Effects of Faith Counseling in the Promotion of HIV Screening in District Level Health Clinics in Tanzania

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**Introduction**

**Research Question**

Our primary question is whether the implementation of faith-related counseling in district level general health clinics has an impact on the uptake of HIV screening resources. One tangential exploratory question is regarding the analysis of which demographic groups are most affected by faith counseling in the promotion of screening. Another area of interest is in determining the demographic groups least likely, in both treatment and control groups, to utilize the HIV screening resources. Our hypothesis is that employing faith counseling in the district level health clinics will be associated with an increase in the amount of people who choose to get tested for HIV.

**Purpose of the Study**

In 2013, the United Nations AIDS board set forth to create new goals for the global treatment and relief efforts surrounding the HIV/AIDS epidemic. They created a three-fold target to be achieved by 2020: 90% of those living with HIV aware of their HIV status, 90% of those diagnosed on antiretroviral therapy (ART), and 90% of those receiving ART being virally suppressed. While there is only one year left until the original target deadline of 2020, the proportion of those who have HIV that have been diagnosed is only 75%, far below the targeted value (UNAIDS). This percentage is estimated to be even lower in Tanzania because only 28.4% of people ages 15-49 had been tested for HIV within the last 12 months, a percentage that has been steadily declining from previous years. HIV tests and antiretroviral therapy are free welfare services to the entire Tanzanian population, provided by the government in collaboration with multiple foreign aid and relief organizations. But resources for treatment of the epidemic mean little if there isn’t sufficient diagnosis of HIV across the population. Thus, our study aims at addressing the first of the UNAIDS goals by investigating how to encourage people to get screened for HIV.

 The Tanzanian society places a strong emphasis on religion. Roughly 96% of the population practice some religion, with the primary faiths being Christianity, Islam, and native religions like that of the Maasai. With such a heavily religious society, it’s vital to address this cultural context in attempting to pinpoint the strategies that are effective in combating HIV. There are limited resources in Sub-Saharan healthcare systems, so it’s important to distinguish which pre-existing structures, like the church, have the largest impact on reaching these healthcare goals. There are many healthcare facilities that are religiously affiliated and much of the healthcare system in Tanzania already incorporates religious counselors, but it is in no way systematic across the nation. In this way, an analysis of this counselor’s effectiveness in encouraging people to get screened is important in the future of resource allocation.

**Literature Review**

The primary study from which our research was based was the trial conducted by Ezeanolue, Echezona et al. in Nigeria on faith-based interventions and its effectiveness in getting expectant mothers to be screened for HIV. This study took place at church hosted baby showers and used the treatment of a congregation’s education and discussion of the importance of HIV testing with the control of a physician’s similar discussion to elucidate whether a faith leader would have better results in uptake of HIV screening resources. The study found a significant difference between the two groups with 92% pregnant women in the intervention group had an HIV test compared with 55% in the control group. This study also looked into other factors that were associated with an increase in the decisions to test, which included gainful employment and a low number of previous pregnancies. The study used each church as a cluster and then randomized the treatment and control groups based on cluster.

 We found similar methods in studies of faith interventions for medical purposes in the United States. Studies from Elder, J P et al. and Drake, Bettina F et al. looked at subsets of the US population that were more likely to be influenced by a religious leader as opposed to a medical leader, and used these interventions to encourage the groups to be screened for cancer. In the case of Elder, J P et al., the researchers looked into cancer screening among church-going Latinas and the study of Drake, Bettina F et al. prostate cancer screening among African American men. Both studies used similar methods of cluster randomization and found significant results in the use of faith leaders for cancer screening promotion.

 Finally, we looked into studies on the climate surrounding HIV testing in Tanzania specifically. A study that consisted of in-depth interviews and focus groups around the Kilimanjaro region highlighted that patients were more likely to get tested if they were assured of a high quality of care from their healthcare practitioner, confidentiality of their consultation, and the availability and accessibility of ancillary resources (Njau, Bernard et al.). The paper’s discussion of the importance of trust in HIV educators lends well toward the idea of a local and trusted faith counselor being used in this capacity. Another important study that informs this research is on strategies towards male engagement in HIV care in Sub-Saharan Africa (Sharma et al.). This study showed that men were much less likely to get involved in HIV services. They’re around 15% less likely than women to be tested. One barrier that the researchers found that is causing some of this gender inequity of testing is the perception that health clinics offer only “women-centered” services. Our proposed study could thus work as an extension to this research in trying to elucidate whether men are still less likely to elect to get tested once they are present at the clinic, or whether the largest barrier is men coming to the clinics.

