman, L.J., Mantell, J.E., Tsoi, B., Lopez-Rios, J., Chabra, R., DiCarlo, A., Watnick, D., Rivera, A., Teitelman, N., Cutler, B., & Warne, P. (2015). Barriers and facilitators to engagement of vulnerable populations in HIV primary care in New York

- City. *Journal of Acquired Immune Deficiency Syndromes*, 69(1), S16-S24. https://doi.org/10.1097/QAI.000000000000577
- Romaszko, J., Cyrnes, I., Draganska, E., Kuchta, R., Glinska-Lewczuk, K. (2017). Mortality among the homeless: Causes and meteorological relationships. *PLoS One*, *12*(12), e0189938. http://doi.org/10.1371/journal.pone.0189938.
- Salters, K.A., Parent, S., Nicholson, V., Wang, L., Sereda, P., Pakhomova, T.E., Kibel, M., Chau, W., Closson, K., Parashar, S., Barrios, R., Montaner, J.S.G., & Hogg, R.S. (2021). The opioid crisis is driving mortality among under-served people living with HIV in British Columbia, Canada. *BMC Public Health*, 21, 680. https://doi.org/10.1186/s12889-021-10714-y.
- Smith, E., & Badowski, M. (2021). Telemedicine for HIV care: Current status and future prospects. *HIV/AIDS: Research and Palliative Care*, *13*, 651-656. https://doi.org/10.2147/hiv.s277893.
- Spinelli, M., Jones, B., & Gandhi, M. (2022). COVID-19 outcomes and risk factors among people living with HIV. *Current HIV/AIDS Reports*, 19(5), 425-432. https://doi.org/10.1007/s11904-022-00618-w.
- Stoner, M.C.D., Haley, D.F., Golin, C.E., Adimora, A.A., & Pettifor, A. (2019). The relationship between economic deprivation, housing instability and transactional sex among women in North Carolina (HPTN 064). *AIDS and Behavior*, 23, 2946-2955. https://doi.org/10.1007/s10461-019-02611-8.
- Thompson, R.G., Elliott, J.C., Hu, M, Aivadyan, C., Aharonovich, E., & Hasin, D.S. (2017).

 Short-term effects of a brief intervention to reduce alcohol use and sexual risk among homeless young adults: results from a randomized controlled trial. *Addiction Research* &

- *Theory*, 25(1), 24-31. https://dx.doi.org/10.1080/16066359.2016.1193165.
- Tofighi, B., Sindhu, S.S., Chemi, C., Lewis, C.F., Dickson, V., Vaughan, V., Lee, J.D. (2019).

 Perspectives on the HIV continuum of care among adult opioid users in New York City:

 A qualitative study. *Harm Reduction Journal*, *16*(58). https://doi.org/10.1186/s12954-019-0329-z
- Travers, J.L., Hirschman, K.B., & Naylor, M.D. (2020). Adapting Andersen's expanded behavioral model of health services use to include older adults receiving long-term services and supports. *BMC Geriatrics*, 20(58). https://doi.org/10.1186/s12877-019-1405-7
- Walley, A.Y., Palmisano, J., Sorensen-Alawad, A., Chaisson, C., Raj, A., Samet, J.H., &
 Drainoni, M. (2015). Engagement and substance dependence in a primary care-based addiction treatment program for people infected with HIV and people at high-risk for HIV infection. *Journal of Substance Abuse*, *59*, 59-66.
 https://doi.org/10.1016/j.jsat.2015.07.007
- Wolfe, H.L., Baughman, A., Davoust, M., Martinez, L.S.S., Rajabiun, S., & Drainoni, M. (2021).

 Client satisfaction with community health workers in HIV Care Teams. *Journal of Community Health*, 46, 951-959. https://doi.org/1-.1007/s10900-012-00978-1
- Wu, K., Tie, Y., Dasgupta, S., Beer, L., & Marcus, R. (2022). Infection and non-injection drug use among adults with diagnosed HIV in the United States, 2015-2018. *AIDS and Behavior*, 26, 1026-1038. https://doi.org/10.1007/s10461-021-03457-9.

