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San Francisco Department of Public Health
Population Health Division

San Francisco PrEP and Data to Care Demonstration Projects

Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons

CDC-RFA-PS15-1506

Note: CDC Form 0.1113 Assurance of Compliance and the Indirect Cost Rate Agreement are not included in the Table of Contents but are included with the application.

A. BACKGROUND

The City and County of San Francisco (SF) was one of the first and hardest hit epicenters of the HIV epidemic. As of December 31, 2013, SF had 15,901 residents living with HIV – 13% of California's living HIV cases. Nine out of every 10 living HIV cases in SF are among men who have sex with men (MSM). Locally, MSM continue to be disproportionately impacted by HIV, comprising 86% of all HIV cases newly diagnosed in 2013, with 27% of new diagnoses among MSM of color.[1] The good news is that new infections are decreasing, and in 2014 multiple individuals and organizations including the San Francisco Department of Public Health (SFDPH) established the multi-sector, independent **Getting to Zero Consortium (G2Z)**, with the long-term goal of Zero HIV infections, Zero HIV Deaths, and Zero HIV stigma. Its short-term goal is to reduce both HIV infections and HIV deaths by 90% from their current levels by 2020. The G2Z strategic priorities describes a comprehensive approach with three signature initiatives which relate directly to the strategies supported through PS15-1506: 1) PrEP expansion, 2) Provision of antiretroviral therapy in the setting of acute HIV infection or upon diagnosis and 3) Retention in HIV care.

SFDPH has a long history of selecting and supporting scalable, evidence-based interventions to prevent HIV transmission, including partnering with the University of California, San Francisco in 2010 to make SF the first U.S. city to recommend offering antiretroviral treatment as soon as an individual is diagnosed with HIV. The same year, in close collaboration with community and health systems partners, we made a concerted effort to shift resources toward increasing the frequency of HIV testing among MSM, injection drug users (IDU), and transfemales (TF) residents.[2] Approximately 58% of MSM,[3] 38% of IDUs,[4] and 51% of TF[5] in SF have now tested for HIV in the prior six months. Yet there is still much work to be done. Between 300 and 400 people become newly infected with HIV each year in SF, with the majority of these new infections among MSM and TF and the highest incidence rates among MSM and TF of color.[6] The resources from this grant will provide further support to scaling-up our local efforts by addressing critical gaps in PrEP uptake, particularly among persons of color, and enhancing our activities to proactively use data from HIV surveillance to identify HIV-diagnosed individuals not in care, link them to care, and support them to stay in care.

SF has been on the forefront of PrEP research and implementation for over a decade. We participated in early safety studies of tenofovir for PrEP[7,8] and were a site in the global iPrEx trial – a Phase III clinical study that enrolled almost 2500 sexually active MSM and TF in nine cities, including SF.[9] In 2012, SF launched the U.S. PrEP Demonstration Project (DAIDS Protocol ID: #11879). This multisite, open-label demonstration project focused on uptake and adherence to PrEP among MSM and TF. In SF, 300 people were enrolled at SF City Clinic (SFCC), the municipal STD clinic. Uptake was high across all three study sites nationally (SF, Miami, and Washington, DC); in SF 56% of those who were potentially eligible chose to enroll. Of the three sites, we had the highest retention rate, with only 12% of those who enrolled discontinuing PrEP before week 48.[10] While African Americans and TF were no less likely to enroll in the study than whites or MSM, they were under-represented in the study cohort, with only 9 African American MSM and 5 TF among the 300 participants enrolled. These findings reflect the need for increased PrEP education and outreach to MSM of color in SF, and for enhanced efforts to support retention and adherence for this disproportionately affected population.

While PrEP awareness appears to be increasing in SF overall – community-based surveys through the National HIV Behavioral Surveillance (NHBS) demonstrated a rise in PrEP awareness from 20% in 2006 to 44% in 2011 – PrEP awareness remains low among key priority populations. In the local TEACH2 survey among 233 TFs in SF in 2013, only 32 (14%) had heard of PrEP, and only one of those 32 was willing to use PrEP for HIV prevention. PrEP use has increased over the last several years, with 5,059 individuals reporting PrEP use in 2013. However, few MSM of color and TF have initiated PrEP in SF. **This proposal will address the urgent need for strategies to increase PrEP knowledge and uptake in these populations, to prevent further disparities in the HIV epidemic.**

Through the DAIDS PrEP demonstration project, we developed screening, counseling, insurance and care navigation, and clinical protocols for PrEP delivery and adapted them for ongoing use in SFCC, which has started over 120 clients on PrEP in the last year. Yet despite these efforts, patients and providers face a number of barriers in PrEP access and delivery. In May 2014 we distributed a 20-question email survey to primary care providers in the SF Bay Area to gather local data on experience with, attitudes towards, and training needs around providing PrEP. In a convenience sample of approximately 101 prescribing clinicians (see Table 1 for demographics of respondents) we found high willingness to prescribe PrEP to patients at ongoing risk of HIV infection (76% overall extremely or highly likely to prescribe). At the same time, many responding clinicians expressed concerns about PrEP, including toxicity, adherence, drug resistance, drug cost, and side effects; 65% wanted training on aspects of PrEP, especially on the operational aspects of PrEP delivery, such as visit frequency, HIV testing, and counseling patients on adherence and sexual risk behavior. Respondents wanted to receive training through multiple methods, including person-to-person (95% telephone warmline or face-to-face) or electronic (online course 55%, online document repository of clinical 73% and counseling (63%) guidelines, video vignettes (27%)). This highlighted a high willingness to prescribe, but also significant concerns and training needs, which we will address through this proposal by outreach and education to clinicians by the training methods they prefer, including individual public health detailing, clinical mentoring, mini-workshops, and a repository of on-line resources, such as videos of fictional counseling sessions, webinars, and document libraries. We will also continue to partner with the Centers for Disease Control and Prevention (CDC)-funded PrEP Warmline at the University of California SF (UCSF), located on the SFDPH campus of SF General Hospital (SFGH), whose staff includes some of the members of our team.

Table 1. Provider Survey Demographics (N=101)

	White	69%
Race/ethnicity	African American	27%
	Latino	8%
Median Age		44
Gender	Female	56%
	Male	44%
Length of time in practice	>10 years	53%
	10 years or fewer	47%
Certification	MD/DO	73%
	NP/PA	11%
Specialty	Family medicine	51%
	Internal medicine	26%
	Infectious disease	12%
Experience caring for HIV+ patients	Yes	79%
	No	21%
Insurance taken	Private	49%
	Medi-Cal	90%
	Other public	63%
	Uninsured	68%

When it comes to those who are already HIV-positive, we are also making strides. From 2009-2013, the number of people newly diagnosed with HIV in SF declined from 463 to 359 new diagnoses.[2] Yet, while some improvement has been seen in those years, **many who are diagnosed continue to fall out of care or fail to become virally suppressed**, an indication that ARV medication has not been started or adhered to as needed. (See Figure 1).[1] In recent years,

Figure 1. SF Continuum of HIV Care, 2009-2012.

between 84% and 89% of people newly HIV-diagnosed in SF were linked to care within 3 months of diagnoses and in 2012, 68% of people newly diagnosed achieved viral suppression within 12 months (Figure 1). However, our surveillance data shows that African-Americans and Latinos are less likely to have timely linkage to care and viral suppression when compared to Whites.[1]
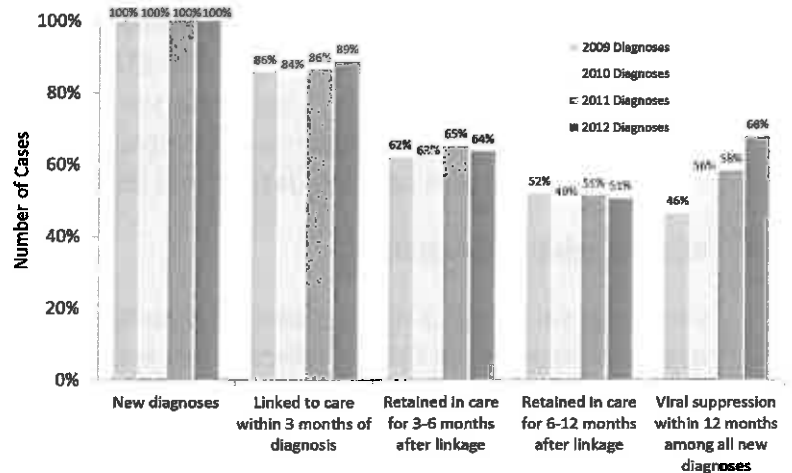
B.1. APPROACH – CATEGORY 1 (PrEP)

i. Purpose
Funding for Category 1 will enable us to implement high-impact, evidence-based strategies to improve uptake of PrEP among people at substantial risk for HIV in SF, especially MSM of color and TF. Our jurisdiction is keenly aware that Pre-Exposure Prophylaxis (PrEP) is a critical tool to reduce HIV infections among persons at substantial risk of acquiring HIV and optimizing the health outcomes of people living with HIV. The activities detailed below align both with the G2Z strategic priorities and the National HIV/AIDS Strategy (NHAS) goals of reducing new HIV infections, and reducing HIV-related disparities and health inequities.

