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The New York Times

Study That Paid Patients to Take H.I.V. Drugs Fails

By Donald G. McNeil Jr.

Feb. 24, 2015

SEATTLE — A major study testing whether Americans would take their H.I.V. drugs every day if they were paid to do so has essentially failed, the scientists running it announced Tuesday at an AIDS conference here.

Paying patients in the Bronx and in Washington — where infection rates are high among poor blacks and Hispanics — up to \$280 a year to take their pills daily improved overall adherence rates very little, the study's authors said.

The hope was that the drugs would not only improve the health of the people taking them, but help slow the spread of H.I.V. infections. H.I.V. patients who take their medicine regularly are about 95 percent less likely to infect others than patients who do not. The Centers for Disease Control and Prevention estimates that only a quarter of all 1.1 million Americans with H.I.V. are taking their drugs regularly enough to not be infectious.

Paying patients \$25 to take H.I.V. tests, and then \$100 to return for the results and meet a doctor, also failed, the study found.

"We did not see a significant effect of financial incentives," said Dr. Wafaa M. El-Sadr, an AIDS expert at Columbia University and the lead investigator. But, she said, there is "promise for using such incentives in a targeted manner."

Cash payments might still work for some patients and some poor-performing clinics, she said.

Other H.I.V.-prevention research released here Tuesday offered good news for gay men but disappointing results for African women.

Two studies — both of gay men, one in Britain and the other in France — confirmed earlier research showing that pills to prevent infection can be extremely effective if taken daily or before and after sex. Both were stopped early because they were working so well that it would have been unethical

to let them continue with men in control groups who were not given the medicine.

But a large trial involving African women of a vaginal gel containing an antiviral drug failed — apparently because 87 percent of the women in the trial were unable to use the gel regularly.

The failure of the cash-incentives trial — known as HPTN 065 for H.I.V. Prevention Trials Network — was a surprise and a disappointment to scientists and advocates. It had paid out \$2.8 million to 9,000 patients in 39 clinics over three years, but the clinics where money was distributed did only 5 percent better than those that did not — a statistically insignificant difference.

Some small clinics and those where patients had been doing poorly at the start of the study did improve as much as 13 percent, however.

People in other countries have been successfully paid to stop smoking while pregnant and to get their children to school. In Africa, paying poor teenage girls to attend school lowered their H.I.V. rates; scientists concluded that it eased the pressure on them to succumb to "sugar daddies" — older men who gave them money for food, clothes and school fees in return for sex.

One study presented here at the annual Conference on Retroviruses and Opportunistic Infections estimated that every prevented H.I.V. infection saved \$230,000 to \$338,000. Much of that cost is borne by taxpayers.

Mathematical modeling suggested that paying people up to \$5,000 a year could be cost effective, Dr. El-Sadr said, but \$280 was settled on after a long, difficult debate.

Paying more than \$280 at some clinics was not an option, she said; achieving statistical relevance would have meant signing up even more clinics. The study had already involved almost every H.I.V. patient in the Bronx and Washington.

"I don't think anyone has an answer to what amount would be sufficient without being excessive," Dr. El-Sadr said.

One advocate suggested that more money could work — in the right setting.

"In South Africa, \$280 is a lot of money," said Mitchell Warren, the executive director of AVAC, an organization that lobbies for AIDS prevention. "For that much, you'd definitely get some behavior change."

The two studies among gay men looked at different ways to take pills. A 2010 American study, known as iPrEx, showed that taking Truvada — a combination of two antiretroviral drugs — worked if taken daily.

The British study, known as PROUD, used that dosing schedule, and men who took the pill daily were protected 86 percent of the time.

In the French trial, known as Ipergay, men were advised to take two pills in the two days before they anticipated having sex and two in the 24 hours afterward.

Those who took them correctly also got 86 percent protection.

"The problem," Dr. Susan P. Buchbinder, director of H.I.V. prevention research for the San Francisco health department, said in a speech here commenting on the study, "is that studies have shown that men are very good at predicting when they will not have sex and not good at predicting when they will."

The African study, known as FACTS 001, was a follow-up to the smaller trial from 2010, which showed that South African women who used a vaginal gel containing tenofovir, an antiviral drug, before and after sex were 39 percent better protected than women who did not.

But it also found that many women failed to use the gel because it was messy or inconvenient or because partners objected.

In this trial, there was virtually no effect.

One problem, said Dr. Helen Rees, the chief investigator, was that the women were very young — the median age was 23, and most lived with their parents or siblings.

"They had no privacy for sex," she said. "They had to go outside to use the product."

Mr. Warren, of AVAC, said: "The women wanted a product they could use. But this particular product didn't fit into the realities of their daily lives."

The development means that advocates are hoping even more that other interventions for women now in trials will work. They include long-lasting injections of antiretroviral drugs and vaginal rings that can be inserted once a month and leach the drugs slowly into the vaginal wall.

Another trial in Africa, the Partners Demonstration Project, conducted among couples in which one partner had H.I.V. and the other did not, found it was extremely effective to simultaneously offer treatment to the infected partner and preventive drugs to the uninfected one until the other's drugs took full effect.

In the group getting the treatment, there were zero infections that could be traced to partners who were in the study.

How do you encourage better HIV care? Pay patients to take their medication

By Jessica Firger On 6/19/17 at 11:53 AM EDT

Health care for HIV patients has come a long way. Advances in research have led to the development of highly effective antiretroviral drugs, allowing a person who is HIV-positive to live a long and healthy life. The problem, however, is that many patients don't adhere to treatment plans. They may go months, even years, without visiting a physician, or skip life-saving medications.

There are many reasons why people with HIV don't get the medical attention they need. Lack of funds and time, as well as limited access to medical care, contribute to the problem. But a group of researchers at Mailman School of Public Health at Columbia University in New York City say they've found a solution.

A new study published Monday in *JAMA Internal Medicine* suggests that incentivizing HIV care through small monetary awards—paid as gift cards in sums of \$25 to \$100—could help increase the rates of HIV viral suppression, reduce transmission and lower mortality rates of the virus. Overall, the study found the financial incentive model boosted the number of patients who achieved viral suppression (by taking their drugs regularly). However, it had less of an impact on ensuring that patients went to doctor appointments on a more regular basis.

"Some of these providers had started out being quite skeptical of our financial incentives, but they came to the realization that it's another tool to solidify the relationship between the provider and the patient," says Wafaa El-Sadr, co-author of the paper.

For the study, El-Sadr and her colleagues worked with 37 HIV test sites and 39 care clinics in the Bronx, New York, and in Washington, D.C. They randomized the facilities in two categories: ones that provided the financial incentive plan, and ones that simply delivered standard of care without incentives. The study lasted roughly a year and a half at each participating medical facility and was funded by the National Institutes of Health.

The financial incentives were provided as coupons redeemable within three months for two cash-equivalent gift cards. They included \$25 for getting blood drawn for HIV-related tests, and \$100 for meeting with a clinician and developing a care plan for individuals who tested positive at the facility. Study participants also received a \$70 gift card for suppressed plasma viral load (which means medication was being taken regularly by a patient). Patients needed to be tested on a regular basis in order to be eligible for that award.

During that time, health care workers gave a total of 1,061 coupons to patients who met with physicians. The clinics also provided 39,359 gift cards given to 9,641 HIV-positive patients.

The researchers found that using a financial incentives program increased the number of patients who achieved viral suppression by nearly 4 percent. Additionally, 5 percent of patients who achieved viral suppression hadn't done so before enrolling in the incentives program.

