Initiation of Rapid Start Antiretroviral Therapy (ART) in Men Who have Sex with Men (MSM)

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Abstract

Background: Human immunodeficiency virus (HIV) persists as a significant global health problem. Men-who-have-sex-with-men (MSM) remains the primary mode of HIV transmission in all regions of the United States, accounting for about 70% of new HIV infections each year. The U.S. South carries a heavier HIV burden when compared with other regions of the country. Current national and international guidelines recommend that all persons with a confirmed HIV positive (HIV+) test should begin antiretroviral therapy (ART) as soon as possible after diagnosis. Considerable variation in time to starting ART exists due to barriers to accessing medication which are multi-factorial and include linkage and access to HIV medical care, financial classification, insurance issues and method of receipt of medication. To reduce HIV-associated morbidity, mortality, new HIV infections, and related health care costs, rapid initiation of ART is necessary to decrease time to viral suppression. Early diagnosis and treatment of HIV affords MSM the opportunity for improved quality of life and a decrease in forward transmission of HIV infections. Consequences of delayed therapy, using traditional processes for engaging in care, result in increased number of AIDS diagnoses, non-AIDS associated co-morbidities and HIV transmission.

Purpose: The purpose of this research project was to implement an accelerated ART program in an Infectious Disease Clinic in the southeastern U.S. among HIV+ MSM to reduce the time from date of initial HIV+ diagnosis to linkage to care (initial intake visit), thereby decreasing the number of days until the first dose of ART was administered, resulting in decreased time to viral load suppression, and improving linkage and retention in HIV care after initiating ART.

Methods: Permission to conduct the study was granted from the Institutional Review Board of

the University of North Carolina at Greensboro; a waiver of informed consent was granted due to the retrospective nature of this study. A university-based infectious disease (ID) clinic in the southern U.S. initiated an accelerated start ART program among HIV+ MSM. The rapid start ART program for newly diagnosed HIV+ MSM involved the initiation of ART across an MSM population between the ages of 18-34. A goal was set of ≤14 working days from diagnosis (HIV positive test result) to intake (linkage to care) visit and ≤7 days from intake visit to receipt of first dose of antiretroviral medication. Strategies focusing on rapid treatment initiation show promise in improving linkage and retention in care with the added benefit of decreasing time to viral suppression. Twenty newly diagnosed HIV+ MSM were included in the retrospective chart review. Ten charts were reviewed for MSM aged 18-34 who were newly diagnosed pre-intervention (between 2016 to 2018) and ten charts were reviewed for MSM who were included in the intervention group (diagnosed between March 2022 to October 2022).

Results: Of the 20 charts reviewed, 10 participants were managed by rapid start ART, the pre-intervention group received the clinic's standard of care. In the pre-intervention group 7 patients were scheduled for a linkage-to-care care visit within 14 days of their HIV diagnosis; 9 patients in the intervention group were scheduled for a linkage-to-care visit within 14 days of HIV diagnosis. Among the pre-intervention group it was an average of 30.9 days between the linkage-to-care visit and taking the first dose of ART, while the intervention group took their first dose of ART within 24 hours of their linkage to care visit. Nine patients in the intervention group were virally suppressed at the time of the first visit with their primary HIV provider, while 7 patients in the pre-intervention group were virally suppressed at the first medical provider visit. All intervention patients accepted rapid start. There were no adverse events or drug toxicities necessitating change of therapy. No participants were lost to follow-up in either group.

Recommendations and Conclusions: Due to the small size of the sample population for this project, replication of the interventions in a larger group of newly diagnosed HIV+ MSM is recommended. Participants were able to begin ART through the disbursement of donated meds so that ART could be initiated as soon as possible after confirmed HIV diagnosis. There is need for a formalized process for accessing ART by medication samples or activation of medication assistance cards for patients to receive starter packs of ART to last 7-14 days (pending approval of HIV medication assistance program or prior authorization processes for privately insured patients).

Key Words: men-who-have-sex-with-men, gay and bi-sexual men, rapid start antiretroviral therapy, linkage to care, retention in care, barriers to rapid start ART, barriers to accessing ART, treatment as prevention (TasP), human immunodeficiency virus (HIV), ending the HIV epidemic, HIV medication assistance, HIV linkage to care, nurse led HIV care, advanced practice nurse led HIV care.

Background and Significance

Early in the HIV epidemic a positive diagnosis was considered fatal. However, research has shown that with the development of combinations of new antiretroviral drugs, PLWH who are diagnosed early and are receiving treatment can have longevity comparable to people who do not have HIV (Rodriguez et al., 2019). Programs focused on early diagnosis and rapid initiation of ART lead to improved quality of life for the individual and reduction in viral transmission for the communities in which PLWH reside (Rodriguez et al., 2019).

Despite advances in new treatment therapies, improvements in access to care and evidence of some decline in the number of new cases of HIV in the United States, HIV remains a significant global health problem. In 2020, globally there were 38.4 million people living with

HIV (PLWH); there were 1.5 million new cases of HIV; and 650,000 people died from AIDS-related complications (JC3032_AIDS_Data_book_2021_En.Pdf, n.d.). At the beginning of the U.S. HIV epidemic there was fear that it would spread to the public unconstrained. These fears were unfounded. The risk of acquiring HIV in the U.S. is concentrated in certain geographical locations among specific populations (CDC, 2020). In all regions of the U.S., men-who-have-sex-with-men (MSM) are by far the most vulnerable and affected group. MSM account for about 70% of new HIV infections each year, even though they make up only 2% of the population, with the highest burden being among young, Black, and Latino MSM (CDC, 2020). The southern U.S., including North Carolina, continues to be disproportionately impacted by newly diagnosed cases of HIV. In 2016 and 2017 more than one-half of all new HIV diagnoses occurred in the U.S. South and Washington, D.C. (Rodriguez et al., 2019). According to the 2020 HIV Annual Surveillance Report, as of December 31, 2020, there were 34,963 people living with HIV (PLWH) in North Carolina, including those initially diagnosed in another state (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021). Persons between the ages of 20-34, represented the highest rate of newly diagnosed cases of HIV (27.4 per 100,000), comprising 54.4% (N=587) of the newly diagnosed population (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021). In North Carolina, consistent with national trends, the highest rate of newly diagnosed HIV is among Black/African American adolescent and adult men, 55.0 per 100,000, furthermore, the most likely mode of transmission (reported 56.3%) in this group was MSM contact (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021).