ii. Outcomes
By the end of the project period, we expect to achieve the following outcomes for Category 1:
SHORT-TERM OUTCOMES:
- Increased capacity of SFDPH to implement PrEP support activities for people at substantial risk of HIV, especially MSM and TF, particularly persons of color (the "target population")
- Increased knowledge and awareness of PrEP for HIV prevention among the target population
- Increased provider knowledge and awareness of PrEP, and training in clinical management of PrEP for HIV prevention among providers
- Increased capacity of SFDPH to integrate services and share and utilize data across HIV, STD, Hepatitis programs, and the SF Health Network to help identify those who can benefit from PrEP, especially the target population

INTERMEDIATE OUTCOMES:
- Establishment of policies, procedures and protocols to implement PrEP support activities for the target population
- Increased number of providers trained to offer PrEP to the target population
- Increased number of PrEP prescriptions for the target population

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- Establishment of policies, procedures and protocols to integrate services and share data across the SF Health Network and HIV, STD and Hepatitis programs to help identify those who can benefit from PrEP, especially the target population
- Enhancements to the Public Health Network Information Exchange (PHNIX) information system to support ongoing data-driven decision making around PrEP activities

iii. Strategies and Activities

Our proposal details a number of strategies designed to increase PrEP uptake overall and address disparities in PrEP knowledge, access, and uptake, particularly among MSM of color and TF in SF. A core element of these strategies is the establishment of a 1.0 FTE Lead PrEP Coordinator position at SFDPH. The Lead PrEP Coordinator will manage the day-to-day activities of the program and help ensure that each of the activities and staff are functioning with maximum efficiency and effective communication. S/he will be supported by a 1.0 FTE Health Educator who will manage details of protocol development and dissemination to stakeholders.

1. Collaborations

We have a long history of community collaboration with HIV care agencies, HIV advocates, and persons living with HIV/AIDS. For this project, the SFDPH and CDC will work closely with the Getting to Zero Consortium (G2Z). The PrEP activities proposed here arose out of the G2Z strategic planning process and have the full support of the G2Z membership. As always, we will also work closely with dozens of community-based organizations and community clinics, which together create the HIV Prevention and Care Network that is so important to our city. This includes regular leadership and engagement with the HIV Prevention Planning Council and the Ryan White Care Council, both of which are filled with people living with HIV, and community leaders representing agencies serving people living with HIV.

2. Target Populations

MSM (including those who inject drugs) make up 89.0% of people living with HIV in San Francisco[1] despite being only 7.7% of the total population citywide.[11,12] Twenty-seven percent of cases are among MSM of color, and although the overall numbers of cases diagnosed in SF among MSM each year is declining, most of the decrease is seen in white MSM, with diagnoses among MSM of color holding relatively steady as seen in Figure 2.[1] **Even**

Figure 2. Cases diagnosed with HIV infection among MSM by race/ethnicity, 2006-2013, SF.

more distressing, per consensus estimates, a full 38% of TF in SF are living with HIV with a shocking 2.6% becoming infected each year (the incidence rate is 3.88% among TF who inject drugs).[12] For these reasons, we are focusing our PrEP strategies and activities on MSM and TF at high risk for HIV infection, with emphasis on people of color.
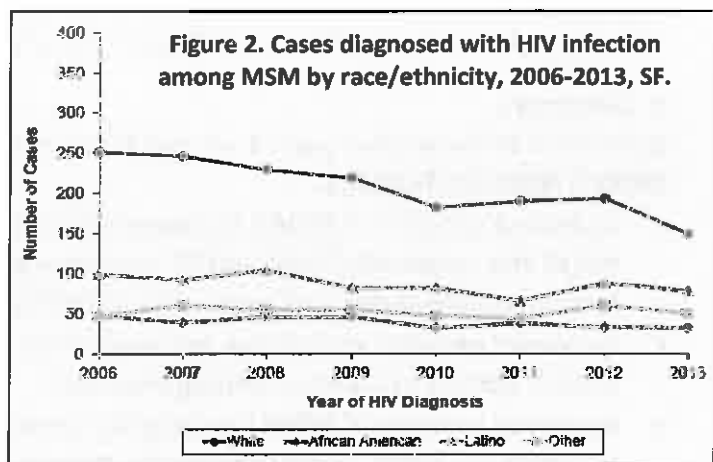
3. Activities

Activity 1: Analysis and Further Assessment of Gaps

In the first half of year 1, we plan to conduct a detailed analysis of the data related to barriers to PrEP usage for our target population. This analysis will be conducted by a 1.0 FTE Senior Epidemiologist working within the HIV Surveillance Unit of SFDPH, and will involve a mixed-methods approach: analysis of data in the HIV surveillance, HIV Counseling, Testing, and Referral (CTR), SF Health Network, and STD testing data systems; brief surveys, focus groups, and key informant interviews with members of the target population; and focus groups and key informant interviews with HIV care providers in settings most utilized by the target population for care. The analysis will answer a series of key questions:

1) What are additional barriers to PrEP for our target population?
2) Where are members of our target population currently seeking HIV/primary care?
   a. Where were those newly diagnosed with HIV getting primary care *before* diagnosis?
   b. What proportion of our target population (particularly MSM of color and TF) do not currently have a medical home?
3) What is the optimal and preferred site of PrEP screening and delivery for the priority populations (i.e. primary care, pharmacies, a CBO, municipal STD clinic)?
4) What are barriers to providing PrEP in the settings identified in #3, above?

This analysis is a critical part of our overall strategy, because as stated earlier, we know that in our existing work to increase PrEP uptake in SF, African American MSM and TF have been significantly underrepresented; additionally, of those who *do* enroll, their rates of PrEP retention and adherence are significantly lower than other groups.[13] This illustrates a need for innovative strategies to engage this target population in PrEP and support their adherence to the medications. This requires an enhanced understanding of their particular barriers to PrEP uptake, and exploration of which strategies may be most effective to improve rates of engagement in PrEP within these communities.

Activity 2: Targeted Community Engagement

In the second half of year one, once our barrier analysis (Activity 1) has concluded and a final report is disseminated to project staff and key stakeholders, we will begin outreach for members of the target population who are not already in primary care, or in care but not sure about PrEP as an HIV prevention strategy that could work for them. The exact methods of outreach will be determined by the project staff based on the findings of the assessment; however, we expect that this outreach will involve both a social marketing campaign and the use of Popular Opinion Leaders to reach the target population. In the US PrEP demonstration study, we found that 65% of self-referred clients had heard about PrEP from a friend or sex partner, demonstrating the importance of peer-influence in driving PrEP uptake.[14]

1) Social Marketing: DPH has contracted with Better World Advertising (BWA) to conduct "listening sessions" with members of the G2Z Consortium in the summer of 2015 to learn the inventory of current local and national social marketing campaigns to increase PrEP uptake. There are many resources currently in place and BWA will analyze opportunities and needs, as well as identify efficiencies and reduce potential overlap. During the same time period, BWA will also conduct listening sessions with key HIV prevention CBOs in SF; following the listening

sessions, BWA will present the concepts to focus groups of consumers for input and fine-tuning. The expectation is that by the time 15-1506 is awarded, a campaign will already have been planned and funding from this grant will be used to implement the final model.

