

Impact of UCSF Telehealth Appointments on Patient Attendance and Medication Adherence

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Table of Contents

Summary	3
Intervention and Evaluation Question.....	4
Description of intervention to be evaluated:	4
Description of existing state of knowledge on this outcome in the country where the intervention is implemented:.....	4
Evaluation Question of Interest	4
Define the Target Population and Sampling Frame	4
Discussion of Casual Chain	4
Evaluation Design	5
Description of Study Groups.....	5
Study Design.....	5
Discussion of Casual Framework for Research Question	5
Minimization of Selection Bias.....	6
Minimization of Confounding Factors	6
Impact Heterogeneity by Intervention, Beneficiary Type, and Context.....	6
Limitations	6
Data Collection	7
Instruments to Be Used	7
Sampling Methodology	7
Sample Size Calculation/Power Analysis.....	7
Description of Data Collection Methods in the Field	7
Target Audience	8
Policy Relevance	8
Ethical Issues.....	8
Timeline	8
Table	Error! Bookmark not defined.
Bibliography.....	9

Summary

The UCSF HIV Telehealth Project is a program focused on improving the quality of and access to care for patients with HIV through the use of electronic interactive healthcare consultations that reduce geographic barriers to receiving specialty services. By using real time live video connections, patients will have direct access to experts and specialists in HIV care at UCSF without having to travel to a centralized location.

The goal of this study is to assess the impact of telemedicine services at San Francisco's local community clinics on patient-oriented outcomes. Our hypothesis is that telemedicine would safely improve patient attendance rates, which we measure by average patient check-ins. We also hypothesize that telemedicine would be associated with higher medication adherence rates, which we measure according to patient surveys and drug refill records.

Intervention and Evaluation Question

Description of intervention to be evaluated:

HIV is a chronic condition that requires consistent and significant management of health, medication and nutrition. The UCSF HIV Telehealth Project offers telehealth appointments for HIV positive patients seen by primary care providers in a community health care clinic setting through established partnerships as an alternative to having patients travel all the way to the UCSF HIV Clinic for specialist visits. It is the goal of the project to connect patients at their community clinic site to specialists at a university-affiliated HIV clinic location, which are often difficult to reach by public transportation in San Francisco. The intervention to be evaluated: the impact of telehealth appointments on patient appointment attendance, and drug medication adherence.

Description of existing state of knowledge on this outcome in the country where the intervention is implemented:

Transportation barriers are often cited as barriers to healthcare access. These barriers lead to missed appointments and delayed medication use. Because of this, there can be consequences in chronic care management, especially in HIV because the person's immune system is compromised and without consistent treatment, the HIV virus can develop into AIDS. A study in Chicago concluded that overall evidence supports the transportation barriers are an important barrier to healthcare access, particularly those with lower incomes, under/uninsured. (Syed, Gerber and Sharp)

Evaluation Question of Interest

Do Telehealth Appointments increase patient appointment retention, and increase drug prescription adherence? Because community clinics are more easily accessible by location, patients who have access to telehealth appointments at these community clinics will have increased patient appointment retention, and drug prescription adherence when compared to patients who must make the appointments at the university hospital further away.

Define the Target Population and Sampling Frame

The target population of this study is those that will benefit from having HIV Telehealth care, those chronically infected with HIV that are low income, under/uninsured living in urban areas without reliable access to transportation.

Discussion of Casual Chain

- Input
 - Funds and equipment will be available to provide telehealth appointments between community clinics in underserved areas of San Francisco and the University specialists
- Activity
 - Patients have telehealth appointments with university specialists
- Output
 - Patients have increased/easier access to healthcare specialists for questions and communication
- Outcomes Observable Data:
 - Patients receiving treatment will have higher appointment attendance rates
 - Patients receiving treatment will have higher medication adherence rates
- Long Term Outcome:
 - Patients and doctors better manage HIV+ status with less incidences of complications and have less risk of dying from AIDS.

