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# THE USE OF A VIDEO-BASED INTERVENTION TO MOTIVATE GAY AND BISEXUAL MEN ON PREP TO USE CONDOMS

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Ethan Cardwell, Student

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Dr. Corrine Williams, Director of Graduate Studies

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# THE USE OF A VIDEO-BASED INTERVENTION TO MOTIVATE GAY AND BISEXUAL MEN ON PREP TO USE CONDOMS

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CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the  
requirements for the degree of  
Master of Public Health  
in the  
University of Kentucky College of Public Health  
By  
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## **Abstract**

Based on need and available resources, gay and bisexual men who have sex with men (GBMSM) in the Castro neighborhood of San Francisco, California represent the target population for this intervention. Through funding by the Center for Disease Control the Strut Clinic in collaboration with the University of California Berkley is proposing a video-based intervention with the following SMART objectives.

Objective 1: Efficiently develop and integrate a video-based intervention in the Strut Clinic within the first six months of the funding cycle.

Objective 2: Sustain an increase of consistent condom use to 30% of participants and up to a 10% increase in overall condom use from baseline to all participants in the study for up to 12 months after the intervention.

Objective 3: Decrease the incident cases of all sexually transmitted infections to rates lower than the general male population of San Francisco County by the end of the 3-year funding cycle.

This intervention is an adaptation of the currently used high impact prevention for sexually transmitted infections *Safe in the City*. The video contains three vignettes using multiple theories to influence behavioral changes regarding condom use. The intervention will be evaluated by applying the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework. This intervention will allow providers an inexpensive alternative to current protocol, which reduces the transmission of sexually transmitted infections among their patients by reducing migration away from condom use.

## **Target Population**

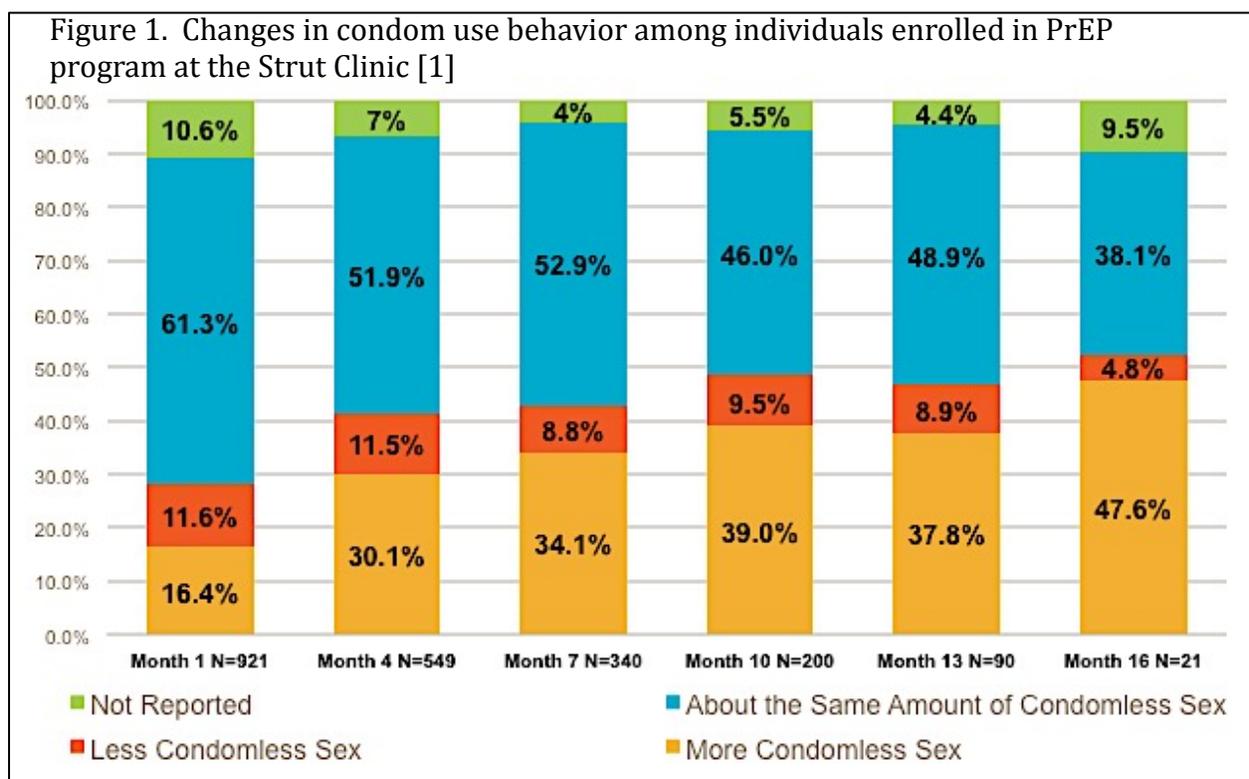
When determining disparities in the field of sexual health sexual, gender minorities continue to be disproportionately affected. Since the first outbreak of HIV in the United States in the early 80's, rates of infection have been disproportionately higher in men who have sex with men [2]. Over the past decade, HIV/AIDS prevention has moved to treatment as prevention (TasP), which involves using antiretroviral treatment (ART) to decrease the risk for transmission and acquisition of HIV. Pre-exposure prophylaxis or PrEP is a companion innovation to TasP, using similar components of the ART medications. PrEP is a daily oral medication taken by those at risk of acquiring HIV and can reduce risk by up to 92% (95% CI 40-99) with consistent use [3].

Although this method of prevention can be successful for HIV prevention, current trends in data indicate a migration away from the use of condoms for safer sex [4]. As a result of this migration, there are significant increases in the transmission and acquisition of sexually transmitted infections (STI's) in populations using PrEP. The FDA approved PrEP as a prevention method for HIV in 2012, meaning the year 2011 acts as a baseline for this disparity. According to the National HIV Behavioral Surveillance in San Francisco, the consistent use of condoms in men who have sex with men decreased from 30.5% in 2011 to 18.6% in 2014 [5]. One of San Francisco's main PrEP prescribing clinic's has observed a cascade of care for PrEP patients that shows a clear migration away from condom use after patient enrollment [1].

With this migration away from condom use in gay and bisexual men who have sex with men (GBMSM), San Francisco is observing increases in STI rates particularly in men. Figure 2 is a summary of the 2015 STI data from the San Francisco Department of

Public Health, which demonstrates these increases [6]. Interpretations of this graph show how STI transmission/acquisition increased at a greater rate after the year 2011.