2) Popular Opinion Leader (POL): In addition to social marketing, our project will draw on a proven strategy for delivering HIV and STD prevention messages to MSM and TF, especially those of color: the Popular Opinion Leader (POL) intervention. POL is a community level intervention in which respected community members are recruited and given training on HIV risk reduction strategies. These leaders then engage their friends in conversations designed to reduce HIV risk while normalizing healthier sexual behaviors.[15] In their 1992 study, Kelly et al demonstrated a 15 – 29% reduction in HIV risk behaviors when trained peer leaders communicated risk reduction recommendations to friends.[16] Among African American men ages 18 – 30, Jones and colleagues demonstrated that a POL intervention specifically adapted for African American MSM significantly increased condom use and decreased both the number of partners for and episodes of unprotected sex. This intervention has been proven effective when adapted for Latinos as well. The *Promotores* program, implemented among young Latino MSM in Texas and California, demonstrated both an increase in HIV/STD knowledge and a reduction in risk behaviors.[17] For our project, we will write an RFP and subcontract $145,000 to CBOs with experience using POL, and the established reputation and relationships with MSM of color and TF. This strategy is in line with the recommendations of the PrEP User Subcommittee of the Getting to Zero Consortium, which has called for the use of PrEP Community Ambassadors to network and provide education in different high-risk communities in San Francisco.

3) Navigation to PrEP: We will then build upon these strategies to improve our ability to educate and directly link members of the target population to PrEP services. Strategies that have been recently recommended by the PrEP User Subcommittee of the Getting to Zero Consortium and/or the SF Transgender Advisory Group will be vetted during the barrier analysis period (Activity 1), and potentially incorporated into our outreach strategies under this proposal. They include:

- PrEP advertisement and navigation using hookup apps such as Grindr, SCRUFF, Hornet, and BarebackRT, with a PrEP Navigator available to answer questions about PrEP to app users
- Increasing the use of PrEP-related Town Halls (presentations at churches, community centers, bars, etc.) and participation in events such as the Gay Pride parade or Castro Street Fair
- PrEP navigation services that are based online, including the *PleasePrEPMe.org* website that provides geolocation of the nearest PrEP clinics, chat-based access to a Navigator to answer questions and provide referrals, and an online database that allows someone to plug in zip code, income, and insurance status to receive information on local providers or benefits.

Activity 3: "Data to PrEP"
Building on the idea of the Data to Care evidence-based intervention (Category 2), we also plan to implement a series of data-based strategies to assist SFDPH identify and reach out to those with the greatest need for PrEP. As part of this activity we will also work to build the capacity of

our Disease Intervention Specialists (DIS) to recognize PrEP eligibility and directly refer members of the target population to settings where they can obtain PrEP.

First, we will use STD surveillance, SF Health Network, Hepatitis, and HIV CTR data to identify those with greatest need for PrEP, so that a PrEP Navigator can reach out to them and offer support for linkage to PrEP services. This will involve an 0.5 FTE Epidemiologist Informatician/Systems Designer to conduct the analysis of data in existing systems, as well as approximately 400 hours of system developer time to develop system functionality within our Public Health Network Information Exchange (PHNIX) data system (Consilience Software), scheduled to be launched within year 1 of this project. This will include the ability to flag individuals who are prime candidates for PrEP and provide their contact information to Navigators who can support them in obtaining PrEP.

Secondly, we recognize that our DIS staff are in an exceptional position to identify and facilitate connections with members of the target population who are strong candidates for PrEP. These staff are trained and employed specifically to reach out to those who are at high risk for or have recently contracted or been exposed to an infectious disease. We plan to build DIS capacity to recognize PrEP eligibility and provide direct information and referrals for PrEP to those at highest risk, through funding 0.5 FTE of a DIS who will function as our PrEP champion. This DIS will do ongoing training and support for their colleagues, and will work with internal data to ensure we are presenting PrEP as a routine part of HIV and syphilis Partner Services.

Once our DIS staff are fully trained, we will combine their skills with enhanced data system functionality to more thoroughly integrate PrEP services into Partner Services and STD testing and treatment efforts. While PrEP is more commonly connected with HIV testing services it is a novel strategy to use data to integrate PrEP services into Partner Services and STD testing. However, individuals with a rectal STD and those who are named in HIV or syphilis Partner Services interviews – if not already HIV-positive – are by definition at high risk for HIV. We plan to use our data systems and our DIS to identify those individuals quickly, and offer not just HIV and STD testing but also a direct connection to PrEP services. Similarly, someone who comes into any public service location for an STD test and has a positive result will also be flagged and rapidly approached by a DIS or other Navigator for linkage to PrEP.

One important and novel component of this activity is our plan to implement procedures for **active surveillance of PrEP**. The PrEP Metrics subcommittee of the Getting to Zero Consortium has recommended the following activities to help us have a clear understand of PrEP use in SF, which we will undertake with this grant, using an epidemiologist to coordinate activities:
1) Regularly pulling data from the electronic medical records of SF Health Network providers, about the number of patients prescribed PrEP, by site.
2) Adding questions about PrEP use to the data collection form for the HIV CTR database, to gather information from people testing for HIV in public counseling and testing sites.
3) Working with pharmacies, starting with Walgreens and Kaiser, to set up systems for regular reporting of PrEP prescriptions to SFDPH.

Activity 4: Building Provider Capacity to Offer PrEP
Finally, we recognize that one of the biggest limiting factors to widespread use of PrEP in SF is not simply interest on the part of the target population, it is their ability to obtain affordable,

accessible, and stigma-free PrEP services. Providers may not understand PrEP, or may be unwilling to prescribe PrEP based on concerns about clinic flow or the inability to offer the regular follow-up care required for maintenance of a PrEP regimen. Some providers may be worried that PrEP might lead to risk compensation or that the medication may cause harmful side effects for their patients. Providers that may *want* to offer PrEP may have limited capacity, and often have competing health issues to address with their patients. We plan to address these barriers and build provider capacity to offer PrEP through a series of 3 strategies:

1) Developing tools/materials to improve provider knowledge of PrEP: There are many materials available on the internet, including via the CDC Provider Portal that informs and encourages medical providers to prescribe PrEP. However, there is a shortage of actual practical implementation tools (checklists, protocols, etc.) that help providers actually get a PrEP program off the ground. In the first year of the project, we will conduct in-depth interviews with around a dozen providers, to understand potential barriers to PrEP, and identify what tools and guidelines would be most helpful. We will also conduct an exhaustive search of available materials (including those already developed by Kaiser Permanente and the New York City STD/HIV Prevention Training Center) so as to avoid "reinventing the wheel." We will then take those findings and develop a series of tools adapted for SF clinicians, to encourage the start or support of PrEP programs. To accomplish this, we have budgeted a 0.5 FTE position in the Center for Learning & Innovation during year 1 of this grant; this person will be responsible for development, compilation, and dissemination of these tools. Additionally, as part of the U.S. PrEP Demo Project, the SFCC created a protocol with various tools (counseling worksheets, insurance navigation tips, a visit-by-visit guide to implementing PrEP, etc.) that are useful for a PrEP program based at a municipal STD clinic. These materials will be adapted to other settings, such as private provider's offices, public primary care clinics, or community organizations.

2) Academic detailing: Academic detailing involves trained medical professionals providing one-on-one evidence-based outreach to providers with the goal of objectively presenting the latest scientific information on significant and time-sensitive medical interventions to benefit providers who have limited availability to stay independently informed of new scientific findings. It applies the social marketing techniques of pharmaceutical detailing to academic-based education initiatives by using: interactive dialogue, engaging presentations, visually stimulating materials, and accountable behavioral change objectives. This method of education outreach is an effective alternative to the traditional didactic method of CME that is often unable to engage providers to substantiate behavior change. To increase accessibility and effectiveness, academic detailing takes place in providers' own offices at their convenience and encounters typically range from 3-30 minutes. **Academic detailing is associated with statistically significant behavior change** and has been proven to successfully reduce drug costs,[18] scale-up routine HIV testing,[19] increase smoking cessation efforts, and optimize effective prescription of medications by primary care providers.[20]

In October of 2014, the SFDPH initiated a program to detail non-DPH primary care providers in SF on opioid safety and naloxone co-prescription. We developed materials for the intervention, built a list of primary care providers based on a list of providers who prescribed opioids to Medi-Cal patients, and began detailing providers in February of 2015. As of April 2015, this program had resulted in successful detailing of 35 providers. Information is forthcoming about

the impact this detailing intervention had on opiate prescriptions, though literature about the impacts of academic detailing suggests it is likely to demonstrate positive impact.

