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Lea Wilkinson Date

Linking Individual Faith Together with My Highly Active Antiretroviral Therapy (LIFT My HAART)

A Two-Phased Grant Proposal

By

Lea Wilkinson

Degree to be awarded: M.P.H

Executive M.P.H

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Bachelor of Arts

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An abstract of
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Abstract

Linking Individual Faith Together with My Highly Active Antiretroviral Therapy (LIFT My HAART)

A Two-Phased Grant Proposal

By Lea Wilkinson

The number of children newly infected by HIV in low- and middle-income countries has fallen by 40%. This constitutes considerable progress towards the global scale-up of Prevention of Mother-to-Child Transmission (PMTCT) initiatives. For the first time in history, the Elimination of Mother-to-Child Transmission (EMTCT) is an attainable public health goal. For the past decade, Zambia has successfully implemented an efficient nationwide response to the HIV/AIDS epidemic within its borders. During this time, Zambia has worked hard as a nation to achieve key milestones in the coordination and management of their national response. However, a concerning trend is starting to take hold within the country that threatens Zambia's success in PMTCT. Mounting pressure is present in some Christian communities for both men and women to stop Antiretroviral therapy (ART) for the hope that God will heal them through prayer. Women are statistically more drawn to churches that teach this belief, which contributes to their decision to stop ART. For an HIV-positive pregnant woman, the decision to substitute prayer for Highly Active Antiretroviral Therapy (HAART) could impact the life of her unborn child through mother-to-child transmission (MTCT) of HIV. To leverage the role that Christian religion plays in an HIV-positive pregnant woman's decision-making, as a way to ensure improved HAART adherence and reduced MTCT, this grant proposal outlines a two-phased process targeting HIV-positive pregnant women and Christian leaders in Lusaka, Zambia.

The first phase is a mixed-method investigation of both HIV-positive pregnant women and the local Christian leaders in Lusaka, Zambia. The research will help identify the factors that may impact HAART treatment adherence among this population. The second phase uses information gathered through key informant interviews and surveys to aid in the creation of a community based program designed to Link Individual Faith Together with HAART (LIFT My HAART). The purpose of the initiative is to influence how HIV-positive pregnant women are counseled by those they look to for spiritual guidance. The goal is to increase treatment adherence for HIV-positive pregnant women who identify with the Christian faith.

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To my family, I would have never made it to this point without your never-ending understanding, support and encouragement. Nalikutemwa!

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Chapter I: Part A

Introduction

The World Health Organisation (WHO) reported in 2013 that the number of children newly infected by HIV in low- and middle-income countries had fallen by 40% (WHO, 2014). This constitutes considerable progress towards the global scale-up of Prevention of Mother-to-Child Transmission (PMTCT) initiatives. For the first time in history, the Elimination of Mother-to-Child Transmission (EMTCT) is an attainable public health goal.

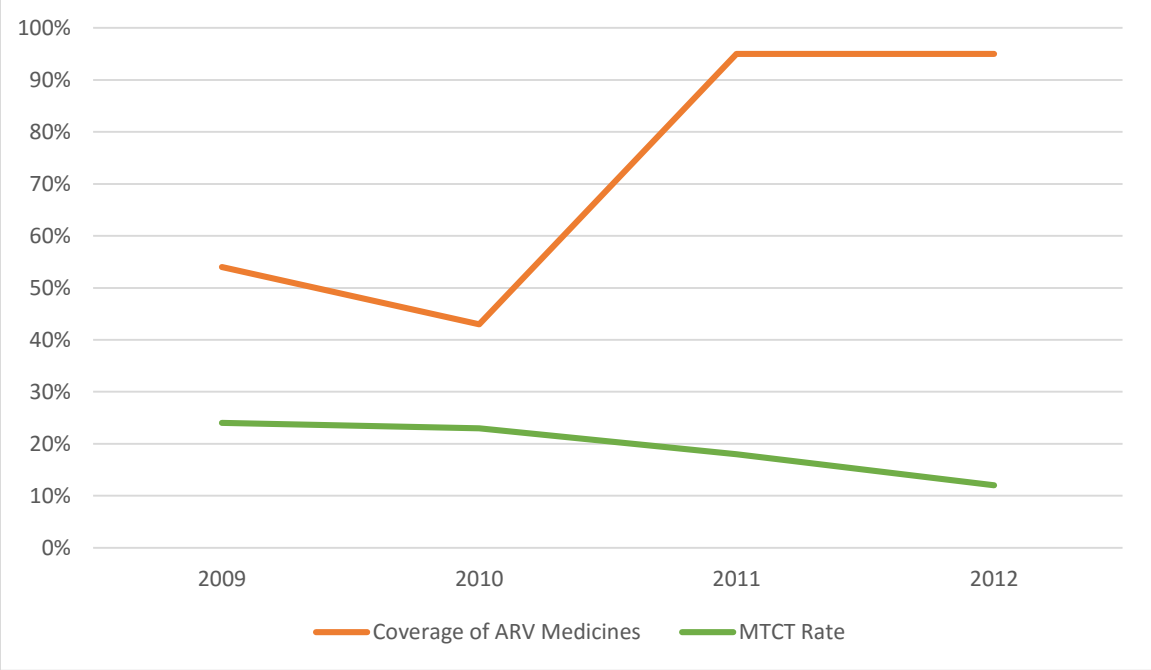
For the past decade, Zambia has successfully implemented an efficient nationwide response to the HIV/AIDS epidemic within its borders (Zambia Ministries of Health, 2014). During this time, Zambia has worked hard as a nation to achieve key milestones in the coordination and management of the national response as outlined in the National AIDS Strategic Framework (NASF) (National AIDS Council, 2014). In PMTCT alone, Zambia reports a decrease in vertical transmission from 24% to 12% between 2011, and 2013 (National AIDS Council, 2014).

To enhance the success that Zambia has achieved in the fight against HIV/AIDS, the Honorable Minister of Health, Dr. Joseph Kasonde endorsed the immediate adoption of Option B+ as the nation's new response towards EMTCT on January 14, 2013 (The Interagency Task Team, 2013). The institution of Option B+ within Zambia will provide lifelong antiretroviral drugs (ARVs) to HIV-positive pregnant women, free of charge.

The use of ARVs is effective in suppressing the HIV virus and has been shown to slow or even stop the progression of HIV within the body (World Health Organisation, 2016). CD4+ T cells are cells within the body that play a key role in protecting it from infection. During the course of the HIV infection, CD4 cells are compromised and unable to keep a person's immune system strong (National Institute of Allergy and Infectious Diseases, 2009). Historically, in Zambia, ART was not given to HIV-positive pregnant women until their CD4 count fell below 200. Option B+ will provide ARVs irrespective of a women's CD4 count. Additionally, infants born to HIV-positive mothers will also receive ARV drugs from birth to six weeks of age, regardless of their selected feeding method. The Zambian Ministry of Health has outlined the overall objective for the implementation of Option B+ as a reduction in the vertical transmission of HIV to less than 5% (Zambia Ministry of Health, 2013).

The ramping up of PMTCT and the impact of Option B+ can be seen within Zambia. The Zambia National AIDS Council reported in 2012 that there were 81, 727 HIV-positive pregnant women who delivered babies in Zambia; of those women, 88% received direct care via ART for PMTCT. This was an increase from 2009. Another increase was reported in 2013, the same year when Option B+ was introduced, when 97% of HIV-positive pregnant women received ART to reduce the threat of vertical transmission (National AIDS Council, 2014). Figure 1.1 outlines the relationship between increased usage of Highly Active Antiretroviral Therapy (HAART) for HIV-positive pregnant women and the rate of MTCT.

Figure 1.1: Relationship Between ARV Coverage and MTCT Rate in Zambia from 2009-2012



Source: UNAIDS

The Problem

There are unquestionable successes in PMTCT within Zambia; the country is on target to reduce the number of new HIV infections among children by 90% in 2015 (National AIDS Council, 2014). However, there is a concerning trend that is starting to take hold within the country that threatens to impede Zambia's successes in this endeavor. The literature suggests that there is pressure in some Christian communities for both men and women to stop ART for the hope that God will heal them through prayer (Endeshaw et al., 2015; Tofa, 2014; Seeling et al., 2014; Musheke, Bond, & Merten, 2013; Horn, 2012; Manglos & Trinitapoli, 2011; Togarasei, 2010). Further, women may be more drawn to churches that teach this belief, contributing to their decision to stop ART. For a pregnant woman the decision to substitute prayer for ART could impact the

life of her unborn child through mother-to-child transmission of HIV. The latter occurs during pregnancy, labor, delivery or breast feeding from an HIV-positive mother to her baby. Without intervention, mother-to-child transmission rates can range between 15% - 45%. When an HIV-positive pregnant woman adheres to her highly active antiretroviral therapy (HAART), the risk to her child of vertical transmission can be reduced below 5% (WHO, 2015). The development of this belief affects all PLWHA who decide to follow the prophets. However, for the purposes of this thesis, the population of focus is HIV-positive pregnant women in Zambia.

Understanding the Problem

The increased influence of religious leaders exhorting believers to stop their ART regimens presents a double challenge for women living with HIV: it affects their own adherence to ARVs and threatens the gains made in PMTCT with an eventual goal of EMTCT. In order to better appreciate the problem, one must first understand both women and religion as they pertain to Zambian culture.

Women in Zambia

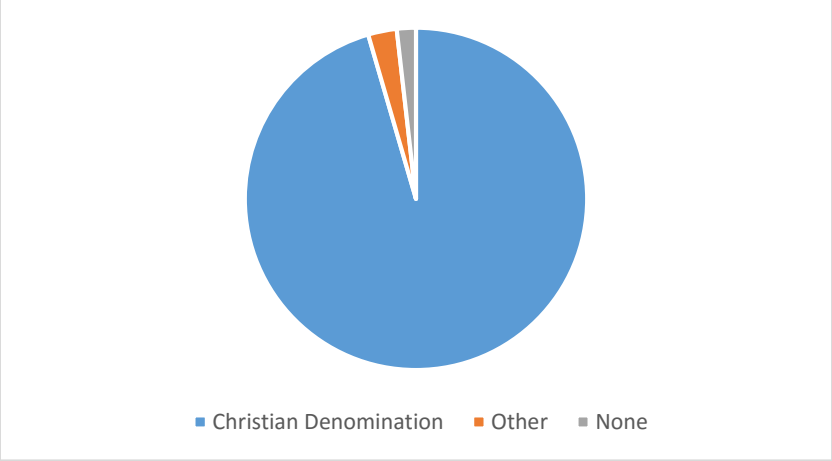
Pregnant women and HIV-positive individuals are considered a vulnerable population by WHO (World Health Organisation, 2015). The 2013-14 Demographic and Health Survey (DHS) reported that 15% of women as compared to 11% of men were infected with HIV. Zambia is also one of the top 25 countries with the greatest estimated number of pregnant women in need of ART (UNICEF, n.d.). Women are more vulnerable to the HIV virus for a number of reasons. Historically, Zambian women are not supported or encouraged when it comes to advocating for their own sexual rights.

They are, in fact, taught not to refuse sex or insist on condom usage from their male partners under any circumstances. This leads to a common occurrence of multiple sexual partners among men, leaving women with an increased vulnerability to contracting HIV even if they remain faithful to their male partners (Milimo et. al., 2005). In additional to cultural and gender norms, women are also physiologically more susceptible to contracting HIV. Biologically, women have a greater mucosal surface area for exposure to HIV pathogens as opposed to men, and are also more likely to experience tissue injury during intercourse. The latter is even more common in Zambian culture where dry sex is a common cultural practice (Ramjee & Daniels, 2013; Mbikusita-Lewanika, et al., 2009). These biological factors increase the risk of infection with every sexual encounter for women (Ramjee & Daniels, 2013; UNAIDS, 2009).

Religion in Zambia

In 1991, the now-deceased President Frederick Chiluba declared Zambia as a "Christian Nation," and in 1996, the declaration was added to the country's constitution (The Republic of Zambia, 1996). Christianity plays a pivotal role in Zambian culture. The CIA reports that 95.5% of the population identify with some form of Christianity (CIA, 2015). Figure 1.2 outlines the religious representation within Zambia.

Figure 1.2: Religious Representation in Zambia



Source: Data from the CIA, 2015

There is no separation between church and state within Zambia; in fact, the government has incorporated theology as part of the public school curriculum and it is required through grade 7 (U.S. Department of State, 2007). Quite often, prayer is used to open official government meetings and events. Preachers can be seen orating in public places such as in the market or on public transportation. There are even specific greetings in local languages for a person who has just come from or is going to church. The church has a powerful presence in Zambia; people believe deeply in the religious ideals that surround Christianity and look to religious leaders for guidance. As such, these leaders hold within them the power to influence individual behavior and establish or re-enforce societal norms.

In 2010, Gaydos et. al. carried out a survey of the existing literature as it pertains to religion and reproductive health. Through this research of 377 peer-reviewed articles, it was discovered that only 52 articles were published regarding the African continent

(Gaydos et. al., 2010). As such, there is a great deal of room for research in efforts to provide a deeper understanding of the link between religion and reproductive health. The intertwining factors between women and religion in Zambia set the stage to provide some further insight into this new field. As there is still relatively little research into the influence of religion, specifically concerning HIV-positive pregnant women in Zambia as it relates to adherence to HAART, this thesis grant proposal seeks to outline a small contribution into this newly developing, and exceptionally valuable, field of study.

Chapter I: Part B

Introduction

Chapter 1, Part A outlined the public health problem as summarized by the following highlights:

- The vast majority of Zambians identify with some form of Christianity
- Some HIV-positive individuals in Zambia are choosing to abandon their ART as a way of proving their devotion to God in efforts to utilize faith and religion as a means of reversing their HIV status.
- Women are considerably more vulnerable to HIV as compared to men in Zambia as a result of biological, cultural and gender norms.
- There is little research to date in the field of religion and reproductive health.
- There is a need for additional research to better understand the correlation between religion and the desire to abstain from HAART in HIV-positive pregnant women in Zambia.

This section of chapter 1 presents a grant proposal (Chapter V) outlining a two-phased grant application. The first phase will be a mixed-method investigation of both HIV-positive pregnant women and the local Christian leaders in Lusaka, Zambia. The research will help identify the factors that may impact HAART adherence among this population.

The second phase of the proposal uses information gathered through key informant interviews and surveys from Phase I. This information will aid in the creation a

new initiative in partnership with Christian Leaders, the Zambian Ministry of Health (MoH) and Churches Health Association Zambia (CHAZ) through a community based program designed to Link Individual Faith Together with HAART (LIFT My HAART). The purpose of this initiative would be to influence how HIV-positive pregnant women are counseled by those they look to for spiritual guidance. The goal would be an increase in treatment adherence for HIV-positive pregnant women who identify with the Christian faith.

Target Audience

The target audience of Phase I will consist of two populations; HIV-positive pregnant women who identify themselves as having a strong faith (specific demographic variables will be discussed later on) and Christian leaders who actively engage in counseling HIV-positive pregnant women through his/her ministry.

Phase II will utilize a target audience consisting of Christian leaders as key partners as well as CHAZ and MoH. The secondary target audience will be HIV-positive pregnant women and their families.