San Francisco is a diverse city with a large population of GBMSM. According to the Gallup U.S. Daily survey, San Francisco has the largest LGBT population of any metropolitan city [7]. Due to the large number of GBMSM and push from the Center for Disease Control, the uptake of PrEP for HIV is high. According to the National HIV Behavioral Surveillance

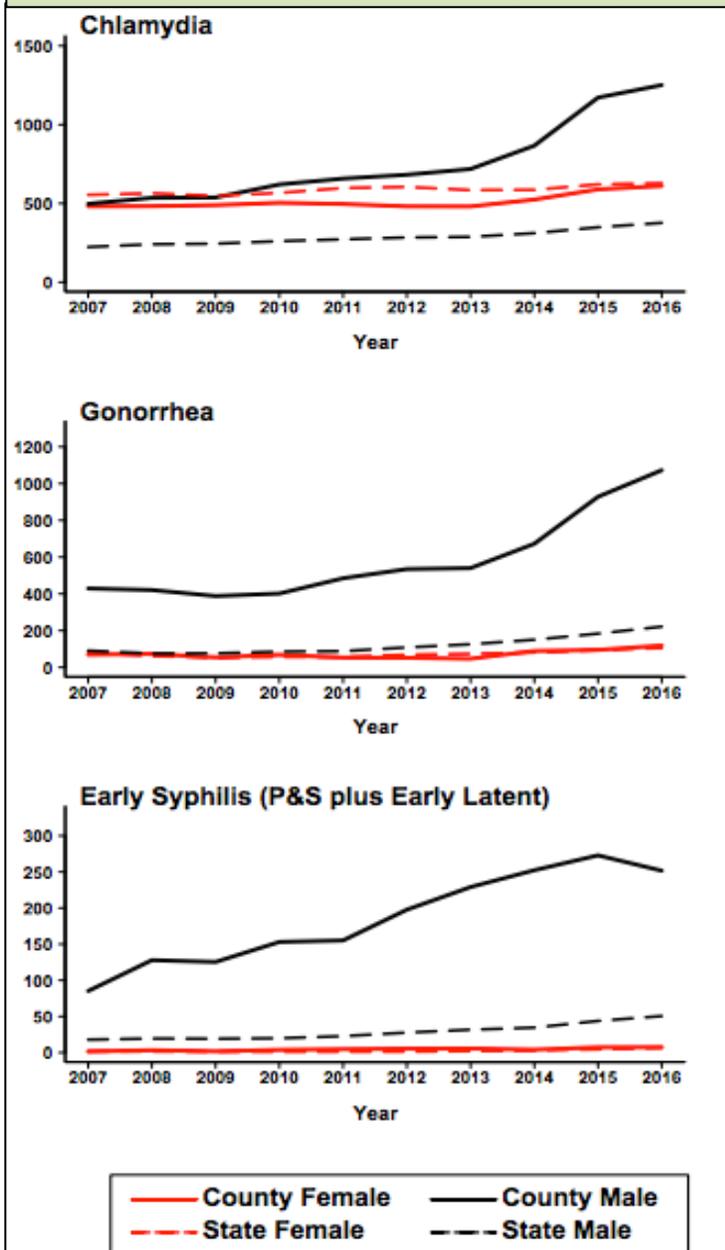


(NHBS) system, in 2014 San Francisco had the highest rate of GBMSM PrEP use of any city in the United States [8]. Since the introduction of PrEP, sexually transmitted infections in San Francisco particularly have been steadily increasing. These increases are occurring at a much greater rate than the state of California as a whole.

## The Castro in San Francisco

The STI data alludes to a migration away from condom use, which could be attributed to the introduction of PrEP as a prevention method. Studies have shown that the use of PrEP as a prevention method for HIV can lead to risk compensation for other STIs [4]. It has come into question as to whether the prescription of PrEP should persist if there is such an

Figure 2. Yearly San Francisco County-- Chlamydia, Gonorrhea, and Early Syphilis rates per 100,000

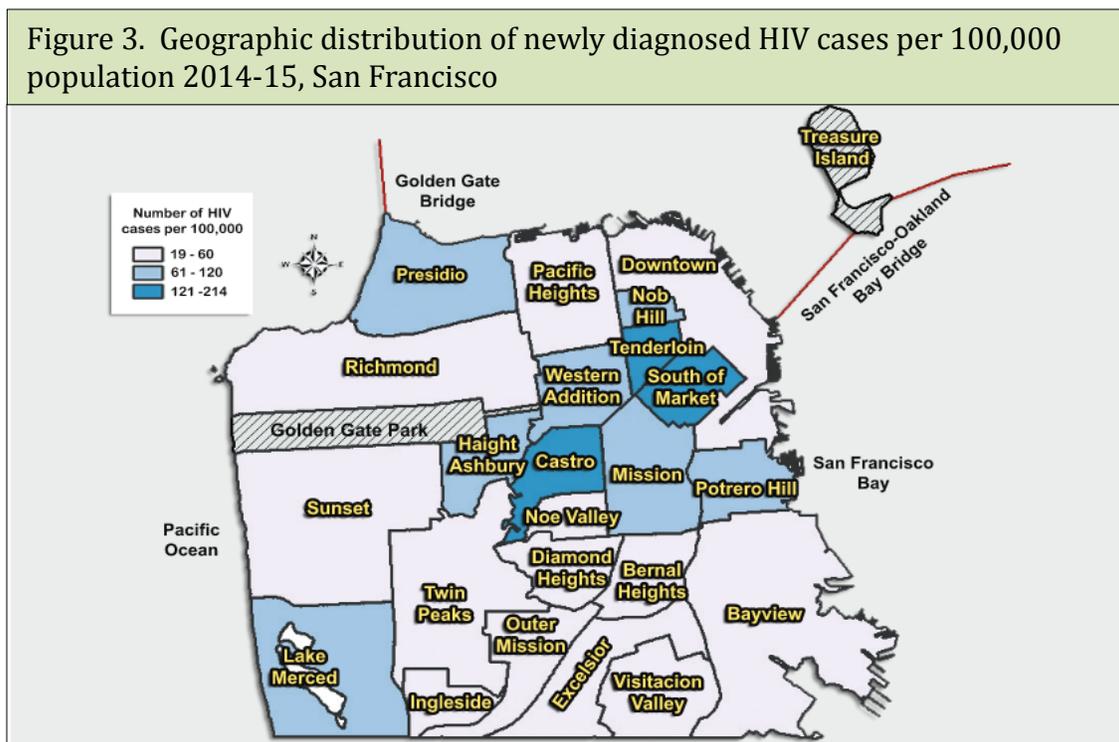


increase in other STIs. As a city, San Francisco has some of the highest rates of new HIV diagnosis in the U.S. Further examination of the city indicates specific neighborhoods exhibiting higher rates of HIV diagnosis.

Based on the map in Figure 3, the Castro, Tenderloin, and South of Market have the highest rates of new HIV diagnosis. The Castro had the highest rate of 214 per 100,000, which is three times higher than the San Francisco average [6]. Of those newly diagnosed in San Francisco (2015), 82% were men who have sex with men [6].