Appendix A: Script for Recruitment of Patients

Hi, I'm Mara. I'm a Registered Nurse on the HIV Team. I'm working on a project with the University of Massachusetts We are trying to understand HIV treatment for patients in the Directly Observed Therapy program and are interested in surveying a few folks to get some insight into their experiences.

I would love to hear about your opinions and experiences. The survey will take about 20 minutes, and you will receive a 25-dollar gift card when we complete it. Would you be interested in participating today?

You will not have to pay for anything associated with the study. The investigator for the study and the study team will collect your answers to the questions asked and organize them in a de-identified manner that may be used or shared in conjunction with the study. You may withdraw or take away your permission to use and disclose your health information at any time before beginning the survey. Questions can be skipped without penalty, and you may skip any question that you choose. If you begin the survey but are unable to complete it or we are interrupted, you will still receive a \$5.00 gift card for your time. Participation in the survey will in no way impact your access to DOT treatment.

Your doctor may be an investigator in this project. In addition, the primary investigator of this project may be one of your nurses. You do not have to participate in any project or research study offered by your doctor or nurse. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the project with your family, friends, or family doctor. Being in a project or research study is different from being a patient. As investigators, your doctor and nurses are interested both in your clinical welfare and in the conduct of this project. If you do not wish to participate in this project, this will not

negatively impact your participation in the DOT program nor your access to any type of assistance.

Appendix B: UMass IRB Approval

UMassAmherst

Human Research Protection Office

Mass Venture Center 100 Venture Way, Suite 116 Hadley, MA 01035 Telephone: 413-545-3428

Date: August 15, 2022

To: Professor Karen Kalmakis and Mara Thomas, College of Nursing

From: Professor Lynnette Leidy Sievert, Chair, University of Massachusetts Amherst IRB

Protocol Title: Outcomes of Directly Observed Therapy in People Living with HIV who Experience

Homelessness and Substance Use Disorder

Protocol ID: 3688

Review Type: Expedited – NEW Category: 7 Approval Date: 08/15/2022

Award #:

No Continuing Review Required

This study has been reviewed and approved by the University of Massachusetts Amherst IRB, Federal Wide Assurance # 00003909. Approval is granted with the understanding that investigator(s) are responsible for:

Consent forms - A copy of the approved consent form (with the IRB stamp) must be used for each participant (Please note: Online consent forms will not be stamped). Investigators must retain copies of signed consent forms for six (6) years after close of the grant, or three (3) years if unfunded.

Use only IRB-approved study materials (e.g., questionnaires, letters, advertisements, flyers, scripts, etc.) in your research.

Revisions - All changes to the study (e.g. protocol, recruitment materials, consent form, additional key personnel), must be submitted for approval in e-protocol before implementing the changes. New personnel must have completed CITI training.

Final Reports - Notify the IRB when your study is complete by submitting a Close Request Form in the electronic protocol system.

Serious Adverse Events and Unanticipated problems involving risks to participants or others - All such events must be reported in the electronic protocol system as soon as possible, but no later than five (5) working days.

Annual Check In - HRPO will conduct an annual check in to determine the study status.

Please contact the Human Research Protection Office if you have any further questions. Best wishes for a successful project.