The Research Question and Hypotheses

The research question identified for this grant proposal is: Does religious culture predict whether an HIV-positive pregnant woman will adhere to HAART in Lusaka, Zambia? The following hypotheses will be addressed:

H1: Problematic expressions of the Christian faith present in Zambia encourages HIV-positive pregnant women to become non-compliant with HAART.

H2: Many Christian leaders are urging HIV-positive pregnant women to rely on faith healing rather than scientifically proven medications.

H3: The understanding of the importance of HAART and the role it plays in PMTCT are overshadowed by some Christian beliefs and the idea that God will heal.

H4: Partnerships with Christian leaders and faith-based organizations (FBOs) that encourage adherence to HAART within a religious framework are key to encouraging HAART adherence, thereby reducing the prevalence of health issues related to non-compliance among pregnant women in Zambia.

Actions Prior to the Start of the Grant Activities

Prior to Phase I of this study, an existing partnership with CHAZ, the country's largest indigenous FBO will be re-established. A Memorandum of Understanding (MoU) will be signed making CHAZ an official partner in this research grant. CHAZ was formed in 1970 under the auspices of both Catholic and Protestant Church institutions and represents 16 different Catholic and Protestant denominations (CHAZ, 2013). This alliance is crucial to the success of the study as CHAZ is already a trusted and known

member of the community. As a partner, CHAZ will also play a key role throughout the research and subsequent trainings.

This research team will also hold community based informational meetings with Christian leaders, in partnership with CHAZ and MoH, to explain what the upcoming research is about and answer any questions that may come up. These communities based meetings are key to building rapport with Christian leaders and necessary for paving the way for Phase I of research.

Phase I

This phase incorporates a mixed method research study designed to gather data leading to a deeper understanding of the impact that religion and faith have on an HIV-positive pregnant woman's decision to adhere to HAART. Over an 11-month period, key informant interviews and surveys with Christian leaders and HIV-positive pregnant women will take place.

Since the number of HIV-positive pregnant women in Lusaka Province is unknown, the sample size will come from a comparison of the number of HIV-positive women in Lusaka Province and the number of pregnant women in the province. The Zambia DHS 2013-14 reported that 19.4% of women are HIV-positive in Lusaka Province with about 9.87% of the population identifying as pregnant women (Zambia Central Statistics Office & Zambia Ministry of Health et. al., 2014). Using an incidence rate of 1.93, the sample size would be 530 HIV-positive pregnant women. However, a sample size of only 508 individuals will be utilized due to the religious breakdown within

the country, as explained below. The surveys will be divided among known Christian denominations in Zambia, as outlined in figure 1.3, the sampling grid.

Figure 1.3: Phase I Sampling Grid

	HIV-positive Pregnant Women <25	HIV-positive Pregnant Women 25+
Catholic	54	54
Protestant (includes multiple denominations)	200	200
Total	508	

The CIA reports additional religions in Zambia other than Catholic and Protestant. There are 2.7% of individuals within the country that identify as "other," including Muslim, Buddhist, Hindu and Baha'i. An additional 1.8% of the population identify as "none" with regard to religion (CIA, 2015). Those included in the "other" and "none" categories have been excluded from this sample, as the numbers are statistically insignificant to this particular study. Jehovah's Witnesses, though present in Zambia, are also excluded from the sample for the aforementioned reason.

Qualitative and Quantitative Research

Selection of Interviewing Facilities

CHAMP Zambia reports 348 health facilities (including government and private clinics, 1st, 2nd, and 3rd level hospitals and other health facilities managed by NGO's or religious organizations) (CHAMP Zambia, 2012). (CHAMP Zambia, 2012). In partnership with CHAZ and the Zambian MoH, ten government-run health facilities (excluding all hospitals and NGO managed facilities) will be selected as locations to

recruit individuals who are willing to participate in the study. Clinics will be identified based upon the number of people served and the presence of operational ante-natal and HAART clinics. Of the clinics who meet both criteria, the ones serving the largest populations will be selected. Given that 95.5% of Zambians identify as Christian (CIA, 2015), utilizing the religious affiliation of a clinic site as a criterion to selection is unnecessary. Access to the facilities will be supported and granted by MoH. CHAZ will help to identify Christian leaders within the community to participate in the interviews and surveys.

Key Informant Interviews and Surveys

It is customary in Zambia to make "formal greetings" when carrying out any visits to government-run medical facilities. This is an imperative avenue of cultural respect that must be followed before beginning the study. This includes first and foremost, a visit with the MoH to announce the research team and the reason for entering the health facilities. Upon arrival at the health facility, a visit must be paid to the "in charge," the person responsible for running the clinic. The purpose of this visit is to introduce the research team, but also to seek collaboration in identifying potential women to participate in the key informant interviews.

Selection of Survey Participants

Participants for interviews and surveys will be recruited from the PMTCT Antenatal Clinic (ANC), which is open one day per week at each of the selected clinics. A total of 50 participants will be identified from each of the ten health facilities with the two facilities servicing the largest population interviewing 54 individuals each. In order

to ensure a random selection process, every fifth patient who enters the PMTCT-ANC clinic will be asked to participate in the interview and survey, unless they have been excluded from the participant pool. Once identified, participants will be interviewed in a confidential setting within the clinic while awaiting their PMTCT-ANC services. Each participant will be fully informed about the purpose of the study and what her participation entails. Women who are unable to read will have the form read out loud to them. In these cases, a signature will still be required on the informed consent form once the participant feels comfortable enough in her understanding of the form to sign. All women who choose not to participate in the study, or who are found to be ineligible, will be made fully aware that their decision to decline or inability to participate in an interview will not affect their access to treatment through the clinic. Informed consent and interviews will be provided in English, and two different local languages, Nyanja and Bemba. These particular languages have been selected as English is the official language of Zambia, and Bemba and Nyanja are the two most common Bantu languages spoken within the country. The CIA World Factbook estimates that 33.4% speak Bemba and 14.7% speak Nyanja (CIA, 2015).

Interviews and surveys will also be given to 100 selected Christian leaders within Lusaka. As CHAZ is already established within the community, the organization will help to identify Christian leaders. In order to qualify as a participant in the study, each leader must actively engage in counseling HIV-positive pregnant women through his/her ministry. Team members will also be looking to identify Christian leaders who are open and willing to join the team as a facilitators during Phase II.

Multi-lingual Zambian nationals employed through CHAZ will administer the interviews and surveys in Nyanja and Bemba when needed; otherwise, this research team will conduct them in English. All CHAZ employees who will be conducting interviews and surveys will be trained by a member of this research team. In the event that a CHAZ employee will be conducting the interview and survey, a member of this research team who possesses a conversational level of Bemba and Nyanja will also be present. A payment of a 5kg bag of mealie meal will be given to each interview participant to acknowledge the time and effort they have given to the study.

Survey and Interview Constructs

The surveys are intended to quantify the factors that may impact HAART adherence. Although religious factors are the focus of this thesis proposal, other influences must be taken into consideration in order to create the most effective training materials for Phase II. Those who have been selected to participate in the interview will also be given a survey.

Survey Constructs

Participant	Research Category	Type of Information Gathered Through Questions
HIV-positive pregnant women	Demographics	Age, primary language, home clinic, household composition, marital status, serodiscordant/seroconcordant status, spouse taking ARVs, Christian denomination, educational attainment, reproductive history, number of times per week attending church,
Religious leaders	Demographics	Age, primary language, duration of religious leadership,

		church affiliation, educational attainment
HIV-positive pregnant women	Treatment and HIV-related variables	When HIV status became known, when HAART started
HIV-positive pregnant women	Religious support	Support seeking behavior from Christian leaders
Religious leaders	Counseling behavior	Number of times in the past 30 days religious counseling was provided in general and specifically to HIV-positive pregnant women
HIV-positive pregnant women	HAART Adherence	Frequency of HAART adherence in past 7 days
HIV-positive pregnant women	Beliefs about HAART Adherence	Do you believe that you: should stop taking HAART when you feel better, only take it when you are feeling sick, take them at the same time every day
HIV-positive pregnant women	Religious Activity	Times per week attending church
HIV-positive pregnant women & Religious leaders	Religious beliefs pertaining to HIV	Do you believe that HIV is a punishment from God? Do you believe that God will heal HIV?
HIV-positive pregnant women	Religious beliefs pertaining to HIV	Are you worried that the church will shun you if you do not stop taking HAART?
HIV-positive pregnant women & Religious leaders	Importance of HAART	Do you believe that HAART is an important factor in controlling HIV?
HIV-positive pregnant	Religious influence on HAART	Has anyone ever told you that you must choose between your faith and HAART?

women		
Religious leaders	Religious perspective on HAART	Do you ever counsel HIV-positive pregnant women to stop HAART?

Interview Constructs

Participant	Research Category	Type of Information Gathered Through Questions
HIV-positive pregnant women	Reasons for church selection	Determinants of church selection
HIV-positive pregnant women Christian leaders	Religious healing	God's healing powers both specific to HIV and across other ailments as well
HIV-positive pregnant women Christian leaders	Medications and HAART	Views on medications in general and specifically HAART
HIV-positive pregnant women Christian leaders	Non-compliance	Reasons for HAART non-compliance
HIV-positive pregnant women Christian leaders	HIV knowledge	Can you describe what HIV is?
HIV-positive pregnant women Christian leaders	MTCT knowledge	Can you describe what MTCT is?
HIV-	HAART knowledge	Can you describe what HAART is?

positive pregnant women Christian leaders		
HIV-positive pregnant women	Religious impact on daily life	How does God influence your daily life?
HIV-positive pregnant women	Religious impact on HAART	Support received from church, involvement in church since status became known
Christian leaders	Religious perspective on HAART	Describe the type of advice/counseling you provide to HIV-positive pregnant women

Reasons for Exclusion from the Interview and Survey Pool

Participants may be excluded from the interview and survey pool for the following reasons:

HIV-positive pregnant women

- A woman is not HIV-positive or pregnant
- She does not identify as either Catholic, Protestant or an affiliated denomination such as Methodist, Baptist, 7th Day Adventist, Pentecostal, United Church of Zambia (UCZ) or Anglican will not be considered for the interview. These exclusions include those who identify as Muslim, Hindu, Jehovah's Witness or indigenous beliefs only.
- She does not speak English, Bemba or Nyanja. Though English is the official language of Zambia, there are more than 70 different languages spoken within the country (CIA, 2014). Within Lusaka, English, Nyanja

and Bemba are the most commonly spoken languages. However, it is not uncommon to find someone who is unable to speak any of the aforementioned three languages. Informed consent, interviews and surveys will be provided only in English, Nyanja and Bemba.

Christian Leaders

- Does not identify as Catholic, Protestant or an affiliated denomination such as Methodist, Baptist, 7th Day Adventist, Pentecostal, United Church of Zambia (UCZ) or Anglican
- Do not actively participate in counseling HIV-positive pregnant women through their ministry
- Does not speak English, Bemba or Nyanja as outlined above

Data Collection Activities

Data collection activities will take place during the first year of the proposal. These activities will pave the way for Phase II, the implementation of LIFT My HAART. Program activities are outlined in figure 1.4 below.

Figure 1.4: LIFT My HAART Program Activities

Months	Participants	Activity
1	***LIFT My HAART team, CHAZ*, clinic sites**	**Introduction to MoH, MoU with CHAZ, Identification and introduction to clinic sites, community based informational meetings with Christian leaders**
2-12	**HIV-positive pregnant women (n = 508) and religious leaders (n = 100) at ten identified clinics or within the community**	**Key informant interviews and surveys, data analysis. Continuation of community based informational meetings**
9-12	***LIFT My HAART team*, CHAZ**	**Data analysis and creation of training curriculum/materials**

Analysis of Qualitative Data

The data gathered from each of the interviews will be transcribed verbatim and translated into English when necessary. The transcribed narrative data will be coded and analyzed using MAXQDA software.

Analysis of Quantitative Data

Quantitative data will be analyzed using SPSS. The data collected will provide important statistical information about demographic and socioeconomic characteristics of the interview participants. It will also provide valuable information about adherence behavior, distinct views on religion, medication and other factors that may influence HAART adherence. Data will be used to create training materials that specifically address the target audience. It will also provide a quantifiable aspect to the qualitative data gathered during the key informant interviews.

Data Usage

The data gathered during Phase I will be utilized to inform the programming for Phase II. After analyzing both the qualitative and quantitative data, a training curriculum will be created based upon the results of the gathered data. The partnership with CHAZ will continue, but the focus will switch from a research partnership to a programmatic collaboration. A time period of 3 months will be allotted at the end of Phase I to create the training materials and prepare for the commencement of Phase II.

Phase II – Program Implementation of LIFT My HAART

LIFT My HAART Program Outline

LIFT My HAART is a collaboration between this research team, CHAZ and the Zambian MoH. As a means of improving adherence among HIV-positive pregnant women, the goal of the program is behavior change as it pertains to Christianity and the effect it has on an HIV-positive pregnant woman's decision to adhere to her HAART. It is a training program designed to help Christian leaders in Lusaka understand the connections between faith and HAART. The trainings will enhance Christian counseling to HIV-positive pregnant women by helping them to understand HAART as an expression of faith. Training materials will be created utilizing data from Phase I interviews with HIV-positive pregnant women and Christian leaders. This will ensure that training messages are delivered in a respectful and non-threatening way. Interactive workshops will be carried out for 100 identified Christian leaders.

The trainings will be based upon the social-ecological model (see figure 1.5 below) utilizing the theory that taking action across each of the five levels, will better help to prevent this developing trend. The model uses five nested hierarchical levels individual, interpersonal, community, organizational and policy. Each one providing the framework for a better understanding of the multifaceted and interactive effects of personal and environmental factors that determine behavior. Incorporating this approach into the trainings will provide a multi-level approach to the long-term adherence of HAART by HIV-positive pregnant women. This will save lives as well as help Zambia to reach its goal of EMTCT.

The trainings will be facilitated by LIFT My HAART team members, CHAZ employees and Christian leaders. They will take place at ten various locations within Lusaka. The locations will be determined in collaboration with this research team, CHAZ and MoH. Each training will consist of only ten participants. The smaller group size will allow for a more personal and individualized training style. It will also encourage greater group participation. The materials created will be based upon the data gathered during Phase I. Though the exact content will not be known until the research is completed, but constructs of the training will provide basic counseling skills and ways to engage HIV-positive pregnant women in a way that allows her to incorporate HAART as an expression of faith. In addition to the research based materials, each training will offer sessions on general HIV, HAART and MTCT education. The trainings will be divided into two separate training periods with a break in between. The first training will take place over five days, while the second will last for three days. The divided training schedule provides each participant time to return to his/her community for an opportunity to apply the new information learned through the initial training. After a period of two weeks, the participants will return for the second portion of the training fueled with practical experience to share with their peers. The sessions during this time will build upon the skills practiced during the break. It will include experiences of counseling sessions, barriers experienced and lessons learned.