Evaluation Design

Description of Study Groups

- **Treatment Groups:**
 - Randomly assigned into treatment groups will be told to make appointment with nearest community clinic sight with Telehealth connection
- **Control Groups:**
 - Patients will not be told to make appointments with local community based clinics and will be told to continue making appointments with specialists at UCSF without knowledge of Telehealth intervention to prevent spill-over effect

Study Design

Study Design:

The population of the study is HIV+ men and women in San Francisco. The sample size of the study is comprised of new enrollees in to the clinic. This will be a prospective cohort study where new enrollees to the UCSF HIV Clinic will be randomized and assigned to two groups. We will determine the number needed from this population by doing a power calculation. Once the ideal number of enrollees have been acquired, they will have a baseline physical visit to measure attendance rate through patient check-in, and adherence rate of medication through self reporting and monitoring of medication refills at the partner pharmacy. They will then be randomly assigned into the control group (traditional physical visit) or the treatment group (telehealth appointment group). They will see the same physicians and same specialists as well. Once they are randomized into the two groups, we will look for balance in the characteristics of: HIV viral count, gender, age, sexual orientation, race, income level, and marital status. We will use logistic regression to determine the statistical significance of the differences between the two groups to ensure that these groups have no statistically significant differences, and to ensure that these two groups are balanced.

We wanted to use a prospective cohort study to with a control group because we wanted to have a true counterfactual for the study. The counterfactual minimizes unseen bias from the environment that may negatively or positively affect the outcomes of patient attendance and medication adherence. We wanted to randomize the patient population because we also wanted to minimize selection bias. Some patients may be more likely to choose the intervention more than the control, and vice versa. These differences can bias the results making it difficult to see the true impact of the telehealth program intervention.

Therefore a randomized controlled trial was best for measuring the impact of telehealth appointments on patient attendance and medication adherence. It is internally valid because the patients are randomly assigned to treatment and control. The characteristic differences between treatment and control should be statistically insignificant through randomization and then checked through matching.

Discussion of Casual Framework for Research Question

The counterfactual for this study is patients that would not have received the telehealth appointments to see UCSF specialists, but instead see these UCSF specialists directly. Observable data is what we can measure in patient attendance, and medication retention. We can only measure how often the patient shows up for appointments, and how the patients take medication by the number of refills/schedules he takes. We cannot measure outside influences, like having an unofficial care-taker, or other unforeseen circumstances that may help or hinder the patient from getting to the medical appointment.

This study facilitates causal inference through minimizing biases that may affect the impact of having the intervention for the desired outcomes of increased patient attendance and medication adherence. The randomization should minimize selection bias, and minimize any differences in characteristics between patient and control groups. The counterfactual eliminates any bias from unseen environmental factors that could influence HIV positive attendance and medication adherence.

Minimization of Selection Bias

The study minimizes selection bias and significant differences between groups by way of randomizing subjects into the groups.

Minimization of Confounding Factors

The study minimizes confounding factors by randomization of subjects, matching of subjects, multivariate analysis of factors affecting HIV chronic care, age, education, income, etc.

Impact Heterogeneity by Intervention, Beneficiary Type, and Context

The study design will be able to capture differences in groups by measuring the known variables that may affect the intervention/income, and with randomization there shouldn't be a bias towards the treatment or control groups.

Limitations

1. Patients that choose into the UCSF HIV Clinic may have characteristics that are significantly different from the general HIV positive patient population, so there is a limit on the external validity of the study
2. Patients that are already close to the UCSF HIV Clinic may have an advantage over patients that live further away, however randomization should minimize this bias

Data Collection

Instruments to Be Used

In order to collect data on patient attendance, we will use administrative data and records on patient check-in. This measure will be a proportion that captures the number of completed visits in the numerator and the number of total scheduled (completed plus no-show) visits in the denominator during the observed period of interest. Medication adherence, the extent to which patients take medications as prescribed by the specialist, will be assessed by patients' self-reporting, as well as by monitoring of medication refills. This will require the administration of patient surveys or questionnaires, as well as access to administrative data at the partner pharmacy. The patient surveys will assess drug adherence and reasons for missing doses. Patient's medication containers will be periodically reviewed and their renewal dates will be noted. The instruments that are being used are quantitative in nature.

Sampling Methodology

The population of interest is HIV positive patients in the San Francisco area. The sampling frame consists of those who choose to enroll in the UCSF HIV Clinic. The sample for the study will be drawn by random sampling, in which each new enrollee in the UCSF HIV Clinic has the same probability of being drawn. The intervention and control groups will be determined by random assignment.