Our PrEP academic detailing program will include the following elements:

- Adapting New York's "PrEP and PEP Action Pack" for clinicians.[21]
- Hiring of a 1.0 FTE Nurse Practitioner (NP) who will serve as the front-line academic detailer, reaching out to providers. This detailer would be more of a *probe* than the traditional pharmaceutical model of "pushing" a product. While of course s/he would encourage the use of PrEP with patients, in this case the lead detailer would provide information, then report back to the detailing support team if someone is interested but unlikely to begin prescribing PrEP without additional follow-up and technical support to reduce barriers.
- Funding additional 0.5 FTE of an existing NP with detailing experience to support and follow-up with interested providers. Whenever a provider appears interested in PrEP but is concerned about technical issues such as clinic flow or other implementation matters, the lead detailer will refer that provider to the support detailer for follow-up. They will be available to clinicians in person, via phone, or through email as needed to support their use of PrEP on an ongoing basis, until this support is no longer necessary.
- Training and ongoing support of the detail team. Experience has shown that academic detailing is not an easy task, and to be successful it is critical to provide ongoing training, supervision, and support of detailers. Our detailers will be supervised by Dr. Stephanie Cohen, Medical Director SF City Clinic; furthermore, the detailing team will be sent to a formal academic detailing training within the first 3 months of their hiring.

3) Establishment of "Communities of Practice" (CoPs): In year 1 of the grant, the staff position in the Center for Learning & Innovation dedicated to establishing PrEP tools/materials for providers will devote their remaining 0.5 FTE to recruiting providers to participate in one of a number of CoPs. CoPs will be defined by role (i.e. administrators, test counselors, primary care providers) and by type of service organization (i.e. non-clinical organizations that work closely with the target population such as sociocultural groups, neighborhood organizations, or churches; HIV prevention agencies already providing PrEP services; and health clinics trying to start PrEP programs). All providers can participate, but providers who are diagnosing HIV/STDs among their patients/clients, especially MSM of color and TF, will be identified via surveillance data review and actively invited to join a CoP. Participation in a CoP will involve two benefits: a) access to an online forum for PrEP providers, where clinicians can ask their peers for advice on challenging cases or situations and receive rapid advice or other responses from others in the CoP, and b) Videoconferencing every two months to discuss PrEP implementation issues in depth with other similar providers. Project ECHO demonstrated the value of videoconferencing for hepatitis C providers in New Mexico. In 2009, the Robert Wood Johnson Foundation funded a pilot project to extend this module to Washington State, and videoconferences were added in the area of HIV/AIDS.[22] We currently partner with the Univ. of Washington to use this technology to support health departments in PrEP implementation nationally. This videoconferencing technology only requires a regular computer webcam; ease of implementation facilitates use with a wide variety of providers.

After set up work in the first year, the Health Program Coordinator will work full-time to facilitate and manage these CoPs, including managing logistics, inviting expert presenters, handling technical aspects of videoconferences, and maintaining provider membership in CoPs.

4) Reaching out to Community Service Providers: Finally, we recognize that CBO service providers frequently serve clients at elevated risk for HIV, including MSM of color and TF. For this reason, we have allocated a 1.0 FTE Health Worker to serve as a PrEP Navigator, building and maintaining relationships with community service providers who work well with this target population. These include HIV test counselors, case managers, outreach workers, substance use counselors, and syringe access providers. Similar to the work described in the *Academic Detailing* section, for this activity staff will reach out to these providers to assess their knowledge and willingness to refer for PrEP, and provide education or technical support when needed, to encourage strong PrEP referrals.

B.2. APPROACH – CATEGORY 2 (DATA TO CARE)

i. Purpose
Funding for Category 2 will enable us to fully implement the CDC Data to Care intervention in SF and increase the proportion of HIV-diagnosed MSM and TF in SF who are virally suppressed, especially for people of color. Our jurisdiction is keenly aware that Data to Care is a critical tool to reduce HIV infections among persons at substantial risk of acquiring HIV and optimizing the health outcomes of people living with HIV. The activities detailed below align both with the G2Z strategic priorities and the NHAS goals of reducing new HIV infections, and reducing HIV-related disparities and health inequities.

ii. Outcomes
By the end of the project period, we expect to achieve the following outcomes for Category 2:
SHORT-TERM OUTCOMES:
- Increased capacity of SFDPH to implement Data to Care activities for HIV-diagnosed MSM, TF, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care (the "target population")
- Increased capacity of SFDPH to conduct outreach to the target population

INTERMEDIATE OUTCOMES:
- Increased capacity of SFDPH to use surveillance, program, and clinical data to accurately identify members of the target population who reside in San Francisco
- Increased capacity of SFDPH to contact members of the target population
- Increased capacity of SFDPH to refer the target population to HIV medical care
- Increased proportion of all HIV-diagnosed MSM and TF who are virally suppressed
- Reduced length of time between identification of the target population and their successful engagement or re-engagement in HIV medical care

iii. Strategies and Activities
In 2011, we developed the Linkage, Integration, Navigation, and Comprehensive Services (LINCS) program, designed to link newly diagnosed people to HIV medical care, and provide

short-term navigation services to previously diagnosed patients who are out of care. LINCS is currently staffed with 1.5 FTE Navigators who work to provide short-term navigation for people living with HIV for up to 90 days, with the goal of linking or re-linking people to care. LINCS clients are identified almost exclusively through provider referral at this time. Overall, this program has been successful: in 2012 and 2013, 315 patients were referred to LINCS. 116 (37%) were located and enrolled in LINCS, and 74% of those were successfully re-linked to care. 3-12 months after case closure, 51% of those who were re-linked to services by LINCS were virally suppressed, compared with only 23% of those who were not re-linked (p=0.007).[23]

We recognize the value in utilizing surveillance data to support continuous, high-quality HIV care. To that end, LINCS is currently working with HIV surveillance staff to pilot a Data to Care process in which prior to attempting to locate the client, HIV surveillance staff assess whether the patient is receiving care elsewhere or has moved using routinely collected HIV surveillance data. For a summary of current Data to Care activities see Table 2 below.

Table 2: SF Data to Care: Current use of HIV Surveillance to support LINCS activities.

Activity	Data Flow
1. Determine if patients testing HIV-positive at SFDPH funded testing sites are new or known cases to prioritize linkage and partner services activities to newly diagnosed patients.	The LINCS program receives names of patients testing HIV-positive at SFDPH funded test sites. HIV Surveillance determines if these HIV-positive patients are new or known cases. Returns information to LINCS.
2. Determine if sex partners named by a newly diagnosed patient are already known to be HIV+ to prioritize partner services for HIV-negative partners.	The LINCS program collects names of sex partners from newly diagnosed index cases. HIV Surveillance determines if these partners are HIV-infected or negative. Returns information to LINCS.
3. Refer patients testing positive in private medical sites to LINCS for linkage and partner services.	HIV Surveillance identifies people testing HIV positive at private medical sites. Returns this information to LINCS.
4. Determine if not-in-care (NIC) clinic patients are receiving care elsewhere or have moved out of SF prior to referral of cases to LINCS or further clinic action.	LINCS provides names of clinic patients who appear to be NIC from their caseload to HIV Surveillance. HIV Surveillance determines if these patients are receiving care elsewhere or have moved.

Using the wealth of available surveillance data to focus and prioritize our efforts on those who need it most will not only increase our efficiency, but it will reduce HIV-related health disparities in SF by increasing the percentage of people who are virally suppressed in the target population.