## Community Resources

When conducting our initial community needs and resources assessment we used mostly secondary data to identify areas within the city of San Francisco with the most need. We used the San Francisco Department of Public Health and the Center for Disease Control and Prevention as data sources for determining HIV and STI prevalence trends in the area. We then cross-referenced these with resources found through an Internet search for gay-friendly and HIV/AIDS focused organizations. Results found that the Castro area of San Francisco had the highest volume of both need and resources to conduct our intervention. After identifying MSM in the Castro as our target population, we used key informant interviews and focus groups to determine any needs or resources that may have been missed in the initial assessment. There were two stages of formative data collection: interviewing key informants or those working on the frontlines in the organizations



determined to be resources in the initial assessments, and an interview of peer opinion leaders that were identified from the key informant interviews. The primary data gave us a better understanding of what the community perceived to be its needs and resources.

The main resource identified in this community was the Strut clinic located in the center of The Castro. The Strut is the primary resource in this community for the health of gay and bisexual men who have sex with men. Strut is the new home for health and wellness from San Francisco AIDS Foundation; “We’re a place where gay, bi and trans men can find tools and support to manage physical, emotional and social aspects of health [9].” This statement from the Strut website summarizes what all they offer; this includes free condoms, HIV and STI testing, and counseling and enrollment for PrEP, which are important resources for this intervention. Strut has also established several different social groups that could be used as a resource for peer opinion leader in this intervention.

As of summer 2016, the Strut clinic had enrolled 1,252 individuals into their PrEP program and of those 1,248 were GBMSM [1]. This number is only expected to increase as the program develops. The program at Strut is also conducting behavioral surveys and observed exactly what was anticipated. According to Figure 1, the clinic’s cascade of care for PrEP patients shows a clear migration away from condom use [1]. Based on this information we believe it is possible to reach approximately 800 participants each year for a total of 1,600 people over the two-year recruitment period. This is under the assumption that the clinic consistently enrolls new PrEP patients at twice their prior rate.

### **Community Advisory Board**

The purpose of the Community Advisory Board is to organize a group of individuals to help mobilize the intervention that we have developed. The majority of the Advisory board for

this intervention will be individuals involved in the Strut clinic. Strut has their own team of about 15 individuals that are focused on sexual health services. There are three individuals who have agreed to sit on the board: the HIV/STI Data Manager, the PrEP Benefits and Navigation Manager, and Joshua O'Neal the Director of Sexual Health. These individuals are pertinent because their positions integrate closely with the intervention. Other members of the board would include members of the community identified as key informants during formative data collection.

It is also just as important that the board consist of individuals living in the community, not just professionals working in the community. The board will include the GBMSM that were identified as key opinion leaders in their community, by the key informant interviews conducted at the beginning of the study. The opinions of these insiders will be crucial to making sure that the intervention is relatable to the target audience.

Throughout the implementation of this intervention, we want to be sure that we are continually assessing the need of the community in order to make the intervention is successful. After implementation has begun, the advisory board will meet bi-annually to discuss how things are going with the project and determine if we are still meeting the needs of the community. We would also be analyzing the PrEP and STI data from Strut, to see if we are making an impact and discuss possible obstacles to implementation. At the end of year one, after the study has time to really get some traction, another survey will assess the needs of the community and how community members feel about the ongoing project.

Although I have listed quite a few individuals as part of the Advisory Board, I don't expect the board to be more than 12 individuals from the community, including myself. I also expect that throughout the course of the project it may be important to add other members of the community to this board, so the board will potentially expand. This board will be crucial to the implementation and continual assessment required to make this intervention a success in the Castro of San Francisco. Due to the nature of this study being a randomized control trial, the community advisory board will not have much involvement during the implementation of the intervention. This is important for the randomization; we do not contaminate the control arm.

### **Reach**

The way that this program intervention is designed it would be virtually impossible to estimate the exact numbers of individuals reached because the numbers will continue to increase at an unknown rate. The best way to go about discerning the reach of the intervention is to use data from the Strut Clinic PrEP enrollment program. The goal of the intervention is not to get people on PrEP, but to educate those on PrEP to adhere to their medication and use condoms in conjunction.

The goal of the intervention is to reach 75% of newly enrolled individuals attending the Strut clinic in the Castro for a PrEP prescription. With the intervention being a randomized control trial the 25% not reached by the intervention are in the study, but will act as controls. Medical records from the clinics will be used to see that these goals are met to the best of our ability. We will be recruiting patients for 2 years of the grant period, to complete the intervention video educating them on PrEP adherence and using condoms. Once we have reached as many current patients as possible with the intervention video,

then recruitment will no longer be required. Recruitment strategies are not necessary for a new patient prescribed PrEP because the point of the intervention is to make viewing this video be a requirement upon prescription. Meaning new patients will be automatically placed into the intervention during the enrollment process. A key component of this recruitment strategy is using medical record alerts to make sure that individual who have received the intervention or control are flagged and reached for post-test assessments.

The retention period for each individual in the intervention is only 12 months because this is the point at which they will be given the final post-intervention survey. This time frame was used because it is the standard follow up time for a PrEP intervention, based on published literature. This post-intervention survey will be conducted by the same recruitment individual and should be quickly conducted in the waiting room of the lobby. This is another point where the PrEP prescription process will do all/most of the work for us. While on PrEP individuals are required to come into the clinic every three months for a variety of test to ensure everything is going okay with their prescription. Therefore, assuming that the individual is adherent and attending appointments like they are supposed to. then we will be able to reach the individual. As stated before in order to remain on PrEP and receive a prescription refill, you must attend the clinic routinely every 3 months for testing purposes. We will be using the same system as before, medical record alerts, to keep track of individuals that need to receive the post-intervention survey during their clinic visit. Based on data from the clinic, we can expect a 60% cascade every three months for post-survey data collection, these numbers can be seen in Figure 4 [1]. Although this is not an ideal scenario for retention, the post-survey data represents the secondary aims of the intervention and require less data to prove significant.

## **Program Approach**

In conjunction with the University of California, Berkeley, the Strut Clinic is proposing an intervention study to change the condom use behavior of GBMSM on PrEP for HIV. The intervention uses the high impact prevention (HIP) *Safe in the City (SITC)*, which is a video-based intervention targeted at individuals in clinic waiting rooms [10]. The original video contains three vignettes that are used to increase knowledge, the perception of STI/HIV risk, condom use, and self-efficacy and skills. The 23-minute video originally was designed for waiting rooms in STI clinics and utilized the following theories: Social Cognitive Theory, the Information-Motivation-Behavioral Skills model, and Theory of Planned Behavior, to influence behavior. According to the team developing the original material, these theories target the cognitive and behavioral factors and have presented the best evidence for STI interventions [11]. These theories were combined through the use of constructs like condom use skills and condom negotiation that had been shown to be effective in previous studies [12, 13].

The evidence for this intervention comes from a three-city study (including San Francisco) that found significant reductions in STI diagnosis in the intervention group [10]. More recent studies have found that the low-cost video-based intervention positively influences STI-related attitudes and behaviors [14]. The intervention material has not been updated since its original development in 2008 and has also not been adapted to address PrEP users during enrollment.