Sample Size Calculation/Power Analysis

Because the intervention's benefits are not assigned by clusters, the evaluation sample can be constructed by taking a simple random sample of all new enrollees in the UCSF HIV Clinic. The outcomes of interest that the program is designed to improve are appointment attendance rates and medication adherence rates. According to 2009-2010 data, out of 862 San Francisco residents that were diagnosed with HIV, 434 patients (58%) were retained in care for 6-12 months, and 431 (50%) achieved viral suppression within 12 months of HIV diagnosis (San Francisco Department of Public Health). The average rate of adherence to antiretroviral medication varies by the method used to assess it and the group studied, but is reportedly approximately 70% (National Quality Center).

We will assume that investment in the intervention would be justified if patient retention and medication adherence improved by 50%. We will assume an effect size of 0.50, which is a realistic measure based off a study evaluating the effect of home-based telehealth on clinical care outcomes. Because there have been no evaluations performed on the impact of telehealth appointments on HIV+ patient retention and medication adherence in San Francisco, we will use effect size 0.50, which is conventionally interpreted as a medium effect. We will assume a significance level of 5% with a t statistic of 1.96, and a reasonable level of power of 80% with a t-statistic of 0.84. A reasonable level of power for the evaluation being conducted is 0.8. The sample size will be defined as:

$$N = \left[\frac{\sigma^*(t_{(1-k)} + t_{\alpha^*} \sqrt{\frac{1}{P(1-P)}})}{\beta_E} \right]^2$$

Description of Data Collection Methods in the Field

The evaluation will be performed by a research group at UCSF's Office of Telemedicine, which is well-positioned to collect data from both the comparison group at the UCSF HIV Clinic as well as the treatment group at the local community clinics. Baseline data will be collected by accessing administrative data on new enrollees in the UCSF HIV Clinic. The data collection group will be responsible for working with the centralized UCSF Clinic and with the local community clinics to attain records on patient attendance. Efforts should be made to ensure that measurement of the outcome is consistent across all clinics; for example, the data of interest are patient check-ins in proportion to no-shows and patient cancellations, so cancellations by the clinic should be excluded from the analysis. For data collection on

medication adherence, the medical staff at all of the clinics involved will be trained to administer the written surveys to patients at the end of each telehealth consultation.

Target Audience

The target audience of this study is those that are involved in reallocating resources to increase access to multidisciplinary specialty care for individuals with HIV/AIDS in San Francisco. If telehealth appointments are shown to have a causal effect on improving patient retention and medication adherence, then the UCSF HIV Telehealth Project would perhaps warrant further investment and expanded implementation. This would be of interest to the community clinics, where the telehealth technology would be implemented, and the UCSF HIV Clinic, which is the program implementing agency, as well as to its partners and funders, such as the San Francisco Department of Public Health, the City and County of San Francisco, and San Francisco General Hospital Foundation.

Policy Relevance

The goal of the UCSF HIV Telehealth Project is to provide resource allocation in a time of decreasing funds for HIV care and to improve access to subspecialty services needed to properly treat individuals with HIV/AIDS. Thus, this study is relevant to donors, policy makers, government, management teams at UCSF and at community clinics, and any other stakeholders that are involved in increasing healthcare access to HIV+ patients in a time of scarce resources and limited funding. Proven impact of the program and high levels of patient retention will be necessary in order to achieve scale at community clinics throughout San Francisco and to continue to receive funding and grants from foundations and from the Health Resources Services Association (HRSA). This program is one of the first that is focused on telemedicine in the inner city, rather than rural settings, so if it is proven credible, then this study could also lead to increased recognition of the role that telehealth and community clinics can play in urban and University settings throughout the United States. If further studies were performed to weigh the cost effectiveness and efficacy of telemedicine interventions with other

Ethical Issues

Because of limited financial and administrative resources, randomized assignment was used to assign program benefits to subjects in order to insure an equitable selection method. However, patients were not ranked based on need, because the process of ranking is too error prone and subject to definitional uncertainty; this may be considered an ethical issue, particularly when dealing with the HIV+ population, if more vulnerable individuals are not selected as beneficiaries. Rollout of the program could mitigate this issue to a certain extent, but it may not be sufficient or the timing may be too delayed if patients are already lost to follow-up.

There is also an ethical need to protect the rights and promote the welfare of all subjects involved in the study. The subjects in the treatment group should be assured that their consultations will be held confidential and that their telehealth sessions will not be recorded or videotaped.

Timeline

The baseline data will be collected when the sample is identified, and then the individual units will be randomized into treatment and control groups. The data on patient check-ins will be recorded throughout the one-year interval. Surveys on medication adherence will be administered at each patient appointment.

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