1. Collaborations

As with Category 1, the San Francisco Getting to Zero Consortium (G2Z) is a major source of support and collaboration for these Category 2 activities. Additionally, within SFDPH, the LINCS Navigation program relies on partnerships with the SF Health Network and SF General Hospital-based medical providers, community testing agencies, and other SFDPH providers to improve patient health by increasing accessibility to HIV primary care, HIV treatment, and relevant services. The HIV care Navigators work with HIV positive patients intensively to help them

engage in primary medical care and connect them to long-term case management and other services through warm referrals and direct handoffs. These existing successful collaborations between SFDPH and the clinical and service organization sites discussed in this application will continue and should help maximize the likelihood of success of this Data to Care project.

2. Target Populations

The SFDPH HIV Surveillance Branch tracks the demographic characteristics, geographic location and care indicators for all people living with HIV and for people newly diagnosed with HIV each year in SF. In addition, SFDPH is an HIV Incidence Surveillance site funded by CDC to calculate an estimate of new HIV infections (as opposed to new diagnoses) each year in SF. Current data indicate that the areas in SF where HIV-infected persons are least likely to be virally suppressed are the Excelsior, Bayview, Outer Mission and the Tenderloin (see Figure 3). Data additionally suggest that in order to address gaps and inequalities in access to HIV care and prevention services, the SFDPH should prioritize services in these same neighborhoods[24] – areas with the highest concentration of Latinos, African Americans, and TF – to decrease disparities in HIV incidence among the sub-populations less likely to be virally suppressed. Furthermore, data from HIV Incidence Surveillance found that the rates of HIV incidence are disproportionately high among MSM compared to the overall incidence rate in the City, and among African Americans and Latinos compared to Whites.[1] This suggests that to prevent the greatest number of new infections, the SFDPH should prioritize HIV prevention services in the Castro, an area with the highest proportion of people living with HIV and the highest proportion of people newly diagnosed with HIV as well as the largest population of MSM (see Figure 4).

Figure 3. Geographic distribution of proportion of living HIV cases diagnosed through 2011 who achieved viral suppression in 2012

Figure 4. Geographic distribution of persons living with HIV, December 2013, SF

For these reasons, as with Category 1 we have decided to focus our Data to Care strategies and activities on <u>MSM and TF at high risk for HIV infection, with emphasis on people of color.</u>

3. Activities

SFDPH is currently preparing for launch of the Public Health Network Information Exchange (PHNIX), an integrated, secure, web-based system for all public health reporting, surveillance, case management, investigation, prevention, and control activities for HIV, STDs, TB, hepatitis, and general communicable disease. Currently, HIV testing, partner services, linkage

and navigation, and surveillance data are collected in separate databases. By the end of 2015, HIV data will be fully integrated into a single, web-based, client-centered information system. By the end of 2016, we expect full integration of HIV data with STD and hepatitis C program and surveillance data.

Activity 1: Prioritization/Configuration of the Not-In-Care (NIC) List

It is currently expected that when PHNIX launches in year 1 of this grant, the HIV module will include integrated information about:

- All HIV surveillance data (formerly pulled directly from eHARS)
- All HIV CTR data (formerly managed via EvaluationWeb)
- All Partner Services data (formerly managed by the STD data system, ISCHTR)
- All HIV care linkage and retention data (formerly managed by ISCHTR)
- All laboratory requisitions and results from the SFDPH Microbiology Lab, including HIV diagnostic tests, CD4 counts and viral loads.

To support the use of Data to Care, we already have experience generating NIC lists directly from eHARS, which we will continue to do for this project until PHNIX has successfully launched. However, once launched, PHNIX will have functionality to produce reports that include:

- People who are >90 days from HIV diagnosis and have not yet received a viral load or CD4
- People who are <90 days from HIV diagnosis and have not yet received a viral load or CD4
- People who lack evidence (in HIV CTR data) of ever being referred to HIV medical care
- Evidence of ARV treatment, from any of the integrated data sources
- Evidence of viral suppression, from any of the integrated data sources

Through this project, we will dedicate epidemiology, informatics, and IT developer resources toward investigating how changes to the NIC list data and formatting will impact intervention effectiveness, identifying process improvements, and making system changes accordingly. We will do this with a 1.0 FTE Epidemiologist/Data to Care Specialist will work closely with the Senior Epidemiologist to determine the optimal priorities for the NIC list data and configuration. For example, it may make sense to enter "risk profile" as part of HIV testing data collection, regardless of the test result. Or, it may make sense to emphasize one particular demographic or service activity to flag an individual for rapid follow-up, or to change the time interval for report generation or definition as "NIC" and eligible for outreach and follow-up. This epidemiologist will also work with a 0.5 FTE Epi Informatician/Systems Designer and PHNIX system developer(s) to examine opportunities to use these data in novel ways, such as confirming care status of HIV-positive individuals named through Partner Services interviews, or HIV-positive individuals who have a detectable viral load *and* are diagnosed with an STD, and targeting education, training, and support services to providers whose clients are at highest risk for falling out of care.

When changes to the PHNIX system are recommended, these changes will be made by the system developer and/or the software developer as needed; approximately additional 300 hours of system developer time and $25,000 for fees to Consilience software (for change requests that cannot be done in-house) are budgeted for this purpose, in year 1.

Activity 2: Linkage and Re-engagement Field Work

SFDPH conducts navigation services to support linkage and re-engagement through LINCS, currently staffed with 1.5 FTE Navigators who work to re-link people to HIV care within 90 days. When they receive information from a medical provider about an HIV-positive patient who appears to have fallen out of care, the Navigators use a variety of different data sources to try to track down the patient. They then reach out with a combination of phone calls, texts, emails, letters, and in-person visits, in accordance with the well-established tenets of contact tracing used by DIS to contact someone for partner notification services following an HIV or syphilis exposure. Once our LINCS Navigators find a person and confirm they have indeed fallen out of care, they work with that person to assess barriers to care and help them be connected to a medical home – this has the added benefit of facilitating greater primary health care access for individuals who may otherwise still be uninsured and without regular medical care. Once an appointment for HIV care has been made, the Navigators facilitate them keeping the appointment, through reminders, provision of medical transportation, etc. as needed.

Currently, the LINCS program has the capacity to serve 200-300 clients per year. However, an analysis of HIV surveillance data leads us to believe that there are approximately an extra 4,000 people who are living with HIV in SF and not engaged in care. As discussed earlier, our data also show that we have significant disparities in HIV care and viral suppression, and those exist in MSM and TF,[24] which is why we are focusing on those groups. With this grant we will be able to changes to the LINCS program to greatly enhance our capacity and effectiveness, including:

1) **Expanding capacity of the LINCS outreach team:** Through this proposal we will be able to hire three additional Navigators, and this additional staffing will help ensure that we can do timely follow up for individuals who appear on the NIC list, especially those who are prioritized per decisions made as part of Activity 2. This will include the ability to do rapid follow-up for individuals named in a Partner Services interview (as HIV or syphilis contacts) – if they are determined by examination of HIV surveillance data to be known HIV-positive and NIC, they will be urgently contacted by the LINCS team. Similarly, our Navigators will be able to prioritize outreach to individuals who are HIV-positive, newly diagnosed with an STD, and appear on the NIC list. These changes should significantly increase the numbers of high-risk individuals reached by LINCS, and greatly improve the outcomes achieved by the program. **It will also allow us to strengthen the system for feeding updated data from field staff back to HIV surveillance through the PHNIX system**, as increased LINCS staff will support reporting of data back to HIV surveillance, better ensuring high quality program and surveillance data.

2) **Offering contingency management for those at highest risk:** Contingency management is a strategy based on the idea that a person will change behaviors voluntarily when they receive positive incentives (often financial) to support that change. Contingency management has been successfully used to facilitate the use of post-exposure prophylaxis (PEP) among MSM who use stimulants,[25] and also by the Positive Reinforcement Opportunity Project (PROP) in SF, which began as a pilot program of the SFDPH in 2003 to reduce methamphetamine use among MSM and was so successful[26] that it is currently still ongoing as a program of the SF AIDS Foundation. Though HPTN 065 (TLC-Plus) did not show a significant impact of financial incentives on viral suppression during their 3-year HIV research study, it *did* find that financial incentives increased the proportion of patients with an undetectable viral load in clinics where fewer than 65% of patients were undetectable at study start.[27] Given this, we are encouraged that we will see

positive effects of contingency management designed to improve HIV care retention for those members of the target population having significant difficulty remaining in HIV care.