Providing financial incentives to increase health care compliance is not a new idea. Studies and pilot programs that use monetary rewards exist to encourage adherence to <u>diabetes management</u>, or to help patients <u>lose weight</u> or <u>stop smoking</u>. Some critics argue that such programs are not sustainable due to their high cost. But El-Sadr argues that in the long run, such programs could actually save health care dollars.

"Sometimes we tend to think what something costs rather than the cost it can prevent," she says. "Preventing someone from getting an HIV infection can prevent many years of costs of care and medications. You prevent the cost of hospitalization, illness and loss of work."

In future research she hopes to gain a greater understanding of the patient demographic that benefits the most from incentive programs. Additionally, El-Sadr wants to explore whether the program would be as effective in rural areas as it appears to be in urban areas such as New York City and Washington,

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D.C.

She also wants to learn what patients are using the money for. The current study didn't track the use of the cards, so El-Sadr and her fellow researchers don't know if the funds went toward paying for nonessential items or for necessities like groceries and utility bills. She says it's possible the incentive funds were used to cover additional expenses related to health care, such as co-payments on doctor visits and medications, or for child care and transportation to and from clinics.



HIV/AIDS Value Based Payment Arrangement

Measurement Year 2018 Fact Sheet



HIV/AIDS Value Based Payment Arrangement

This fact sheet has been prepared to assist payers and providers to more thoroughly understand New York State's Medicaid Human Immunodeficiency Virus (HIV) / Acquired Immunodeficiency Syndrome (AIDS) Value Based Payment (VBP) Arrangement. It provides an overview of the Arrangement, including a summary of the categories of care covered by the Arrangement and the types of measures recommended for use in HIV/AIDS VBP Arrangements.

Introduction

As part of the plan to transition to VBP statewide New York State (NYS) has identified certain groups, called subpopulations, within the Medicaid population for whom highly specialized, intensive care is required. The goal for these subpopulation VBP arrangements is to improve care coordination across traditional provider siloes, ensuring all healthcare providers work together to meet the needs of the member. Medicaid members with HIV infection or AIDS represent a complex subpopulation, some of whom also suffer from comorbidities such as mental health and substance use disorders (SUD). While HIV or AIDS status will be the primary criterion for subpopulation inclusion, effectively treating this subpopulation also means screening for and treating other conditions that complicate the condition. These comorbidities add to the complexity of care delivery and underscore the importance of providing coordinated, integrated care at appropriate points across the care continuum.

HIV/AIDS VBP Arrangements include the total cost of care for the members in order to incentivize all care professionals, including behavioral health providers, community-based providers, medical specialists, and other health care professionals, to provide high quality care. By rewarding VBP Contractors based on quality and cost-effectiveness within a total cost of care budget, VBP Contractors¹ are encouraged to focus on care coordination and high-value, evidence-based practices across the care delivery spectrum. Savings in an HIV/AIDS VBP contract can be primarily achieved through providing appropriate interventions for HIV/AIDS and other comorbid conditions, leading to a reduction in acute medical events and treatment, and a lower total annual cost of care. Social determinants of health such as housing status and economic self-sufficiency are also important variables to address.

This fact sheet provides an overview of New York State's HIV/AIDS VBP Arrangement and is organized in two sections:

- Section 1 describes the care included in the HIV/AIDS Arrangement, the method used to define the attributed population, and the calculation of associated costs under the VBP Arrangement;
- Section 2 describes the quality measure selection process and the categories of measures recommended for use in HIV/AIDS VBP Arrangements.

Section 1: Defining the HIV/AIDS VBP Arrangement and Associated Costs

The HIV/AIDS VBP Arrangement addresses the total care and the associated costs of that care for the members attributed under the Arrangement, regardless of where, how, or for what reason the care was delivered. VBP Contractors assume responsibility for the quality and cost of care for all conditions and types of care for attributed members, including primary care, specialty care, emergency department visits,

¹ A VBP Contractor is an entity – a provider or group of providers – engaged in a VBP contract.



hospital admissions, and medications (with a cap for specialty, high-cost drugs).² The majority of Medicaid members within the HIV/AIDS subpopulation are either enrolled in a managed care plan or an HIV/AIDS Special Needs Plan (SNP). The HIV SNPs are a special type of Medicaid managed care plan that provides a network of experienced HIV-service providers, HIV specialist Primary Care Physicians (PCPs), and a comprehensive model of case management. SNPs are also required to promote access to essential support services such as treatment adherence and housing and nutrition assistance, and to reach multicultural/non-English speaking communities.

Constructing the HIV/AIDS VBP Arrangement: Time Window and Services

The HIV/AIDS VBP Arrangement encompasses all services provided to the attributed member population during the contract year. This includes preventive care, sick care, and care for all chronic conditions, including procedures and surgeries with a date of service or discharge date within the contract year. Members of the HIV/AIDS subpopulation may seek care through community health centers, Designated AIDS Centers (DACs) or other hospital-based programs, or their primary care physician.

Eligible Member Population

Medicaid members in a Medicaid Managed Care Organization (MCO) or SNP who are diagnosed with HIV/AIDS and who are not dually eligible for Medicare can be included in HIV/AIDS VBP Arrangements. Members who test positive for HIV, but have not been formally diagnosed by a care provider, are not eligible for inclusion because they are not able to be attributed to a specific provider or provider group.

Medicaid members eligible for inclusion under a VBP subpopulation arrangement are *not* eligible for inclusion in other VBP arrangements. Subpopulation arrangement types include HIV/AIDS, Health and Recovery Plans (HARP), Managed Long Term Care (MLTC), and Intellectually/Developmentally Disabled (I/DD). Subpopulation arrangements are mutually exclusive; a member can only be enrolled in one or the other. MCOs and VBP Contractors can decide which subpopulation designation takes precedence for the member.³ Members included in subpopulation arrangements are also excluded from Total Care for the General Population (TCGP) and Integrated Primary Care (IPC) arrangements.

Member Attribution

Medicaid member attribution defines the group of members for which a VBP Contractor is responsible in terms of quality outcomes and costs. It becomes the basis for the aggregated total cost of care in a target budget for VBP. The NYS Roadmap details attribution guidelines for VBP Contractors and Medicaid MCOs for each arrangement.

New York State's guideline for member attribution in HIV/AIDS VBP Arrangements is to the Medicaid MCO-assigned PCP.⁴ However, an MCO and VBP Contractor may agree on a different type of provider to drive the attribution on the condition that the State is adequately notified.

² The VBP Roadmap includes categories of costs that may be excluded from VBP arrangements, where appropriate. For more information see New York State Department of Health, Medicaid Redesign Team, A Path toward Value Based Payment: Annual Update, June 2016: Year 2, New York State Roadmap for Medicaid Payment Reform, June 2016. p. 72. (Link)

³ Ibid. p. 15.

⁴ Ibid. p. 23.



Calculation of Total Cost for the Arrangement

The total cost for the attributed membership in HIV/AIDS VBP Arrangements includes all Medicaid-covered care provided during the contract year. The total cost of the HIV/AIDS VBP Arrangement is based on the cost of that care (defined as the total amount paid by the Medicaid MCO or SNP), including all costs associated with professional, inpatient, outpatient, pharmacy (with a cap for specialty, high-cost drugs), laboratory, radiology, ancillary, and behavioral health services aggregated to the attributed population level. The aggregate costs can be further analyzed to identify and understand sources of variation and opportunities for improvement in quality of care and resource use.⁵

Section 2: VBP Quality Measure Set for the HIV/AIDS Arrangement

The 2018 HIV/AIDS Quality Measure Set was developed drawing on the work of a number of stakeholder groups convened by the Department of Health (DOH) to solicit input from expert clinicians around the state. The HIV/AIDS Clinical Advisory Group, or CAG, convened specifically to make VBP quality measure recommendations. One of the key innovative aspects of the HIV/AIDS VBP arrangement is the incorporation of quality measures related to the goals outlined in New York State's three–point plan from the 2015 End the AIDS Epidemic Blueprint. The HIV/AIDS VBP arrangement will include quality measures related to retaining individuals with HIV/AIDS in the healthcare system and facilitating maximum viral load suppression.