Figure 1.5: Social-Ecological Model

Recruitment of LIFT My HAART Program Participants

Participants of the Lift My HAART program will be identified in three different ways and invited to participate in the program:

1. Christian leaders who express interest in understanding more about religion and HAART during their interviews and community meetings
2. Utilizing CHAZ's knowledge of local Christian leaders who are identified as promising participants
3. Christian leaders who are expressing an interest in participating in the program

During Phase I, researchers will also be looking to identify Christian leaders, through community based informational meetings and during the interviews and surveys, who are interested in the idea of being a part of this initiative and willing to join the team as facilitators to their peers during Phase II. Those considered for peer facilitator positions must not be actively speaking out against HAART adherence unless they indicate that they no longer wish to do so. Increasing the number of Christian leaders who are provided with IEC and counseling skills to help HIV-positive pregnant women utilize HAART as an expression of faith, increases the number of women exposed to the message.

LIFT My HAART Program Activities

LIFT My HAART program activities will start during year 2 of the proposal and can be seen below in figure 1.6.

Figure 1.6: LIFT My HAART Program Activities

Months	Participants	Activity
11-12	**LIFT My HAART team CHAZ, MoH**	**Identification and preparation of training sites**
13-22	**LIFT My HAART team CHAZ, MoH, participants**	**LIFT My HAART Trainings**
22-24	**LIFT My HAART team CHAZ, MoH**	**Preparation of final reports Dissemination of information**

LIFT My HAART Follow-up

Initial follow-up of the Christian leaders is incorporated into the divided training schedule. After a two-week field experience, participants will return for additional training. As this proposal only covers a two-year period of time, CHAZ has agreed to continue on with the follow-up of the Christian leaders through their organization once the funding period for this grant is completed.

Dissemination Plan

During the last three months of the funding period, the results of the key informant interviews, surveys and trainings will be submitted via report to the Zambian MoH. These reports will explain in detail the outcomes of the research and subsequent trainings, barriers encountered as well as suggestions for a way forward. As MoH is a partner LIFT My HAART they will have firsthand knowledge of the two years spent researching and training. The MoH has acknowledged the need for this type of research and initiative and is committed to continuing the trainings of Christian leaders under its own funding.

Potential Barriers

LIFT My HAART is a program that identifies and addresses the very personal issue of faith and reproductive health through Information, Education and Communication (IEC) of Christian leaders within the community. The delicacy of this program cannot be expressed enough, and barriers to participation are expected, especially since LIFT My HAART is the first of this kind of program for Christian leaders. Collaboration with CHAZ is paramount at this intersection. CHAZ is a well-known and respected Christian affiliated NGO that also provides 30% of the national health care within Zambia (CHAZ, 2013). This puts CHAZ in an incredibly unique position as rapport has already been established with the community and with Christian leaders. Additionally, efforts will be made during phase I to identify religious leaders who are interested in joining the LIFT My HAART team as facilitators during the trainings. This will allow for an element of personal understanding of religious leaders as

participants in the trainings. The religious leaders identified to become part of the LIFT My HAART team will also be able to lead by example when it comes to their colleagues.

Another potential barrier deals with the aspect of behavior change. As previously mentioned research has pointed out, some Christian leaders believe HIV to be a punishment from God. For those who believe this, changing the presence of internal prejudice will be difficult. The LIFT My HAART initiative seeks Christian leaders as participants who are not actively speaking out against HAART adherence, but who are also not wholeheartedly supporting it. Targeting this particular population will avoid the offensive practice of telling a person his/her personal beliefs are wrong. At the same time, it will increase the number of Christian leaders within the community who are exposed to, and educated about HIV and HAART adherence. This will allow for a greater number of Christian leaders to come to their own, educated, conclusions on the subject. Those who chose to support HAART adherence as an expression of faith will then be able to convey that opinion to the HIV-positive pregnant women whom they counsel. The Zambian MoH and CHAZ have also identified a need for this type of research and subsequent programming. Both have committed to continuing on with the LIFT My HAART initiative and carry out additional trainings and follow-up in the years to come.

Risks

Given the delicate nature of this proposal there are some risks that need to be taken into consideration. There is a possibility that women may feel as if they are being urged to choose between their faith and HAART. There is also the risk that, even if Christian leaders choose to support HAART there will be a lack of support (outside of the church) for HIV-positive pregnant women. While there is no way to ensure that these

risks will not be present, there are measures that can be taken to minimize the risks at hand. Circles of Hope is a support circle for HIV+ individuals in Zambia. This local NGO works through churches to speak out against stigma through personal testimonies. They also provide in-home support for individuals living with HIV/AIDS. Each woman who is identified, or declined, as a possible study participant will be provided with a referral to Circles of Hope. This will be done in the hopes of mitigating any feelings of pressure to choose between faith and HAART. It will also provide an available support structure outside of the church. Additionally, since Circles of Hope works in partnership with the church, members from this NGO will be invited to facilitate a session during the trainings with Christian leaders. These sessions will provide information about Circles of Hope as a community based support structure as well as providing another link between Church and community.

Chapter 1 Part B Summary

The purpose of the Lift My HAART program is to establish a partnership with Christian leaders within Lusaka to help them understand the relationship between religion and HAART. This is done through trainings designed to encourage behavior change concerning the way religious counseling is carried out for HIV-positive pregnant women. The hope is that the new counseling will help HIV-positive pregnant women find a balance between their religious beliefs and HAART, as opposed to feeling like they must choose between the two. There is little research completed supporting this type of project, but the evidence that is available will be outlined in Chapter II: Literature Review.

Definition of Terms

Antenatal Clinic (ANC): A clinic held on pre-determined days of the week specifically for the care of pregnant women.

Antiretroviral Therapy (ART): Using a combination of different antiretroviral drugs to suppress the HIV virus and slow the rate at which HIV replicates itself within the human body.

Antiretroviral Drugs (ARVs): The type of drugs used to suppress the HIV virus and slow the rate at which HIV replicates itself within the human body.

CD4+ Count: A lab test that measures the number of CD4 T lymphocytes (CD4 cells) in a sample of blood.

Churches Health Association of Zambia (CHAZ): Zambia's largest non-government health provider with 151-member health institutions. CHAZ member health institutions account for 50% of formal healthcare in the rural areas and 35% of the national health care system. Also a partner with the MoH.

Demographic and Health Survey (DHS): A project implemented by ICF International and funded by USAID created to gather and disseminate health and population data in developing countries.

Elimination of Mother-to-Child Transmission of HIV: Ending the transmission of HIV from an HIV-positive mother to her child.

Faith Based Organization (FBO): A religious or other charitable entity affiliated with one or more religious organizations.

Highly Active Antiretroviral Therapy (HAART): Using a combination of at least three different antiretroviral drugs used to slow the rate at which HIV replicates itself within the human body.

Memorandum of Understanding (MoU): A formal agreement between two parties establishing an official partnership.

Ministry of Health (MoH): A branch of government that maintains the central responsibility for medical and preventative care services in Zambia. Also engages in a partnership with CHAZ.

Mother-to-Child Transmission of HIV (MTCT): An HIV-positive mother passing HIV to her child during pregnancy, labor, delivery or through breastmilk.

National AIDS Strategic Framework (NASF): The third in a series of national strategic frameworks in Zambia produced by the National HIV/AIDS/STI/TB Council.

Non-Government Organization (NGO): An organization that does not affiliate itself with any part of the local government or a for-profit business. NGOs can be funded by other governments, foundations, businesses or private entities.

Option B+: WHO guidelines for the treatment and care of HIV-positive pregnant women.

People Living with HIV/AIDS (PLWHA): A term used for a person living with HIV/AIDS.

Prevention of Mother-to-Child Transmission of HIV (PMTCT): Stopping the transmission of HIV from an HIV-positive woman to her child both ante- and postnatally.

Prophet: A person who claims to be a mouthpiece for God.

The World Health Organisation (WHO): An agency of the United Nations that was established in 1948 and charged with improving the health of people around the world through the direction and coordination of health within the United Nations' health system. Programs and technical support are provided in communicable and non-communicable disease, strengthening health care systems, preparedness, surveillance and response, and promoting overall health throughout the life cycle. The WHO main headquarters are located in Geneva, Switzerland.

Vertical Transmission: The HIV pathogen can be transmitted across the placenta, through breast milk, during or after birth. Another name for Mother-to-Child Transmission.

Zambia National Broadcasting Corporation (ZNBC): Zambia's local news and television station.

Chapter II: Review of Literature

Introduction

There is very little research done to examine the intersection between religion and HIV in Africa (Takyi, 2003), and even less exploration into the influence of religion and the role it plays in predicting whether or not HIV positive pregnant women will adhere to their HAART within Zambia specifically. As such, this chapter will review the existing literature on religion and reproductive health in general. This review of literature will also identify any gaps within the research in efforts to substantiate the need for further exploration into the link between religion and HAART adherence within Zambia.

Review of Literature

Religion and Health Related Behaviors

Despite the presence of literature regarding religion and medicine, there is relatively little research pertaining specifically to religion and reproductive health (Lentz & Majumdar, 2014; Gaydos et al., 2010; Gyimah et al., 2006) or religion and HIV (Kastner et al., 2014; Seeling et al., 2014; Adogame, 2007; Pargament et al., 2004; Takyi, 2003; Garner, 2000). Upon broadening the scope of study, a recurring theme across the literature does suggest that there is a link between religion and health behaviors (Takyi, 2003; Garner, 2000; Lagarde et al., 2000). The concept of religion is a powerful force within some individuals. It can drive a person's decision making as it pertains to their own health and the path they choose to travel concerning their own treatment and care

(Endeshaw et al., 2015; Gaydos et al., 2010; Park & Nachman, 2010; Lagarde et al., 2000).

Multiple studies refer to individuals with chronic illness resorting to religion as a coping method (Steglitz et al., 2012; Caixeta et al., 2012; Manglos & Trinitapoli, 2011; Gaydos et al., 2010; Park & Nachman, 2010). For some people, turning to religion can be a source of comfort and support when faced with disease or infection (Fradelos et al., 2015; Coats et al., 2015; Steglitz et al., 2012; Pargament et al., 2004). On the other hand, turning to religion can sometimes cause an interpersonal conflict (Pargament et al., 2004). Keonig et al. identify four major categories that outline the impact of religion on healthcare: "medical decision-making, beliefs that conflict with medical care, spiritual struggles that create stress and impair major health outcomes and disease detection and treatment compliance" (Koenig, 2004).

As Takyi's 2003 research points out, religion can be identified as a potential barrier for the utilization of health services (Takyi, 2003). Other researchers have pointed out that this can include aspects of maternal and child health care, including decisions to use various forms of contraception (Adogame, 2007) or other health related medications such as the use of antiretroviral therapy (ART) (Endeshaw et al., 2015; Park & Nachman, 2010; Koenig, 2004).

Healing Churches

Christian communities define healing in a variety of ways. For some of these communities, healing is understood as the reversal of symptoms of HIV or AIDS illness, as well as the possibility of a cure (Togarasei, 2010). As such, churches that define

healing this way may be attractive for people in search of some form of alleviation from physical ailment (Pfeiffer, 2002a) in part because they connect extraordinary healing to the work of the Holy Spirit (Agadjanian, 2005) or to salvation of one's soul (Takyi, 2003).

Multiple studies specifically discuss Pentecostalism, and the impact this particular Christian tradition has on health behaviors (Seeling et al., 2014; Horn, 2012; Togarasei, 2010; Garner, 2000), with many outlining a burgeoning trend in the encouragement of HIV positive individuals to abandon their ART as a means of securing a cure through the church (Endeshaw et al., 2015; Tofa, 2014; Seeling et al., 2014; Musheke, Bond, & Merten, 2013; Horn, 2012; Manglos & Trinitapoli, 2011; Togarasei, 2010). Endeshaw's 2015 research reports that some "priests call the virus 'a punishment from God'" or that "holy water can cure HIV and should be taken instead of medication" (Endeshaw et al., 2015). Others believe that the presence of antiretroviral (ARV) drugs encourages individuals to be sexually promiscuous or irresponsible by promoting the idea of the using medication to "save them if they contract HIV" (Togarasei, 2010).

Healing Churches, Women, HIV and ART

A common theme across the literature is a struggle with initiation, adherence and retention of ART by HIV positive individuals, despite an increasing availability of ARV drugs. Within the same literature, abandonment of ART for faith healing is another recurring theme (Hodgson et al., 2014; Tofa, 2014; Musheke et al., 2013, 2012; Maman et al., 2009; Rosen et al., 2007; Wanyama et al., 2007). This includes the power of prayer

and its ability to heal oneself of HIV (Musheke et al., 2015, 2013; Think Africa Press, 2013; Roura et al., 2010; Wanyama et al., 2007).

In Sub-Saharan Africa, where women are disproportionately affected by HIV and AIDS (UN Women, 2015), the idea of a cure for health related issues through prayer linked with a healing church is appealing to many women (Pfeiffer, 2002b). Agadjanian notes that healing churches attract mostly poor and disadvantaged individuals, namely women (Agadjanian, 2005). The appeal of healing churches makes women especially vulnerable to making the decision to rely solely on faith as opposed to intertwining their personal religion beliefs with the use of ART.

Summary of Current Problem and Study Relevance

The literature suggests that there is pressure in some Christian communities for both men and women to stop ART for the hope that God will heal them through prayer. Further, women may be more drawn to churches that teach this belief, contributing to their decision to stop ART. For a pregnant woman the decision to substitute prayer for ART could impact the life of her unborn child through mother-to-child transmission of HIV. The latter occurs during pregnancy, labor, delivery or breast feeding from an HIV-positive mother to her baby. Without intervention, mother-to-child transmission rates can range between 15% - 45%. When an HIV-positive pregnant woman adheres to her HAART, the risk to her child of vertical transmission can be reduced below 5% (WHO, 2015). There is little research on HIV-positive pregnant women and the role that religion plays in their adherence to highly active antiretroviral therapy (HAART). Religious

leaders and HIV positive pregnant women should be a key focus in this area of research. A two pronged approach could further the nascent research on this topic and develop models for community programs to address this public health issue. The first component would increase understanding from HIV positive pregnant women about the influence of religious beliefs on their decisions to maintain their HAART regimen. The second component would sensitize religious leaders to encourage ART as an expression of women's own faith.

Types of Funding Agencies

The fight against HIV and AIDS has expanded across the globe with multiple countries contributing resources. The top five contributing countries are the United States, followed by the United Kingdom, France, Germany and the Netherlands (Avert, 2015).

In the U.S., The President's Emergency Plan for AIDS Relief (PEPFAR) is the largest commitment from any nation to combat a single disease internationally (U.S. Department of State, n.d.-a). PEPFAR programs have a special focus on improving health outcomes for women and children by utilizing existing structures and supporting countries through capacity building and the initiation of sustainable programs (U.S. Department of State, n.d.-a). Priority is given to the initiation and development of new partners, which includes FBO's throughout the world. PEPFAR falls under the leadership of the Office of the US Global AIDS Coordinator and Health Diplomacy with some of the primary implementing agencies being the Department of State (DoS), the U.S.

Agency for International Development (USAID), Department of Health and Human Services (HHS) and Peace Corps (U.S. Department of State, n.d.-b).

Within the private sector, the Bill and Melinda Gates Foundation is the largest funder of international HIV efforts (Avert, 2015). While the foundation's largest efforts are focused on discovering and developing an HIV vaccine, it supports efforts to protect at risk populations from HIV infection (Bill & Melinda Gates Foundation, 2015).

There are also multilateral donors such as UNAIDS, the World Health Organisation (WHO) and the Global Fund. Each of these organizations provides funding support to international HIV efforts based upon funding from partner countries. Once the money is given to the multilateral agency, the decision on how to spend funds is no longer up to the donor country unless it has been earmarked for a specific purpose, such as HIV and AIDS initiatives.