The setting in particular that this intervention is designed for is STI clinic waiting rooms and as previously identified the Strut clinic is a key resource for GBMSM in the Castro. The resources necessary for the overall intervention are on the “front end” in the

creation of the video and printing of the video posters. Due to the minimum capacity of this intervention, it could easily be replicated in other locations, particularly at clinics with a high volume of PrEP enrollment.

The Strut clinic already has a thriving PrEP program and this intervention should only boost this program. There are some interventions that are already occurring in these settings, but they are working separately to promote PrEP and condoms to MSM. The point of this intervention is to promote them together as a form of dual protection. Overall, the intervention is designed to expose GBMSM on PrEP in the Castro to the message that PrEP and condoms should always be used together as a dual protection against HIV and STI's.

**Adaptations:**

The intervention design makes changes to the original material of SITC but does not change the theories behind the behavior change or the way it is delivered. This adaption should not alter the success of the program because it does not remove any component of theory used to change behavior in the original design. One minor adaption that could be particularly advantageous for the Castro, is the use of popular opinion leader as actors in the newly developed material. This actually incorporates another theory of behavior known as the social diffusion theory. This theory has been used in Popular Opinion Leader, another HIP for HIV promoted by the CDC. The theory suggests that behavior change can be initiated and diffuse into a population if enough opinion leaders adopt the behavior [15]. We are aware that using POLs can have drawback if the person is not well liked by all members of the community. In order to combat this we are recruiting POLs from various social groups in the Castro, which will increase the likelihood that viewer will identify with

at least one of the actors. In this intervention, the behavior to adopt would be the use of condoms and PrEP simultaneously for protection against HIV and STIs.

The original video is designed for an intervention on condom use, so the video itself will be updated/adapted to include the interplay between PrEP and condom use. This means leaving in points about how to use condoms but also including skills for PrEP adherence and how those who are PrEP should continue to use condoms. The actors used for the adapted intervention material will be those who were identified as peer opinion leaders and used in the focus groups in the development stage of the intervention.

Another minor adaption that will occur to this intervention is the use of technology to deliver the information. As technology advances, it is important to adapt the intervention, so it is relatable and disseminated to the best of our ability.

Fidelity is important for all program implementation. Those who are using this program will be given a specific guide to follow with checks every three months to make sure it is being implemented properly. These checks should keep everything running smoothly and accurately so that the intervention is successful as possible.

### **Materials Accuracy and Staff:**

By allowing a few individuals from the community to read over the program material and getting their feedback, we can ensure that the language used is appropriate for the target population. At this point, the materials will also be reviewed to make sure that they are inclusive and non-stigmatizing. Staff/volunteers will be trained to ensure that they are inclusive and non-stigmatizing when distributing program material. Asking individuals who are in the intervention if they feel as though there is any stigma or exclusion from the staff or volunteers could monitor this.

We will also ask the materials to be reviewed by the original developer of SITC to ensure that all theories for behavior change are met based on the original materials.

### **Dissemination**

After the program has been completed, the results, regardless of the success of the program, will be communicated to the public. That being said, the strategy for dissemination will vary depending on the success of the intervention. This variation is due to the fact that both of these intervention being combined for this program are disseminated/communicated via the CDC website.

The plan for dissemination if the program is unsuccessful is simple. The results will be published in an academic journal, explaining the program and possibilities for why it was unsuccessful. Another part of this plan would be to contact the CDC about possibly re-evaluating these programs and their success. It is equally important to disseminate unsuccessful results, but I do think it will be much more difficult to fund this dissemination and it will also be more difficult to obtain publications. If funding allows, then the program results can be presented at academic conferences as a way to campaign for further research in the area.

The plan for dissemination if the program is successful is as follows. First, the results will be published in an academic journal, explaining the program and the degree to which it was successful. The next step would be to insert a plug on the CDC website with the results of the program and how the two EBI's can be used together in a successful intervention. Just like with the unsuccessful results, the results will be presented at an academic conference in hopes of encouraging further studies of the program. The

dissemination of a successful intervention is important for obtaining funding to extend/expand the program.

Evaluating the dissemination of this program will be somewhat difficult. It would be possible it measures how much the publication is view and cited, but beyond that, it will be difficult to do any evaluation. The biggest problem I expect to run into with dissemination is funding and evaluation. It is our plan to set aside money in the grant budget that is designated for dissemination, in hopes to avoid this issue.

**Study Design & Analysis**

In order to ensure that we can establish causality for this intervention it is important to carryout the study in a way that could replicate previous finding. Based on the way this study was originally conducted we will be using an unequal 3:1 intervention: control monthly block randomization. Depending on the month newly enrolled PrEP patients will be placed in the study arm for that month. In order to control when the intervention can be accessed a link will be used to restrict the availability of the video link during the control months. The control group will receive the normal PrEP enrollment and counseling provided by the clinic and the intervention will receive the regular enrollment with the SITC adaptation during enrollment. Table 1 shows the differences in enrollment protocol for control and intervention patients.

Table 1: Steps for PrEP enrollment comparing intervention and non-intervention [16].	
Control Enrollment	Intervention Enrollment
1. Registration paperwork	1. Registration paperwork
2. Routine HIV/STI visit	2. Routine HIV/STI visit
3. PrEP Eligibility	3. PrEP Eligibility
4. Obtaining health history	4. Obtaining health history
5. Reviewing current medications	5. Reviewing current medications
6. Performing a physical exam	6. Performing a physical exam
7. Reviewing lab results	7. Reviewing lab results

8. Clinician Assessment for PrEP or PEP	8. Clinician Assessment for PrEP or PEP
9. Provide PrEP Counseling	<b>9. Provide PrEP Counseling</b>
10. Discussing adherence strategies	<b>10. Discussing adherence strategies</b>
11. Providing the prescription	<b>11. Deliver Intervention video</b>
12. Referring to the benefits counselor	<b>* This will be a combined discussion that hits the points the video does not.</b>
13. Notification of client's PCP	12. Providing the prescription
	13. Referring to the benefits counselor
	14. Notification of client's PCP

Figure 4 gives the full 12-month intervention plan for each patient in the intervention. Upon enrollment all patients will take a pre-enrollment behavioral survey to assess various skills and knowledge being targeted by this intervention. Patients will then begin PrEP enrollment and receive either control or intervention protocol. Patients will be asked to take a post-enrollment behavioral surveys at 3 and 12-months. The data from these surveys will be analyzed using two-sampled t-test to determine significant differences for the various scales used.