Researchers have reasoned that the burden of HIV in the South is heightened by barriers to engagement in care due to stigma and residing in a rural setting (Rodriguez et al., 2019). HIV-related stigma impacts the willingness of PLWH to utilize available resources to initiate prompt

treatment. Evidence reveals that living in a rural setting is a risk factor for access to routine HIV testing, later HIV diagnosis and decreased readiness to take advantage of efficacious treatment to improve quality of life and reduce HIV morbidity and mortality (Rodriguez et al., 2019). PLWH who reside in rural settings face stigma, social isolation, long travel distances to access care, limited transportation and significantly reduced access to health care providers with HIV expertise (Rodriguez et al., 2019). Lack of Medicaid expansion in many southern states is likely a contributing factor to reduced access to and being retained in HIV care (Gant et al., 2022).

Once PLWH are linked to care, how soon ART is initiated depends on several factors, such as whether a patient is insured versus uninsured or whether they can provide the necessary documentation to verify their eligibility for federally funded HIV medication assistance programs (HMAP) or pharmaceutical company sponsored drug assistance programs. A study of people living with HIV (PLWH) from 2004-2009 showed a median time from diagnosis to starting treatment was ten months (Ford et al., 2018). Boyd et al. (2019) makes clear that "No clinician should continue to operate on a '2-3 months' or CD4 threshold strategy for initiating ART, even with people who have asymptomatic HIV" (p. 6). Much of this additional time was spent assuring patient readiness to begin treatment in hopes of improving ART adherence. According to Ford et al (2018) this presumption is not evidence based and results in PLWH being lost to follow-up while waiting to begin treatment. Current national and international guidelines recommend that all persons with a confirmed HIV+ test should begin antiretroviral therapy (ART) as soon as possible after HIV diagnosis (Saag et al., 2020). Successful treatment of HIV requires early initiation of therapy to slow disease progression, and decrease secondary HIV transmission (Chen et al., 2018).

Purpose

The purpose of this research project was to plan, implement, and evaluate a rapid start ART intervention among newly diagnosed HIV+ MSM, 18-34 years old who were referred to this infectious disease clinic for primary HIV care. The clinic has as its mission to provide HIV primary medical care and support services to residents of North Carolina. The clinic receives federal grant funding through the Human Resources Services Administration (HRSA) and currently serves over 1800 HIV+ patients for care and prevention. HRSA expects its grantees to build capacity to improve linkage, engagement, and retention in care.

Specifically, this project addressed the following aims:

- To have newly diagnosed HIV+ MSM linked to care ≤ 14 days from HIV+ diagnosis.
- To administer first dose of ART ≤ 7 days from date of linkage to care visit
- To decrease time to viral load suppression, defined as a viral load <200 copies HIV RNA/ml of plasma
- To improve retention in care (initial visit with primary HIV provider within 6-8 weeks of intake)

Review of Current Evidence

The literature review entailed a search of the following databases and search engine tools: CINAHL, OVID, PubMed and, Google Scholar. The abstracts, citations, and reference lists of full-text articles were reviewed. Governmental websites such as the Centers for Disease Control and Prevention and the North Carolina Department of Health and Human Services, Communicable Disease Branch were accessed. The following search terms were used in the literature review: *men-who-have-sex-with-men, gay and bi-sexual men, rapid start antiretroviral therapy, linkage to care, retention in care, barriers to rapid start ART, barriers to accessing*

ART, treatment as prevention (TasP), human immunodeficiency virus (HIV), ending the HIV epidemic, HIV medication assistance, consequences of delayed entry into HIV care, HIV treatment delay, HIV in the southern United States, HIV linkage to care, nurse led HIV care, advanced practice nurse led HIV care.

HIV Prevalence

Epidemiological studies have shown the disproportionate impact of HIV on the Deep South ("the Deep South": Alabama, Florida, Georgia, Louisiana, North Carolina, South Carolina, Tennessee, Texas). The South's population is comprised of a larger percentage of blacks/African Americans than the rest of the U.S. (Prejean et al., 2013), which is consistent with the high prevalence of HIV in this country. CDC data from 2017 showed the HIV diagnosis rate for the Deep South largely exceeded that of the Northeast, Midwest and West (51.9%, 117.6%, 71.3% greater, respectively) (Jeffries & Henny, 2019). "Persons in the South have relatively more opportunities for exposure to HIV" (Jeffries & Henny, 2019, p. S341). HIV associated mortality is similarly reflected in its higher rates among PLWH in the South (Jeffries & Henny, 2019). HIV remains a prevalent public health concern in the Deep South which includes North Carolina. According to the 2020 HIV Annual Surveillance Report, as of December 31, 2020, there were 34,963 PLWH in North Carolina, including those initially diagnosed in another state (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021). In 2020, 874 men were newly diagnosed with HIV in North Carolina (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021). Among these men 68% reported MSM contact as mode of HIV acquisition (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021). Persons between the ages of 20-34, represented the highest rate of newly diagnosed cases of HIV (27.4 per 100,000), comprising 54.4% (N=587) of the newly diagnosed population (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021).

Of particular concern is that the highest rate of newly diagnosed HIV is among Black/African American men, 55.0 per 100,000, furthermore, the most likely mode of transmission (reported 56.3%) in this group was men-who-have-sex-with-men (MSM) contact (North Carolina HIV/STD/Hepatitis Surveillance Unit, 2021). The group under study includes a sub-population of MSM classified by DHHS as adolescent and young adults (AYA) who have HIV acquired through sexual activities (*Adolescents and Young Adults with HIV | NIH*, 2021). Characteristics among this sub-group which make HIV treatment and management particularly difficult are that only 40% of the AYA are aware of their HIV and it is estimated that only 6% to 30% are virally suppressed (*Adolescents and Young Adults with HIV | NIH*, 2021).