We will offer contingency management to 300 individuals with pre-specified criteria associated with low likelihood of re-engaging in care. We will spend the first six months of the grant identifying those criteria through evaluation of the LINCS experience to date. Individuals in the contingency management program will be offered gift cards valued at $20 if they complete an initial primary care visit, $20 if they have recommended routine labs drawn, and a bonus of $60 (total $100) if they achieve virologic suppression within 90 days of re-linking to care. When a LINCS client meets the pre-specified criteria, the LINCS Navigator will provide the patient with information about:

- The number of cards available (3) during the 90 day enrollment period
- When the cards will be provided (right after the completion of the PCP visit)
- That cards will not be replaced if lost/stolen, and are the responsibility of the patient

The Navigator will track the provision of all gift cards, and if s/he does not escort the patient to the appointment, s/he will verify the patient's attendance via the EMR or by calling the clinic.

3) Using the Combination Health Department/Healthcare Provider Model: In 2014, 19 (58%) of 33 HIV-positive clients referred to LINCS by their primary care provider for assistance with re-linkage and engagement were identified by surveillance as having relocated or being in care elsewhere. After matching 118 referred patients from a SFDPH clinic to eHARS, 73 **(62%) were identified as having relocated or engaged in care elsewhere.**[28] This figure is especially relevant because a large portion of LINCS resources – in addition to resources of the provider – were spent following up on cases where people had simply chosen to see another provider for their HIV care, and not informed the original provider of that decision. Through this proposal, we plan to proactively offer this combination model of Data to Care as a service for providers in SF. This will have a number of benefits. First, it will allow medical providers and LINCS staff to spend more of their resources on those who are legitimately NIC. Second, it will lead to dataset improvements to be used for the Data to Care intervention overall, by proactively integrating provider data and allowing for triangulation using multiple data points. Finally, it will improve relationships between the SFDPH and private HIV care providers, helping to strengthen the effectiveness of the LINCS program overall for all people living with HIV in SF.

4) Building capacity for front-line HIV workers in HIV care clinics: Too often, the burden to improve retention in HIV care focuses on people living with HIV, with little attention given to the systemic obstacles faced by HIV-positive people and their providers alike. Structural barriers (e.g. hours of operation, appointment scheduling logistics, substance use and/or tardiness policies), rapidly changing systems of care, and a lag in technological advancements can all negatively affect retention rates. Additionally, cuts in administrative and training support provided to HIV frontline workers (non-clinicians and non-administrative staff) has made it especially challenging to ensure workers have a robust understanding of public benefits in an Affordable Care Act (ACA) environment, as well as knowledge of client retention best practices. For this reason, we have budgeted funding to hire skilled consultant(s) as Subject Matter Experts to work with frontline staff in clinics and community partner agencies that provide HIV care and wrap-around services to HIV-positive patients. This position will collaborate with

frontline staff to identify and mitigate factors that inhibit patient retention, increase cross-agency collaboration, and develop knowledge of PrEP and PEP. Additionally, they will provide technical support to reduce barriers and improve retention overall, thereby reducing the need for re-engagement in the first place.

Activity 3: Connecting PHNIX to External Clinical Data Systems

As was described earlier, PHNIX is scheduled to launch in the first year of this grant; however, functionality does not yet include integration of data from various clinical systems, such as the AIDS Regional Information and Evaluation System (ARIES), a centralized HIV/AIDS client management system that allows for coordination of client services among medical care, treatment and support providers, and provides comprehensive data for program reporting and monitoring. Based on the national CareWare system, ARIES is used by Ryan White-funded service providers in California. Through this proposal, we have planned for 300 hours of system developer time to explore feasible options and map at least one major care system, building functionality into PHNIX to integrate the information for use in Data to Care activities. This will be strong enhancement to our current system, and will allow for far more accurate information to be used in Data to Care than with use of eHARS and STD surveillance data alone.

C. APPLICATION EVALUATION AND PERFORMANCE MEASUREMENT PLAN

Routine monitoring, evaluation, and quality improvement of public health activities is essential to ensuring services are delivered in a timely and efficient manner and that data are used effectively. Therefore, throughout this project we will:

- Evaluate our current business processes, data collection practices, and data systems for identifying high-risk clients for PrEP as well as clients NIC or with unsuppressed viral loads
- Enhance our current data collection and data uses to monitor PrEP activities
- Maximize and integrate secondary data sources to enhance PrEP and Data to Care activities
- Develop quality assessment tools to ensure high quality PrEP data and HIV surveillance data
- Develop predictive analytics, real-time reporting tools, and dashboards to monitor performance on key project indicators

The details of our demonstration project activities, including program monitoring and evaluation, and quality assurance activities, are available in our **Work Plan** included with this application. That Work Plan demonstrates that we will immediately start many program activities at funding start; those that require planning and start-up will be ready for launch within 6 months of the start date. **Table 3 on the following page identifies our project goals and objectives, evaluation questions, data collection strategies, and utilization of results.**

Table 3. Performance and Evaluation Plan Matrix

CATEGORY 1: PrEP						
Goal	Objective	Page Ref	Evaluation Question(s)	Data Collection/ Analysis Activities	Who responsible?	Results will be...
Increase the number of PrEP prescriptions for people at substantial risk of HIV in San Francisco, especially MSM and transgender persons, particularly persons of color	By 6 months into the project period, complete analysis of existing data and additional needs assessment for the target population and providers, identifying barriers to PrEP use and recommended strategies to improve PrEP uptake and adherence	5	-What are the barriers to PrEP for the target population? -Where are the target populations seeking care? -What are the barriers to providing PrEP to the target population seeking care?	-Analysis of routinely collected surveillance data -Targeted questionnaires -Focus groups	Senior Epi, Health Educator	Refined strategies to increase PrEP knowledge, uptake and adherence, and guide provider training
	By the end of year 1, we will have final plans, policies, procedures and protocols to implement PrEP activities for the target population	5	-Have the final plans, policies, procedures and protocols been developed for each setting identified?	-Documented plans, policies, procedures and protocols	Epi PrEP Specialist, Epi Informat/SD	Final plans, policies, procedures and protocols M&E Plan
	By the end of year 1, we will have launched a citywide social marketing campaign to encourage PrEP use among our target population	5	-What information and messaging do members of our target population need to increase interest in, uptake, and adherence to PrEP?	-Counts of media events, website hits, and similar metrics	Health Educator	Increased number of persons self-referring for PrEP to clinics/providers
	By the end of year 1, the SFDPH will have established policies, procedures and protocols to enhance current data systems to integrate services and share data across applicable sites.	6,7	-What enhancements to PHNIX will facilitate integration of PrEP services, monitoring, and evaluation into current SFDPH program activities?	-Information system development requirements	Epi PrEP Specialist, Epi Informat/SD	New business rules that facilitate integration of PrEP services, M&E of program activities
	By the end of year 1, we will have created and disseminated at least 3 new provider educational materials/tools, reaching ≥1000 target pop members	7,8	-What information, training and practice support does provider need to increase or improve PrEP delivery?	-Counts of materials and tools finalized	Health Program Coord.,NP, Health Educ.	Final materials and tools to support providers in prescribing PrEP
Reduce the number of new HIV infections among MSM and transgender persons in San Francisco	By the end of year 3, at least 75% of ≥200 providers reached through academic detailing will be actively prescribing PrEP to their patients.	8	-What strategies appear to have the greatest impact on provider interest in training to provide PrEP to the target population?	-# of providers trained, attendance logs -PrEP prescriptions	PrEP Coordinator, Senior Epi	Improved rates of PrEP prescriptions for target pop. by trained providers
	By the end of years 2 and 3, we will have conducted at least 6 videoconference consultations for PrEP each year in one or more of our new "Communities of Practice"	9	-Does the videoconference format work sufficiently to support providers engaging in the communities of practice for PrEP?	-Counts of videoconferences -Summaries of participant evaluation forms	Health Program Coordinator	Increased comfort with prescribing and managing PrEP among providers in COPs
	By the end of each project year, SFDPH will complete four Continuous Quality Improvement cycles, to officially document lessons learned from that year and accordingly, plan adjustment to project protocols for the future	19	-What were the major challenges we faced this year? -What changes to our project protocols are likely to lead to increased prescription of PrEP among SF providers?	-Staff meeting notes -Corrective action reports -Quarterly and annual reports	PI, Project Director, PrEP Coordinator Leadership Team	Improved PrEP activities in future years, to better serve our target population and providers