Medical records will be monitored and used to identify incident cases of all STI diagnosis throughout the two-year data collection phase. All study participants can be

Enrollment		3 months		12 months	
Pre-Intervention Survey in waiting room. (\$10)	Intervention applied during enrollment visit.	Post-Intervention Behavioral Survey & STI check. (\$15)	Post-Intervention Behavioral Survey & STI check. (\$25)		
N= 1,600		N= 960	N= 576	N= 346	

surveyed using medical records from the clinic and will be noted at any time during the study. Cox proportional hazards models will be used to assess hazard ratios for STI incidence during the study period with a denominator of person-months. Various models will be analyzed using covariates such as age, race, and sexual orientation. All analysis will

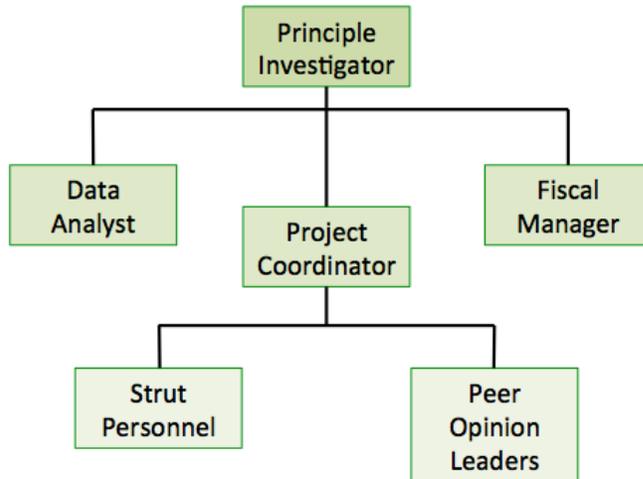
be conducted using SAS statistical software and will be presented at the 0.05 significance level.

### **Project Management**

Due to the simplicity of this project and limited resources, there is only one Principle Investigator who will oversee this project. Ethan Cardwell, MPH, will be in charge of project staff for the implementation of this intervention at the Strut Clinic. The PI will be responsible for overseeing the material development, resource management, and grantee activities. The PI will oversee both the Project Coordinator and the Biostatistician.

P. Coord, BPH, is the project coordinator and is in charge of overseeing data collection and intervention implementation at the Strut clinic under the supervision of the PI. The project coordinator is responsible for the day-to-day operations of the intervention. As project coordinator, they will also be responsible for all coordination between UC Berkley and the Strut Clinic. This means interacting with the clinic staff to ensure that the intervention is implemented correctly and collecting the survey data for the behavioral portion of the intervention.

D. Analy, MPH, is the biostatistician responsible for all data management and analysis during and after intervention implementation. The data analyst for this project will be responsible for monthly data entry and data reviews for this project. The fiscal manager for this project will assist the PI in overseeing the grant funding for this project. To understand the hierarchy for the management of this project, view the figure below.



### **Performance Measures**

The way my intervention is designed there will be randomization into two cohorts; control group, receiving only part of the intervention, and the intervention group who receive the entire intervention. As patients are prescribed PrEP they will be randomly assigned to one of the groups. The outcomes to analyze are the consistency of condom use via survey and STI occurrence via medical record.

These outcomes are very different from one another and I believe will require differential evaluation designs. For the first outcome, the study design will be prospective cohort study where patients are followed over a one-year period from the same cohort. In this design, both the cases and the control will come from the same cohort and will have the same measurement of condom-use via survey at 3, 6, and 12 months. This was chosen because we want to determine if the intervention is actually working naturally in the population. The greatest benefit of doing the study this way is that we can determine

causality. The biggest disadvantage I see is the potential for loss-to-follow-up, especially the 6-12 month follow-up.

<b>Evaluation</b>	<b>Measure</b>
Formative [11]	<p>Determining the validity of the video produced for the video will be conducted using the same methods used for the development of the <i>Safe in the City</i> intervention.</p> <ol style="list-style-type: none"> <li>1. Identify an appropriate theoretical framework, an intervention medium, and key messages. <ul style="list-style-type: none"> <li>- Social cognitive theory</li> <li>- Information-motivation-behavior model</li> <li>- Theory of planned behavior</li> </ul> </li> <li>2. Collaborate with a film company to integrate the framework and key messages into an entertaining product. <ul style="list-style-type: none"> <li>- Surveillance data and the demographic characteristics and levels of STD morbidity of patients at the at the Strut clinic were used to identify appropriate actors. <b>As well as, focus groups to identify peer opinion leaders matching these identified demographics.*</b></li> </ul> </li> <li>3. Facilitate a multistep participatory process involving members of the priority audience (i.e., STD clinic patients), clinic staff, and community reviewers. <ul style="list-style-type: none"> <li>- Research staff conducted focus groups at three stages of video development: storyline development, scriptwriting, and postproduction editing.</li> </ul> </li> </ol>
Effectiveness & Reach	<p><u>Demographic:</u> Age, race/ethnicity, gender, etc.</p> <p><u>Incident cases of STI's</u> (gonorrhea, chlamydia, syphilis, and HIV)  <ul style="list-style-type: none"> <li>- Laboratory analysis via the Strut Clinic lab services.</li> </ul> </p> <p><u>Condom Use:</u>  Condom Use Self-Efficacy Scale (CUSES) [17]  <ul style="list-style-type: none"> <li>- 28-item Likert Scale</li> <li>- CUSES correlated significantly with the ATC scale (r=.51, p.001) and the CSE (r=.55, p.001) with evidence of convergent validity.</li> <li>- Cronbach's alpha = .91, test-retest correlation = .81</li> </ul> <b>The short form used in the intervention will not include</b> </p>

	<p>the questions pertaining to the purchase of condoms, as this is not relevant. *</p> <p><u>Perceived Risk:</u>  A 6-item scale assessed perceived risk relative to non-HIV STI diagnosis (obtained Cronbach's alpha = 0.80). A sample item from that scale is, "Getting a <b>sexually transmitted infection*</b> is beyond my control[18]."</p>
<p>*Adaptation  **All adaptations assessed for validity and reliability during pilot phase.</p>	

The second outcome is the occurrence of STI's, which I assume will be much rarer than the first outcome. Because of this, I would like to use a modification to the cohort design and do a case-cohort design. In this design as cases of STI's occur they will be matched to someone in the same cohort that will act as a control. I chose this design because it will help identify common exposure of those who are contracting STI's in either intervention or non-intervention groups. This should inform different components of the intervention and identify weaknesses in the intervention. The most challenging part of this study is that it will be difficult to conduct and analyze the data, which will be useful in the long run.

## **Evaluation**

### **Formative Evaluation**

Determining the fidelity of the video produced for this project will be conducted using the same methods used for the development of the *Safe in the City* intervention[11].

1. Identify an appropriate theoretical framework, an intervention medium, and key messages.

This has already been done by the makers of the SITC intervention and will combine Cognitive Theory, the Information-Motivation-Behavioral Skills model, and Theory of Planned Behavior.

2. Collaborate with a film company to integrate the framework and key messages into an entertaining product.

For the purposes of this intervention we are working with digital arts students at UC Berkley to develop the video for this intervention.

3. Facilitate a multistep participatory process involving members of the priority audience (i.e., STD clinic patients), clinic staff, and community reviewers.