Because the HIV/AIDS VBP Arrangement is a total cost of care subpopulation arrangement, a full complement of physical and behavioral health measures is included in the measure set to ensure members in care for HIV/AIDS receive high quality health care, in addition to specialty care for HIV/AIDS. The physical health measures were drawn from the measure sets developed by the Diabetes, Chronic Heart Disease, and Pulmonary CAGs and from the measures recommended for Advanced Primary Care (APC) by the Integrated Care Workgroup. Likewise, the behavioral health measures were drawn from the measure sets developed by the Behavioral Health CAG.

Measures recommended by the CAG were submitted to NYS DOH, the Office of Mental Health (OMH), and the Office of Alcoholism and Substance Abuse Services (OASAS) for further feasibility review and, ultimately, to the VBP Workgroup, the group responsible for overall VBP design and final approval for NYS Medicaid. During the final review process, the HIV/AIDS VBP measure set was aligned with existing Delivery System Reform Incentive Payment (DSRIP) Program and Quality Assurance Reporting Requirements (QARR) measures, and measures utilized by Medicare and Commercial programs in NYS, where appropriate. The measures were further categorized as Category 1, 2, or 3 based on reliability, validity, and feasibility, and by suggested use as either Pay-for-Reporting (P4R) or Pay-for-Performance (P4P).

Measure Classification

In May 2016, NYS published the initial recommendations of the HIV/AIDS CAG on measures for use in HIV/AIDS VBP Arrangements and included a review of the types of data needed for the recommended measures. Additionally, the report addressed other implementation details related to VBP arrangements. Upon receiving the CAG recommendations, the State conducted additional feasibility review and analysis to define a final list of measures for use during the 2017 VBP Measurement Year (MY). Each measure was designated by the State as Category 1, 2, or 3, according to the following criteria:

⁵ Additional information on total cost of the arrangement and use in contracting will be made available through other DOH materials in the future.

⁶ New York State Department of Health, New York State's Blueprint to End the AIDS Epidemic, 2015. (<u>Link</u>)



- CATEGORY 1 Approved quality measures that are felt to be clinically relevant, reliable and valid, and feasible:
- CATEGORY 2 Measures that are clinically relevant, valid, and probably reliable, but where the
 feasibility could be problematic. These measures will be further investigated during the VBP Pilot
 program; and,
- CATEGORY 3 Measures that are insufficiently relevant, valid, reliable and/or feasible.

Note that measure classification is a State recommendation. Although Category 1 measures are required to be reported, Medicaid MCOs and VBP Contractors can choose the measures they want to link to payment and how they want to pay on them (P4P or P4R) in their specific contracts.

Category 1

Category 1 quality measures as identified by the CAGs and accepted by the State are to be reported by VBP Contractors. A subset of these measures is also intended to be used to determine the amount of shared savings for which VBP contractors would be eligible.⁷

The State classified each Category 1 measure as either P4P or P4R:

- P4P measures are intended to be used in the determination of shared savings amounts for which VBP Contractors are eligible.⁸ In other words, these are the measures on which payments in VBP contracts may be based. Measures can be included in both the determination of the target budget and in the calculation of shared savings for VBP Contractors; and,
- P4R measures are intended to be used by the MCOs to incentivize VBP Contractors for reporting
 data to monitor quality of care delivered to members under the VBP contract. Incentives for
 reporting should be based on timeliness, accuracy, and completeness of data. Measures can be
 reclassified from P4R to P4P through annual CAG and State review or as determined by the MCO
 and VBP Contractor.

Not all Category 1 measures will be reportable for Measurement Year 2018, as reporting on some of these measures will be phased in over the next 2 years. Please see the Value Based Payment Reporting Requirements Technical Specifications Manual⁹ for details as to which measures must be reported for the measurement year. This manual will be updated annually each fall, in line with the release of the final VBP measure set for the subsequent year.

Categories 2 and 3

Category 2 measures have been accepted by the State based on agreement of measure importance, validity, and reliability, but were flagged with concerns regarding implementation feasibility. These measures will be further investigated in the early stages of VBP implementation. The State requires that VBP Pilots select and report a minimum of one Category 2 measure per VBP arrangement for MY 2018 (or have a State and Plan approved alternative). VBP Pilot participants will be expected to share meaningful feedback on the feasibility of Category 2 measures when the CAGs reconvene during the Annual Measure Review.

⁷ New York State Department of Health, Medicaid Redesign Team, A Path toward Value Based Payment: Annual Update, June 2016: Year 2, New York State Roadmap for Medicaid Payment Reform, June 2016, p. 34. (<u>Link</u>) ⁸ Ibid.

⁹ 2018 Value Based Payment Reporting Requirements; Technical Specifications Manual, Nov 2017, File is located in the Quality Measures tab of the VBP Resource Library (<u>Link</u>)



Measures designated as Category 3 were deemed unfeasible at this time for a number of reasons. These include concerns about valid use in small sample sizes of attributed members at a VBP contractor level and limited potential for performance improvement in areas where statewide performance is already near maximum expected levels. These Category 3 measures will not be tested in pilots or included in VBP arrangements in 2018.

Annual Measure Review

Measure sets and classifications are considered dynamic and will be reviewed annually. Updates will include additions, deletions, change in categorization, and reclassification from P4R to P4P or P4P to P4R based on experience with measure implementation in the prior year. The complete Category 1 and 2 measure set includes a subset of the IPC Measure Set determined relevant to the HIV/AIDS VBP Arrangement by the State. 10 During 2018 the CAGs and the VBP Workgroup will reevaluate measures and provide recommendations for MY 2019. A full list of the MY 2018 HIV/AIDS VBP measures is included in the NYS VBP Resource Library on the DOH website. 11

¹⁰ The IPC measure set is the same set that will be used for the TCGP arrangement in 2018. Therefore, this is referred to as the TCGP/IPC measure set in other VBP-related documents.