**Study Design**

**Rationale for Variable Selection**

Our main outcome measure will be a binary response of whether or not the patient chose to be screened for HIV in order to determine whether the faith-based intervention is associated with the patients’ choice. It will only include the patient's’ decision during their visit to the clinic and will not consider those patients who may decline to be screened during the visit but get screened on a later occasion.

Our predictors include whether or not they received faith-based counseling during their clinic visit, gender, religion, age, education level, distance from the clinic, employment status, when (if ever) they were last tested for HIV, and current diagnosis/reason for visiting the clinic. Our main predictor of interest is if they received the counseling and how that may affect their decision to be screened. Gender, age, education level, and employment status are basic demographics that we will use to explore how much different demographic groups are affected by the faith counseling promoting the screening. Religion will be used as a demographic but also as a way to determine which type of faith-based counselor (Christian, Muslim, or indigenous religion) will be present during the consultation. Distance from the clinic, when they were last tested, and current diagnosis are included because they could affect the patient’s decision to be tested during the visit. A patient who has a longer journey to the clinic may be more likely to decide to be tested because it would be more difficult to return later. If a patient was recently tested, they may be less likely to feel like they should be retested. A patient who came to the clinic for a completely unrelated reason may be less likely to decide to be tested than a patient who may have explicitly come to be tested.

**Confounding Variables**

An individual’s perceptions of HIV and potential stigmas they may have against HIV could influence their decision of whether or not they want to be tested. There is no way to accurately quantify the stigma and so we can not include it in our model. Similarly, if a patient has specific religious views that impact their healthcare decisions it could affect their decision. In addition, we have no way of controlling for people who may have already been told about HIV testing through a community organization, religious meeting, or other source. All three of these are not feasible to include as variables in our study because they are not easily quantifiable but should be considered when analyzing results.

**Inclusion and Exclusion Criteria**

We will include patients at and above the age of consent for HIV testing in Tanzania (16 years and older). Of special note is that people aged 16-17 years old are considered “mature minors” and are able to give their own consent to be tested but cannot see their own results before a parent or guardian sees the results. We will have to make sure those people do not feel extra pressure from our study about making their decision. People of all religious affiliations and non-religious people will be included. Patients who are already HIV positive will be excluded, as will people who opt out of the trial and choose not to share their religion because religion is central to our study. The informed consent procedure will specifically notify patients that they will be asked about their religious beliefs so that they may decide whether or not they would like to participate.

**Ethical Considerations**

Given that the study is taking place in the developing country of Tanzania, rather than the United States as a developed nation, there are some ethical considerations that should be made before proceeding with the trial. Foremost of which is the necessity of this specific location of the clinical trial. It is pertinent that the study happen in Tanzania, as opposed to the US, because of its special context of limited resources, a highly religious society, and a high prevalence of HIV. As noted in the literature review, the relevant studies for which this extension trial is based off of, focus on religious subsets of the population. The influence of a faith counselor would not be as effective in a more Westernized context that has a higher diversity of faith backgrounds. Thus to achieve this studies’ purpose, the trial’s location in Tanzania is necessary. Further on that point, the study’s findings will be specifically applicable and beneficial for the Tanzanian people as its generalizable population.

Other ethical considerations include the presence of clinical equipoise in the trial. Since the use of religious counselors has not been proven to be effective, the study is not consciously giving superior treatment to one arm of the trial over the other. Since every patient visiting a healthcare facility in Tanzania is able to receive free HIV testing, whether or not they are participants of the trial, there is little concern over ethics in sample selection. Furthermore, the study population will benefit from the program of education from either healthcare provider or faith counselor with little risks since the treatment is education. Hence the risk to benefit ratio is favorable.

There is consideration with the use of religion as it relates to healthcare in whether this produces undue religious influence on the sample population. However, in the setting of Tanzania, using religious leaders from within the community to address a population that is roughly 96% religious (Christian and Muslim) is important in deciding effective care measures of underserved populations. If pre-existing resources in a low-resource environment could aid in the fight against the HIV epidemic, then the strategy should be further explored.

Although the age of consent for HIV testing in Tanzania is 16 years and older, 16-17 year olds are considered “mature minors” and have special considerations for enrollment in our trial (UNICEF). As mature minors, they can legally consent to be tested for HIV. However, the results are considered confidential and will first be shown to their parents or guardians and not the patients themselves. For any of the patients who are considered mature minors and visit the clinic during our trial, we should make sure to to emphasize this so they may give informed consent.