Research staff conducted focus groups at three stages of video development: storyline development, scriptwriting, and postproduction editing. Using the feedback from these focus groups will be crucial in developing a reliable and relatable video for the target population. The evaluations at these stages in intervention formation will be used for quality improvement of the intervention material.

## **RE-AIM Evaluation**

### Reach

Based on the design of this study we will be able to reach all newly enrolled participants during the months randomized to intervention. We are asking the nurses enrolling PrEP patients in the intervention to indicate that the patient received the video intervention opposed to the standard enrollment protocol. By comparing the date of enrollment with the intervention status of the participant we will be able to determine if we are properly reaching the target population. If this appears to be a problem during the implementation

phase of the study, then a check will be put in place to ensure the Strut staff are showing the video to the patients.

The study design for this project is randomized control trial, so it is important to ensure that we are maximizing the reach of the intervention without contaminating the control group. For this reason we are not incorporating any advertisements for the video-based intervention until after the first three years of data collection. The post-intervention survey will be used to determine the level of contamination that may have occurred during the data collection period.

Another component of this intervention is to determine if there are sustained behavior changes that occur in the intervention versus control. It is important that the reach for this portion of the study remains as high as possible, but it is suspected that there will be some loss to follow-up. To reduce this we will be contacting individuals at the 3 and 12-month periods if they have not made appointments at the clinic and sending them an online link to the survey. By doing this we are not completely reliant on clinic attendance for participation. Through the use of incentives and the online survey option we will maximize the reach for the behavioral portion of this intervention. All missing surveys will be evaluated to find commonalities and possible changes that could increase reach.

### Effectiveness

The primary goal of this intervention is to use a relatively efficient and reliable video-based method to reduce the incidence of STI's in PrEP users. Secondary outcomes of this intervention include: (1) increasing the self-efficacy of participants to use a condom properly (putting them on and taking them off) and (2) their ability to negotiate condom

use with new and existing partners and (3) determine the perceived severity of a non-HIV STI diagnosis.

The primary goal of the intervention will be measured using laboratory analysis/clinical medical record to determine incident cases of chlamydia, syphilis, gonorrhea, and HIV. Data will be collected in 3-month intervals, which will align with appointment schedule for the PrEP prescription. Data will only be analyzed after the first interval and in six-month intervals after that. It is not necessary to perform analysis in smaller increments due to redundancy.

Secondary analysis will be conducted at the initial visit before and after the intervention, three and twelve months for each participant. The pre (\$10) survey at the initial visit assesses all secondary outcomes for self-efficacy and perceived severity. At the three-month visit, the survey (\$15) will assess only secondary outcomes for self-efficacy. The final survey at the twelve-month visit (\$25) will again assess all secondary outcomes for self-efficacy and perceived severity. Data for secondary outcomes will be analyzed at the end of each study year. As these are secondary analysis it is not anticipated that problems will arise with data collection and they are not as pertinent as the primary goal.

### Adoption

In order to evaluate how efficiently the intervention was adopted into the clinic by the staff, we will be using short surveys at 3, 12, and 24-months of the data collection phase of the project. These surveys will allow us to make any changes suggested by the staff to make the intervention to be more easily adopted into current protocol. By evaluating the efficiency of adoption for this intervention we can use the information to motivate other clinics in San Francisco to uptake the intervention in their clinic protocol.

### Implementation

It is important to ensure that the process of delivery of the intervention is effective and convenient for the participants. A set of questions about the process will be used in the post-survey given to participants at their initial visit. These questions will be analyzed continuously at three-month intervals to ensure a standard of quality persists through the entire intervention. If problems arise they will be addressed accordingly for quality improvement of the intervention.

### Maintenance

The purpose of this study is to prove the intervention designed is effective and easily integrated into the clinic setting. At the end of the study period the intervention will be completely integrated into the Strut clinic protocol for PrEP enrollment. This means that all newly enrolled patients at the Strut clinic will be reached by the intervention. In order to increase the reach of the intervention, we will work with the clinic staff and peer opinion leaders to disseminate the intervention to other clinics throughout the city. This will make this intervention a standard in the protocol for PrEP enrollment in all of San Francisco. With San Francisco being a leader in PrEP uptake, success of the intervention should encourage other cities and STI clinics to adopt this intervention as a standard. **We will also be conducting a cost-effective analysis of the intervention in order to increase the likelihood that other clinics will uptake the intervention.**

### Partnerships and Collaborations

Funding for this project is in accordance with the Center for Disease Control HIV Compendium Grant. The purpose of this grant is to adapt currently promoted high impact interventions to address current issues around HIV prevention. All decisions regarding

data collection and usage will be determined in cooperation with the CDC, UC Berkley, and the Strut clinic.

This project will be conducted in collaboration with the Strut Clinic and the University of California-Berkley. Appendix D indicates the letter of support and the memorandum of understanding by the Strut Clinic. This document was drafted in collaboration with the Director of Medical Services and the Director of Sexual Health at the Strut Clinic. The clinic is the optimal location to introduce this intervention, due to their success with their PrEP enrollment programs and implementation of other interventions for GBMSM.

The Strut Clinic is the main collaborator on this project. The clinic will be the location for the intervention and where all data collection will occur. As stated in the MOU, the clinic has agreed to add the video-based intervention to their protocol for PrEP for HIV enrollment. They have also given us access to electronic medical records for participants in order to determine sexually transmitted infections diagnosis. In order to conduct surveys throughout the data collection phase of the project, the clinic has afforded us a small room to conduct surveys. After the study is complete we will be collaborating with other clinics in San Francisco to incorporate the intervention into their PrEP enrollment protocol.

In addition to working with the clinic, the UC Berkley Department of Epidemiology will be working the UC Berkley Department of Art Practice to sponsor a visual art production competition. The winner will receive a \$4,000 scholarship and will collaborate with our team to produce the video-based materials needed for this intervention. The details can be seen in the draft announcement with the letter of support form the UC Berkley Department of Art Practice found in Appendix E.

### **Capacity of the Strut Clinic**

As stated previously, this intervention does not require extensive capacity during the first three years of this project. The Strut clinic already has the capacity for a PrEP program that supports the number of participants needed for this project. The video-based intervention should not place further burden on the PrEP enrollment program being conducted at the Strut Clinic. We are also providing a staff member to the clinic to relieve any initial burden caused by the implementation of this program and to collect the behavioral data.

Another important component of capacity for this organization is the place it holds in the community. The clinic plays a major role as the largest clinic in the Castro and acting as a resource of health for gay and bisexual men who have sex with men. This is important for the continuation of the project after the RCT phase of this project. By building capacity with other organizations throughout the duration of the first three years of the project this will allow for dissemination to other clinics in San Francisco.