Although there are a number of key donors supporting HIV and AIDS efforts across the globe, The Bill & Melinda Gates Foundation notes that international funding for HIV has declined in recent years, making it important for these bilateral and multilateral donors to achieve the largest impact possible (Bill & Melinda Gates Foundation, 2015). Within the HIV funding arena, there have been few efforts to understand the intersection between religion and HIV and AIDS (Horn, 2012) or the perceptions of ART articulated by faith leaders (Roura et al., 2010).

Chapter III: Methodology

Grant Announcement

Under the umbrella of the Department of Health and Human Services (HHS), the National Institutes of Health (NIH) in partnership with the National Institute of Mental health (NIMH) and the National Institute of Allergy and Infectious Diseases (NIAID) issued a funding opportunity for "Strengthening Adherence to Antiretroviral-Based HIV Treatment and Prevention" under an R21 mechanism. The purpose of the Funding Opportunity Announcement (FOA) was to encourage research to better understand and foster adherence to ARVs (Department of Health and Human Services, 2014). The emphases of the FOA consisted of studies regarding Pre-Exposure Prophylaxis (PrEP) and ART with the latter being the focus area for the grant outlined in this thesis. Emphasis was placed on the development of achievable interventions that would improve and sustain PrEP or ART adherence. Furthermore, the interventions identified and created should be able to be quickly implemented in clinical, community and policy environments to improve HIV treatment and prevention outcomes (Department of Health and Human Services, 2014).

Proposal Review Criteria

The Strengthening Adherence to Antiretroviral-Based HIV Treatment and Prevention FOA outlined five key criteria that would be taken into consideration during the review process. They are significance, investigator(s), innovation, approach and

environment. For the purposes of this thesis, the significance, innovation and approach sections will be addressed.

Significance

The criteria under the significance section are outlined in the FOA as follows:

- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Zambia is closer than ever to eliminating Mother-to-Child transmission (MTCT) of HIV. This is evidenced by a decrease in vertical transmission of HIV from 24% to 12% between 2011 and 2013 (National AIDS Council, 2014). As previously outlined in Chapter 2, a review of literature, it is suggested that there is growing pressure within some Christian communities for both men and women to stop treatment with the expectation that God will heal them through prayer (Endeshaw et al., 2015; Tofa, 2014; Seeling et al., 2014; Musheke, Bond, & Merten, 2013; Horn, 2012; Manglos & Trinitapoli, 2011; Togarasei, 2010). Studies have also shown that women maybe more drawn to healing churches (Agadjanian, 2005). Already a vulnerable population, this attraction by women, to healing churches poses a barrier to continued progress within the

field of HAART adherence, and thus, the Elimination of Mother-to-Child Transmission (EMTCT).

As a way of better understanding the role that Christian religion plays in HIV-positive women's decision-making to adhere HAART, and to ensure improved adherence and reduced mother-to-child transmission LIFT My HAART has been created. This initiative will be carried out in collaboration with Churches Health Association Zambia (CHAZ), local Christian leaders and the Zambia Ministry of Health (MoH). The goals of the proposal are to improve adherence among HIV-positive pregnant women through faith based health promotion activities and to strengthen counseling skills among religious leaders who routinely counsel HIV-positive women in the course of their work. This will be achieved through a two-phased process targeting women and religious leaders.

The first phase will be a mixed-method investigation of both HIV-positive pregnant women and the local Christian leaders in Lusaka, Zambia. The research will help identify the factors that may impact HAART treatment adherence among this population.

The second phase of the proposal uses information gathered through key informant interviews and surveys from Phase I. This information will aid in the creation a brand new initiative in partnership with Christian Leaders, the MoH and CHAZ through a community based program designed to Link Individual Faith Together with HAART (LIFT My HAART). The purpose of this initiative would be to influence how HIV-positive pregnant women are counseled by those they look to for spiritual guidance. The

goal would be an increase in treatment adherence for HIV-positive pregnant women who identify with the Christian faith.

The proposal identified 2 specific aims to be achieved over the course of the proposal time period.

Specific Aim 1: To evaluate the relationship between HIV-positive pregnant women in Zambia and the role and influence that their Christian faith has on HAART adherence.

Key informant interviews and surveys will be carried out with 508 HIV-positive pregnant women as well as with 100 identified Christian leaders who actively engage in counseling HIV-positive pregnant women through ministry within Lusaka. These interviews will assess the viewpoints, perceptions and opinions about HAART and how adherence is affected by religion.

Specific Aim 2: To improve HAART adherence among HIV-positive pregnant women.

The proposal outlines the creation and implementation of trainings that are culturally appropriate to 100 Christian leaders within Lusaka, Zambia. These trainings will strengthen counseling skills among local religious leaders who routinely counsel HIV-positive women in the course of their work. Christian leaders who work at a community level and understand the benefits of HAART will then be able to encourage adherence within a religious framework. This will affect the long term adherence of HAART by HIV-positive pregnant women.

Innovation

The criteria under the innovation section are outlined in the FOA as follows:

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

The idea of community based programs is not new to the public health field. However, partnerships with Christian leaders have never been incorporated in community based programming. Although there are numerous NGOs and MoH programs currently running in Zambia concerning HIV and maternal and child health, there are none that focus solely on the training of religious leaders as a response to the increasing numbers of HIV-positive pregnant women choosing faith over HAART.

The Centre for Infectious Disease Research in Zambia (CIDRZ) has a large maternal and child health program operating in over 336 clinic sites in Lusaka, Eastern and Western Provinces, but many of their programs focus on prevention and treatment interventions. Additional programs that offer similar services include: Marie Stopes which is an organization that offers sexual and reproductive health to women in Zambia; Population Services International (more commonly known in Zambia as Society for Family Health); Project Concern International and The Programme for Appropriate

Technology in Health (PATH), which focuses on the unique HIV prevention needs of women, but does not concentrate specifically on religion and women. None of these programs have trained Christian leaders to respond to the increasing number of HIV-positive pregnant women who let faith influence their decision to adhere to HAART. While CHAZ focuses more on overall health, it is the largest NGO health provider in Zambia. It was founded by Catholic and Protestant Church health. There are currently 151 health facilities representing sixteen Catholic and Protestant denominations. These health care facilities provide 30% of the national health care in Zambia(CHAZ, 2013). The partnership with CHAZ, outlined in the proposal, will provide the needed link between religion and health care.

The proposed research has the potential to improve the treatment outcomes of HIV-positive pregnant women and prevent MTCT of HIV through a community based program. It will provide HAART education to community-based Christian leaders, offering them tools to counsel HIV-positive pregnant women on a way to identify a link between HAART and their own personal faith. This will also mitigate the poor health effects of stopping HAART and decrease the number of women who choose to do so based on religious pressures.

Approach

The criteria under the Approach section are outlined in the FOA as follows:

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish in the specific aims of the project?

- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

In order to improve adherence among HIV-positive pregnant women the proposal presents a two-phased initiative targeting HV-positive pregnant women and religious leaders.

- ***Phase I:*** A mixed methods research study to identify the role that Christian religion plays in an HIV-positive pregnant women's decision to choose her faith over HAART adherence.
- ***Phase II:*** Analysis of the collected data to inform the development and implementation of a training program for Christian leaders in Zambia. The goal of the training program is to reduce the number of HIV-positive pregnant women who abandon HAART as an expression of faith by providing IEC skills to Christian leaders.

The proposal is driven by the following hypothesis:

H1: Problematic expressions of the Christian faith present in Zambian encourages HIV-positive pregnant women to become non-compliant with HAART.

H2: Many Christian leaders are urging HIV-positive pregnant women to rely on faith healing rather than scientifically proven medications.

H3: The understanding of the importance of HAART and the role it plays in PMTCT are overshadowed by some Christian beliefs and the idea that "God will heal".

H4: Partnerships with Christian leaders and faith-based organizations (FBOs) that encourage adherence to HAART within a religious framework are key to encouraging HAART adherence, thereby reducing the prevalence of health issues related to non-compliance among pregnant women in Zambia.

As with any situation, the barriers to this proposal are present, but all are able to be overcome. The potential barriers and solutions have been identified at the following:

- Religious leaders may be hesitant to participate in the training program – this will be addressed through partnerships with the Zambian MoH and CHAZ. Both are present and trusted entities within the community. It is anticipated that their established relationships with Religious leaders will mitigate any feelings of hesitation to participate.
- Behavior Change – As previously mentioned, some Christian leaders believe HIV to be a punishment from God. For those who believe this, changing the presence of internal prejudice may be difficult. This will be addressed through the involvement of peer facilitators during the trainings. Peer facilitators are Christian leaders who are interested in playing a leadership role among their peers within this initiative. They will be able to best address their peers in a non-offensive way and also lead by example when it comes to their colleagues.

- Time limitations – LIFT My HAART focuses on behavior change, which takes time to implement. It is not possible to reach every Christian leader in Lusaka through this proposal within the time allotted. However, the proposal sets the stage for continued endeavors by carrying out the research needed to better understand the public health problem at hand. It also uses that research to create a training program designed to improve adherence among HIV-positive pregnant women by providing Information, Education and Communication (IEC) skills to Christian leaders. The Zambian MoH and CHAZ have also identified a need for this research and subsequent training program. As such, they have committed to continuing the trainings under their own funding once the proposal time line is exhausted.

The Grant Review Process

The review committee were provided the FOA (Appendix A), grant proposal (Chapter V of this thesis) and an external reviewer form (Appendix B) that was created by Emory University on May 16th via email. The expert reviewers were asked to review the FOA and grant proposal in its entirety and provide feedback. They were also asked to complete the external reviewer form. Each reviewer was provided with two calendar weeks to look over the proposal. The review team was informed that their comments would be seen only by the student, and not shared among others members of the review team. Communication between this student and the expert reviewers was electronic.

LIFT My HAART Grant Reviewers

LIFT My HAART was reviewed by five expert reviewers. Each reviewer was selected based upon their personal experience and expertise pertaining to grant writing, HIV/AIDS, MCH, PMTCT, project management and/or field experience specific to Zambia.

Johanna M. Hinman, MPH, MCHES

Johanna M. Hinman, MPH, MCHES is the Associate Director of Education for the Department of Surgery in the School of Medicine of Emory University. Johanna has 17 years of experience in public health education, health communication, program planning and project management. Johanna also teaches a grant writing class in the Executive MPH Program at RSPH.

Beth Anne Pratt, PhD

Beth has a PhD in Anthropology from Boston University. Her doctoral research focused on childhood and social, economic, and political change among Kisongo Maasai in northern Tanzania. Living and working for two years in a rural African community shaped her insight into the cultural, political, and economic factors influencing the provision and uptake of health technologies and services. Based in Africa since 1996 (Tanzania, Kenya, Uganda, Zambia, Egypt), she has since had wide-ranging, cross-sectoral experience working on livelihoods and health issues in numerous countries. In the health sector, Beth has focused primarily on issues of access to health technologies,

health systems strengthening, primary care services and innovative health financing in developing countries, especially within initiatives focused on maternal and child health.

Wendy Zijdel, RN, CNS

Wendy has a nursing degree from the Utrecht Medical Centre in the Netherlands and a postgraduate degree as clinical nurse specialist from the University of Utrecht in the Netherlands, where she focused on research in HIV/AIDS in adults and children. She is the current program manager for the NGO Zambian Governance Foundation (ZGF) in Lusaka, Zambia. Wendy has 20 years of experience in working and living in developing countries, such as Uganda, Bangladesh, Ethiopia, and Zambia. She began her development career working with Doctors without Borders and worked in emergency cholera and malnutrition projects as well as HIV integrative and community development programs.

Wendy has extensive field and research experience in urban and rural Zambia. As a program manager of research programs under the Center of Infectious Disease Research Zambia (CIDRZ). Wendy set up and managed large research programs, funded by CDC and the Doris Duke Charitable Foundation focusing on PMTCT.

Katy Weinberg, MBA, BA

Katy Weinberg, MBA, is the Program Manager for Boston Children's Hospital's Global Health Program. She has over 10 years of experience in global health and community programming, and has lived, worked or studied in China, the Caribbean, New Zealand, South Africa and Zambia. Katy holds an MBA in non-profit and international

management from Boston University and has an undergraduate degree in sociology and anthropology from Carleton College.

Katy served as a member of the Peace Corps from 2006-2008 in rural Zambia, working as an HIV/AIDS awareness and prevention volunteer alongside counterparts in the Ministry of Health. Katy brings a deep understanding of the Zambian culture and field experience to the review committee.

Elizabeth Egelski, MPH, BA

Elizabeth holds an MPH from Tulane University and a BA in Business Administration from Michigan State University. She has over 10 years of public health experience and is a current evaluator at the University of California where she manages and coordinates research programs related to nutrition and physical activity behaviors and obesity prevention efforts that support policy change in the educational system.

Prior to her work at UC Berkeley, Elizabeth spent 3 years living in Zambia, first as a Peace Corps Volunteer focusing on community education of HIV/AIDS in rural Zambia, then as an HIV educator for CHAMP, a Zambian NGO focusing on strengthening organizational and community response to HIV/AIDS. Elizabeth has extensive field experience and a first-hand understanding of Zambian culture.

Chapter IV: Incorporation of Reviewer Comments

This chapter outlines the comments made by five expert reviewers. A special thanks to Johanna Hinman, MPH, MCHES; Beth Ann Pratt, PhD; Wendy Zijdel, RN, CNS; Katy Weinberg, MBA, BA and Elizabeth Egelski, MPH, BA. The review panel provided insight based upon their respective areas of expertise.

Reviewer 1 Comments:

Reviewers should answer following questions. On a scale of 1-5 do you feel:

1 = Strongly agree; 2 = Agree; 3 = Neither Agree nor Disagree; 4 = Disagree; 5 = Strongly disagree

1. The proposal is responsive to the RFA. 1
2. The proposal is well thought out and theoretically sound. 2
3. The PI makes a compelling case that the proposed research/project/program is necessary. 1
4. The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated. 2
5. The proposed work is innovative and sets the groundwork for future work in this area. 2

Comment 1 (referring to Specific Aim 1): More detail on "evaluating the relationship" between pregnant women's faith and their behaviors would be useful.

Response: Thank you for your comment, I have taken another look at this aim and have made changes to make it more clear.

Comment 2 (referring to Specific Aim 1): Specific aim 1 does not really include action items – seems more like a description of the results of Specific aim 2.

Response: I have added in additional language to this aim as per the comment above.

Comment 3: The aims appear achievable

Response: Thank you.

Comment 4 (referring to Specific Aims section): The partners described, particularly CHAZ, seem appropriate and useful for this project. Having an existing relationship with a well-established Christian NGO should facilitate recruitment and implementation of the project. There is a clear focus on a particular issue and particular population group.

Response: Thank you for your positive feedback.

Comment 5 (referring to Specific Aims section): There is no mention on the specific aims page of the community awareness campaign mentioned later – this seems an important component of the overall project, perhaps even an aim in and of itself.

Response: Good point. I have actually decided to take out the community awareness campaign. After giving it some additional thought, it seems like it would be too big of an undertaking for a two-year proposal. Though I think it is a good component, I think it is more important to spend time and resources on the actual research and subsequent training program.