Appendix C: Cost Table

Costs of Project

Category

Category			
<i>.</i>	Cost	Unit number	Total Cost
Patient Compensation	\$25.00	10	\$250.00
Taxes and Fees on Patient Gift Cards	\$33.70	1	\$33.70
Mailing Costs (Envelopes and Stamps)	\$5.19	1	\$5.19
Total Available Funding	NA	NA	\$1000.00
Remaining Available for Donation or Other Needs			\$520.00

Appendix D: Project Timeline

Project Timeline

Task	Month						
	October	November	December	January	February	March	April
Recruitment of eligible participants	X	X					
Intervention; Evaluation; Toolkit	X	X	X	X			
Post-test and Analysis of outcomes		X	X	X	X	X	
Results presented to local providers							X

Appendix E: Questions to Be Answered in Chart Review

•	Current viral suppression
	o Yes
	o No
•	Most recent viral load
	0
•	Virally undetectable
	o Yes
	o No
•	Most recent CD4 count
	0
•	Most recent HIV Team PCP office visit
	0
•	Most recent HIV Team RN office visit
	0
•	Date of HIV diagnosis
	0
•	Housing status – where did you spend the majority of your nights in the past week?
	o Double Up
	o Shelter
	o Transitional Housing or Residential Treatment Program
	o Motel
	Supportive Housing
	Housing with No Supportive Services Assisted Living Facilities Naming Harmon Boot Harmon
	Assisted Living Facility, Nursing Home, or Rest Home
	Other
_	
•	Psychiatric disorder listed in EHR "Problem List" O Yes
	YesNo
	Psychiatric Comorbidity(ies)
•	o ICD 10 Codes: F01 – F10.99, F19.959 – F99.99
	Medical comorbidity(ies) listed in EHR "Problem List"
•	• Yes
	o No
•	Medical Comorbidity(ies)
	o Syphilis (A53.9)
	O Hepatitis C – Acute or Chronic (B17.10, B18.2, B19.10)
	O Hepatitis. B – Chronic (B18.12)
	o TB – Latent or Acute (R76.12, Z22.7)
	 History of infectious/parasitic diseases (Z86.19)
•	Substance use disorder listed in EHR "Problem List"
	o Yes
	o No
•	Substance Use Comorbidities

0	ICD 10 Codes: F11.0 – 19.9
Alcoh	ol Use Disorder
0	Yes
0	No
Incarc	eration history – defined as being incarcerated for greater than one week in the last
•	No evidence of past incarceration
0	Evidence of past incarceration
Type o	of ART most recently prescribed
0	Biktarvy
0	Truvada
0	Genvoya
0	Atovaquone
0	Prezcobix
0	Tivicay
0	Descovy
0	Other
Gende	r identity
0	Female
0	Male
0	Nonbinary
0	Other
Race	
0	White
0	Black or African American
0	American Indian or Alaska Native
0	Asian
0	Native Hawaiian or Other Pacific Islander
0	Some Other Race
0	Multiracial
Ethnic	·
0	Hispanic or Latino
0	Not Hispanic or Latino
Age	
0	
Immig	ration status
0	US citizen
	Resident
0	Non-immigrant
0	Undocumented immigrant
0	Unknown
Primai	ry language status
0	English
0	Spanish
0	Some Other Language (please specify):
	Alcoho Alcoho Incarce five ye Type o Condende Conde

Appendix F: Survey for Patient Participants

•	•	T 1' 1	T 7	•
Question	maire.	Hnolich	V/A	reion.
Oucsuoi	manc.	Lingilan	٧C	ı sıvıı.

•	What pronouns do you prefer				
	She/her/hers				

- o He/him/his
- o They/them
- o Ze/Zers/Zem
- Other
- Declined to answer

• With what ethnicity do you identify?

- Hispanic or Latino
- Not Hispanic or Latino
- o Declined to answer

• With what race do you identify?

- o White
- O Black or African American
- American Indian or Alaska Native
- o Asian
- Native Hawaiian or Other Pacific Islander
- Multiracial
- Other
- Declined to answer

• How old are you?

- 0 _____
- o Declined to answer

• Where do you spend the majority of your nights?