¹¹ See the NYS Delivery System Reform Incentive Payment (DSRIP) - VBP Resource Library (Link)



ENHANCING LINKAGES TO AND RETENTION IN HIV PRIMARY CARE FOR TRANSGENDER WOMEN OF COLOR: THE ALEXIS PROJECT

Cathy J. Reback, Ph.D.^{1,2}, Kimberly Kisler, MPH, Ph.D.¹ and Jesse B. Fletcher, Ph.D.¹

¹Friends Research Institute, Inc., Los Angeles, CA 90028 ²David Geffen School of Medicine, Semel Institute of Neuroscience and Human Behavior, University of California, Los Angeles, 90095

Corresponding Author:

Cathy J. Reback, Ph.D. 1419 N. La Brea Ave. Los Angeles, CA 90028 ph: (323) 463-1601 fax: (323) 463-0126

reback@friendsresearch.org

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LOCAL EPIDEMIOLOGY

In Los Angeles County (LAC), the HIV seroprevalence rate among trans women is estimated to be 21 percent,¹ a rate comparable to that among trans women across the United States and other high-income countries,² and 40 percent greater than that observed nationally among men who have sex with men.³ In LAC, trans women of color have the highest estimated seroprevalence rates; African Americans/Blacks, Latinas/ Hispanics, Asians/Pacific Islanders, and Native Americans comprise 90 percent of transgender individuals living with AIDS.⁴ Despite comprising only a tiny fraction of the total population in LAC, transgender individuals are estimated to make up nearly 5 percent of all HIV-infected individuals not linked into HIV care in the County.⁵ The LAC HIV Prevention Plan identified the following co-factors that contribute to trans womens' high risk for HIV infection: substance use, incarceration, sex work, mental health issues, unemployment, STIs, poverty, stigma and discrimination, transphobia, racism, immigration status, language, educational attainment, violence and sexual assault, and homelessness.⁶

¹ Office of AIDS Programs and Policies. (2008). Prevention plan 2009-2013. Los Angeles, CA: Los Angeles County Department of Public Health. Retrieved from http://publichealth.lacounty.gov/aids/PreventionPlan.htm. Accessed on April 8, 2012.

² Baral, S. D., Poteat, T., Strömdahl, S., Wirtz, A. L., Guadamuz, T. E., & Beyrer, C. (2013). Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. *Lancet Infectious Diseases*, 13, 214-222.

³ Centers for Disease Control and Prevention. (2016). HIV Infection Risk, Prevention, and Testing Behaviors among Men Who Have Sex With Men—National HIV Behavioral Surveillance, 20 U.S. Cities, 2014. HIV Surveillance Special Report 15.

⁴ Office of AIDS Programs and Policies. (2008). Prevention plan 2009-2013. Los Angeles, CA: Los Angeles County Department of Public Health. Retrieved from http://publichealth.lacounty.gov/aids/PreventionPlan.htm. Accessed on April 8, 2012.

⁵ Perez, M. (2011). New directions: A briefing to stakeholders. Los Angeles, CA: Los Angeles County Department of Public Health, Division of HIV and STD Prevention. Retrieved from http://ph.lacounty.gov/aids/PresentationsReportsArchive.htm. Accessed on March 23, 2012.

⁶ Office of AIDS Programs and Policies. (2008). Prevention plan 2009-2013. Los Angeles, CA: Los Angeles County Department of Public Health. Retrieved from http://publichealth.lacounty.gov/aids/PreventionPlan.htm. Accessed on April 8, 2012.

PROGRAM DESCRIPTION

THE ORGANIZATIONAL CONTEXT

LAC is an urban, metropolitan city, is both geographically large and populous, and covers over 4,700 square miles (including land and water) with over 10 million residents. It is estimated that 14,428 trans individuals live in LAC with a range of 7,214 to 21,642 dependent upon the definition of "transgender." The estimated ratio of trans feminine and trans masculine individuals is 1:1.

Friends Research Institute, Inc. (FRI) is a 501(c)(3), private, non-profit corporation established in 1955. Friends Community Center, a division of Friends Research Institute, is the community research center, located on the border of Hollywood and West Hollywood in LAC, where The Alexis Project was implemented. LAC is divided into eight Service Planning Areas (SPA); SPA 4, which includes the Friends Community Center site, has an annual rate of 24 per 100,000 population of persons diagnosed with AIDS, which translates to 38 percent of total new AIDS cases annually — the highest rate across all SPAs. Additionally, Friends Community Center is located in the 90028 "hot spot" zip code, an area of current and emerging HIV prevalence.

THE INTERVENTION

Theoretical Foundations

The Alexis Project incorporated three proven models, Social Network Recruitment and Engagement (network), Peer Health Navigation (individual), and Contingency Management (structural), into one multileveled project to optimize HIV health outcomes for trans women of color (see Figure 1). The two behavioral interventions, Peer Health Navigation (PHN) and Contingency Management (CM) were utilized, in concert, to ensure success in treating and retaining trans women of color in HIV care to improve their health outcomes.

Social Network Recruitment and Engagement: Social networking methodology is theoretically based in Respondent Driven Sampling (RDS), which provides coupons that incentivize participants from "hidden populations" to recruit peers into the study. RDS is maximally preferable when the population in question is not only hidden, but relatively closed (i.e., social networks tend to exclusively contain members from the same group), as transgender communities tend to be. Closed network status is especially salient among trans women, as viral loads are commonly high.8

⁷ Boyce, S., Barrington, C., Bolaños, H., Galindo Arandi, C., & Paz-Bailey, G. (2011). Facilitating access to sexual health services for men who have sex with men and male-to-female transgender persons in Guatemala City. Culture, Health, & Sexuality, 14, 313-327. doi: 10.1080/13691058.2011.639393.

⁸ Perez, M. (2011). New directions: A briefing to stakeholders. Los Angeles, CA: Los Angeles County Department of Public Health, Division of HIV and STD Prevention. Retrieved from http://ph.lacounty.gov/aids/PresentationsReportsArchive.htm. Accessed on March 23, 2012.

Peer Health Navigation: The PHN intervention in The Alexis Project was based on the mechanisms of Social Cognitive Theory, a theory which posits interactive causal relationships among personal determinants, behavior, and environmental influences, ^{9,10} and is designed to create improvement in participant self-efficacy. Low self-efficacy is associated with increased HIV risk in sexual minority populations ¹¹ and sub-optimal HIV healthcare outcomes in trans women. ¹² The PHN sessions helped to (1) identify the barriers to HIV care for each particular participant, (2) identify and link participants into other auxiliary needed services, and (3) increase participants' self-efficacy in working with HIV care providers and other social service and treatment facilities. Peer Health Navigators did not provide counseling or psychotherapy; rather, they worked with participants to successfully navigate complicated health care and social service systems.

Contingency Management: CM is guided by the theoretical framework of behavioral economics, which is the application of contingencies to motivate individuals toward health-promoting behavior change. A behavioral economics intervention has particular promise when adapted for low/no income, marginalized and disenfranchised populations. ¹³ The primary element of behavioral economics captured in CM is providing a direct and immediate reinforcement for health behaviors. The principle of conditionality, i.e., making the reward contingent upon the operant behavior change, distinguishes CM from just providing a traditional incentive. ¹⁴

Key Components of the Intervention

Peer Health Navigation: As part of the PHN component of the intervention, a Peer Health Navigator met with each participant to develop a client-centered treatment plan and directly link the participant to HIV primary health care and/or other needed physical, mental health, and/or psychosocial services (e.g., hormone therapy, dental care, hepatitis testing/care, TB testing/care, mental health counseling and/or psychotropic medication, substance abuse treatment, needle exchange, legal services, job training/development, transportation assistance). PHN is a tool that combines the individualized and well-rounded approach of individual case management with the specific goal of removing barriers that can impede access to and retention in HIV care. PHN, based on a client-centered philosophy, works to reduce obstacles that inhibit a

⁹ Bandura, A. (1994). Social cognitive theory and exercise of control over HIV infection. In R.J. DiClemente & J.L. Peterson (Eds.), *Preventing AIDS: Theories and methods of behavioral interventions* (pp. 25-29). New York, NY: Plenum Press.