Vulnerable Populations

Vulnerable populations living in the South which have been significantly impacted by HIV include Latinos, Native Americans (despite their small number of annual HIV diagnoses), and gay, bisexual and other MSM – who accounted for 65.5% of diagnoses in the Deep South (Jeffries & Henny, 2019). Knowing the data distribution of HIV in the South does not explain why there is such an impact of HIV on these groups. Jeffries and Henny (2019) assert that social determinants (SDH) explain why these populations are more vulnerable to contracting HIV. According to Jeffries and Henny factors associated with increased vulnerability to HIV include "poverty, education, access to health care, homophobia, transphobia and HIV stigma" (Jeffries & Henny, 2019, p. S341). Research of SDH also supports that HIV-related stigma, discrimination and poverty which disproportionately affects the South as a whole and blacks/African Americans living in the South in particular (Watson et al., 2019).

Consequences of Delayed Linkage to HIV Care

There are major health consequences to delayed and/or untreated HIV. HIV impairs the immune system through the destruction of a type of white blood cell called CD4+ or T-cells (Castro et al., 1993). These CD4+ or T-cells recognize viruses and bacteria and help the body fight infections. Over time, if left untreated, HIV destroys so many CD4+/T-cells that the body becomes less able to fight infections and diseases, this condition is known as immunodeficiency (Castro et al., 1993). As the CD4+/T-cell count decreases, the amount of HIV in the blood, measured in copies per milliliter (a drop of blood) increases – this is called the viral load. PLWH who have significant immunodeficiency which is not treated (ART is not initiated) progress to AIDS (Acquired Immune Deficiency Syndrome). AIDS is defined as having a CD4+/T-cell < 200 cells/mm^3 or having an illness that is not usually seen with people with healthy immune systems (Castro et al., 1993). These illnesses are called opportunistic infections, see Table 1.

2014 CDC Revised Classification System: Stage 3-Defining Opportunistic Illnesses in HIV Infection

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchia, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive+
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset age > 1 month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy attributed to HIV^
- Herpes simplex: chronic ulcers (present for >1 month) or bronchitis, pneumonitis, or esophagitis (onset at age > 1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (> 1 month's duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary of brain
- *Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated or extrapulmonary
- *Mycobacterium tuberculosis* of any site, pulmonary+, disseminated, or extrapulmonary
- *Mycobacterium*, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jirovecii* (previously known as "*Pneumocystis carinii*") pneumonia
- Pneumonia, recurrent+
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain, onset at age > 1 month
- Wasting syndrome attributed to HIV

*Only among children aged < 6 years
+Only among adults, adolescents, and children aged ≥ 6 years
^Suggested diagnostic criteria for these illnesses are defined in prior surveillance case definitions

Table 1

Delayed linkage, treatment and engagement in HIV care leads to negative clinical outcomes, public health, and increased financial burden on the health care system (Siwak et al., 2019). PLWH who are linked to care late have compromised immune systems which cause them to be diagnosed with common opportunistic infections, subsequently, they suffer from increased

morbidity and mortality from AIDS-related and non-AIDS defining illnesses. Tominski et al. (2017) reports that nearly one-third of patients are still being diagnosed with a late stage of HIV disease. Late presenter, defined by testing positive for HIV while having a CD4+ cell count of < 350 cells/mm^3 and/or presenting with an AIDS-defining illness (Gant et al., 2022). Delays in entry into care result in missed opportunities for treatment and early viral load suppression. Additionally, besides the negative impact of delayed entry into care on the individual PLWH, there is a toll placed on the communities in which they reside due to increased risk of HIV transmission and health care resource utilization (Tominski et al., 2017). These patients are typically presenting with lower CD4+ cell counts and therefore are more likely to succumb to opportunistic infections they acquire.

Funding for HIV Care in the South

Despite the high prevalence and incident cases of newly diagnosed HIV in the South, previous research has shown that by geographic regions federal funding inequities exist, with the South receiving a lower distribution of financial resources per person living with HIV when compared with other regions of the U.S. (Reif et al., 2017). The Ryan White program was established in 1990 to provide HIV care to low-income PLWH (Hatcher, 2020). Traditionally, federal funding through the Ryan White Care Act has been allotted to regions of the U.S. based on HIV case counts within metropolitan areas. This has resulted in large amounts of funding going to metropolitan services where resources for HIV testing and care services are more readily available and accessible (Hatcher, 2020). The financial burden of HIV medical care costs on the U.S. healthcare system is astounding. In 2019 the estimated average lifetime HIV-related medical care cost for a person living with HIV was $425,285 (Bingham et al., 2021). This

estimate is important for informing economic evaluations of HIV prevention, early diagnosis, and rapid start treatment strategies. To improve linkage to care and early ART initiation, efforts must be intensified to disseminate federal funding to provide fiscal and structural support in the South where the HIV epidemic is heavily concentrated. Ensuring that patients with a known HIV diagnosis are engaged and retained in medical services, and most importantly, are adherent to an ART regimen is key to reducing the economic burden of HIV.

Current Recommendations for Rapid Start

Rapid start of ART has been shown to improve patient linkage and retention in care (Bacon et al., 2021). Several benefits of rapid start ART have been identified in the literature including reduction in time to viral suppression, decreased morbidity and mortality and reduction in sexual HIV transmission (Ford et al., 2018). Enhanced efforts to access ART medication, regardless of payer source, make rapid initiation of ART achievable (Benbow et al., 2021). One example is The CrescentCare Start Initiative, based in New Orleans, has successfully demonstrated a reduction in mean time linkage to care, 1.3 versus 30 days (Halperin et al., 2018).

Early treatment leads to early viral suppression which extends the lives of PLWH and prevents HIV transmission (Fauci et al., 2019). Interventions that improve HIV clinic visit attendance that have a clear impact on viral suppression are needed to end the HIV epidemic and should be prioritized for implementation (Fauci et al., 2019).

Obstacles and Barriers to Rapid Start Initiation

MSM of color continue to face social and structural barriers to accessing high quality HIV care. Qualitative research studies have shown that barriers to HIV engagement in care are

varied and complex. PLWH who are not engaged in care have no ability to initiate rapid start ART. Kuchinad et al (2016) describe factors which inhibit care engagement including fatalistic beliefs about HIV, mental illness, low social support, stigma, poor patient-provider relationships, housing instability, lack of transportation access, absence of employee benefits (i.e. health insurance, prescription drug coverage, sick leave, child care). Reducing barriers to rapid start could make accelerated initiation of ART the standard of care thereby reducing healthcare costs associated with untreated HIV (Benson et al, 2020). Failure to engage in care and thus initiate treatment when HIV can be managed as a chronic condition result in disease progression and premature death due to a severely compromised immune system. The Strategic Timing of AntiRetroviral Treatment (START) and TEMPRANO clinical trials clearly showed that rapid initiation of ART led to reduction in morbidity and mortality (Benson et al., 2020). Furthermore, other studies conducted in the U.S. have shown that rapid viral suppression leads to improved health care outcomes (increased longevity, decreased morbidity) and of great importance, improved retention in care, which is one of the aims of this project (Benson et al., 2020).