Comment 6 (referring to Significance section): There are clear indications that the relationship between religion and HAART adherence needs further study.

Response: Thank you. Yes, this is definitely a relationship that needs further study.

Comment 7 (referring to Significance section): This project represents an opportunity to engage two important populations – HIV+ pregnant women and Christian religious leaders.

Response: That was my hope, especially given the strong religious presence in Zambia and the high incidence of MTCT, it made sense to incorporate both populations into this proposal.

Comment 8 (referring to Significance section): Despite progress in reducing mother-to-child transmission of HIV, challenges remain, and progress has slowed. In a predominantly Christian nation where religious leaders hold sway, the proposed activities represent strong potential for making a substantive difference in HAART adherence among HIV+ women.

Response: Thank you, I agree. Although this grant proposal was for thesis purposes only, the need for further research is real.

Comment 9 (referring to Significance section): There is not much detail on the strength/credibility of individual religious leaders within Zambian communities, nor on the degree of religiosity of the population of interest. Both of these factors would seem to be significant in terms of the degree of influence anti-treatment messages might carry and the extent to which an intervention will have to counter ongoing religious messages.

Response: Paragraph four outlines the religious beliefs and influence of Christian leaders in Zambia.

Comment 10 (referring to Innovation section): The cited research includes some papers regarding links between religion and health but indicates gaps remain regarding religion among pregnant HIV+ women.

Response: Very true. When I was doing my literature review, the gaps in research became very evident.

Comment 11 (referring to Innovation section): The proposed project is narrowly novel within this particular field – partnerships between public health and religion are hardly new, but the specific focus here would be a new application of engagement.

Response: Agreed, the proposed project itself is not new. It is the concept of engaging Christian leaders as a way to encourage behavior change as it pertains to HAART adherence that would, hopefully, identify this project as novel. When I lived in Zambia there was a push to engage traditional healers and educate them on HIV. At the time traditional healers were not typically supporters of ART, but over time the behavior shifted and now there are many traditional healers who support ART while still respecting their own traditional practices.

Comment 12 (referring to Innovation section): As noted, working with religious leaders for public health programs is not new, but this particular application is novel.

Response: Agreed

Comment 13 (referring to Innovation section): The proposal builds upon existing work regarding religion and health. The proposed activities would build upon the good standing of religious leaders in the community.

Response: Yes, that was the intent of this proposal. Building upon existing work will help move the research along and help fill in the present gaps.

Comment 14 (referring to Innovation section): Little detail is given on prior work in Zambia (or other predominantly Christian African nations) between religious leaders or organizations and health workers on HIV, even though the major partner (CHAZ) is said to be a well-respected Christian organization. The degree of influence of this organization or other partnerships is not clear.

Response: Good point, I have added additional information about CHAZ and its presence within Zambia.

Comment 15 (referring to Approach section): The overall strategy is well reasoned and appropriate. Interviews as the main methodology make sense to gain a greater understanding of the issues surrounding pregnant HIV+ women's behaviors and beliefs about HAART and their religious faith.

Response: Thank you for your positive feedback.

Comment 16 (referring to Approach section): Challenges are not really addressed clearly in the proposal.

Response: Thank you for this constructive and valuable feedback. I have added to the potential barriers section in the proposal.

Comment 17 (referring to Approach section): The approach of partnering with religious leaders (rather than, for example, contradicting them directly) is both logical and commendable. Interviews with both pregnant women and religious leaders are important to understanding the nuances of these issues.

Response: Thank you for your supportive comment.

Comment 18 (referring to Approach section): Many details are lacking in this section – who will conduct the interviews? Is the sample size overly ambitious for the time line? There is to be a community awareness campaign, but no details are provided as to development and testing of the messages.

Response: I appreciate your feedback. I've added more clarity to the interview portion of the grant. Originally, I had 7 months for the interviews with an additional 4 months of extra time to make up any missed interviews. I have changed the interview time to a full 11 months. This will mean that only 14 people per week would need to be interviewed in order to stay on schedule. I have decided to take out the community awareness campaign portion of the proposal. I think that it is a nice idea, but after giving it some thought (sparked by your comment) it seems that fitting the development and testing of messages into the 2-year time frame would be overly ambitious. Perhaps this is something to table and reconsider at a different time.

Comment 19 (referring to Approach section): The overall approach of partnering with religious leaders is sound. However, there is a very fine line between partnership and paternalism when it comes to potentially contradicting the teachings of a religious community. How will these religious leaders be engaged in ways that respect their faith

and the dignity of their positions within their communities? What steps will be taken to ensure the public health messages do not incur backlash among the communities or cause stigma for the women who do adhere to HAART?

Response: Some religious leaders will become part of the LIFT My HAART team. The will also be the facilitators of the trainings. I have added some additional information into the proposal to make this clearer. I see your point about public health messages and the concern for causing backlash amongst the communities. I've taken out the community awareness campaign (for scheduling reasons), but I also think that it will alleviate this concern. The literature suggests that women are abandoning treatment as an expression of faith when encouraged by their religious leaders. The hope for the trainings is that it will be more of an upstream approach by partnering with and education religious leaders on the importance of HAART. The curriculum and training materials will be created based upon data gathered from phase I. I have added more explanation about this into the proposal under the "Lift My HAART Program Outline" section.

Comment 20 (referring to overall impact): The large number of interviews proposed should provide broad knowledge of the issues being considered by HIV+ pregnant women as well as religious leaders. Direct engagement of religious leaders is a positive and logical partnership. The project stands to make a difference in mother-to-child transmission of HIV.

Response: Thank you for your positive feedback.

Comment 21 (referring to overall impact): There is a lack of detail in the proposal about the questions that will be asked in the interviews and the likely messages to be

promoted in the community awareness campaign that make the full impact of the proposed project difficult to judge. Campaign messages that appear to directly contradict religious messages may risk creating backlash among the communities they are meant to serve – will partnering religious leaders be engaged in developing the messages?

Response: Agreed, I have added in more detail about the interview questions. As mentioned before, I have removed the community awareness campaign portion of the proposal.

Reviewer 2 Comments:

Reviewers should answer following questions. On a scale of 1-5 do you feel:

1 = Strongly agree; 2 = Agree; 3 = Neither Agree nor Disagree; 4 = Disagree; 5 = Strongly disagree

1. The proposal is responsive to the RFA. 1
2. The proposal is well thought out and theoretically sound. 2
3. The PI makes a compelling case that the proposed research/project/program is necessary. 1
4. The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated. 1
5. The proposed work is innovative and sets the groundwork for future work in this area. 1

Comment 1: Lea, this is a super cool idea!!

Response: Thank you so much!

Comment 2 (referring to the Specific Aims introduction): Here I would think about how you employ the terminology purpose, goal and aims etc. throughout the proposal. As well as to make sure that when you use them here, you are clear on whether you are referring to your research or the program. So the Aim is the larger thing you want to achieve by the research. The Goals are what you hope to accomplish through the aim. And the Objectives are how you are actually going to accomplish the goals. It's not just that you want to understand x, y, and z. It's that you want to use the role religion plays in the life of women to accomplish your goals.

Response: Thanks for your detailed comment. It was very helpful and I've made adjustments throughout this section and the proposal.

Comment 3 (referring to Specific Aim 2: This I see as the methodology, as opposed to an aim.

Response: Agreed, I have made changes to Specific Aim 2.

Comment 4 (referring to Specific Aim 2): So one thing I would question here is whether or not this is specifically an aim. The aim is what you want to achieve, the KI interviews the means by which you achieve it.

Response: Good point, I have made changes to Specific Aim 2 to make it more of an aim and less of an objective.

Comment 5 (referring to Specific Aim 3): So again, here, I see this as objectives, outputs, and outcomes here….as opposed to aims.

Response: I definitely see your point. I have made changes to Aim 3 to make it more of an aim and less of an objective.

Comment 6 (referring to Significance section paragraph 3): Interesting!!!

Response: Yes, I thought so too. It is very interesting how some understand the term "healing".

Comment 7 (referring to citation): I would just say CIA here.

Response: Agreed, I have made the change to the citation.

Comment 8 (referring to Significance section paragraph 5, second sentence): I think you could cut this sentence and just begin talking about the project.

Response: Yes, after reading it with your comment in mind, the sentence does seem unnecessary.

Comment 9 (referring to Significance section paragraph 5): Ok, so above you said you wanted to understand HIV-positive women AND religious leaders. And here you say just HIV-positive women. So you might want to make sure you are consistent with what you are saying you want to do. Also…you don't want to "sensitize" if I understand correctly, right? You want to design trainings. So this takes it from sensitization into IEC.

Response: Yes, good point, I have included religious leaders into this section and have reworded the sentence about sensitizing religious leaders.

Comment 10 (referring to Innovation section paragraph 4): Is there a way you can flesh this out with quant data? Can you track adherence behaviour for each woman specifically? Or is this information not available?

Response: Thank you for your suggestion. I have added in a sentence about collecting adherence behavior data as part of the data gathered on the surveys, as well as through the clinics (where available).

Comment 11 (referring to Innovation section paragraph 4 sentence 3): Here are you going to consider things besides religion when it comes to adherence, because there may be other factors involved?

Response: I can definitely see your point and agree that there may be other factors that contribute to HAART adherence. I've added in some language to clarify.

Comment 12 (referring to Innovation section paragraph 4 sentence 8): So MORE than sensitization correct! Make sure the reader knows this!

Response: You're right, more than just sensitization. I've incorporated IEC skills, and also included religious leaders, and through them, HIV-positive pregnant women.

Comment 13 (referring to Approach section paragraph 1): So again…go back through and make sure you are using these terms "goal" "aim" etc. consistently all the way through. Maybe take a step back and create a kind of log-frame-y thing in a separate document that you can print and refer to as you edit in order to keep it all straight?

Response: Good idea, log-frame-y thing made! I've identified this as an aim rather than a goal.

Comment 14 (referring to Phase II section under Approach): I'm wondering if you might want a Phase III stakeholder engagement stage…for feedback and iterative learning? Just a suggestion. Obviously it would depend on time and resources, but it might be interesting and create a nice lessons learned section for a thesis.

Response: That is a great suggestion! If this research were to be actually carried out, that would definitely be something to include. For the purposes of my thesis, I will leave a Phase III out.

Comment 15: (referring to H4 in Approach section): These are very interesting. I'm wondering if you will detect differences as to religious leaders/counselors perceptions if you talk to reps from different religions?

Response: I thought they were interesting as well. I would also be curious about the different perceptions of different religions. When I was doing my literature review, references to the Pentecostal church were prominent when referencing religious leaders who encourage women to stop treatment as an expression of their faith.

Comment 16 (referring to the space between the hypotheses and the next paragraph): Right here you might want a sub-heading "Methodology"?

Response: Good suggestion, I've added in the subheading. It definitely makes it easier to read.

Comment 17 (referring to the interviewing facilities): You may want to think about how you are going to get access to these? And describe how they will be identified/sampled?

Response: Great suggestion! I wrote about it in my thesis, but did not include it in the proposal. I have added in additional information.

Comment 18 (referring to the number of religious leaders to be interviewed): How many?

Response: 100. I've added that into the text.

Comment 19 (referring to identifying religious leaders to join as facilitator for phase II): That is good. But if they are actively lecturing women that God is going to heal them, they might not want to participate. You may want to keep recruitment for Phase III separate from Phase II research?

Response: The religious leaders we are looking to recruit for Phase II would not be those who are actively preaching against HAART adherence (though we would hope to find said leaders to participate in the interviews). We would be looking only for those who are open and willing to join the team as facilitators. These leaders may not necessarily be preaching against HAART adherence, but they may not actively be supporting it either. So the more leaders we have openly supporting HAART as an expression of faith means that the number of women who are exposed to the message will be increased. I have expanded upon the information and also moved it to the Phase II section.

Comment 20 (referring to reasons for Exclusion from the Interview and Survey Pool section): With this, one thing you might want to do is go back through and ensure that

Christianity is used instead of religion? It's made clear here…but it wasn't made so very clear earlier? So make sure that it is spelled out throughout the proposal?

Response: Great point, I have made that clarification throughout the document.

Comment 21 (referring to the Quantitative Data section): You may want more variables here…there may be other things that impact adherence? Additionally, how will this inform trainings and materials. You might want to think on this one a bit. What is the purpose of the quantitative survey? What else can you say here?

Response: Agreed, I've added more detail to this section.

Comment 22 (referring to quantitative data analysis): So here I think you need more. What is the data being analyzed for? What do you want to find out? How will this help you exactly? I think it is important. But I think you need to write more here as to why you think it is important. What is it going to do?

Response: Thank you for this comment. It really gave me a chance to think much further about the quantitative data and the role it plays in this proposal. I have added additional thoughts into this section.

Comment 23 (referring to LIFT My HAART Program Outline): Again, make sure "goal" is used consistently throughout. Is this the aim? Or is the goal?

Response: I have changed the original Aim (as per your comments), so with the new way that the Aim is written, this is now a goal.

Comment 24 (referring to the social-ecological model): This one might need to be fleshed out? What are the five levels?

Response: Good point. I've added more into this section.

Comment 25: So you may want a bit more detail about the trainings? What is going to happen? How will these go? The content will be informed by the research. But are they going to be lectures? Stakeholder engagement as to the findings? Practicums? How does it work?

Response: Thanks for your suggestion, I have added in additional information.

Comment 26 (referring to potential barriers section): Other potential barriers though? Maybe the hypotheses for example turn out to be not true? Does this affect what you are doing? Also….if the aim is improved adherence…what else could be barriers to the program outcomes?

Response: Thanks for your suggestions. I've expanded upon the potential barriers section, and divided them by phase.

Reviewer 3 Comments:

Reviewers should answer following questions. On a scale of 1-5 do you feel:

1 = Strongly agree; 2 = Agree; 3 = Neither Agree nor Disagree; 4 = Disagree; 5 = Strongly disagree

1. The proposal is responsive to the RFA. 2
2. The proposal is well thought out and theoretically sound. 2
3. The PI makes a compelling case that the proposed research/project/program is necessary. 1

4. The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated. 3
5. The proposed work is innovative and sets the groundwork for future work in this area. 3

Comment 1: Very interesting to read! I placed my comments in the balloons. Overall quite good, though missed some in depth descriptions here and there and some stronger evidence based links to the core problem. Hope this is helpful! Good luck with working further on it!

Response: Thank you for your comments, they are much appreciated and will be very helpful.

Comment 2 (referring to Specific Aim 2): Not sure if this can go in the same aim: religious leaders and HIV positive women for interviews, since they will receive quite some different questions and will have very different inclusion criteria. Is there a way to make this 2 aims?

Response: After reviewing some of the other comments, I've decided to remove Specific Aim 2 as it was more of an objective rather than an aim. I've made sure to keep this information later on in the proposal though.

Comment 3 (referring to Significance section, paragraph 2, sentence 3): Using "this" before "God can heal" sounds opinionated and a bit accusative.

Response: I can see your point. I've removed "this" and replaced it with "a".

Comment 4 (referring to Significance section, paragraph 3, sentence 1): Where did you get this information? Is there a link to research around this? Maybe websites/books, etc.

Response: That came from the research I did for the literature review chapter of my thesis. I've added in a citation.