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Appendix A- Budget Justification

**Budget Justification**

**Project: A Video-Based Intervention for PrEP and Condom Dual Protection in Gay and Bisexual Men who Have Sex with Men**

**Time Period: September 1, 2017 - August 31, 2020**

**A. Salaries and Wages**

Position Title and Name	Annual Salary	%FTE			Salary Request			Fringe Request	Total 3-year Request
		Year 1	Year 2	Year 3	Year 1	Year 2	Year 3		
Principle Investigator Ethan Cardwell, MPH	\$70,000	50%	30%	30%	\$35,000	\$22,533	\$23,209	\$24,146	\$90,888
Project Coordinator (Vacant)	\$50,000	100%	100%	100%	\$50,000	\$53,310	\$55,456	\$66,949	\$225,715
Data Analyst (Vacant)	\$32,000	10%	10%	15%	\$3,200	\$3,200	\$4,800	\$2,350	\$11,950
Fiscal Manager (Vacant)	\$32,000	5%	5%	5%	\$1,600	\$1,600	\$1,600	\$1,175	\$5,975
<b>Total Personnel</b>					<b>\$255,509</b>			<b>\$100,135</b>	<b>\$334,528</b>

**Ethan Cardwell, MPH**, will serve as Principal Investigator (PI) (35% / 36 calendar months). Mr. Cardwell is a Research Associate from University of California at the Strut | Gay, Bi & Trans Men’s Health & Wellness in the Castro, San Francisco. He has training and experience in health behavior, PrEP-use, and condom migration in the target population (Gay and Bisexual Men who have Sex with Men). This experience makes him the ideal candidate to serve as the PI for this research. He has worked for the past 5 years in sexual health center around Gay, Bisexual, and Transgender populations. His experience started as co-investigator on several projects at the Institute for Sexual and Gender Minority Health and Wellbeing at Northwestern University. Currently, he is working with the University of California Berkley College of Public Health as an associate researcher. In this role he is working on two CDC grant funded studies looking at HIV prevalence in transgender commercial sex workers and PrEP adherence in gay and bisexual men who have sex with men. He plays the role of co-investigator on both of these projects. Mr. Cardwell will be responsible for developing study protocols and approval of these protocols and will be responsible for supervision of the budget; supervision of the project coordinator; communications between UC Berkley and Strut, including the biannual report. He will be responsible for overall conduct of formative research and server as the primary scientific liaison.

**Project Coordinator, BPH** (100% / 36 calendar months) will serve as the Project Coordinator for the project. Mr. Coord is a recent graduate from the University of California Berkley, earning a Bachelor's degree in public health. During his four years in undergraduate study he worked on a research project centered around the acceptance of PrEP in gay men. As part of his curriculum Mr. Coord completed a 200-hour practicum with Strut: Gay, Bi & Trans Men's Health & Wellness Clinic. Based on these experiences and education he has the necessary qualifications to coordinate this project between the Strut Clinic and UC Berkley. His primary responsibilities include: (1) provide support to Mr. Cardwell on this project and other relevant activities, (2) work with the Strut Clinic to coordinate use of the facility as location for the intervention, (3) recruit participants and conduct the described intervention, (4) assist in analysis and interpretation of the collected data for manuscripts and presentations.

**Data Analyst, MPH** (100% / 18 calendar months) will serve as the Biostatistician for this project. Analy is research assistant at UC Berkley with a Master's degree in biostatistics. His research interest focuses on applying statistical and epidemiological methodologies and study designs to LGBT\* research. As biostatistician for the project he will serve by providing high-level statistical expertise and guidance; advise on all related data collection procedures assist with all project data analyses and subsequent manuscripts.

**\*Fiscal Manager** (5% / 12 calendar months) is the financial manager of the currently funded project in UC Berkley's College of Public Health. He is responsible for ensuring that all award spending is in line with the approved guidelines and procedures.

**\$207,458**

Please note that personnel fringe costs vary based on the following benefits schedule, which can also be found at <http://www.research.uky.edu/ospa/info.html>. Fringe benefits are escalated as described in the table below. Fringe benefits are requested as prorated based on the percentage of salary/wage support requested, as described above.

<b>Benefit</b>	<b>Faculty</b>	<b>Staff</b>	<b>Post Doc</b>	<b>Hourly Employees</b>
<b>Retirement</b>	10.00%	10.00%	N/A	N/A
<b>Social Security</b>	7.65%	7.65%	7.65%	7.65%
<b>Other Fringe</b>	3.4%	3.7%	0.8%	0.8%
<b>Total Percent</b>	21.05%	21.35%	8.45%	8.45%
<b>PLUS Prorated Amount for Health and Life Insurance Multi-Year Projects include a 10.5% increase in insurance per year. Amounts shown below are for the '14-'15 year.</b>				
<b>Employee</b>	\$5,592	\$5,592	\$5,592	N/A
<b>Employee+Children</b>	\$7,272	\$7,272	\$7,272	
<b>Employee+Spouse</b>	\$8,712	\$8,712	\$8,712	
<b>Employee+Family</b>	\$10,224	\$10,224	\$10,224	
<b>Life Insurance</b>	\$3/month	\$3/month	\$3/month	N/A

**B. Material Development**

Item Requested	Number Needed	Unit Cost	Year 1 Amount Requested	Year 2 Amount Requested	Year 3 Amount Requested
Ipad + Repair	2	\$600	\$1,200	\$600	\$600
Printed Material			\$500	\$500	\$500
Key Informant Interviews			\$5,300		
Video Production					
– Time for participants (fee for service)			\$20,000		
– Production Contract			\$5,000		
– Production Set			\$1,000		
– Travel for participants			\$5,000		
– Food			\$2,000		
<b>Total Supplies</b>			<b>\$40,000</b>	<b>\$1,100</b>	<b>\$1,100</b>

In support of our formative research goals and data collection, we are requesting funds to purchase two iPads for the Project Coordinator to use in survey data collection at the Strut clinic. We will need a reliable and durable iPads configured to receive 4G/LTE Internet signal.

**Printed Materials**

The project requires the use of numerous forms of printed material including, but not limited to, video scripts and movies posters.

**Video Production Contract**

This project requires utilizes a video-based intervention, which will require a production contract. The contract will be with the graduate program in video production at UC Berkley, which should reduce the cost.

**C. Travel**

	Year 1	Year 2	Year 3
Total	2000	6500	13000

Out of state travel: We request \$15,000 in travel funds to support the cost of Ethan Cardwell’s travel to attend SSSS Annual Conference for two year of the grant period and the international AID Society Conference in the third year.

We are also requesting find for ground transportation between the clinic and UC Berkley, as well as overnight stay in Atlanta, GA at the CDC.

**D. Other**

	Year 1	Year 2	Year 3

Key Informant Interviews	\$5,300		
Incentives	\$10,000	\$30,000	\$10,000
Strut Sub-Award	\$10,000	\$20,000	\$15,000

Participant Incentives. In order to encourage participation in the study participant will be given a \$10 gift card for the completion of the first survey, a \$15 gift card for the completion of the second survey, and \$25 gift card for the completion of the final survey.