Benefits of Rapid Start

With the improvement of ART medications which are more effective in causing rapid viral suppression and resulting in fewer side effects, treatment guidelines have been updated to support early initiation of ART regardless of CD4+ count. The World Health Organization, National Institutes of Health, Department of Health and Human Services and International Antiviral Society USA all updated their guidelines in 2018, recommending "rapid start" or initiation of ART as soon as possible after diagnosis, among persons who are treatment naïve.

Current evidence demonstrates that early initiation of ART as soon as possible after HIV diagnosis increases uptake of ART which leads to retention in care (Stanton et al., 2019). The CASCADE randomized clinical trial conducted by Lebhardt et al (2018) showed a 15% increase in subjects remaining in care at one-year when ART was offered to them on the day of HIV positivity. The literature also supports that early initiation of therapy results in more frequent visits which relates to greater engagement in care which reduces time to viral load suppression (Koenig et al., 2017).

Nineteen (19) journal articles, 6 STI surveillance reports, and current 4 HIV treatment guidelines were reviewed. Nineteen articles were selected for inclusion as they pertain to barriers, challenges, successes, and strategies for improving rapid start among HIV+ MSM. The articles selected address the special needs of the HIV+ MSM population regarding confidentiality, avoiding stigma and accessing care in a culturally competent environment. The articles include randomized control trials, and pilot research protocols.

Methods

The literature review supports the need for fiscal, human, and structural resources for rapid ART initiation projects throughout the South where the HIV epidemic is heavily concentrated. Early initiation of ART reduces HIV transmission in communities and provides individual protection to PLWH by allowing them to maintain a healthy immune system by suppressing viral replication. Rapid viral suppression through ART adherence is a mainstay for assuring longevity and quality of life among PLWH.

Design

This project was initiated for the purpose of starting newly diagnosed HIV+ MSM on ART as soon as possible after HIV diagnosis was confirmed. The study presents a retrospective analysis of the demographic characteristics and the start time of ART for the intervention or rapid start group who were linked to care between March 2022 to October 2022, when compared with a pre-intervention group of patients who were referred for care between 2016-2018. These patients were referred from a variety of HIV testing sites including primary care providers, health departments, HIV/AIDS service organizations and from inpatient settings.

An abbreviated review of the literature aimed at sharing rapid start projects from across the south was shared with the team members before the first meeting. The group then met to discuss strategies for streamlining the current intake process for newly diagnosed, treatment naïve patients. As most of the patients seen in the clinic are African American MSM, the team agreed that the target population would be newly diagnosed HIV+ MSM 18-34 years of age. Historically, newly diagnosed, HIV+ patients linking to care at the ID clinic involved several visits prior to initiating ART. The team decided new intake activities would be compressed into the initial linkage to care visit, see Figure 1. The intake process for newly diagnosed HIV+ patients was streamlined so that baseline labs were collected at the linkage to care visit and the HMAP or other medication assistance program applications were initiated for under or uninsured patients. Patients were offered the option to begin ART immediately and if they agreed they were dispensed a 7-14 supply of medication. See Appendix A which differentiates the pre-intervention linkage-to-care process from the intervention process.

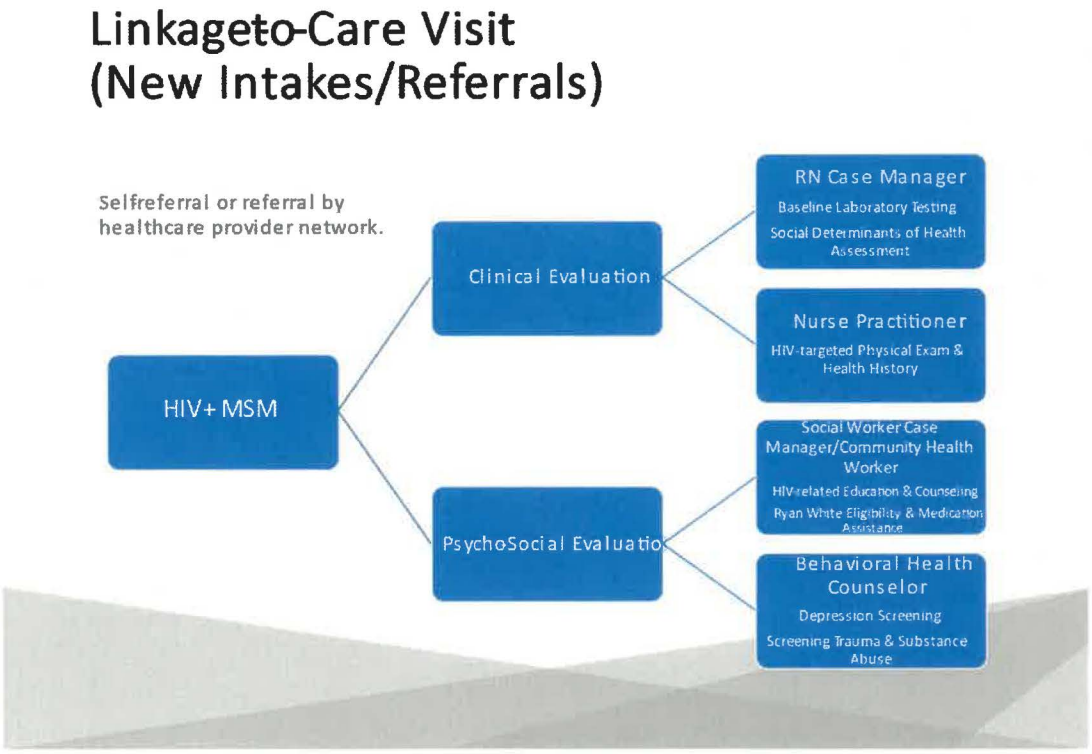

Figure 1

Translational Model

The Institute for Healthcare Improvement (IHI) (2017) developed a tool to evaluate process changes called the Plan-Do-Study-Act (PDSA) cycle. See Appendix B. Utilizing this tool, stakeholders plan for the change they wish to see implemented (Plan). Next the team implements the change (Do). When the change is implemented what occurs because of the change is noted and analyzed (Study). Lastly, the team makes refinements to the change process, if needed, in preparation for the next PDSA cycle. For this project, the PDSA cycle was chosen to compare pre-intervention initiation of ART data with post-intervention findings of a population of HIV+ MSM who were newly diagnosed with HIV and were started on ART using

an accelerated process.