Comment 5 (referring to Significance section, paragraph 5): Can you build this out a bit more through examples maybe.

Response: This is explained in detail in the approach section. I believe the significance section should stick to highlighting how the research will push forward the knowledge base within the field.

Comment 6 (referring to Innovation section, paragraph 2): I would describe this information in more detail. Argue a bit clearer as to why the CIDRZ program are limiting.

Response: I mention later on in the paragraph that none of the programs work specifically with religious leaders. This would include CIDRZ.

Comment 7 (referring to Innovation section, paragraph 2, sentence 5): Try to be more creative with this word, such as yet or though.

Response: Thank you for your suggestion. I have added the word "also", as the sentence is talking about PATH and how they also do not concentrate specifically on religion and women.

Comment 8 (referring to Innovation section, paragraph 3): would change the location of this paragraph to place as second paragraph instead of third. Seems to flow slightly better.

Response: I had to read through it a couple of times and I can see the flow both ways. I had ultimately decided to move the paragraph as you suggested, but then read your next comment, and ended up keeping it where it was originally based upon the changes I've made per your next comment.

Comment 9 (referring to Innovation paragraph 4): I find the phase I and II info is often repeated, yet with slightly different words. It makes it wanting to skip through parts of the proposal.

Response: I agree with you. Thank you for this suggestion. I've removed the explanation of phase I and II and added in more information pertaining specifically to the innovation of the proposal. I think I was originally trying to explain the innovation through explaining the phases of the project, but your comment has really helped me understand that I should be more direct in my explanation of the innovation. Thank you!

Comment 10 (referring to Approach section, H2): I am not sure if would use this as a hypothesis, 'many' is vague, and there is accusation in there, that is not stated as proof anywhere. (maybe take this out, as it is information that is being mentioned in earlier writings).

Response: Thank you for your suggestion. I would like to keep this hypothesis in because it is a major part of the speculation I make pertaining to the research outcome.

Comment 11 (referring to Approach section, interviews and surveys): do not quite follow the jump into CHAMP in here all of a sudden. Why do you need them versus CHAZ where you speak of before?

Response: Thank you for catching this! I was meaning to write CHAZ, but accidentally put CHAMP as I was using them as a reference. I have corrected this to CHAZ.

Comment 12 (referring to Approach section, Specific Aim 2): 'by' religion?

Response: You are right, it should have read 'by' religion, not just religion. Based upon other reviewer comments, I've decided to reword each of the Specific Aims.

Comment 13 (referring to the interviews with Christian Leaders): What are the criteria in more exactness for the Christina leaders?

Response: You have a good point; I have expanded upon this section.

Comment 14 (referring to the interviews with Christian Leaders): I find this topic slightly sensitive and if not addressed well in this proposal quickly too accusing. How would you address this and avoid this so you keep having access to this group without offending them? I feel on edge thinking about how the response will be from the churches on this topic if this is defined as it is.

Response: This is a very valid point, thank you for your comment. I was not making it as clear as I had hoped. Those who will be selected participants in the training will only be there of their choice. The ideal participant would not be actively speaking out against HAART, but might not be actively supporting it. I have also moved part of this section

and expanded upon it in the ‘interviews and survey’ section under Approach. I think it fits better there.

Comment 15 (referring to Reasons for Exclusions from the Interview and Survey Pool): Would build this out more.

Response: I think it is pretty clear already. Anyone who is not able to speak English, Bemba or Nyanja will be excluded from the study. I explained why in the previous paragraph.

Comment 16 (referring to Analysis of Qualitative Data): I would build out the qualitative more. What kind of questions would you ask? You do mention this in quantitative more. What is your aim with the data, or the objectives to be more precise?

Response: Thank you for your comment, I agree with you and have added a section showing the constructs of the interviews and surveys.

Comment 17 (referring to selection of survey participants): What additional information do you think to fund through the survey versus the other interviews?

Response: This is a good point. I’ve rearranged this section a bit, and combined the information with the paragraph just before this and the newly added table of interview and survey constructs.

Comment 18 (referring to LIFT My HAART program name): I really LOVE the name of this project!!

Response: Thank you so much!

Comment 19 (referring to LIFT My HAART Program Outline): What is the training content? Especially to justify why you need to train this amount of days and need a return training.

Response: Good point! The research will guide the exact content of the trainings, but I have added the general constructs into the proposal.

Comment 20 (referring to LIFT My HAART Program Outline): As I mentioned before; offending the religious leaders is a dangerous sloop, since you actually want their cooperation. Maybe stay closer to strengthening education, try to stay away from accusing them from what they currently do to keep women away from HARRT during pregnancy. Just imagine that one of these religious leaders reads your proposal.

Response: Agreed. The purpose of the trainings would never be to ostracize a participant for his/her beliefs. The trainings will be centered around HIV, HAART, MTCT and nutrition education, as well as general counseling skills to help Christian leaders work with HIV-positive pregnant women in a way to help them see HAART as an expression of faith. I have added this detail into the proposal. I also added in additional language in the 'selection of participants section' section. We would be looking for those who are interested and willing to participate in the trainings.

Comment 21 (referring to potential barriers section): It feels that CHAZ is too general in its description with their religious leaders, it feels a bit not through. what they will be doing exactly in this study. I would try to build this out a bit more, how this will be 'on the ground'.

Response: I have added in additional language about CHAZ and the role it will play 'on the ground' in the LIFT My HAART Program Outline section.

Comment 22 (referring to potential barrier section): How will you evaluate this? Evaluation is always a good component and do not forget to write about piloting and preparing communities for what will be coming with your interviews and surveys

Response: I have added more detail into the potential barrier section. I have also added information about community based informational meetings into the program activities and recruitment of Christian leader peer facilitators.

Comment 23: This is easy to read. The topic is clearly a need to be researched and studied more in the Zambian context.

Response: Thank you. It is definitely a burgeoning field, and one that needs much more research.

Reviewer 4 Comments:

Reviewers should answer following questions. On a scale of 1-5 do you feel:

1 = Strongly agree; 2 = Agree; 3 = Neither Agree nor Disagree; 4 = Disagree; 5 = Strongly disagree

1. The proposal is responsive to the RFA. 1
2. The proposal is well thought out and theoretically sound. 1
3. The PI makes a compelling case that the proposed research/project/program is necessary. 1

4. The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated. 3
5. The proposed work is innovative and sets the groundwork for future work in this area. 2

Comment 1 (referring to Significance section, paragraph 2, sentence 3): it would be interesting to know if this applies across diseases or just to HIV and why.... for example, do they expect God to heal if someone gets malaria or breaks their leg? why for HIV.... is this a hidden or not so hidden stigma?

Response: That is a very interesting, I would also be curious about this. This would be a good question for Phase I research. The response to this question would also be good information to use for the trainings in Phase II. I have added this into the constructs of the interview guide/surveys.

Comment 2 (referring to Significance section, paragraph 3, sentence 5): it would also be interesting to know a bit about why people are involved with specific churches.... is it a choice? is it because it is closest? When I was there, people seemed to switch Churches all the time.

Response: Another good suggestion for the interview guide!

Comment 3 (referring to Specific Aims section): A very well thought out and important project.

Response: Thank you!

Comment 4 (referring to Specific Aims section): You are assuming people want the best for these women.... I am not 100% sure that there is that much awareness/compassion.

Response: I would definitely like to think that people want the best for these women. Even though that may not be the case for everyone, the LIFT My HAART initiative focus on creating awareness and compassion for the Christian leaders who participate in the training. It starts with 100 leaders counseling HIV-positive pregnant women at their own churches and talking to their colleagues about this. Over time, 100 leaders turn into 200 leaders and so on… that would be my hope.

Comment 5 (referring to Innovation section, paragraph 3): if you are saying that the churches view HIV as a possible punishment, an interesting addition to your study would be to try to figure out why and what could be done to change that attitude. Would that not be more impactful?

Response: Agreed! I have added that into the constructs for the interviews.

Comment 6 (referring to Innovation section, paragraph 4): ohhh, you keep answering my questions right after I have them.... which is great. but I still think that you lay out a pretty concise plan for working with the women, but if this is a prevalent idea that HIV is a punishment, that will be a significant lift/change of attitude that will require more forethought than just saying that 'trainings will be given'

Response: I agree; I need to explain the innovative side of the proposal much better. I have actually removed this paragraph (as per another reviewer's suggestions) because

there was repetitive talk about Phase I and Phase II. I have changed the paragraph directly above it to better reflect the innovation for this proposal.

Comment 7 (referring to the Innovation section): It really is amazing how prevalent this role of religion is and how little has been done to change these attitudes.

Response: Yes! That is what makes this research so needed. Especially in a country like Zambia where religion is paramount.

Comment 8 (referring to the Innovation section): Again, this builds on important work already happening that is missing this niche.

Response: I agree.

Comment 9 (referring to Data Collection Activities): I worry about your timeline.

Response: I understand. I have expanded the time line for the interviews and data analysis. When I created this timeline, I envisioned the LIFT My HAART team along with representatives from CHAZ devoting 100% of their working time to this. When you break down the numbers, the team would need to interview 13 people per week in order to stay true to the timeline. And the data analysis will begin immediately.

Comment 10 (referring to Approach section, Specific Aim 3, paragraph 1): Yes!

Response: Thank you for your enthusiasm! The program implementation part is very exciting. I have rearranged the Specific Aims (now there are 2), but I have added this information into the new Specific Aim 1.

Comment 11 (referring to Approach section, LIFT My HAART Program Outline): Again though, if they truly think HIV is a punishment, how will they be motivated to

change this internal prejudice? In my opinion, this is going to be the largest challenge in your study and you should mention it here with some background information on how to change people's core believes and if it is possible (think about how Catholics fight birth control, even though it inherently helps women, for example.... I don't think it is enough to say 'this will help the women')

Response: That is a very good suggestion. I had added this into the potential barriers section.

Comment 12 (referring to the overall impact): As mentioned, this is an overlooked, but real problem in the Zambian community. It is tangible, but no NGOs/MOH currently addresses it. I think addressing the religious leaders and helping assure the woman have access to HARTT will be a huge asset to the community and something that might be incorporated into future efforts by partner NGOS/MOH.

Response: That would be my hope for an initiative like LIFT My HAART. As you said, it is a very real problem in Zambia.

Comment 13 (referring to overall impact): As mentioned, I believe it will take time to change attitudes, but that doesn't mean it shouldn't be done!

Response: Agreed! Behavior change never happens quickly, but we must start somewhere to make change.

Comment 14: Overall, I think this is a very thoughtful proposal and I would think with the right team, it could be very impactful.

Response: Thank you!

Reviewer 5 Comments:

Reviewers should answer following questions. On a scale of 1-5 do you feel:

1 = Strongly agree; 2 = Agree; 3 = Neither Agree nor Disagree; 4 = Disagree; 5 = Strongly disagree

1. The proposal is responsive to the RFA. 1
2. The proposal is well thought out and theoretically sound. 2
3. The PI makes a compelling case that the proposed research/project/program is necessary. 1
4. The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated. 2
5. The proposed work is innovative and sets the groundwork for future work in this area. 1

Comment 1 (referring to Specific Aims): But, beyond gathering info, you are planning to develop a training. I would make that more clear.

Response: Yes, much more than gathering info. I've changed the opening paragraph around per other reviewer's comments. The following paragraph explain the two different phases, and that is where the training is explained further.

Comment 2 (referring to Specific Aims, paragraph 3): I can't remember what HAART involves, but does it involve adherence training? I would maybe explain a bit

about the deficiencies in HAART and why you want to improve upon it (not necessarily at this point in the proposal, but at some point…. Unless this proposal assumes the reviewer has a deep knowledge of HIV/AIDS treatment). Also, is LIFT My HAART a new initiative that you would be creating with this proposal or something that already exists upon which you plan to improve upon?

Response: HAART stands for Highly Active Antiretroviral Therapy. In the U.S., there is a program called HAART Inc. It is a social services organization out of Baton Rouge, LA. I am thinking that my use of the word "program" may have been a little confusing here. I have changed that to make it more clear. "New initiative" was already in the text, but I have added "brand new initiative" to make it more clear that this is not improving upon something that is already existing.

Comment 3 (referring to Specific Aim 1): I'm still a little confused as to how aim 1 and 2 differ…. Aren't you accomplishing aim 1 through aim 2 … i.e., aim 2 is the method through which you will achieve aim 1? I may be misunderstanding this…

Response: That is a very good point. I have changed around the specific aims a great deal. There are now only 2 specific aims in the proposal.

Comment 4 (referring to Specific Aim 1): I would maybe state this in a more neutral way unless you have evidence that this non-compliance is an expression of their faith.

Response: Good point. We know that women are being told by some religious leaders to abandon HAART because God will heal them, but there is currently not any scientific evidence in the form of research. I have changed aim 1 to make it more clear.

Comment 5 (referring to Specific Aim 3): Are the trainings "LIFT My HAART"?

Response: LIFT My HAART is the name of the overall initiative. I have also removed aim 3 and combined it with the new aim 2.

Comment 6 (referring to Specific Aims section): The aims could be strengthened by more clearly detailing the expected outcomes and how they will contribute to greater ART adherence.

Response: This is a good point. I have clarified the Specific Aims section.

Comment 7 (referring to Specific Aims section): While the number of surveys conducted and leaders trained are discussed, the longer-term outcome of increased adherence to ART is not.

Response: Thank you for your comment. This is a valid point. I have added in language to clarify this.

Comment 8 (referring to Specific Aims section): Barring resistance from interview respondents and Christian leaders, the aims seem achievable.

Response: Thank you

Comment 9 (referring to Specific Aims section): While Christian leaders may attend and participate in the training, there is no mention of how it will be determined that they put the training into practice. Additionally, although leaders may be trained and putting their new knowledge and skills into practice, the women who they may try to reach might be hesitant to their new approach and/or may have other leaders still influencing them otherwise.

Response: The training is divided up into two separate sessions with a two-week break in between. This will allow for some sort of follow-up to determine how their new skills are being put to use. I agree with you though, that this is not a solid follow up plan. I have added in some additional language outlining follow up through CHAZ. Also, whilst the women may be hesitant, it is more likely that they will follow along with their Christian leaders. Zambia is a deeply religious country and religious leaders hold a great deal of clout within the community. Additionally, it is believed that the decision to stop treatment as an expression of faith is encouraged by some of the Christian leaders themselves and not the women. This proposal hopes to address this in an upstream manner by focusing efforts on IEC of the Christian leaders themselves.

Comment 10 (referring to Significance section): The importance of religion and faith, and influence of leaders in those communities have in Zambia is an area of significance that is currently being overlooked.

Response: Agreed!

Comment 11 (referring to Significance section): More detailed explanation for how the results will be used and outcomes determined, is needed. A dissemination plan for the results of the survey and key informant interviews could be described – will these results be used to inform the field in general, or just to develop the training?

Response: Thank you for your suggestion. I have added a "dissemination plan" section into the Approach section of the proposal.

Comment 12 (referring to Innovation section): As it appears that addressing the influence of Christian leaders on pregnant HIV-positive women adhering to ART is

lacking in Zambia, this is a novel approach to understand upstream determinants of ART treatment adherence.

Response: Thank you.