**Subject Recruitment Plans and Consent Process**

Those that come into the designated health clinics on the specified trial dates will be eligible to be considered as subjects for the clinical trial. From this recruitment, subjects will be enrolled insofar as they qualify past the exclusion criteria and have signed the consent form. This process will continue until the allotted amount of subjects from each clinic has been reached.

A detailed consent form, as found at the end of this proposal, will be given to each eligible patient in their primary language. After reading the consent document that details the extent and purpose of the trial and informs the patient that they will be asked questions about their demographics (including religion), they will be given the chance to ask questions and either opt in or out of the study.

**Randomization Method and Blinding**

We will use one-stage cluster randomization. Clustering will facilitate the randomization process because it will be more cost-effective to have the faith counselors stay in one location (the treatment group clinics) rather than travel between the locations to randomize at an individual level. This will reduce the cost of moving the counselors between clinics and decrease potential logistical issues, which is especially important in a low-resource area such as Tanzania. It also can reduce potential treatment group contamination. Many district-level health clinics have little privacy so if randomization occurred at an individual level, there would be the potential for patients to mingle with other patients and discuss their experiences, which would introduce bias into the trial. In addition, patients are often treated in the same room as other patients in those clinics so contamination would be very difficult to prevent if randomization was done at an individual level.

There will not be any blinding in the clinical trial. It would be impossible to prevent the patient from knowing that they are receiving faith-based counseling. The patient will know which group they are in, as will the health care professional.

**Data Collection & Follow Up**

The data collection will be handled by the healthcare professional in charge of the medical consultation. Patients will self-report gender, religion, age, education level, distance from health facility, when they were last tested for HIV, and employment status. The diagnosis code and choice to be screened or not will be reported by the healthcare professional. Although we believe the patients have no motivation or reason to give untruthful answers, we could still attempt to cross-validate some of their answers such as when they were last tested for HIV. Answers to the questions will be electronically recorded.

There will be no follow-up. We are only seeing if patients choose to get tested in their visit directly after receiving the counseling. We are not interested in patients who may choose not to get tested but change their mind on a later day because those decisions could be due to other influences outside of our control.

**Statistical Plan**

**Hypothesis**

Through a comparison of literature, we estimated the proportion of patients under typical circumstances (control group) that will agree to be tested for HIV to be similar to the 12%, the percentage of those in the population of Tanzania that have been tested within the last 12 months (UNAIDS). From this baseline, we predict that the use of a faith counselor will increase the proportion of subjects that will agree to be tested to 35%, which means a 10% difference in proportions. Thus our hypotheses are as follows:

1. Null Hypothesis: PFCG - PCG = 0
2. Alternative Hypothesis: PFCG - PCG > 0

Where PCG is the proportion of patients under typical circumstances (control group) that will agree to be tested for HIV and PFCG is the proportion of the patients who’ve talked with a faith counselor that will agree to be tested.

**Sample Size and Power**

To calculate the necessary sample size to obtain our desired power, we used the calculation as established by Donner, Birkett, and Buck in their sample size equation for a comparison of proportions in a cluster randomized trial with binary outcomes. By convention, we chose to use an alpha=0.05 and power=0.80. The equation also necessitates a value, kappa, that corresponds to the amount of association between the different clusters in the sample. For this value, we will be using the 0.10 value of the intracluster coefficient (ICC) that was used in the study of congregation-based intervention in HIV testing (Ezeanolue et al.). Because the World Bank estimates an approximate 95 patients a day at district-level health facilities in Tanzania (World Bank Group). Accounting for patients who have already been diagnosed with HIV or who do not wish to participate, we will set the number of subjects per cluster at 60 so as to get sufficient sample size in one day. Through the equation we find a requirement of approximately 358 people in each arm of the trial (treatment and control), which means there will need to be 6 clinics participating in each arm, so 12 total clusters in the sample.

**Length of Study**

Given the fact that we need around 700 participants from 12 clinics and the average district-level hospital sees around 95 patients a day, we will only need to run our study for one day to collect a sufficiently large sample. We will run our study during the normal business hours for the Tanzanian district-level clinics for one day and will continue to run the study for the entire day even if we reach our minimum sample size requirement before the day ends.