Population

The target population for this project was HIV+ MSM ages 18-34. Ten participants were selected consecutively from patients referred for care from 2016 to 2018. The intervention group of 10 participants was selected from HIV+ MSM referred between March 2022 to October 2022. Inclusion criteria: 1) newly diagnosed with HIV, 2) assigned male sex at birth, 3) sexually active within the preceding 12 months. Exclusion criteria: 1) MSM without a detectable viral load, 2) MSM who are unwilling to begin ART as soon as possible after HIV diagnosis, 3) MSM who have taken post-exposure prophylaxis (PEP), 4) MSM who have taken pre-exposure prophylaxis (PrEP), 5) patients < 18 or > 34 years of age.

Setting

A university-based, ambulatory, infectious disease clinic in the southeastern U.S. initiated an accelerated start HIV ART program. The clinic receives federal funding to support primary HIV to PLWH. The stakeholders comprising the team to implement this project included the following: Chief of Infectious Disease, Registered Nurse Case Manager, Community Health Workers, Referral Coordinator, Clinical Pharmacist Practitioners, Social Work Case Managers, Behavioral Health Services counselors, and a Nurse Practitioner who served as the Team Leader.

Project Implementation

Upon referral to the ID clinic, patients were scheduled for an intake appointment (i.e., linkage to care visit), by the Referral Coordinator for no greater than 14 business days from the date of the positive HIV test result. The Referral Coordinator conducted a telephonic pre-visit

screening to determine if patient was insured, had been hospitalized within the prior 6 months, had transportation, had stable housing. Transportation was arranged for the intake visit as needed.

Patients were referred from various settings by medical practices, health departments, HIV/AIDS Service Organizations, Disease Intervention Specialists, county jails, and the emergency department targeted testing (ETT) program for the regional tertiary care medical center. The referral coordinator obtained records of confirmatory test result and other relevant documentation associated with HIV testing. Patients were offered transportation assistance, if needed.

The linkage to care visit consisted of a clinical evaluation (i.e., targeted medical history and physical), HIV-related education and counseling, review of insurance benefits (if any). Uninsured patients provided proof of income and residence along with photo identification to apply for the HIV Medication Assistance Program (HMAP) or other patient assistance programs (PAP) through which they could access ART. They had blood drawn for baseline laboratory tests:

- HIV quantitative viral load
- Baseline HIV genotypic resistance profile
- Baseline CD4 cell count (CD4 profile which includes CBC)
- Testing for hepatitis A, B, and C viruses
- Comprehensive metabolic panel (creatinine clearance, hepatic profile)

At the conclusion of the intake visit patients were offered ART (unless immediate ART start was deemed to be contraindicated by the Nurse Practitioner/Team Leader). A 7–14-day starter pack of donated medication was provided to uninsured patients while they awaited approval for

HMAP/PAP. Patients with private insurance also received a starter pack of ART while insurance benefits were being established. Medicaid and Medicare (Part D plan) beneficiaries had prescriptions sent electronically to their pharmacy of choice or designated pharmacy assigned by their prescription drug plan. Short-term adherence follow-up was conducted telephonically by a Clinical Pharmacist Practitioner within 1-2 weeks of ART initiation to assure patients were taking meds as prescribed and were not suffering adverse events. Patients were scheduled for an appointment with their assigned HIV provider for ongoing adherence counseling and primary care services within 8 weeks of ART initiation.

Instruments

Data was collected from the electronic health record by retrospective chart review. See Appendix C which was utilized as the data collection tool for this project to obtain demographics, linkage-to care, start of ART, and HIV provider visit data. Data was collected from 10 participants in the pre-intervention group as well as the intervention group. From the intake tracking logs of newly diagnosed HIV+ MSM who entered care between 2016-2018, 10 patients meeting inclusion/exclusion criteria were selected for retrospective chart review. The same randomization process was utilized for the intervention group entering care between March 2022 to October 2022. The following data about patients was collected:

- Race
- Ethnicity
- Date of HIV+ test result
- Referral source
- Linkage-to-care visit date

- Age at intake visit

- Funding source for ART

- Date 1st dose of ART taken

- Viral load level at first primary HIV provider visit (6-8 weeks after initiating ART)

IRB Approval

The project was approved by the University of North Carolina at Greensboro institutional review board. Participants were selected who met eligibility criteria. Five patients were excluded due to age being > 34 years. Patients were started on ART appropriate treatment regimens consistent with the CDC recommended standard of care for treatment naïve, newly diagnosed PLWH.

Data Analysis

The principal investigator (PI) consulted with a statistician employed within the UNC-Greensboro School of Nursing. The PI utilized a password protected Excel spreadsheet to store patient data collected from the retrospective chart reviews. Mann-Whitney u test was used to evaluate for differences between groups because participants were not paired or normally distributed, they were independent samples. See Appendix D. All statistical tests were 2-sided, and $p<0.05$ was considered statistically significant. Analysis was done using SPSS software. Descriptive statistics were used to describe the target population of HIV+ MSM

Results

Twenty-five patients were reviewed between 2016 and October 2022. Five patients were excluded because they exceeded 34 years of age. Ten patients in the pre-intervention and 10 patients in the intervention group were studied. Of the pre-intervention group, 7 were Black/African American and 3 were White. The average age was 27.3 years. Seven participants were scheduled for a linkage-to-care visit within 14 days of HIV+ diagnosis. Disease intervention specialists (DIS) referred patients 50% of the time, 40% were referred by medical providers and 10% were referred by a local health department. There was an average of 15.9 days from date of referral to the linkage-to-care visit taking place. And it was an average of 30.9 days from the date of linkage to care visit until the date of first dose of ART. Four participants were enrolled in HMAP to receive ART, 3 were privately insured and 1 received donated meds, 1 was a Medicaid beneficiary and 1 completed the application process for a pharmaceutical sponsored PAP because they were over-income for HMAP eligibility.