- o Doubled Up
- o Shelter

0	Street
0	Transitional Housing or Residential Treatment Program
0	Motel
0	Supportive Housing
0	Housing with no Supportive Services
0	Assisted Living Facility, Nursing Home, Rest Home
0	Unknown
0	Other
0	Declined to answer
-	u feel that you have people in your life who can support you in your HIV
diagn	Yes
0	No
0	Don't know
0	Declined to answer
• Is then	re a primary person in your life who supports you in particular?
0	Yes
0	No
0	Don't Know
0	Declined to answer
• If so,	what kind of a relationship do you have with this person?
0	Friend
0	Child
0	Parent
0	Other family member
0	Romantic partner
0	HIV Team Medical Staff
0	Something/someone else
0	Not applicable/No support person
0	Other

	0	Declined to answer			
•	Does anybody else know that you are taking ART?				
	0	Yes			
	0	No			
	0	Don't know			
	0	Declined to answer			
•	Is it ev	ver difficult for you to take your ART when someone can see you?			
	0	Yes			
	0	No			
	0	Don't know			
	0	Declined to answer			
•	Is the	re anyone who regularly reminds you to take your ART?			
	0	Yes			
	0	No			
	0	Don't know			
	0	Declined to answer			
•	If so,	what kind of relationship do you have with this person?			
	0	Friend			
	0	Child			
	0	Parent			
	0	Other family member			
	0	Romantic partner			
	0	HIV Team Medical Staff			
	0	Something/someone else			
	0	Declined to answer			
•		g the past month, have you ever not taken your ART because you did ant someone to find out?			
	not wa	Yes			

o No

o Don't know

	0	Declined to answer
•	In gen	neral, do you find taking your ART:
	0	Very easy
	0	Easy
	0	Not very easy
	0	Difficult
	0	Very difficult
	0	Declined to answer
•		past year, have you ever had problems getting your ART on time se you were not able to reach the clinic or Engagement Center? Yes
	0	No
	0	Don't know
	0	Declined to answer
•		g the past month, have you ever missed a dose of your ART because you of have enough food?
	0	Yes
	0	No
	0	Don't know
	0	Declined to answer
•	How v	would you rate your health before starting ART? Would you say it was:
	0	Excellent
	0	Very good
	0	Good
	0	Fair
	0	Poor
	0	Declined to answer
•	Now t	hat you are taking ART, how is your health? Would you say it is:
	0	Excellent

o Very good

	0	Good
	0	Fair
	0	Poor
	0	Declined to answer
•	Have	you experienced any side-effects since you started taking ART?
	0	Yes
	0	No
	0	Don't know
	0	Declined to answer
•	Which	n side-effects of ART have been the most bothersome for you?
	0	Fatigue/tired
	0	Dry mouth
	0	Diarrhea
	0	Nausea
	0	Headache
	0	Body aches/pains
	0	None
	0	Other
	0	Declined to answer
•	Durin or lon	g the past six months, did you ever stop taking your ART for 48 hours ger? Yes
	0	No
	0	Declined to answer
•	Do yo	u trust the HIV Team professionals who help you take your ART?
	0	Yes
	0	No
	0	Declined to answer
•		re anything the HIV Team professionals do that helps you be more g to take your ART?

- Cigarettes as incentives
- Clean needles/syringes as incentives
- Food as incentives
- Other incentives
- Gift Cards
- Housing case management
- Medical case management
- o Other
- Declined to answer
- o More/better incentives to come to clinic
- More/better clean needles/syringes/other injection supplies
- More/better opportunities
- More/better outreach case management
- More/better community education
- Support group
- Supervised drug injection site
- o Other
- Declined to answer

• Do you have any suggestions for ways that health programs can help improve The lives of people living with HIV in this community?

- More/better incentives to come to clinic
- More/better clean needles/syringes/other injection supplies
- More/better opportunities
- More/better outreach case management
- More/better community education
- Support group
- Supervised drug injection site
- Other
- Declined to answer

How do you feel about the ART DOT program?

- o I like it and find it helpful.
- I like it but do not find it helpful
- o I do not like it but find it helpful.
- o I do not like it and do not find it helpful.
- Other
- Declined to answer

Have you missed any ART doses over the last three days?