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CATEGORY 2: Data to Care

Goal	Objective	Page Ref	Evaluation Question(s)	Data Collection/ Analysis Activities	Who (responsible)	Results will be…
Increase the percentage of MSM and TF diagnosed with HIV who are engaged in HIV care	Within the first 6 months of year 1, SFDPH will generate a prioritized list of the target population not in HIV medical care (the "NIC list") from eHARS.	13	-What adjustments are needed to the SAS code in eHARS in order to generate an optimal NIC list from existing data?	-Number of generated NIC lists - Log of NIC list code adjustments	Senior Epi, Epi/Data to Care (DTC) Specialist	Improved identification of target pop NIC
	Within the first 6 months of year 1, at least 3 new staff members will have been hired and trained to conduct outreach to our target population	14	-Have staff received all the appropriate training and orientation needed to well-versed in Data to Care strategies for this target pop?	-Documentation of hiring -Documentation of training	Medical Director City Clinic, DIS	Improved capacity of SFDPH to support retention for the target pop
	By the end of year 1, we will have protocols and standard operating procedures for Data to Care, including agreements for data sharing between health departments and health care providers when necessary	13,22	-What details must be documented to create completed procedures for generation of a NIC list via PHNIX? -Have the final plans, policies, procedures and protocols been developed for Data to Care?	-Documented plans, policies, procedures and protocols -Signed data sharing agreements	Epi Informatician /SD, System Developers	Improved capacity of SFDPH to support retention for the target pop through use of integrated data
Increase the percentage of MSM and TF diagnosed with HIV who have a suppressed viral load	By the end of year 1, we will have processes for integrating existing STD, Hepatitis and other surveillance data with lab reporting within PHNIX	13	-What datasets are available that would support Data to Care? -What processes are needed to complete dataset integration?	-System documentation and integration mapping	Epi Informatician /SD, System Developers	Improved capacity to support care retention through integrated data
	By the end of year 1, SFDPH will be able to generate a fine-tuned, prioritized NIC list of the target population from PHNIX	13	-What delivery format is most useful for LINCS staff to facilitate rapid action on the NIC list?	-Number of times NIC list generated from PHNIX	Epi Informatician /SD	Improved, useful identification of target pop NIC
	By the end of years 2 and 3, LINCS staff will have successfully contacted at least 500 additional people per year from our target population	14	-What are the barriers still experienced by LINCS staff preventing successful contact of people on the NIC list?	-Number of successful contacts from LINCS Navigators	DTC Navigators	Reduction in NIC rates for the target pop overall due to LINCS intervention
	By the end of year 3, the proportion of people in our target population who are not in care will have decreased to ≤15%.	14,15	-What are barriers to retention for people who remain on the NIC for at least 6 months after LINCS contact?	-Proportion of living HIV cases with a CD4/VL lab	Epi DTC Specialist, DTC Navig.	Reduction in NIC rates for the target pop overall
	By the end of year 3, the proportion of people in our target pop who are virally suppressed will have increased to 85%.	14,15	-What are the barriers to viral suppression for MSM and TF successfully contacted by LINCS?	-Proportion of living HIV cases with undetectable VL	Epi DTC Specialist, DTC Navigators	Increased viral suppression rates for our target pop
Increase survival of MSM and TF diagnosed with HIV	By the end of year 3, the proportion of our target population successfully engaged or re-engaged in HIV medical care within 90 days of being identified as NIC will have increased by ≥25%.	14,15	-What are the barriers to engagement and retention in HIV care for people who remain on the NIC for at least 90 days after successful contact by LINCS staff?	-Number of days that each person on the NIC list remained before care linkage	Epi Informatician /SD, DTC Navigators	Faster linkage to care after identification for f/u; Increased viral suppression
	By the end of year 3, the average number of days between identification of a person not in care and their successful engagement or re-engagement in HIV medical care will have decreased to 21	14,15	-What are the factors that prevent rapid (<14 days) re-engagement in HIV care for people who are successfully contacted by LINCS staff?	-Average number of days that each person who appeared on the NIC list remained	Epi Informatician /SD, DTC Navigators	Faster linkage to care after identification for f/u; Increased viral suppression in the

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	days.		before care linkage		target pop
By the end of year 1, we will have developed at least 3 monitoring reports within PHNIX that help us evaluate system function for Data to Care.	19	-What information should be routinely monitored? -How frequently should progress be monitored?	-Count of finalized monitoring reports	Epi Informatician /SD	Specific action plan for improvement of PHNIX for Data to Care intervention
By the end of each project year, SFDPH will complete four Continuous Quality Improvement cycles, to officially document lessons learned from that year and accordingly, plan adjustment to project protocols for the future	19	-What were the major challenges we faced this year? -What changes to our project protocols are likely to lead to increased linkage and retention in care for our target population?	-Staff meeting notes -Corrective action reports -Quarterly and annual reports	PI, Project Director, Senior Epi	Improved Data to Care activities in future years, to better serve our target population and providers

SFDPH has a steadfast commitment to Continuous Quality Improvement (CQI) for all of our projects. This is especially true for Data to Care, since evaluation of this intervention is key to our continued use and improvement of the new PHNIX system. To this end, we have developed a detailed Data to Care evaluation model for PHNIX (available upon request) that includes activities, evaluation questions, enhancements to current data collection, and PHNIX development needs. Enhancements to this PHNIX system that will be developed and evaluated through this project will include matches to external databases not already included in the planned project roll-out, and expansion of navigation questionnaires to collect psycho-social factors and referrals to clinical/social services.

One of the key ways we will ensure CQI throughout this project will be quarterly CQI meetings with key project staff to review progress and document lessons learned, culminating each year in an official CQI review to revise the project protocols, logic model, detailed work plan, monitoring and evaluation strategies, and/or quality assurance activities as needed. This review will be conducted by the Project Director, in coordination with the Lead PrEP Coordinator, the LINCS team, the Director of the SFDPH Office of Equity & Quality Improvement, the Informatics Officer, and the PI. It will involve a series of in-person meetings with project staff, interviews with at least 5 medical clinicians who prescribe PrEP, and satisfaction surveys with members of the target population. Data gathered through these strategies will then be synthesized and analyzed by the Project Director or her delegate, discussed with other project staff as needed to gain context and deeper understanding, and written into a formal CQI report which will be distributed to all key staff and stakeholders involved in the project. The formal report will include an action plan, with specific recommendations and deadlines for changes to project plans, documents, and materials to improve quality of the project in the next year. In addition to dissemination of the CQI plan to project staff and key stakeholders, we are committed to disseminating project findings and lessons learned to policymakers, medical providers, and members of the target population. As we do with so many other initiatives, we will make presentations at community planning and SF Health Commission meetings; we will hold town hall meetings and community forums, and we will make data and summary findings available on our public website. Further, we look forward to contributing to dissemination efforts at the regional and national level, participating in meetings and conferences as well as submitting articles to peer-reviewed journals in order to advance the science of PrEP implementation and Data to Care worldwide.

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D. ORGANIZATIONAL CAPACITY OF APPLICANTS TO IMPLEMENT THE APPROACH

The applicant and lead agency for the project is the SF Department of Public Health, an integrated health department with two major Divisions (see the attached *Organizational Chart*): the SF Health Network and the Population Health Division. Our mission is to protect and promote the health of all San Franciscans, and we are recognized as a public health leader, working closely with community organizations to implement innovative, effective, evidence-based strategies and enacting policies to build healthy, safe and equitable communities. We have an extensive track record of developing and implementing initiatives to promote sexual health and prevent the spread of HIV and other STIs in our city, especially for LGBT individuals. Unlike other public or private systems, the **SF Health Network** contains the crucial components needed to build a seamless continuum of care: patient- centered medical homes provided by primary care clinics located throughout the community; comprehensive behavioral health services including mental health and substance abuse; acute care and specialty hospital services; and other home- and community-based services. Through **PHD**, we assess and monitor the health status of San Franciscans and implement public health interventions.