The intervention group was comprised of 7 Black/African Americans, 1 White, 1 Asian and 1 Hispanic. The average age was 27.4 years. Nine of the participants were scheduled for a linkage-to-care visit less than 14 days from date of HIV+ diagnosis. Like the pre-intervention group, 50% were referred by DIS, 30% by medical providers and 20% by a local health department. Date of referral to linkage-to-care visit averaged 8.7 days, reduced by almost half of what occurred in the pre-intervention group. The average time from linkage-to-care visit to first dose of ART was 0.8 days. This can be attributed directly to the dispensing of donated meds starter-pack of ART regardless of source of prescription drug coverage. Of the intervention group, 3 were Medicaid beneficiaries, 3 applied for HMAP, 3 had private insurance and 1 required a PAP application.

HIV Variables

The average viral load at baseline for the pre-intervention group was 239,471 copies HIV RNA/ml of plasma and 49,233 copies HIV RNA/ml of plasma for the intervention group. The difference in level of viremia could be attributed to the pre-intervention group having more advanced HIV disease; however, no statistical analysis was performed on this data. The average baseline CD4 count was 410 cells/mm^3 in the pre-intervention group and 432 cells/mm^3 in the intervention group which showed no significant difference in the groups. In the pre-intervention group, at the first HIV provider visit, 6 participants were virally suppressed (i.e., viral load < 200 copies HIV RNA/ml of plasma), 1 participant was not virally suppressed, and 3 participants did not have a viral load checked at that visit. Among the intervention group 8 participants were virally suppressed and 2 were not.

The aim of this project was to implement rapid start ART as soon as possible after HIV+ diagnosis. The primary analysis compared ART initiation using accelerated implementation of treatment compared with the clinic's standard of care. Since the p-value of < 0.001 is less than 0.05, the null hypothesis is rejected. This indicates that the distribution of date of intake to date of 1st dose is significantly different from pre to post intervention. Participants tolerated assigned ART without adverse events necessitating therapy change. There were no significant safety concerns.

Barriers to Success

Unfortunately, changes in ID clinic organizational leadership necessitated that the PI change the focus of this project which resulted in delayed IRB approval and placed limitations on time for data collection. Therefore, the PI was unable to evaluate the impact of the intervention on patients' retention in care for a longer period. And although the Mann-Whitney u test showed a positive change effect on the rapid implementation of ART, the sample size was small and targeted on HIV+ MSM for the pre-intervention and intervention groups.

Strengths to Overcome Barriers

Continue utilization of the modified linkage-to-care flow process for newly diagnosed HIV+ patients. Refer to **Figure 1**. The PI would extend follow-up of the intervention cohort at 3, 6, and 12 months to evaluate retention in care. Furthermore, the rapid start intervention should be implemented and studied for all newly diagnosed PLWH for 2 years to better assess impact on continuous viral load suppression and participants' engagement and retention in care.

Discussion

In this study we determined that rapid initiation of ART as soon as possible after HIV diagnosis is practicable to implement in a university-based, ambulatory infectious disease clinic in the southeastern U.S. The streamlined linkage-to-care process was acceptable to patients and clinic stakeholders. As previous studies have shown, accelerated start of ART emphasizes the importance of starting treatment early and promotes ongoing adherence and engagement and retention in care (Bacon et al., 2021). In the intervention group, all participants accepted the offer to begin ART immediately. There were no safety concerns identified, treatment was well-

tolerated and 80% of patients were found to be virally suppressed at the time of their first visit primary HIV provider visit. Early viral suppression helps to maintain a healthy immune system and reduces forward HIV transmission through sexual contact (Ford et al., 2018).

The streamlined linkage-to-care process required intensive coordination of intake assessments by members of the multidisciplinary team. Effort involved attempting to track medical records and health history in preparation for the linkage-to-care visit. Uninsured and unemployed patients with housing insecurity, mental health/substance abuse challenges and transportation issues had the highest use of social worker and community health worker resources to address psycho-social needs. ART was initiated prior to laboratory results being available so the PI was intensely involved with selection of ART regimens which were effective and least likely to cause adverse events.

Because the intervention was feasible to introduce in this population of HIV+ MSM it stands to reason that with early HIV detection and treatment, rapid start is a strategy for prevention of new HIV transmission among MSM population. All participants in the intervention group were retained in care through their initial visit with their primary HIV provider.

Conclusion

Rapid start ART is feasible, acceptable to patients and safe to initiate in newly diagnosed HIV+ MSM, the target population of this project. High prevalence of HIV in the South among vulnerable populations supports the need for innovative, nursing-led interventions to reduce the burden of HIV. Such initiatives can lead to early viral suppression resulting in improved health outcomes for PLWH. Due to the small size of the intervention group used in this project, future projects would require a larger sample size being followed for a longer period to determine the

impact of accelerated initiation of ART on retention in care and long-term viral suppression.

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Appendix A

Differentiation Between Pre-intervention and Intervention Linkage-to-Care Process

Pre-Intervention

Referral:

Patient made a self-referral or was referred by a disease intervention specialist **(DIS)**, medical provider or health department to the ID Referral Coordinator **(RC)**. The RC was provided with demographics and current phone number of the patient. Appointment not scheduled until written verification obtained of positive HIV status.

RC contacted the newly diagnosed patient to arrange linkage to care visit **(LTCV)**. RC informed the patient of location/time of appointment and assessed for barriers to care such as transportation for appointment. The patient was told documentation to bring insurance card (if any), income verification (pay stubs for past 30 days, if any), photo ID, and proof of residency.

LTCV:

Literacy assessment (highest level of education obtained, ability to read and understand written information).

Patient education (HIV-101, important lab values and what they mean, medication adherence, readiness to begin ART)

Barriers to care assessment (food insecurity, housing stability, transportation, chronic health conditions, social supports, mental health challenges, legal issues).