Comment 13 (referring to Approach): I would think that this statement should reflect what is discussed in the "Specific Aims" section… so I would update either/or

Response: Thank you, I have edited this section.

Comment 14 (referring to H3): Seems like the first mention of this acronym… should define it here.

Response: PMTCT is defined in the Significance section.

Comment 15 (referring to Approach section, Specific Aim 1): Prior to the interview?

Response: To the interview participants. I have clarified that to make it more clear.

Comment 16 (referring to Approach section, Specific Aim 2): Again, not entirely clear how this is different than aim 1…. What am I missing?

Response: Agreed! See note from previous comment. I have made changes to the Specific Aims that address this.

Comment 17 (referring to Data Collection Activities): I'm concerned about the timeline being too short for this activity, but since this is practice…. Not a huge issue.

Response: Thanks for your comment. Your experience is much appreciated. I have made changes to the timeline.

Comment 18 (referring to Quantitative Data): I don't know if you need to discuss how you calculated the sample size (i.e., the number of participants you need to perform the calculations you plan)…?

Response: Good point, I have made changes to this section, and also added in the interview/survey constructs.

Comment 19 (referring to Community Awareness Campaign): This seems a bit over ambitious! Creation of the campaign materials and marketing will take time, unless already in existence…. Plus, is costly. Also, I would think you'd want an evaluation component related to all of your program activities – I would add an evaluation activity to this (even if it's just process data… we estimate that X number of people will be reached…. OR including questions about awareness and effect on behavior that this campaign had on the women in the study)

Response: I agree with you. I was also thinking that it is too much for this timeline. I have removed it entirely from the proposal. The removal of the community awareness campaign does not change the most important parts of the proposal, in fact, it could be another proposal all together… building off of the research and activities from this proposal. I think that its best to stay focused on the research and subsequent trainings.

Comment 20 (referring to Approach section): There was no mention of who would be conducting the surveys and key informant interviews and, correspondingly, how they will be trained and monitored. Likewise, there is mention that Christian church leaders will be recruited to the LIFT My HAART team as facilitators for the training portion of the

intervention, but alternatives if interest is lacking and who will else will be part of this time is not discussed.

It would strengthen your proposal to include this information.

Response: There was mention of multi-lingual Zambian CHAZ employees carrying out the interviews and surveys, but I have expanded upon that to outline how they will be trained. I have also added in that a member of the LIFT My HAART team, who is possesses a conversational level of Bemba and Nyanja will also be present to monitor the interviews and surveys. Good point about having a back-up plan. This was already addressed this in the potential barriers section.

Comment 21 (referring to Approach section): It is mentioned that the collaboration with CHAZ will help to alleviate potential hesitation from the Christian leaders taking part in the training. However, it would be helpful to add concrete examples of how CHAZ will address resistance and uncertainty in the leaders taking part, e.g., they will hold informational meetings in which questions will be addressed, etc. It would also be helpful to add further description on how leaders will be recruited to serve as facilitators for the training.

Response: Thank you for your comment, it presents a very valuable component to the proposal that was not there. I have added in community based informational meetings as well as additional information about the recruitment of Christian leader peer facilitators.

Comment 22: The proposal seems like a novel approach to understand an area of influence on ART adherence that is untapped. Collaborating with an established Christian organization and involving leaders in the facilitation are excellent strategies.

Response: Thank you!

Chapter V: Final Version of the Proposal

Specific Aims

To leverage the role that Christian religion plays in an HIV-positive pregnant woman's decision-making to adhere to Highly Active Antiretroviral Therapy (HAART) as a way to ensure improved adherence and reduced mother-to-child transmission. This initiative will be carried out in collaboration with Churches Health Association Zambia (CHAZ), local Christian leaders and the Zambia Ministry of Health (MoH). The goals of this proposal are to improve adherence among HIV-positive pregnant women through faith based health promotion activities and to strengthen counseling skills among religious leaders who routinely counsel HIV-positive women in the course of their work. This will be achieved through a two-phased process targeting women and Christian leaders.

The first phase will be a mixed-method investigation of both HIV-positive pregnant women and the local Christian leaders in Lusaka, Zambia. The research will help identify the factors that may impact HAART treatment adherence among this population.

The second phase of the proposal uses information gathered through key informant interviews and surveys from Phase I. This information will aid in the creation a brand new initiative in partnership with Christian Leaders, the MoH and CHAZ through a community based program designed to Link Individual Faith Together with HAART (LIFT My HAART). The purpose of this initiative would be to influence how HIV-positive pregnant women are counseled by those they look to for spiritual guidance. The goal would be an increase in treatment adherence for HIV-positive pregnant women who identify with the Christian faith.

Specific Aim 1: To evaluate the relationship between HIV-positive pregnant women in Zambia and the role and influence that their Christian faith has on HAART adherence. We will hold key informant interviews and surveys with 508 HIV-positive pregnant women as well as 100 identified Christian leaders who actively engage in counseling HIV-positive pregnant women through ministry within Lusaka. These interviews will assess the viewpoints, perceptions and opinions about HAART and how adherence is affected by religion.

Specific Aim 2: To improve HAART adherence among HIV-positive pregnant women. We will create and implement trainings that are culturally appropriate to 100 Christian leaders within Lusaka, Zambia. These trainings will strengthen counseling skills among local religious leaders who routinely counsel HIV-positive women in the course of their work. Christian leaders who work at a community level and understand the benefits of HAART will then be able to encourage adherence within a religious framework. This will affect the long term adherence of HAART by HIV-positive pregnant women.

Research Strategy

Significance. The World Health Organization (WHO) reported in 2013 that the number of children newly infected by HIV in low- and middle-income countries had fallen by 40% (WHO, 2014). This constitutes considerable progress towards the global scale-up of Prevention of Mother-to-Child Transmission (PMTCT) initiatives. For the first time in history, the Elimination of Mother-to-Child Transmission (EMTCT) is an attainable public health goal. For the past decade, Zambia has successfully implemented an efficient nationwide response to the HIV/AIDS epidemic within its borders (Zambia Ministry of Health, 2014). During this time, Zambia has worked hard as a nation to achieve key milestones in the coordination and management of the national response as outlined in the Zambia National AIDS Strategic Framework (NASF) (National AIDS Council, 2014). In PMTCT alone, Zambia reports a decrease in vertical transmission from 24% to 12% between 2011 and 2013 (National AIDS Council, 2014).

However, there is a concerning trend that is starting to take hold within the country that threatens Zambia's successes in combating mother-to-child-transmission. Literature suggests that there is pressure in some Christian communities for both men and women to stop treatment in the hope that God will heal them through prayer (Endeshaw et al., 2015; Tofa, 2014; Seeling et al., 2014; Musheke, Bond, & Merten, 2013; Horn, 2012; Manglos & Trinitapoli, 2011; Togarasei, 2010). Studies have shown women may be more drawn to churches that teach a "God can heal" mentality, and this can be a contributing factor for women who decide to stop HAART. For a pregnant woman the decision to substitute prayer for HAART could impact the life of her unborn child by increasing the risk of HIV through mother-to-child transmission. This is a risk during pregnancy, labor, delivery or breast feeding. When an HIV-positive pregnant woman adheres HAART, the risk to her child of vertical transmission can be reduced below 5% (WHO, 2015). However, without intervention, mother-to-child transmission rates can range between 15% - 45%.

Some Christian communities believe that HIV is a punishment from God and will say that the reversal of HIV is possible through prayer (Endeshaw et al., 2015). Even though there is no medical scientific background to this, they consider themselves healed. Religious leader can define healing in a variety of ways. For some, healing is understood as the reversal of symptoms of HIV or AIDS illness, as well as the possibility of a cure (Togarasei, 2010). The churches that define healing in this way may be attractive for people who are searching for some form of alleviation from a physical ailment (Pfeiffer, 2002a); in part because they connect extraordinary healing to the work of the Holy Spirit (Agadjanian, 2005) or to salvation of one's soul (Takyi, 2003).

Zambia is overwhelmingly Christian with 96% of the population identifying with some form of Christianity (CIA, 2015). Religion is so prevalent that the constitution declares Zambia as a Christian nation. Research also shows Zambia to have the fourth highest degree of religiosity as compared to 64 other countries (Stavrova, Fetchenhauer, & Schlösser, 2013). People believe deeply in the religious ideals that surround Christianity and look to religious leaders for guidance in all aspects of their lives. As such, the influence of religious beliefs intersected with health beliefs are significant. Although there is little research into the depth of religious influence on an individual's health beliefs, or more specifically on the decision to take ART, the heightened level of religiosity within Zambia addresses the social influence of religion and society in general. Given this influence, efforts to utilize religion as a way to support HIV treatment are key to moving research forward in this field.

A two pronged approach could further the nascent research on this topic and develop models for community programs to address this public health issue. The first component would increase understanding from HIV-positive pregnant women and Christian leaders about the influence of religious beliefs on an HIV-positive pregnant women's decision to maintain adherence to a HAART regimen. The second component would be to strengthen the counseling skills of Christian leaders through information, education and communication (IEC) so they may encourage women to view HAART as an expression of, rather than an opposition to, their faith. The implementation of this research, and subsequent training program, provides a compelling opportunity to gain a deeper understanding of the role that Christian religion, and religious leaders, play in an HIV-positive woman's decision to adhere to HAART. Thus serving as an upstream community based approach to this public health problem.

Innovation. Research suggests that there is a link between religion and health related behaviors (Takyi, 2003; Garner, 2000; Lagarde et al., 2000). There is relatively little research however, pertaining specifically to religion and reproductive health (Lentz & Majumdar, 2014; Gaydos et al., 2010; Gyimah et al., 2006), particularly examining the intersection between religion and HIV in Africa (Takyi, 2003). The influence of religion and the role it plays in predicting whether HIV-positive pregnant women will adhere to their HAART within Zambia specifically has yet to be explored.

In Zambia there are a number of Non-Government Organizations (NGOs) and Ministry of Health (MoH) programs that currently focus on Maternal and Child Health (MCH). The Centre for Infectious Disease Research in Zambia (CIDRZ) has a large MCH program operating in over 336 clinic sites in Lusaka, Eastern and Western Provinces, but many of their programs focus on prevention and treatment interventions. Additional programs that offer similar services include: Marie Stopes which is an organization that offers sexual and reproductive health clinical services to women in Zambia; Population Services International (more commonly known in Zambia as Society for Family Health); Project Concern International and The Programme for Appropriate Technology in Health (PATH), which focuses on the unique HIV prevention needs of women, but also does not concentrate specifically on religion and women. None of these programs have trained religious leaders to respond to the increasing number of HIV-positive pregnant women who let faith influence their decision to adhere to HAART.

The President's Emergency Plan for AIDS Relief (PEPFAR) however, has partnered with FBO's since its inception in 2003 (J. Blevins; E. Mombo; S. Thurman et al., 2015), allowing it to build upon the respected and trusted presence of FBO's within the community. While CHAZ focuses more on overall health, it is the largest faith-based NGO health provider in Zambia. It was founded by Catholic and Protestant Church health institutions. There are currently 151 health facilities representing sixteen Catholic and Protestant denominations. These health care facilities provide 30% of the national health care in Zambia (CHAZ, 2013). The partnership with CHAZ will provide the link between religion and health care for this proposal.

Religion impacts many individuals; it can influence a person's decision as it pertains to their own health concerning the choices they make in their personal treatment and care (Endeshaw et al., 2015; Gaydos et al., 2010; Park & Nachman, 2010; Lagarde et al., 2000). Religion has also been identified as a barrier to the utilization of health services (Takyi, 2003). As past research has shown, there is a need to address the burgeoning field of religion and reproductive health. Despite the presence of many well-known NGOs within Zambia, there are none that offer programs involving Christian leaders as a

way to encourage HAART adherence in HIV-positive pregnant women. This research offers the possibility not only to expand upon current research by identifying the link between religion and adherence to HAART, but take it a step further by creating and implementing an IEC program for Christian leaders to address the gap between the two. This combination of research and program implementation will lay the foundation for a deep impact within this burgeoning field.

Approach. In order to improve adherence among HIV-positive pregnant women this research team will carry out a two-phased initiative targeting HV-positive pregnant women and religious leaders.

Phase I: A mixed methods research study to identify the role that Christian religion plays in an HIV-positive pregnant women's decision to choose her faith over HAART adherence.

Phase II: Analysis of the collected data to inform the development and implementation of a training program for Christian leaders in Zambia. The goal of the training program is to reduce the number of HIV-positive pregnant women who abandon HAART as an expression of faith by providing IEC skills to Christian leaders.

The proposal is driven by the following hypothesis:

H1: Problematic expressions of the Christian faith present in Zambia encourages HIV-positive pregnant women to become non-compliant with HAART.

H2: Many Christian leaders are urging HIV-positive pregnant women to rely on faith healing rather than scientifically proven medications.

H3: The understanding of the importance of HAART and the role it plays in PMTCT are overshadowed by some Christian beliefs and the idea that "God will heal".

H4: Partnerships with Christian leaders and faith-based organizations (FBOs) that encourage adherence to HAART within a religious framework are key to encouraging HAART adherence, thereby reducing the prevalence of health issues related to non-compliance among pregnant women in Zambia.

Methodology

Specific Aim 1: **To evaluate the relationship between HIV-positive pregnant women in Zambia and the role and influence that their Christian faith has on HAART adherence.** The first phase of this grant incorporates a mixed method research study that gathers data to understand the impact that religion has on HIV-positive pregnant women and their decisions to adhere to HAART. Over an 11-month period, key informant interviews and surveys with 100 Christian leaders and 508 HIV-positive pregnant women will take place.

Interviews and surveys: The interviewing/survey facilities will be determined in partnership with CHAZ. There are 348 health facilities in Lusaka, (including government and private clinics, 1st, 2nd, and 3rd level hospitals and other health facilities managed by NGO's or religious organizations) (CHAMP Zambia, 2012). In partnership with CHAZ and the Zambian MoH, ten government-run health facilities (excluding all hospitals and NGO managed facilities) will be selected as locations to recruit individuals who are

willing to participate in the study. Clinics will be identified based upon the number of people served and the presence of operational antenatal and HAART clinics. Of the clinics that meet both criteria, the ones serving the largest populations will be selected. Given that 95.5% of Zambians identify as Christian (CIA, 2015), utilizing the religious affiliation of a clinic site as a criterion to selection is unnecessary. Access to the facilities will be supported and granted by MoH. CHAZ will help to identify Christian leaders within the community to participate in the interviews and surveys.

Selection of Interview and Survey Participants. Participants for interviews and surveys will be recruited from the PMTCT Antenatal Clinic (ANC), which is open one day per week at each of the selected clinics. A total of 50 participants will be identified from each of the ten health facilities with the two facilities servicing the largest population interviewing 54 individuals each. In order to ensure a random selection process, every fifth patient who enters the PMTCT-ANC clinic will be asked to participate in the interview and survey, unless they have been excluded from the participant pool. Participants completing the survey will also be provided with a written informed consent. Once identified, participants will be interviewed in a confidential setting within the clinic while awaiting their PMTCT-ANC services. Each participant will be fully informed about the purpose of the study and what her participation entails. Women who are unable to read will have the consent form read out loud to them. In these cases, a signature will still be required on the informed consent once the participant feels comfortable enough in her understanding of the form to sign. All women who choose not to participate in the study, or who are found to be ineligible, will be made fully aware that their decision to decline or inability to participate in an interview will not affect their access to treatment through the clinic. Informed consent and interviews will be provided in English, and two different local languages, Nyanja and Bemba. These languages have been selected because English is the official language of Zambia, and Bemba and Nyanja are the two most common Bantu languages spoken within the country (33.4% speak Bemba and 14.7% speak Nyanja) (CIA 2015).