¹⁰ Bandura, A. (2001). Social cognitive theory: An agentic perspective. *Annual Review of Psychology*, 52, 1-26. doi: 10.1145/annurev.psych.52.1.1

¹¹ Safren, S.A., Traeger, L., Skeer, M., O'Cleirigh, C., Meade, C.S., Covahey, C., & Mayer, K.H. (2010). Testing a social-cognitive model of HIV transmission risk behaviors in HIV-infected MSM with and without depression. *Health Psychology*, 29, 215-221. doi: 10.1037/a0017859

¹² Sugano, E., Nemoto, T., & Operario, D. (2006). The impact of exposure to transphobia on HIV risk behavior in a sample of transgendered women of color in San Francisco. *AIDS and Behavior*, 10, 217-225. doi: 10.1007/s10461-005-9040-z

¹³ Baird, S.J., Garfein, R.S., McIntosh, C.T., & Özler B. (2012). Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: A cluster randomised trial. *The Lancet*, 379, 1320-1329. doi:10.1016/s0140-6736(11)61709-1

¹⁴de Walque, D., Dow, W.H., Nathan, R., Abdul, R., Abilahi, F., Gong, E., ... Medlin, C.A. (2012). Incentivising safe sex: A randomised trial of conditional cash transfers for HIV and sexually transmitted infection prevention in rural Tanzania. BMJ Open. 2, e000747. doi: 10.1136/bmjopen-2011-000747

participant in obtaining health-promoting behaviors, focusing particularly on the multiple and complex cofactors that often make it difficult for trans women of color to be linked and retained in HIV care.

During each session, Peer Health Navigators completed the Needs and Barriers Assessment (NBA) tool with each participant; after each session, supplemental progress notes were written to capture the nature of the session and further detail about experiences reported by the participant. At the first session, Peer Health Navigators conducted an assessment of participants' health care history (including past HIV care), unmet service needs and barriers to health care, and the Peer Health Navigator answered any questions a participant had about peer health navigation. Peer Health Navigators reminded each participant of her upcoming appointment and, if necessary, transported and accompanied her to each scheduled appointment.

Participants were encouraged to have ongoing contact with their Peer Health Navigator (i.e., approximately two to three times per week during the first weeks of the relationship). In most cases, the frequency of contacts titrated down after the first quarter of care. Once the Peer Health Navigator-participant relationship was well-established with a consistently maintained treatment plan as well as the removal of barriers to auxiliary services, Peer Health Navigators then worked with participants to become more selfsufficient, building self-efficacy for sustained healthy behavior change. However, participants were able to contact their Peer Health Navigator at any time for information, guidance, and/or support or if another service was required that was not part of the original client-centered treatment plan.

Contingency Management: CM served to increase health outcomes by specifically targeting HIV primary care appointments and HIV milestones for positive reinforcement. Increasingly valuable reinforcers were connected with HIV care visits and reaching and sustaining HIV milestones (see Figure 2). The escalating reinforcement schedule of the CM intervention was structured to serve as a motivator for HIV care-seeking behavior, such that HIV milestones were expected to be achieved with regard to retention in regular HIV care visits, treatment, and medication adherence. Assuming an appropriate regimen (i.e., potent and to which the virus was susceptible) was chosen by the treating provider, the trajectory of HIV RNA decline should be clear and continuous. The Department of Health and Human Services (DHHS) guidelines note that virologic "failure" should be defined by HIV RNA >200 copies/mL measured twice after 24 weeks (6 months) on therapy, and once "undetectable" (below the limits of assay detection, variably 20-75 copies/ mL), should remain undetectable. Interim milestones were chosen on the basis of ART-naïve treatment trial aggregate data and guidance from DAIDS-funded AIDS Clinical Trials Group protocols, based on sensitivity analyses of a number of possible milestone definitions. 15

Providing incentives to reinforce both clinic attendance and HIV milestones in the care and treatment of HIV, and using objective biomarkers was found to be highly effective at accomplishing goals of linkage and maintenance in longitudinal care with on-treatment and successful virologic suppression. Participants who

¹⁵ Ribaudo, H., Lennox, J., Currier, J., Kuritzkes, D., Gulick, R., Haubrich, R., ... Hughes, M. (2009, Feb). Virologic failure endpoint definition in clinical trials: Is using HIV-1 RNA threshold <200 copies/mL better than <50 copies/mL? An analysis of ACTG studies. Paper presented at the 16th Conference on Retroviruses and Opportunistic Infections, Montreal, Canada. Abstract retrieved from http://www.retroconference.org/2009/Abstracts/33925.htm.

achieved all of the targeted HIV health-promoting behaviors accumulated \$500 in CM reward points. CM rewards were redeemable for goods or services that promoted a healthy, prosocial lifestyle (e.g., gift cards to grocery stores and department stores, a bus ticket to travel home for the holidays, shoes, umbrellas, wigs and cosmetics, payment of a phone bill and utility bill, DMV for legal documents). No cash was provided.

Intervention Logic Model

See Logic Model diagram on page 75.

Core Intervention Staff

The Alexis Project core intervention staff included the Principal Investigator (PI), a part-time Project Director, two full-time Peer Health Navigators, a part-time Process Evaluator, a part-time Data Manager, and a part-time Medical Consultant (a MD who specialized in HIV care). The PI met with the full team on a monthly basis and met with the Project Director on a weekly basis. The PI was available for consultation throughout the project as issues arose, and provided direct supervision of the Project Director and the Data Manager. The Project Director assisted with development of most intervention materials, including assessment tools and databases, assisted in training all project-related staff, drafted all progress reports, communicated with partnering agencies and clinics, supervised all project-related staff, and oversaw the project's day-to-day operations. The Project Director provided direct supervision to the Peer Health Navigators and the Evaluator. The Peer Health Navigators worked individually with each participant on-site as well as transported and accompanied participants to project-related appointments in the field. The Peer Health Navigators also collected project-related data through the initial extensive needs assessment and ongoing abbreviated needs assessments, kept progress notes on each participant interaction, maintained locator forms, and performed outreach to recruit new participants as well as locate existing participants to aid in retention. The Evaluator assisted in building systems to collect and track project-related process data, conducted weekly quality assurance reviews on all paper and electronic participant files, generated weekly and monthly reports on project progress, and managed all process data. The Data Manager built the databases, ensured quality control of data management, developed statistical routines for analyzing the data, and performed all data analyses. The Medical Consultant provided annual trainings to update all project staff on any changes to HIV medical care guidelines or protocols, as well as provided a refresher course on how to read labs. The Medical Consultant was also available via phone or email to answer questions related to lab work or HIV treatment options.

Intervention Components including Outreach, Recruitment, and Retention Strategies

Several outreach and recruitment strategies were utilized including: (1) a community-wide social network recruitment and engagement methodology (i.e., Respondent Driven Sampling; see above); (2) venue- and

street-based outreach whereby the Peer Health Navigators conducted outreach in places such as food lines, bars, street corners, and other locations where trans women tend to congregate; (3) dissemination of project flyers, including a postcard-sized flyer and a business card-sized flyer that folded over to fit into a person's wallet or pocket; (4) in-reach was conducted through other programs at Friends Community Center (see Illustration 1); (5) in-services were conducted at local agencies that provide services to trans women; and, (6) community partners, including the two HIV medical care clinics, referred potential participants to the project.

Retention was ensured through the design of the intervention. Peer Health Navigators provided participants with 18 months of unlimited PHN sessions to address any barrier(s) that impeded their ability to be linked and retained in care. By working with participants on tasks such as helping secure housing, gain access to substance abuse treatment facilities, find gender affirming clothes and hygiene products, access food, and a number of other barriers impacting their quality of life, participants wanted to remain in the intervention because their basic and most critical needs were being met.

Additionally, retention was boosted through the rapport built between the participants and Peer Health Navigators. Peer Health Navigators were true peers, trans women of color living with HIV, which allowed the participants to feel safe in having frank, honest discussions about barriers to linkage and retention in care, as well as issues related to medication adherence.