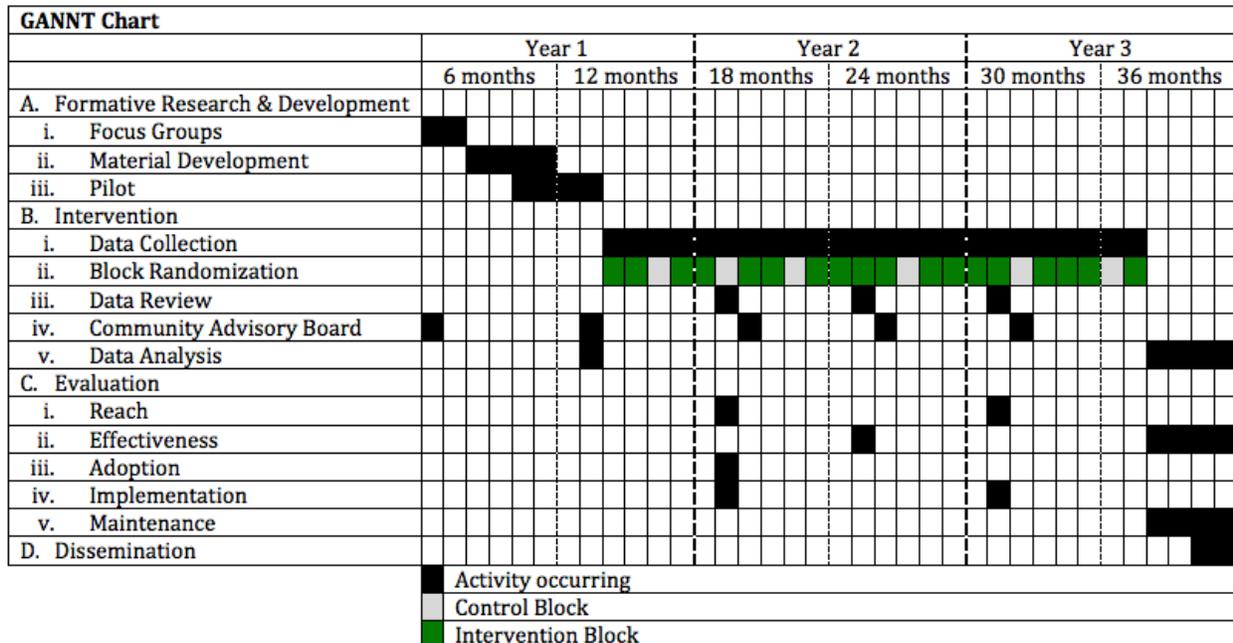
Formative research/interview incentives for Strut staff and the Strut patient are requested to development the intervention material.

**Subaward to Strut Clinics**

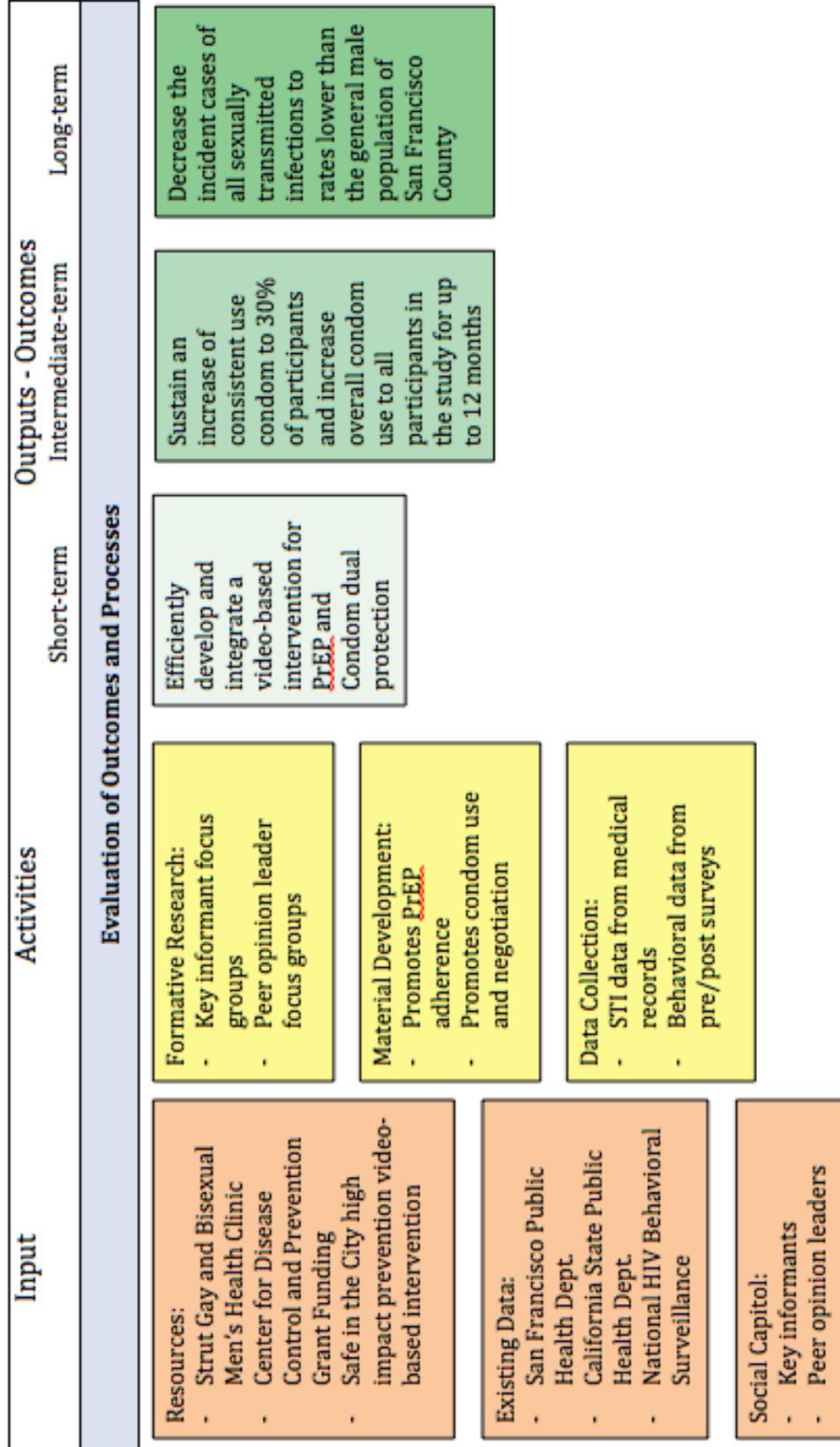
1. Name: Strut
2. Method of Selection:
3. Period of Performance:
4. Scope of Work:
5. Method of Accountability:
6. Itemized Budget and Justification:

**Applied Public Health Research Project**

Appendix B- GANNT Chart



**Logic Model:  
A Video-Based Intervention for PrEP and Condom Dual Protection**



**DRAFTED LETTER**

**DRAFTED LETTER**