- o Yes
- o No
- Not sure
- Declined to answer

What circumstances led you to miss taking your ART?

- No transportation
- Outreach team did not deliver my pills
- Engagement Center or Clinic was closed
- Issues with Pharmacy (out of stock, etc.)
- I was busy doing other things
- I was sick or injured
- o I did not want to take the pills because I do not like how they make me feel
- I did not want to take the pills because I did not want other people to know I was taking them
- Substance use
- Psychiatric illness
- I forgot
- o I did not want to take the pills for another reason.
- o Other
- Declined to answer

• Over the past month, how many times did you miss taking a dose of your medications on a weekend:

o Never

- o Once
- Twice
- Three or more times
- Declined to answer

• What helps you to take your medication on time?

- o Daily direct delivery of medication to me
- Weekly pillboxes
- o Incentives (gift cards, cigarettes, etc.)
- Frequent clinic visits
- Being admitted to hospital
- o Being stably housed
- o Feeling well
- o Support Person
- o Established Routine
- o Other
- Declined to answer

• In the past month, what circumstances led you to miss taking your pills on time?

- Side effects
- Pharmacy problems
- Illness
- Substance use
- Going to the hospital
- Going to treatment center
- Incarceration
- Loss of housing
- Forgetting
- Not being reminded
- Other
- Declined to answer

•	The last time	you were	off ART,	for how	long did	you stop	taking it?
---	---------------	----------	----------	---------	----------	----------	------------

- Two days or less
- Three to six days
- One to two weeks
- More than two weeks
- Less than one month
- More than one month
- Declined to answer

• Overall, how do you feel about being on ART?

- It makes me feel better
- I dislike the side effects
- o I dislike like how it makes me feel
- o I often forget to take it
- I don't mind taking it
- o I am embarrassed to take it
- o It is triggering to me
- o Other
- o Declined to answer

• During the past month, how often have you had a drink containing alcohol?

- o Daily
- Nearly every day
- o 3 to 4 times a week
- Twice a week
- o 1 to 3 times a month
- Never
- Declined to answer
- During the past month, on the days that you drank alcohol, how many alcoholic drinks did you usually have altogether? (One drink = 1 glass of wine, 1 glass of beer, 1 drink of hard liquor).
 - o 1-2 drinks/day

0	3-5 drinks/day
0	6 or more drinks/day
0	Not appliable
0	Declined to answer
• Do yo	u currently use injection drugs?
0	Yes
0	No
0	No, but I use other drugs
0	Declined to answer
	answer to the last question was yes, what drugs have you injected in the nonth? Heroin
0	Fentanyl
0	Cocaine
0	Methamphetamines
0	Ecstasy
0	Ketamine
0	PCP
0	Benzodiazepines
0	Other Opioids
0	Other
0	Not applicable
0	Declined to answer
non-p	g the past month, how often would you say you have injected rescribed drugs? Daily
0	Nearly every day
0	3 to 4 times a week
0	Once or twice a week
0	1 to 3 times a month

0	Never
0	Declined to answer
_	
	ng the past month, on the days that you injected drugs, how many times ou inject?
0	More than 10 times
0	9-10 times
0	6-8 times
0	3-5 times
0	1-2 times
0	Not applicable
0	Other
0	Declined to answer
Are y	ou currently taking prescribed Methadone or Suboxone?
0	Yes
0	No
0	Declined to answer
	g the past month, have you injected with a needle or syringe used by
someo o	one else? Yes
0	No
0	Not applicable
0	Declined to answer
Durin	ng the past month, have you shared or passed on your used needle
or syr	ringe to someone else?
0	Yes
0	No
	Yes, but only with someone who also has HIV
0	
0	Not applicable