Description of the Community Partners

Friends Community Center has numerous community partners that offer additional services to trans women of color including access to HIV medical care, free or low-cost hormone therapy, legal services, residential substance abuse treatment, mental health screening and treatment, primary medical care, housing, and transportation. Friends Community Center staff use their knowledge of the community partners to match the participant with services to meet her needs. In order to remain knowledgeable about culturally appropriate agencies and services, and to maintain personal relationships with our community partners, Friends Community Center staff made site visits to agencies, in pairs of two, on an ongoing basis throughout the implementation of The Alexis Project.

As Friends Community Center is a non-clinical site, formal partnerships with two medical clinics that provide HIV primary care was essential to the success of The Alexis Project. Memoranda of Understandings were established with each clinic. Although the clinics required various documents in order to enroll a participant into HIV medical care, many of the participants did not have this required documentation (i.e., government-issued ID). Therefore, the Peer Health Navigators worked in conjunction with the clinics to ensure participants obtained the required documentation to enroll in medical care as well as assisted the clinics in reminding participants of upcoming medical appointments,

transported participants to appointments, assisted participants with picking up medications, and even accompanied participants to medical appointments to enhance health literacy and assist the participant in understanding how to be an advocate for her health.

Core Intervention Staffing Requirements

Principal Investigator (PI): The PI was responsible for the overall management of the project; project implementation; participant safety; oversaw all program management tasks; assisted with staff hiring and training; attended Community Advisory Board (CAB) meetings; worked with the Project Director, evaluation team, and CAB in the development of the PHN manual; worked with the evaluation team, project staff, and CAB in the interpretation of findings; worked with the evaluation team in preparation of conference presentations and manuscript development.

Project Director: The Project Director was responsible for the day-to-day operations of the project; assisted with staff hiring and training; supervised and coordinated all project activities; oversaw program monitoring activities including program performance indicators; reviewed participant files for quality assurance; conducted in-service trainings at local CBOs and networked with community gatekeepers to enhance community awareness of The Alexis Project; substituted for absent Peer Health Navigators; maintained all program and intervention supplies; worked with the CAB and project staff on the development and implementation of project materials; facilitated CAB meetings; worked with the PI, evaluation team, and CAB in the development of the PHN manual.

Peer Health Navigators: The Peer Health Navigators provided peer health navigation to trans women of color living with HIV through multiple and ongoing sessions; linked all participants to HIV care; linked participants to up-to-date and culturally appropriate ancillary services and provided transportation, as needed; maintained fidelity to the intervention protocols; administered assessments to participants; maintained accurate and complete participant files; maintained accurate written reports, logged all program activities, and wrote daily and monthly staff reports; maintained an accurate and complete up-to-date, culturally appropriate referral list; and, attended CAB meetings.

Process Evaluator: The Process Evaluator oversaw all aspects of the program evaluation including operationalizing process and outcomes indices analysis design and revision; worked with the PI, the Project Director, and CAB in the development of the PHN manual; attended CAB meetings; worked with the PI, Project Director, Data Manager, project staff, and CAB in the interpretation of findings; worked with the PI and Data Manager in preparation of conference presentations and manuscript development.

Data Manager: The Data Manager supervised data management staff and activities; worked with the PI, the Project Director, and CAB in the development of the PHN manual; worked with the PI, Project Director, Process Evaluator, project staff, and CAB in the interpretation of findings; worked with the PI and Process Evaluator in preparation of conference presentations and manuscript development.

Medical Consultant: The medical consultant provided medical consultation; trained project staff on basic HIV medical case management including annual booster sessions; was available to read medical records provided by the collaborating medical providers; reviewed hormonal treatment profiles and ART choices, as needed; provided advice to project staff and other HIV providers on possible drug-drug interactions; consulted with project staff on participants' treatment plans; and, answered questions and addressed concerns regarding participants' treatment experiences and health outcomes.

PROGRAM PLANNING AND DEVELOPMENT

START-UP STEPS

Staff Hiring, Initial Training and Development, Developing MOUs and Partnerships, Developing Administrative and Provider Support and Buy-In, Developing Recruitment Strategies

The start-up for The Alexis Project included but was not limited to the identification of appropriate staff, considerable training for all levels of staff, the development of data collection processes and program materials, and establishing MOUs with partnering HIV clinics. It was vital that trans women of color living with HIV be an integral part of the staffing as the Peer Health Navigators, and have received ongoing training and support throughout the project. Upon hire, all staff received a six-to-eight-week multi-tier training consisting of: (1) in-house trainings by senior staff; (2) outside presentations and seminars provided by community professionals; and; (3) field observations and role plays with senior paraprofessionals and quality assurance through mock assessments.

The PI, Project Director, Process Evaluator, and Data Manager worked closely to develop all program materials and data collection processes including an in-house process evaluation spreadsheet for the Peer Health Navigators to record data on intervention exposure, viral load and medical visits, and CM payouts. Participant-Centered Treatment Plans and progress notes were also used by the Peer Health Navigators to record participant progress and the content of PHN sessions. All paper and electronic files were reviewed for Quality Assurance purposes on a weekly basis to ensure accuracy and completeness.

Provider buy-in was initiated by having the entire project team, from the PI to the Peer Health Navigators, visit each clinical site and hold an informational meeting with all clinic staff (from the front desk to the medical providers). These meetings took place right before project implementation and continued on a quarterly basis throughout the life of the project.

Friends Community Center has a long-standing trans-specific CAB that was utilized to guide project planning, design, implementation, and recruitment, to provide input for ongoing project improvement, and to address any barriers encountered during project delivery. The CAB was multicultural and composed of both trans

women living with HIV and high-risk negative trans women, current and past participants, community members including gatekeepers and stakeholders, local service providers, and members of local community planning and advocacy groups. CAB meetings were held on a biannual basis and all recruitment materials and project progress were reviewed at these meetings. CAB members provided ongoing feedback on the development of recruitment materials, implementation and process monitoring activities, client recruitment strategies and outreach, enrollment, and key project activities. Throughout the delivery of the project, the CAB monitored the cultural appropriateness of the project and modifications were made, as needed.

IMPLEMENTATION AND MAINTENANCE

Barriers and facilitators towards implementation

The greatest barrier to retention in The Alexis Project was the high rate of short- and/or long-term incarceration experienced by the participants. Although these participants were immediately provided with HIV care while incarcerated, upon release they needed to be linked to a HIV care provider to maintain medication adherence. Additionally, while incarcerated these participants often missed a follow-up evaluation time point. However, the Peer Health Navigators developed a strong rapport with the participants and, thus, most of the incarcerated participants returned to The Alexis Project site immediately, often within a day or two, upon release to reestablish their project participation.

Ongoing/refresher Training, Staff Development, and Retention Strategies

There was no turn-over of Peer Health Navigators throughout the implementation of The Alexis Project.

This consistency was a testament to the commitment the staff felt toward the project, and the commitment Friends Community Center had toward maintaining high-quality staff. This consistency also ensured continued rapport with the participants, which enabled high retention in the project.