**Statistical Methods and Analysis Plan (include hypothesis)**

Our hypothesis test for differences in two proportions at follow-up and data will be analysed with the two proportion z-test. We will be using a multi-effect logistic model to account for correlations at the clustering level as well as predictors at the individual level. This method was used in other similar studies such as the Nigeria HIV testing study in which a multi-effect model allowed for the researchers to account for differences between the clinics or churches. These models are multilevel, allowing incorporation of covariates and confounders for the individual level, such as age, education level, and previous HIV testing, and cluster level (clinic) covariates and confounders, such as size of clinic and possible religious affiliation. Adjusted odds ratios between HIV-tested and HIV-non-tested patients will be obtained by controlling the previously mentioned covariates and potential confounding factors.

**Limitations and Issues**

One of the biggest limitations of the study is implementation if we discover that the treatment is effective. For one, it might not be feasible for the clinics to hire the counsellors full-time because there are limited resources. Additionally, if a clinic is situated in an area with one dominant religion, it might make more sense for that clinic to only have one type of faith counselor present instead of trying to provide for all different religions. Each clinic would have to make its own decisions regarding which how many and which types of faith counselors they would like to have available for their patients. The clinics would also have to consider the ethics behind asking about personal religious beliefs in a healthcare setting. Although it may not be a major issue, it is still something that could limit the scope of the results of our study.

Another consideration is the stigma surrounding HIV and AIDS. If people have a prejudice against HIV, there is probably a lower chance of them choosing to get the free testing no matter if they are in the treatment or control group. There is no way to quantify such stigma so there is no way to include it in our models, but it will undoubtedly have an impact on people's decisions. HIV stigma could also discourage people from visiting the clinics in the first place if they feel that they will be discriminated against in a healthcare setting. If that is the case, then our treatment will not be able to reach some of those who might need it most.

Concerning the procedures of our trial, there are the issues of no follow up and self-reported data. Because we will only be conducting the trial for one day and will not be following patients once they leave the clinic, we will have no way of knowing if the counseling ultimately swayed their decision to get tested at a later time. However, we thought this was best because their decision could also be influenced by outside factors after leaving the clinic. As for self-reporting, the patients may provide some inaccurate personal data, but we see no way of verifying all of the information especially in a low-resource area. There also would be little reason for the patients to lie or purposely give false information, but it should still be considered as a potential factor.

**Funding**

To fund the study, we could apply for a grant through the National Institute for Health & the Department of Health and Human Services. They are currently accepting proposals for one entitled “Targeted basic behavioral and social science and intervention development for HIV prevention and care” that fits our research. The expiration date is in January 2020, so we would still have time to decide. We do not need to have funding for the HIV screening tests, but it should cover the expenses for the faith counsellors’ time.

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**Consent Document**

 The study you’re being asked to take part in is for the purpose of expanding knowledge surrounding the screening of HIV in Sub-Saharan settings. This particular study looks at the use of a faith counsellor on decisions to get tested for HIV. This study is focused on the Tanzanian region and located at different health clinics in the area. The population of interest in this study is anyone over the age of 16 that has not previously been diagnosed with HIV/AIDS. You have been chosen to participate in this clinical trial because you fit this criteria. If you are between the ages of 16 to 17, be aware that the health practitioner is required to report the results of your HIV test to your parent or guardian. If you choose to participate in this study, know that your HIV status will not be recorded for the purpose of the trial, only your demographic information, survey responses, and whether or not you chose to get tested. Your name will never be linked with your individual data in the research. Your participation in this study is completely voluntary and you may withdraw from the study if you feel you are not able to participate at any given point. Subjects who opt to not participate will not lose any services otherwise provided at this health clinic.

During your participation in this study, you will be asked to fill out a survey regarding your demographic information and health record regarding your history of HIV testing and reason for your current visit. This survey will also ask about your religious beliefs. Religious beliefs may be conversed about later in this process. Then, after your normal consultation with the physician, you will have a short conversation with a counselor about HIV testing and be asked if you wish to be screened for HIV today at the clinic. Your participation in this study should involve no risks to your health and all answers to survey and conversation questions remain confidential. Following the completion of this study, results may be published in academic journals. Only general patient information will be reported, no private information or names will become public.

I have read the information above or it has been read to me. I have had the opportunity to ask questions about it and I have had my questions answered. I voluntarily consent to participate in this study and understand that I have the right to withdraw at any time without in any way affecting my medical care at this or any future date.

Printed Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Day/month/year)