	0	No
	0	Not applicable
	0	Declined to answer
•		g the past month, did you give, lend, sell, or trade other "works" or ing equipment with someone else, such as cotton, dropper, vial, or cooker? Yes
	0	No
	0	Not applicable
	0	Declined to answer
•	share	g the past month, have you drawn up solution from a common container, d by others? Yes
	0	No
	0	Not applicable
	0	Declined to answer
•	Durin	g the past month, have you injected from a pre-filled syringe?
	0	Yes
	0	No
	0	Not applicable
	0	Declined to answer
•	in this	re anything else that you would like to say about your diagnosis, HIV s community, the HIV Team, ART, DOT, or any other topic we have seed today?
•	-	age in which this survey was conducted:
	0	English
	0	Spanish
Closin • •	Time of	ment ncludes our survey. Thank you very much for your participation. f survey end: onal surveyor notes

Questionnaire: Spanish Version:

	04	
• į	Que	pronombres prefieres? Ella / ella / ella
	0	,
		771 / 11
	0	Ze/Zers/Zem
		Otro
	0	
		Se negó a responder
• ;	Con	qué etnia te identificas?
	0	Hispano/a/x o latino/a/x
	0	No Hispano o Latino
	0	Se negó a responder
• ;	Con	qué raza te identificas?
	0	Blanco
	0	Negro o afroamericano
	0	Indio americano o nativo de Alaska
	0	Asiático
	0	Nativo de Hawai u otra isla del Pacífico
	0	Multirracial
	0	Otro
	0	Se negó a responder
• ;	Cuai	ntos años tienes?
	0	
	0	Se negó a responder
• ;	Dóno	de pasas la mayoría de tus noches?
	0	Doblado
	0	Refugio

Programa de Vivienda de Transición o Tratamiento Residencial

o Calle

Motel

0	Vivienda de Apoyo	
0	Vivienda sin servicios de apoyo	
0	Centro de vida asistida, Asilo de ancianos, Casa de reposo	
0	Desconocido	
0	Otro	
0	Se negó a responder	
¿Sientes que tienes personas en tu vida que pueden apoyarte en tu diagnóstico de VIH?		
0	Sí	
0	No	
0	No sé	
0	Se negó a responder	
¿Нау	una persona principal en tu vida que apoye a quién en particular?	
0	Sí	
0	No	
0	No sé	
0	Se negó a responder	
Si es así, ¿qué tipo de relación tienes con esta persona?		
0	Amigo	
0	Niño	
0	Padre	
0	Otro miembro de la familia	
0	Compañero romantico	
0	Personal medico del equipo rojo	
0	Algo/alguien mas	
0	No aplica/No hay persona de apoyo	
0	Otro	
0	Se negó a responder	
¿Alguien más sabe que usted está tomando ART?		
0	Sí	

	0	No
	0	No sé
	0	Se negó a responder
•	¿Algu	na vez le resulta difícil tomar su ART cuando alguien puede verle?
	0	Sí
	0	No
	0	No sé
	0	Se negó a responder
•	¿Hay	alguien que le recuerde regularmente que debe tomar su ART?
	0	Sí
	0	No
	0	No sé
	0	Se negó a responder
•	Si es a	sí, ¿qué tipo de relación tienes con esta persona?
	0	Amigo
	0	Niño
	0	Padre
	0	Otro miembro de la familia
	0	Compañero romantico
	0	Personal médico
	0	Algo/alguien mas
	0	No aplica/No hay persona de apoyo
	0	Otro
	0	Se negó a responder
•		nte el último mes, ¿alguna vez no tomó su TAR porque no quería que en se enterara?
	0	Sí
	0	No
	0	No sé
	0	Se negó a responder