Continuing education and training was greatly valued and continued throughout the duration of the project. In addition to the mandatory human subjects and Good Clinical Practice/Good Research Practices trainings, all staff at Friends Community Center attended regular annual trainings on relevant topics. These onsite trainings included Outreach Strategies, The Foundation of Harm Reduction, Empowerment When Working with High-Risk Populations, Ethnography as Street-Based HIV Prevention, HIV Treatment 101, Substance Use and the Brain, Steps to De-Escalate Stressful Situations, The ABCs of Hepatitis, Bloodborne Pathogens, Treatments for Co-Occurring Substance Use and Metal Health Disorders, Marijuana and Synthetic Drugs, Medical Marijuana and HIV: What Clinicians Need to Know, Dealing with Difficult Clients/Red Flags, Effecting Change through the Use of Motivational Interviewing, Self-Care for Addiction Professionals, and Disaster and Safety Policy and Procedures Training. Offsite trainings included HIV/AIDS 101, STD 101, Tuberculosis, One-to-One: Individual Level Approaches to HIV Prevention, Synthetic Drugs, Outreach and Linkage to Care, Clearview COMPLETE Training, and the LAC LGBT Community Police Academy.

In addition to onsite and offsite trainings, staff attended national conferences such as the Transgender Leadership Summit in Oakland, the Transgender Health Conference sponsored by the UCSF Center of Excellence for Transgender Health, and local conferences such as the Trans* Health Summit hosted by the Los Angeles County Commission on HIV. Also, staff were encouraged to attend webinars on relevant issues (i.e., hosted by CDC, HRSA, local CBOs) and to attend monthly Transgender Service Providers Network meetings to maintain up-to-date changes in local transgender and HIV services. Finally, the Medical Consultant provided an initial training upon implementation on the basics of HIV treatment (i.e., medications, how HIV affects the body) and how to read HIV lab work such as CD4 and viral load. After the first year of implementation, the Medical Consultant provided annual refresher booster courses as well as offered one-on-one technical assistance to staff on an as-needed basis.

INTERVENTION OUTCOMES

REPORT ON CERTAIN OUTCOMES

From February 2014 through August 2016, 139 participants enrolled in The Alexis Project. Participants selfidentified their race/ethnicity as African American/Black (n=57; 41.0%), Hispanic/Latina (n=44; 31.7%), multi/ other (n=30; 21.6%), and Native American/American Indian (n=8; 5.8%). The age range was 19 through 59 years (median = 34.7), with a mean age of 36.2 (SD=9.7) years. Participants identified their sexual identity as heterosexual (52.4%), gay (25.8%), bisexual (6.5%), lesbian (3.2%), and pansexual/asexual/don't know/other (12.1%). Just over one-third (38.7%) reported less than a high school education, one-third (32.9%) reported a high school diploma or a GED as their highest educational attainment, one-quarter (26.3%) reported some college-level education, and 2.2 percent reported a college degree (n = 137). More than one-third (38.9%) reported that they lived in their own house or apartment (either owned or rented), and just over one-quarter (26.6%) reported currently experiencing homelessness or living in a homeless shelter.

At baseline, 11 participants were unaware of their HIV positivity and, thus, the project's new positivity rate was 7.9 percent. At baseline, 26 percent (33/128) of the participants had never been in HIV care and, among those who had previously been in HIV care, 41.9 percent (n=36/86) had dropped out. Furthermore, at baseline, 48.2 percent (n=67/139) of participants were in need of an ART medication prescription, and 51.1 percent (n=71/139) had an ART medication prescription but were medication non-adherent. Time from enrollment to linkage to HIV care ranged from 0 to 467 days (SD=103.2 days). At intervention completion, i.e., August 2017, 84.9 percent (n=118/139) of the participants were linked to care and 60/135 (44.4%) had achieved and/or maintained viral load suppression.

On average, participants attended 6.7 (SD=6.5) PHN sessions (range 1 to 31 sessions, median = 4 sessions), and 88.4 percent of the participants attended more than one PHN session. Participants earned a mean of \$143.60 (SD = \$139.63) in CM rewards (range \$0 to \$500.00, median = \$90.00).

APPROXIMATE COSTS OF THE INTERVENTION ANNUALLY

The annual cost for operating The Alexis Project, excluding staffing and office space was approximately \$19,500. This included the cost for printing materials (approximately \$1,000), office supplies (approximately \$2,000), risk reduction supplies (approximately \$1,500), and incentives for CM rewards (approximately \$15,000). The maximum CM rewards was \$500 for reaching all targeted HIV health-promoting goals. If a project enrolls approximately 50 participants annually, and approximately 60 percent achieve all HIV health-promoting goals the annual cost for CM rewards would be $$500 \times 50 \times .60 = $15,000$. For scalability purposes, a site might also require a graphic artist to design recruitment materials and advertising costs. Ongoing staffing would include a Project Director at 50 percent effort, and two Peer Health Navigators both at 100 percent effort. Additionally, each site and geographic location will have a different cost for operating supplies, CM rewards, incentives, salaries, fringe benefits, indirect costs, and rent.

LESSONS LEARNED

Although there were many challenges throughout the implementation of The Alexis Project, the project successes far outweighed the challenges. Through this process several "lessons learned" became evident.

Maintaining Boundaries

Peer Health Navigators required ongoing training, guidance, and support in understanding the personal and professional boundaries that were needed in order to work effectively. Given that the Peer Health Navigators were truly peers, they had experienced many of the same issues the participants were currently experiencing. Thus, the emotional weight of working with the participants and the frustration in not being able to solve every issue experienced by the participant was particularly trying for the staff. Very early in the project it became clear that the Peer Health Navigators would benefit from clinical supervision. A clinical psychologist was retained as a consultant to provide bi-weekly clinical case conferencing for the Peer Health Navigators. Having a clinician to discuss specific participant situations as well as the inherent difficulties of working with trans women of color living with HIV was extremely helpful for the Peer Health Navigators. Through trainings and clinical supervision, the Peer Health Navigators learned to set appropriate boundaries and how to be of assistance to the participants without taking on the weight of their worries.

Training Up the Medical Providers

The HIV clinics required a tremendous amount of assistance in providing culturally competent services to trans women of color. Even though both partnering HIV clinics had a long history of serving trans

patients, the HIV clinics still required a tremendous amount of feedback and staff meetings to ensure that each practitioner was providing the trans patients with the best possible culturally appropriate care. This process included: 1) creating posters with trans women of color living with HIV (see Illustrations 2 and 3) that were placed in clinic waiting rooms and assessment rooms as neither clinic had health promotion materials posted that specifically featured trans women; 2) arranging for a medical doctor who specializes in trans health care to provide grand rounds presentations to clinic providers on how to deliver trans-specific health care services (e.g., hormone therapy, sex-specific screenings and exams that do not match the participants' gender expression); 3) providing "Trans 101" trainings to all clinic staff, from the front desk receptionist to the pharmacist to the lab technician to the medical provider; and, 4) assisting the administration in creating or updating trans-affirming policies and procedures such as creating new categories for gender identity on all medical paperwork and in the Electronic Medical Records, and moving from an outdated protocol for the initiation of hormone therapy to an informed consent model.

Adopting a Client-Centered Approach

Recruitment and retention strategies required the Peer Health Navigators to use a client-centered approach and "meet the participant where she is at." This often translated into patience, requiring the Peer Health Navigator to have multiple sessions with a participant before she was ready to make a significant lifestyle change. To that end, it was beneficial for the Peer Health Navigator to disclose her own HIV-positive status to participants, which helped the participant relate to and build trust with the Peer Health Navigator. Additionally, the Peer Health Navigators would often use the knowledge gained in trainings to educate the participant about hormone replacement therapy and ART medication. Many participants would initially prioritize gender confirmation therapies over HIV therapies. The Peer Health Navigators used client-centered language such as "protect your beautiful body" to explain why gender confirmation therapies and surgeries could be ineffectual if she was not adherent to her ART medication. Prioritizing HIV care is living a trans positive life.