Baseline laboratory collection (HIV viral load, CD4+/T-cell panel, complete blood count, comprehensive metabolic panel, quantiferon (TB screening), hepatitis screening (A/B/C), sexually transmitted infection screening (syphilis, gonorrhea, chlamydia), toxoplasmosis, lipid profile, hemoglobin A1C, HIV genotype, urine sample, vitamin D, pregnancy testing (if applicable).

Coverage for ART (completion of HMAP application, insurance verification, Ryan White Eligibility determination, 340b eligibility).

Intervention

Referral:

Patient made a self-referral or was referred by a disease intervention specialist (DIS), medical provider or health department to the ID Referral Coordinator (RC). The RC was provided with demographics and current phone number of the patient. Appointment scheduled immediately, goal of ≤14 days from date of HIV+ test result.

RC contacted the newly diagnosed patient to arrange LTCV. Patient informed of appointment and pre-screened for barriers to care. Arranged transportation to attend appointment, as needed. The patient was told documentation to bring insurance card (if any), income verification (pay stubs for past 30 days, if any), photo ID, and proof of residency.

LTCV:

Literacy assessment (highest level of education obtained, ability to read and understand written information).

Patient education (HIV-101, important lab values and what they mean, medication adherence, readiness to begin ART)

Barriers to care assessment (food insecurity, housing stability, transportation, chronic health conditions, social supports, mental health challenges, legal issues).

Baseline laboratory collection (HIV viral load, CD4+/T-cell panel, complete blood count, comprehensive metabolic panel, quantiferon (TB screening), hepatitis screening (A/B/C), sexually transmitted infection screening (syphilis, gonorrhea, chlamydia), toxoplasmosis, lipid profile, hemoglobin A1C, HIV genotype, urine sample, vitamin D, pregnancy testing (if applicable).

Coverage for ART (completion of HMAP application, insurance verification, Ryan White Eligibility determination, 340b eligibility).

EICV:
Visit with medical provider scheduled for 8-12 weeks after the LTCV. History and physical completed. Labs obtained at LTCV resulted, available for medical provider review and discussion with patient. HMAP approval granted to enable uninsured patients to access ART (unless applicant failed to submit required documentation). Medical provider determined readiness to begin ART and collaborated with patient to select appropriate ART regimen. Patient received instruction on administration of ART prescribed and potential side effects and phone number to contact the clinic for adverse side effects. Patient was given a written prescription to have filled at their preferred pharmacy or was phoned into designated specialty pharmacy, in the case of HMAP enrollees. Medical care visit **(MCV)** for follow-up was scheduled for 8-12 weeks after EICV.

MCV:
Demographic data and H&P updated as needed. Barriers to care re-assessed. Medication adherence assessed if prescription was filled, and ART started. Labs collected to assess effectiveness of ART (HIV viral load, CMP, CD4+/T-cell panel). Refills authorized. Return MCV scheduled for three months.

Intervention LTCV Continued:
Visit included evaluation by Registered Nurse Case Manager and Medical Provider (Nurse Practitioner) to have a HIV medical history, physical examination (H&P), laboratory evaluation and patients were counseled regarding the diagnosis of HIV, its transmission, the health benefits of ART, the importance of adherence to therapy and remaining engaged in care. ART was prescribed immediately using starter packs of donated meds. Prescriptions were electronically submitted to the pharmacy of choice for persons with private insurance, Medicaid, or Medicare beneficiaries. Co-pay card was activated to offset out-of-pocket cost, if needed. Patients were provided with the contact information for their assigned MCM/ Community Health Worker should they have trouble with retrieving ART from local pharmacy of choice or experienced side effects from ART. Patients were assisted to set up patient portal access to the electronic health record so that they could review lab results. MCV scheduled for 6-8 weeks after LTCV.
Patients received a phone call from Clinical Pharmacy Practitioner within two weeks of initiating therapy to assess adherence, side effects or problems obtaining ART.

MCV:
Demographic data and H&P updated. Medication adherence assessed. Confirmed ability to order refills. Re-assessed barriers to care. HIV 101 education reiterated. Counseled on STI prevention and harm reduction. Emphasized "U=U," undetectable equals un-transmittable (PLWH who have an undetectable viral load because they are taking ART are unable to transmit HIV to uninfected partners through sexual contact). Labs collected to assess effectiveness of ART (HIV viral load, CMP, CD4 count). Refills ordered. Next MCV scheduled for 6-8 weeks.

Appendix B
Plan-Do-Study-Act Worksheet

The Institute for Health Care Improvement granted permission to PI from the online resource link via academic e-mail request.

Source: https://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

Institute for Healthcare Improvement

QI Essentials Toolkit:
PDSA Worksheet

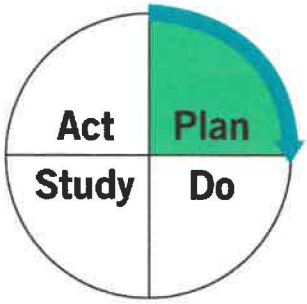
The Plan-Do-Study-Act (PDSA) cycle is a useful tool for documenting a test of change. Running a PDSA cycle is another way of saying testing a change — you develop a plan to test the change (Plan), carry out the test (Do), observe, analyze, and learn from the test (Study), and determine what modifications, if any, to make for the next cycle (Act).

Fill out one PDSA worksheet for each change you test. In most improvement projects, teams will test several different changes, and each change may go through several PDSA cycles as you continue to learn. Keep a file (either electronic or hard copy) of all PDSA cycles for all the changes your team tests.

IHI's QI Essentials Toolkit includes the tools and templates you need to launch and manage a successful improvement project. Each of the nine tools in the toolkit includes a short description, instructions, an example, and a blank template. NOTE: Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

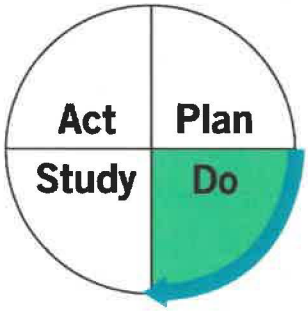
- Cause and Effect Diagram
- Driver Diagram
- Failure Modes and Effects Analysis (FMEA)
- Flowchart
- Histogram
- Pareto Chart
- **PDSA Worksheet**
- Project Planning Form
- Run Chart & Control Chart
- Scatter Diagram

Instructions



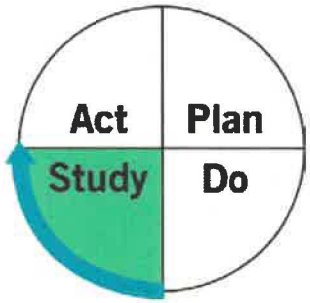
Plan: Plan the test, including a plan for collecting data.