•	En ge	neral, considera que está tomando su TAR:
	0	Muy fácil
	0	Fácil
	0	no muy facil
	0	Difícil
	0	Muy dificil
	0	Se negó a responder
		último año, ¿alguna vez ha tenido problemas para obtener su ART a o porque no pudo llegar a la clínica o al Centro de Compromiso? Sí
	0	No
	0	No sé
	0	Se negó a responder
		nte el último mes, ¿alguna vez se saltó una dosis de su TAR porque no uficiente para comer? Sí
	0	No
	0	No sé
	0	Se negó a responder
•	¿Cóm	o calificaría su salud antes de comenzar el TAR? Diría usted que fue:
	0	Excelente
	0	Muy bueno
	0	Bueno
	0	Justa
	0	Pobre
	0	Se negó a responder
•	Ahora	que está tomando TAR, ¿cómo está su salud? Diría usted que es:
	0	Excelente
	0	Muy bueno
	0	Bueno

	0	Justa
	0	Pobre
	0	Se negó a responder
•		xperimentado algún efecto secundario desde que comenzó a tomar
	ART?	Sí
		No
	0	No sé
	0	Se negó a responder
•		efectos secundarios del TAR le han resultado más molestos?
	٥	Diarrea
		Fatiga/cansancio
	0	Náuseas
	0	
	0	Dolor de cabeza
	0	Boca seca
	0	Dolores/dolores de cuerpo
	0	Ninguno
	0	Otro
	0	Se negó a responder
•		nte los últimos seis meses, ¿alguna vez dejó de tomar su TAR durante 48
		o más? Sí
		No
		Se negó a responder
•		ĭas en los profesionalees del equipo rojo que te ayudan a tomar tu TAR?
	-	górico)
	0	Sí
	0	No
	0	Se negó a responder
•		algo que hagan que le ayude a estar más dispuesto a tomar su ART?
	Selecc	ione todas las que correspondan. Cigarillos como incentivos
		=

- Agujas/jeringas limpias como incentivos o Comida como incentivos Otros incentivos Tarjetas de regalo Gestión de casos de vivienda Manejo de casos médicos Otro Se negó a responder ¿Tiene alguna sugerencia sobre cómo los programas de salud pueden ayudar a mejorar la vida de las personas que viven con el VIH en esta comunidad? Seleccione todas las aplicaciones. Más/mejores incentivos para venir a la clínica Más/mejor para limpiar agujas/jeringas/otros suministros de invección Más/mejores oportunidades Más/mejor gestión de casos de divulgación Más/mejor educación comunitaria Grupo de apoyo Sitio de inyección de drogas supervisado Otro 0 o Se negó a responder ¿Cómo te sientes acerca del programa ART DOT? Me gusta y me resulta útil. me gusta pero no me sirve No me gusta, pero me resulta útil. No me gusta y no me resulta útil.
- ¿Se ha saltado alguna dosis de ART en los últimos tres días?
 - o Sí

Otro

Se negó a responder

o No

- No estoy seguro
- Se negó a responder

• ¿Qué circunstancias le llevaron a dejar de tomar su TAR?

- Sin transporte
- El equipo de extensión no entregó mis pastillas
- o El centro de compromiso, la clínica o la farmacia estaban cerrados
- o Problemas con la farmacia (agotado, etc.)
- Estaba ocupado/a haciendo otras cosas
- Estaba enfermo o lesionado
- O No quería tomar las pastillas porque no me gusta cómo me hacen sentir.
- No quería tomar las pastillas porque no quería que otras personas supieran que las estaba tomando.
- Consumo de sustancias
- Enfermedad psiquiátrica
- Me olvidé
- No quería tomar las pastillas por otra razón.
- Otro
- Se negó a responder

• Durante el último mes, ¿cuántas veces olvidó tomar una dosis de sus medicamentos en un fin de semana?

- Nunca
- o Una vez
- Dos veces
- Tres o más veces
- Se negó a responder

• ¿Qué le ayuda a tomar su medicación a tiempo?