INTERVENTION APPENDIX

The Alexis Project Logic Model

People/ communities you work with and what characteristics they have The resources required for this program to operate

What this program does in day-to-day operations

The "stats" that result from regular program operation

Desired changes for target population as a result of program activities

Trans Women of color

Ages 18-65

Living in Los Angeles County, CA

African American, Latina, Asian, Pacific Islander, Native American, multi-ethnic, and other races/ ethnicities

HIV-positive

Service collaborations with medical providers for HIV care (AIDS Healthcare Foundation (AHF),

Service collaborations for other agencies

LA LGBT Center

Volunteer social network recruiters

2 Full-time Peer Health Navigators (PHN)

1 Part-time Project Director

1 Part-time PI

1 Part-time Process Evaluator

1 Part-time Data Manager

Consultant, Medical Consultant Conduct social network recruitment for HIV testing and social network engagement with those who are aware of their HIV status

Provide HIV counseling and testing as part of social network testing (SNT)

Provide HIV prevention through existing programs for trans women

Provide additional support services including mental health, primary care, hormone therapy, support groups, housing, and youthspecific at partner agencies

Link those who test HIVpositive to a PHN

Link HIV-positive trans women of color to HIV care

Implement combined Peer Health Navigation and Contingency Management intervention

Provide Contingency
Management rewards
for attending HIV care
appointments and achieving
HIV milestones, i.e., reduced
or suppressed viral load (VL)

10 trans women will become volunteer recruiters for the SNT program

60 trans women of color will receive HIV counseling and testing

139 HIV-positive trans women of color will be linked to a Peer Health Navigator (PHN)

85% of those linked to a PHN will be linked to HIV medical care

70% of those linked to HIV medical care will be retained, i.e., at least two completed HIV-related medical visits 3 months apart

100% of HIV-positive trans
women linked to care will receive
a Contingency Management
reward for attending a HIV care
appointment and achieving a
HIV milestone

70% of HIV-positive trans women linked to HIV medical care will report >95% adherence to ART, and an undetectable VL or VL<200

85% of HIV-positive trans women will complete quarterly follow-ups to monitor engagement in care and HIV outcomes Increase in direct linkages to service providers that provide HIV services, substance abuse, mental health, hormone therapy primary care, support groups, housing, youth-specific services for those 25 and other supportive services

Increase in percentage of newly diagnosed trans women of color linked to, re-engaged in or retained in care

Increase in percentage of already diagnosed who were never or not in care trans women of color linked to, reengaged in or retained in care

Decrease in viral load among trans women of color engaged in care

Increased viral load suppression

Figure 1: The Alexis Project Study Design

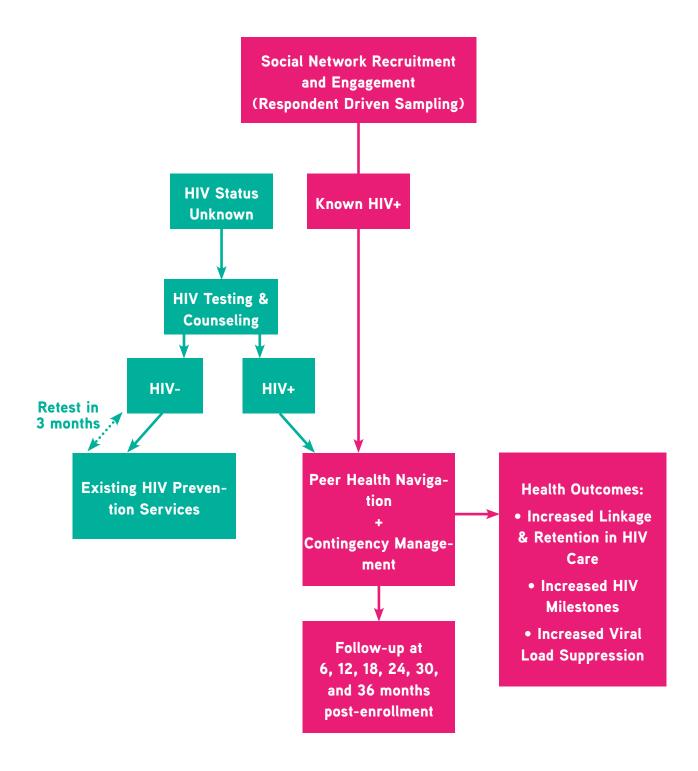


Figure 2: Combined Peer Navigation and Contingency Management Intervention

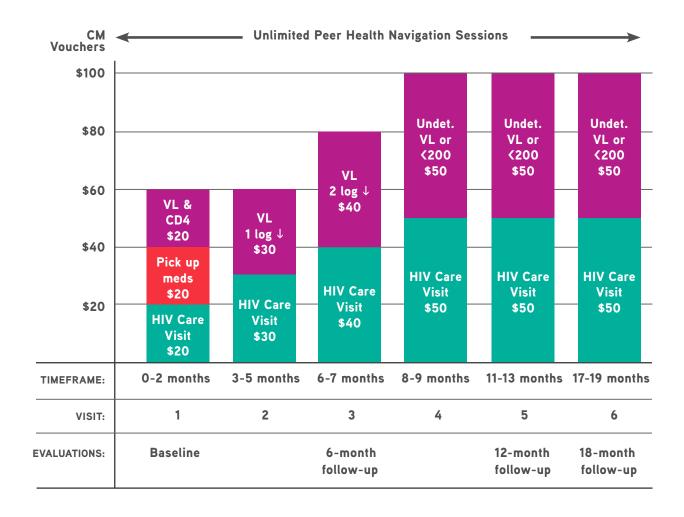


Illustration 1: Recruitment Flyer



HIV+ Trans Women of Color Will Be Immediately Linked to a Peer Health Navigator

We provide HIV testing for those who don't know their status or haven't had an HIV test in the last 3 months.

The Alexis Project combines Peer Health Navigation and Contingency Management interventions into one program.

Eligibility

- · Newly diagnosed HIV-infected trans women of color.
- HIV-infected trans women of color who have never received HIV medical care, or have dropped out of HIV medical care.

Peer Health Navigation

The Peer Health Navigation component of the program works with participants to identify HIV medical care services and other needed services, develop an individual client-centered treatment plan, remove barriers to those services and access those services. A Peer Health Navigator works with each participant to link her into HIV medical care by helping her make medical appointments and, if needed, providing transportation to and from HIV medical appointments. A Peer Health Navigator provides information and emotional support as she works with each participant to address her needs and barriers to accessing HIV medical care.

Contingency Management

The Contingency Management component of the program provides increasingly valuable incentives for attending HIV medical visits and reaching and maintaining HIV milestones. Each participant may earn up to \$500 in incentives if she attends every HIV medical care appointment and reaches every HIV milestone.

Follow-up evaluation assessments are conducted every 6-months throughout the entire project.

The goal of The Alexis Project is for each participant to reach viral load suppression after regular, sustained HIV medical care visits and adherence to HIV medications.

For more information, call or text Angelina or Miranda at 323-793-4645.

Or call our office at 323-512-7014.



The Alexis Project is named after Alexis Rivera who died on March 28, 2012, at the age of 34, from complications related to HIV. Alexis was a proud Latina trans woman, a community activist, a peer advocate and a gatekeeper.

A project of Friends Research Institute. Funded by Health Resources and Services Administration.



Illustration 2 and 3: Posters Developed with Strong Images of Trans Women of Color Living with HIV for the Medical Clinics