- State the question you want to answer and make a prediction about what you think will happen.
- Develop a plan to test the change. (Who? What? When? Where?)
- Identify what data you will need to collect.



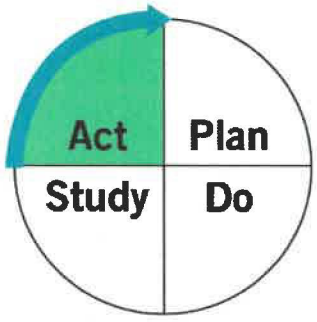
Do: Run the test on a small scale.

- Carry out the test.
- Document problems and unexpected observations.
- Collect and begin to analyze the data.



Study: Analyze the results and compare them to your predictions.

- Complete, as a team, if possible, your analysis of the data.
- Compare the data to your prediction.
- Summarize and reflect on what you learned.



Act: Based on what you learned from the test, make a plan for your next step.

- Adapt (make modifications and run another test), adopt (test the change on a larger scale), or abandon (don't do another test on this change idea).
- Prepare a plan for the next PDSA.

Example: PDSA Worksheet

Objective: Test using Teach-Back (a closed-loop communication model, in which the recipient of information repeats the information back to the speaker) with a small group of patients, in hopes of improving patients' understanding of their care plans.

1. Plan: Plan the test, including a plan for collecting data.

Questions and predictions:

- How much more time will it take to use Teach-Back with patients? It will take more time at first (5 to 10 minutes per patient), but we will start to learn better communication skills and get more efficient.
- Will it be worthwhile? The extra time will feel worthwhile (and possibly prevent future rework).
- What will we do if the act of "teaching back" reveals a patient didn't understand the care plan? If a patient is not able to explain his or her care plan, we will need to explain it again, perhaps in a different way.

Who, what, where, when:

On Monday, each resident will test using Teach-Back with the last patient of the day.

Plan for collecting data:

Each resident will write a brief paragraph about their experience using Teach-Back with the last patient.

2. Do: Run the test on a small scale.

Describe what happened. What data did you collect? What observations did you make?

Three residents attempted Teach-Back at the end of the day on Monday. Two residents did not find anything they needed to ask patients to Teach-Back. Jane found that her patient did not understand the medication schedule for her child. They were able to review it again and, at the end, Jane was confident the mother was going to be able to give the medication as indicated.

3. Study: Analyze the results and compare them to your predictions.

Summarize and reflect on what you learned:

- Prediction: It will take more time at first (5 to 10 minutes per patient), but we will start to learn better communication skills and get more efficient. *Result: Using Teach-Back took about 5 minutes per patient.*
- Prediction: The extra time will feel worthwhile (and possibly prevent future rework). *Result: Jane felt the time she invested in using Teach-Back significantly improved the care experience.*
- Prediction: If a patient is not able to explain his or her care plan, we will need to explain it again, perhaps in a different way. *Result: After a second review of the medication orders, the patient was able to Teach-Back the instructions successfully.*

In addition to the team confirming all three predictions, Jane realized the medication information sheets she had been handing out to parents weren't as clear as she thought. She realized these should be re-written — maybe with the input of some parents.

4. Act: Based on what you learned from the test, make a plan for your next step.

Determine what modifications you should make — adapt, adopt, or abandon:

Jane is planning to use Teach-Back any time she prescribes medication. Although it may take more time, she now understands the importance. The other residents are going to work on using Teach-Back specifically for medications for the next week.

They would like to pull together a team to work on some of the medication information sheets with parent input, but they are first going to gather more information through more interactions in the coming days.

Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

Template: PDSA Worksheet

Objective:

1. Plan: Plan the test, including a plan for collecting data.

Questions and predictions:

-

-

Who, what, where, when:

Plan for collecting data:

2. Do: Run the test on a small scale.

Describe what happened. What data did you collect? What observations did you make?

3. Study: Analyze the results and compare them to your predictions.

Summarize and reflect on what you learned:

4. Act: Based on what you learned from the test, make a plan for your next step.

Determine what modifications you should make — adapt, adopt, or abandon:

Appendix C
Data Collection Tool – Rapid Start ART Project

Randomization #:	Race:	Ethnicity:
Date of HIV Dx:	Date of ID Referral:	Referral Source:
Date of LTCV:	Age at LTCV:	Days from Referral. to LTCV:
Date 1st Dose ART:	Days from LTCV to 1st ART:	Date 1st HIV Provider Visit:
Key:		
Race:	**Referral Source:**	**Medical Care Payer Source:**
B= Black/African Descent	S= Self	U= Uninsured
W=White	MP= Medical Provider	PI= Private Insurance
A= Asian	DIS= Disease Inter. Specialist	MED= Medicaid
AI= Native American	HD= Health Department	Part D= Medicare
P= Hawaiian/Pacific Islander	ETT= ED Targeted Testing	**Funding Initial ART:**
Ethnicity:	OTH= Other	HMAP= HIV Medication Assistance Program
H= Hispanic		PAP= Patient Assistance Program
NH= non-Hispanic	LTCV= Linkage-to-care visit	MED= Medicaid
	ART= antiretroviral therapy	Part D= Medicare
		DM= Donated Meds
Comments:		

Appendix D
Mann-Whitney u Test – Data Analysis

Ranks

	Group	N	Mean Rank	Sum of Ranks
Date of Intake to Date of 1st Dose	Pre	10	14.75	147.50
	Post	10	6.25	62.50
	Total	20		

Nonparametric Tests

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The distribution of Date of Intake to Date of 1st Dose is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	<.001[c]	Reject the null hypothesis.

a. The significance level is .050.
b. Asymptotic significance is displayed.
c. Exact significance is displayed for this test.

Independent-Samples Mann-Whitney U Test Summary

Total N	20
Mann-Whitney U	7.500
Wilcoxon W	62.500
Test Statistic	7.500
Standard Error	12.607
Standardized Test Statistic	-3.371
Asymptotic Sig.(2-sided test)	<.001
Exact Sig.(2-sided test)	.000