- o Entrega directa diaria de medicamentos para mí.
- Pastilleros semanales
- o Incentivos (tarjetas de regalo, cigarrillos, etc.)
- Visitas frecuentes a la clínica

Estar ingresado en el hospital Estar estable alojado Sintiendose bien Persona de apoyo Rutina establecida Otro Se negó a responder En el último mes, ¿qué circunstancias le llevaron a dejar de tomar sus pastillas a tiempo? Efectos secundarios 0 Problemas con la farmácia Enfermedad Consumo de sustancias Ir al hospital Ir al centro de tratamiento Encarcelamiento Pérdida de vivienda Olvidando No ser recordado Otro Se negó a responder La última vez que estuvo fuera de ART, ¿por cuánto tiempo dejó de tomarlo? Por más de 48 horas Menos de una semana

- De una a dos semanas
- Por más de dos semanas
- Menos de un mes
- Por más de un mes
- Se negó a responder

En general, ¿cómo te sientes acerca de estar en ART?

Me hace sentir mejor No me gustan los efectos secundarios No me gusta como me hace sentir A menudo me olvido de tomarlo No me importa tomarlo Me da verguenza tomarlo Me está provocando Otro Se negó a responder Durante el último mes, ¿con qué frecuencia ha tomado una bebida que contenga alcohol? o Diariamente Casi todos los dias 3 a 4 veces por semana Dos veces a la semana 1 a 3 veces al mes Nunca Se negó a responder Durante el último mes, en los días que bebió alcohol, ¿cuántas bebidas alcohólicas bebió en total? (Una bebida = 1 vaso de vino, 1 vaso de cerveza, 1 trago de licor fuerte). 1-2 bebidas/día 3-5 bebidas/día 6 o más tragos/día No aplica Se negó a responder ¿Utiliza drogas inyectables? (Categórico) o Sí No 0 No, pero uso otras drogas

Se negó a responder

•		espuesta a la última pregunta fue afirmativa, ¿qué drogas se ha ado en el último mes?
		Heroína
	0	Fentanilo
	0	Cocaína
	0	Metanfetaminas
	0	Éxtasis
	0	Ketamina
	0	PCP
	0	Benzodiazepinas
	0	Otros opioides
	0	Otro
	0	No aplica
	0	Se negó a responder
•		nte el último mes, ¿con qué frecuencia diría que se ha inyectado amentos sin receta? Diariamente
	0	Casi todos los dias
	0	3 a 4 veces por semana
	0	Una o dos veces a la semana
	0	1 a 3 veces al mes
	0	Nunca
	0	Se negó a responder
•	Durar	nte el último mes, en los días que inyectó drogas ¿cuántas veces lo hizo?
	0	10x/día o más
	0	7x/día

o 5x/día

3x/1

o No aplica

Diariamente

0

	0	Otro
	0 S	se negó a responder
•	¿Actual	mente está tomando Metadona o Suboxone recetados?
	0 S	lí
	0 N	No
	o S	se negó a responder
•	Durante otra per	
	0 N	No
	0 N	No aplica
	0 S	se negó a responder
•	Durante otra per o S	
	0 N	No
	o S	sí, pero solamente con alguien que tambien tenga HIV
	o N	No aplica
	o S	se negó a responder
•		e el mes pasado, ¿se inyectó con una aguja/jeringa nueva, sin usar, que so exclusivo para usted? sí
	o N	No
	0 N	No aplica
	o S	se negó a responder
•		e el último mes, ¿le dio, prestó, vendió o intercambió otros equipos de n con otra persona, como algodón, gotero, vial o cocedor?
	0 N	10
	0 N	No aplica
	o S	se negó a responder
•	Durante	el último mes, ¿ha extraído solución de un recipiente común?

	0	No
	0	No aplica
	0	Se negó a responder
•	Durante el último mes, ¿se ha inyectado con una jeringa precargada?	
	0	Sí
	0	No
	0	No aplica
	0	Se negó a responder
•	• ¿Hay algo más que le gustaría decir en cuanto a su diagnosis, VIH en estsa comunidad, el equipo rojo, ART, TDO, o cualquier otro tópico del cual hemos hablado hoy?	
•	Idioma en el que se realizó esta encuesta:	
	0	Inglés
	0	Español

o Sí