Staffing Expertise and Experience
Both the Category 1 and Category 2 projects will be led by **Tomás Aragón, MD, DrPH**. Dr Aragón is the Health Officer of the City and County of San Francisco, and the Director of PHD. He will provide 0.1 FTE for this grant, and will be responsible for overall planning, implementation, monitoring, and reporting of the program. Dr. Aragon is trained in internal medicine (MD) and epidemiology (DrPH). He is co-PI of SF's Community Transformation Grant, and has extensive experience leading CDC program and research grants.

Dr. Aragón will be supported by **Susan Philip, MD, MPH**, who will serve as the Project Director at 0.2 FTE. Dr. Philip is the Director for Disease Prevention and Control for PHD. She will supervise and train the Lead PrEP Coordinator, and will work closely with other project leads to monitor short-term outcomes and maintain smooth implementation of all project strategies. She will also be responsible for tracking and annual reporting all activities to CDC.

Both Dr. Aragón and Dr. Philip will be supported by our stellar leadership team:
- **Dr. Susan Scheer, PhD, MPH,** the Director of the ARCHES Branch of PHD (HIV surveillance)
- **Dr. Stephanie Cohen, MD, MPH,** the Medical Director of SFCC and Co-Principal Investigator of the NIAID-funded US PrEP Demonstration Project
- **Ms. Tracey Packer**, the Director of Community Health Equity & Promotion for PHD
- **Mr. Israel Nieves-Rivera**, the Director of Equity and Quality Improvement for PHD
- **Ms. Jennifer Grinsdale, MPH,** the Public Health Informatics Officer and lead on PHNIX
- **Dr. Jonathan Fuchs, MD, MPH,** Director of the PHD Center for Learning and Innovation
- **Dr. Susan Buchbinder, MD**, Director of Bridge HIV (formerly SFDPH HIV Research Section) and head of the Steering Committee for the Getting to Zero Consortium
- **Dr. Albert Liu, MD, MPH,** Clinical Research Director of Bridge HIV; PrEP research specialist

All other details of the comprehensive staffing for this proposal, including further details of our staff experience, expertise, and contributions to this project, are available in the *Staffing Plan.*
Workforce Capacity and Competence

As with all our work, our effectiveness depends on the skills and expertise of our project team to deliver technically sound, culturally competent guidance. All staff must complete required online trainings each year, including privacy, data security, and documentation standards. The SFDPH is strongly committed to professional development, and our commitment to continue training along with our reputation as a cutting-edge, evidence-based health department has helped us to attract some of the best professionals in our field. As such, our project staff have exceptional skill and experience coordinating and facilitating development of trainings, policies, and educational materials. However, as described in Sections B1 and B2 (Approach) we have made specific plans to ensure that current and new staff members have adequate training to implement all demonstration project activities. Through CDC's Program Collaboration and Services Integration (PCSI) initiative beginning in 2010, we have made impressive strides toward implementation of a syndemic approach to the prevention of HIV/AIDS, viral hepatitis, STDs, and TB. We are already a model for integration of HIV testing and PrEP with other screening services, and this will only improve with the launch of PHNIX to allow for fully integrated data systems. Finally, as a result of the U.S. PrEP Demonstration Project we have already developed a robust model for referral of eligible clients to PrEP providers, which will be expanded through this grant.

Fiscal Management

The SFDPH manages a $14 million portfolio of CDC-funded HIV prevention, policy, surveillance, and research activities which will directly inform our work on this project. Responsibility for fiscal monitoring and oversight of government grants lies with a six member team based in the SFDPH Grants Unit and led by the Accounting Manager. The Accounting Manager establishes, evaluates and reviews fiscal procedures to ensure internal control and compliance and oversees and manages fiscal audits of Federal, State and private grants.

In order to hire new staff rapidly, we have started the process of requesting all new positions listed in this application through Human Resources and the Controllers Office. Upon the announcement of funding, we will be able to post the positions and begin the hiring process immediately. Additionally, we have a longstanding relationship with Public Health Foundation Enterprises (PHFE), a licensed CA non-profit that has served non-profit and research entities for over 39 years with fiscal, human resource, and contract administration services. Through PHFE, we can rapidly establish contracts with vendors and consultants to support project activities and manage all travel requirements, including staff attendance at all CDC grantee meetings.

Organizational Infrastructure

SFDPH employs more than 12,000 employees in two major hospitals, 21 primary care clinics, 28 behavioral health sites, and more than 30 branches and sections. We have offices and services locations in every neighborhood in the City, and run a state-of-the-art trauma center and inpatient hospital (SF General Hospital). We have or can access any and all types of equipment required for the completion of all project deliverables for any one of our dozens of research and program grants.

Information and Data Systems

SFDPH is served by a large Information Technology (IT) Division, which collaborates extensively with the Department of Technology and Information Systems (DTIS) for the City and County of SF. Together, these entities are able to internally host both Avatar, the electronic health record

system that supports Behavioral Health Services and serves 25,000 clients across SF, and PHNIX, PHD's new integrated IT platform for surveillance, public health action, and preventative services. Thanks to PHNIX, by the end of 2015, HIV data will be fully integrated into a single, web-based, client-centered information system. By the end of 2016, we expect full integration of HIV data with STD and hepatitis C program and surveillance data. Specifically, the first release of PHNIX will include written agreements for data sharing across programs for the purposes of Data to Care, and planned future releases (in years 1 and 2) will enhance Data to Care activities through integration with STD and Hepatitis surveillance data and referrals via existing programs to help identify members of our target population who are not in care.

Compliance with HIV Laboratory Reporting and Data Security Requirements

CA laws require all HIV-related laboratory test results, including CD4 and viral load test results, be reported to the local health department. We have identified all laboratories that perform HIV-related testing in SF and have established mechanisms to receive these test results on a regular basis. Additional laboratory reports are also obtained from medical record reviews or from other health departments for SF cases receiving care outside of SF. The reporting of CD4 and viral load tests is complete for cases receiving care in SF. The HIV-related test results are processed and updated in the case registry at least monthly. All CD4 (<200 and >=200) and viral load (detectable and undetectable) test results that matched to reported cases are maintained in eHARS and reported to CDC. Our HIV surveillance program meets the CDC requirements for laboratory reporting as of December 31, 2013 as outlined in the 2012 Monitoring Report. Each year, CDC benchmarks for completeness of laboratory reporting are met and exceeded.

In year 1 of the PCSI initiative, SFDPH developed an Integration Security and Confidentiality Guideline for the health jurisdiction, using CDC Data Security and Confidentiality Guidelines. All data collection, entry, management, submission, analysis, use, and dissemination procedures are consistent with these guidelines, and our data security and confidentiality policies conform with the NCHHSTP Data Security and Confidentiality Guidelines. We comply with all federal information systems and information processing security policies; our local procedures clearly describe required physical security attributes of all facilities; procedures for protecting, controlling, and handling data during performance of the project, including any development and testing activities; required limitations on employees with respect to the reproduction, transmission, or disclosure of data; physical storage procedures to protect data; procedures for the destruction of source documents and other contract-related waste material; and personnel security procedures. Procedures for electronic and physical data security and data sharing are reviewed and approved by the Overall Responsible Party (ORP) from HIV Surveillance.

All agency personnel having access to identifiable and confidential information receive appropriate annual training and sign confidentiality pledges; this is in concordance with our 'Rules of Behavior' for persons who have access to data systems through this project. We complete an annual review and validation for all system user accounts to ensure compliance and continued need for access. We will conduct a privacy impact assessment (PIA) on all information systems acquired, developed, or used in conjunction with data collected for this project, and work with CDC on an ongoing basis to review security controls and measures and ensure continued compliance with federal information security regulations.