Interviews and surveys will also be given to 100 selected Christian leaders within Lusaka. As CHAZ is already established within the community, the organization will help to identify the Christian leaders. In order to qualify as a participant in the study, each leader must actively engage in counseling HIV-positive pregnant women through his/her ministry.

Multi-lingual Zambian nationals employed through CHAZ will administer the interviews and surveys in Nyanja and Bemba when needed; otherwise, this research team will conduct them. All CHAZ employees who will be conducting interviews and surveys will be trained by a member of this research team. In the event that a CHAZ employee will be conducting the interview and survey, a member of this research team who possesses a conversational level of Bemba and Nyanja will also be present. A payment of a 5kg bag of mealie meal will be given to each interview participant to acknowledge the time and effort they have given to the study.

Quantitative Data. The surveys are intended to quantify the factors that may impact HAART adherence. Although religious factors are the focus of this proposal, other influences must be taken into consideration in order to create the most effective training materials for Phase II.

Survey and Interview Constructs

Survey Constructs

Participant	Research Category	Type of Information Gathered Through Questions
Women	Demographics	Age, primary language, home clinic, household composition, marital status, serodiscordant/seroconcordant status, spouse taking ARVs Christian denomination, educational attainment, reproductive history, number of times per week attending church,
leaders	Demographics	Age, primary language, duration of religious leadership, church affiliation, educational attainment
Women	Treatment and HIV-related variables	When HIV status became known, when HAART started
Women	Religious support	Support seeking behavior from Christian leaders
Leaders	Counseling behavior	Number of times in the past 30 days religious counseling was provided in general and specifically to HIV-positive pregnant women
Women	HAART Adherence	Frequency of HAART adherence in past 7 days
Women	Beliefs about HAART Adherence	Do you believe that you: should stop taking HAART when you feel better, only take it when you are feeling sick, take them at the same time every day
Women	Religious Activity	Times per week attending church
Women & Leaders	Religious beliefs pertaining to HIV	Do you believe that HIV is a punishment from God? Do you believe that God will heal HIV?
Women	Religious beliefs pertaining to HIV	Are you worried that the church will shun you if you do not stop taking HAART?
Women & Leaders	Importance of HAART	Do you believe that HAART is an important factor in controlling HIV?
Women	Religious influence on HAART	Has anyone ever told you that you must choose between your faith and HAART?
Leaders	Religious perspective on HAART	Do you ever counsel HIV-positive pregnant women to stop HAART?

Interview Constructs

Participant	Research Category	Type of Information Gathered Through Questions
Women	Reasons for church selection	Determinants of church selection
Women & Leaders	Religious healing	God's healing powers both specific to HIV and across other ailments as well
Women & Leaders	Medications and HAART	Views on medications in general and specifically HAART
Women & Leaders	Non-compliance	Reasons for HAART non-compliance
Women & Leaders	HIV knowledge	Can you describe what HIV is?
Women & Leaders	MTCT	Can you describe what MTCT is?

	knowledge	
Women & Leaders	HAART knowledge	Can you describe what HAART is?
Women	Religious impact on daily life	How does God influence your daily life?
Women	Religious impact on HAART	Support received from church, involvement in church since status became known
Leaders	Religious perspective on HAART	Describe the type of advice/counseling you provide to HIV-positive pregnant women

Reasons for Exclusion from the Interview and Survey Pool. As this research seeks to identify the role of Christianity in an HIV-positive pregnant woman's decision to adhere to HAART, any HIV-positive pregnant woman or Christian leader who does not identify as either Catholic, Protestant or an affiliated denomination such as Methodist, Baptist, 7th Day Adventist, Pentecostal, United Church of Zambia (UCZ) or Anglican will not be considered for the interview. These exclusions include those who identify as Muslim, Hindu, Jehovah's Witness or indigenous beliefs only. Additionally, anyone who is unable to speak English, Bemba or Nyanja will be excluded from the study.

Analysis of Qualitative Data. The data gathered from each of the interviews will be transcribed verbatim and translated into English when necessary. The transcribed narrative data will be coded and analyzed using MAXQDA software.

Analysis of Quantitative Data. Quantitative data will be analyzed using SPSS. The data collected will provide important statistical information about demographic and socioeconomic characteristics of the interview participants. It will also provide valuable information about adherence behavior, distinct views on religion, medication and other factors that may influence HAART adherence. Data will be used to create training materials that specifically address the target audience. It will also provide a quantifiable aspect to the qualitative data gathered during the key informant interviews.

Specific Aim 2: **To improve HAART adherence among HIV-positive pregnant women.** Phase II of this grant proposal is the implementation of the *LIFT My HAART* program. This program specific materials will be created using the data gathered during Phase I. *LIFT My HAART* will focus on the capacity building of Christian leaders at a grassroots level in Lusaka. *LIFT My HAART* will be implemented in partnership with CHAZ, MoH and selected Christian leaders, who will also be facilitating the trainings to their peers.

LIFT My HAART **Program Outline.** *LIFT My HAART* will be a collaboration among this research team, CHAZ, Christian leaders and the Zambian MoH. As a means of improving adherence among HIV-positive women, the goal of the program is behavior change as it pertains to Christianity and the effect it has on an HIV-positive pregnant woman's decision to adhere to her HAART. It is a training program designed to help Christian leaders in Lusaka understand the connections between faith and HAART. The trainings will enhance Christian counseling to HIV-positive pregnant women by helping them to understand HAART as an expression of faith. Training materials will be created utilizing data from Phase I interviews with HIV-positive pregnant women and Christian leaders. This will ensure that training messages are delivered in a respectful and non-threatening way. Interactive workshops will be carried out for 100 identified Christian leaders. The trainings will be based upon the social-ecological model utilizing the theory

that taking action across each of the five levels, will better help to prevent this developing trend. The model uses five nested hierarchical levels individual, interpersonal, community, organizational and policy. Each one providing the framework for a better understanding of the multifaceted and interactive effects of personal and environmental factors that determine behavior. Incorporating this approach into the trainings will provide a multi-level approach to the long-term adherence of HAART by HIV-positive pregnant women. The trainings will be facilitated by *LIFT My HAART* team members, CHAZ employees and Christian leaders. They will take place at ten various locations within Lusaka. The locations will be determined in collaboration with this research team, CHAZ and MoH. Each training will consist of only ten participants. The smaller group size will allow for a more personal and individualized training style. It will also encourage greater group participation. The materials created will be based upon the data gathered during Phase I. Though the exact content will not be known until the research is completed, but constructs of the training will provide basic counseling skills and ways to engage HIV-positive pregnant women in a way that allows her to incorporate HAART as an expression of faith. In addition to the research based materials, each training will offer sessions on general HIV, HAART and MTCT education. The trainings will be divided into two separate training periods with a break in between. The first training will take place over five days, while the second will last for three days. The divided training schedule provides each participant time to return to his/her community for an opportunity to apply the new information learned through the initial training. After a period of two weeks, the participants will return for the second portion of the training fueled with practical experience to share with their peers. The sessions during this time will build upon the skills practiced during the break. It will include experiences of counseling sessions, barriers experienced and lessons learned.

Recruitment of *LIFT My HAART* Program Participants and Christian leader facilitators. Participants of the *Lift My HAART* program will be identified in three different ways and invited to participate in the program: 1. Christian leaders who express interest in understanding more about religion and HAART during their interviews 2. Utilizing CHAZ's knowledge of local Christian leaders who are identified as promising participants and 3. Christian leaders who are expressing an interest in participating in the program. During Phase I, researchers will also be looking to identify Christian leaders, through community based informational meetings and during the interviews and surveys, who are interested in the idea of being a part of this initiative and willing to join the team as facilitators to their peers during Phase II. Those considered for peer facilitator positions must not be actively speaking out against HAART adherence unless they indicate that they no longer wish to do so. Increasing the number of Christian leaders who are provided with IEC and counseling skills to help HIV-positive pregnant women utilize HAART as an expression of faith, increases the number of women exposed to the message.

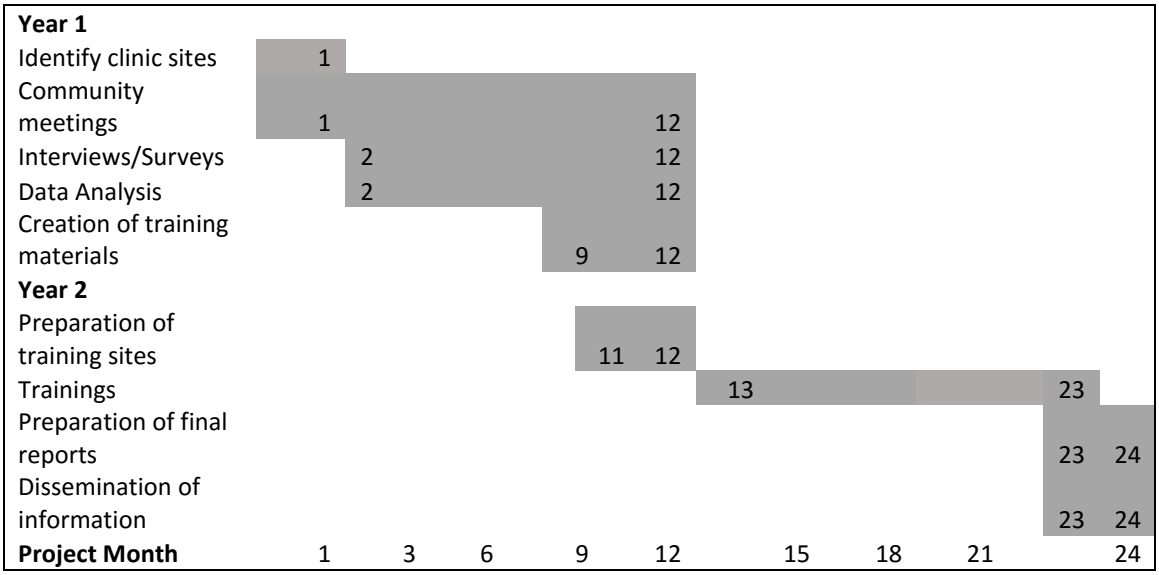
***LIFT My HAART* Follow-up.** Initial follow-up of the Christian leaders is incorporated into the divided training schedule. After a two-week field experience, participants will return for additional training. As this proposal only covers a two-year period of time, CHAZ has agreed to continue on with the follow-up of the Christian leaders through their organization once the funding period for this grant is completed.

Dissemination Plan. During the last three months of the funding period, the results of the key informant interviews, surveys and trainings will be submitted via report to the Zambian MoH. These reports will explain in detail the outcomes of the research and subsequent trainings as well as suggestions for a way forward. As MoH is a partner *LIFT*

My HAART they will have firsthand knowledge of the two years spent researching and training. The MoH has acknowledged the need for this type of research and initiative and is committed to continuing the trainings of Christian leaders under its own funding.

Potential Barriers. *LIFT My HAART* is the first of this kind of program for Christian leaders. It is expected that potential barriers will arise. Some religious leaders may be hesitant to participate in the program. This will be addressed through a collaboration with CHAZ, who is in a unique position as rapport has already been established with the community and with Christian leaders. Additionally, efforts will be made during Phase I to identify religious leaders who are interested in joining the *LIFT My HAART* team as facilitators during the trainings. This will allow for an element of personal understanding by the trainers towards the participants of the trainings. The religious leaders identified to become part of the *LIFT My HAART* team will also be able to lead by example when it comes to their colleagues. Another potential barrier deals with the aspect of behavior change. As previously mentioned research has pointed out, some Christian leaders believe HIV to be a punishment from God. For those who believe this, changing the presence of internal prejudice will be difficult. The *LIFT My HAART* initiative seeks Christian leaders as participants who are not actively speaking out against HAART adherence, but who are also not wholeheartedly supporting it. Targeting this particular population will avoid the offensive practice of telling a person his/her personal beliefs are wrong. At the same time, it will increase the number of Christian leaders within the community who are exposed to, and educated about HIV and HAART adherence. This will allow for a greater number of Christian leaders to come to their own, educated, conclusions on the subject. Those who chose to support HAART adherence as an expression of faith will then be able to convey that opinion to the HIV-positive pregnant women whom they counsel. The Zambian MoH and CHAZ have identified a need for this type of research and subsequent programming. Both have committed to continuing on with the *LIFT My HAART* initiative and carry out additional trainings and follow-up in the years to come.

Projected *LIFT My HAART* Study and Program Implementation Guideline



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Appendix A: RFP

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Mental Health (NIMH) National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	**Strengthening Adherence to Antiretroviral-Based HIV Treatment and Prevention (R21)**
Activity Code	R21 Exploratory/Developmental Research Grant
Announcement Type	New
Related Notices	• NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015) • NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015) • NOT-OD-16-011 - Implementing Rigor and

	Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015) • June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same.
Funding Opportunity Announcement (FOA) Number	**PA-14-125**
Companion Funding Opportunity	PA-14-126, R01 Research Project Grant
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.242, 93.856
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) encourages research to understand and promote adherence to antiretroviral (ARV) regimens for HIV treatment and prevention. Studies addressing pre-exposure prophylaxis (PrEP) and antiretroviral therapy (ART) are the foci of this FOA. The overarching emphasis is on the development of feasible interventions to improve and sustain

	PrEP or ART adherence which could be rapidly implemented in clinical, community, and policy environments to improve HIV treatment and prevention outcomes. The R21 mechanism is specifically intended to encourage new exploratory and developmental research projects. These studies should break new ground or extend previous discoveries toward new directions or applications. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel methodologies, tools, technologies, or interventions that could have an important impact on adherence research or practice. Unlike applications under the R01 mechanism, preliminary data are not required for R21 applications. Preliminary data may nonetheless be included if available.

Key Dates

Posted Date	February 28, 2014
Open Date (Earliest Submission Date)	April 7, 2014
Letter of Intent Due Date(s)	Not Applicable
Application	Standard AIDS dates apply, by 5:00 PM local

Due Date(s)	time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Standard AIDS dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	January 8, 2017
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The R21 mechanism is specifically intended to encourage new exploratory and developmental research projects. These studies should break new ground or extend previous discoveries toward new directions or applications. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel methodologies, tools, technologies, or interventions that could have an important impact on adherence research or practice. Unlike applications under the R01 mechanism, preliminary data are not required for R21 applications. Preliminary data may nonetheless be included if available.

Purpose

This Funding Opportunity Announcement (FOA) encourages research to understand and promote adherence to antiretroviral (ARV) regimens for HIV treatment and prevention. Studies addressing pre-exposure prophylaxis (PrEP) and antiretroviral therapy (ART) are the foci of this FOA. The overarching emphasis is on the development of feasible interventions to improve and sustain PrEP or ART adherence which could be rapidly implemented in clinical, community, and policy environments to improve HIV treatment and prevention outcomes.

A well-articulated theoretical or conceptual framework is essential in all applications submitted under this announcement. Approaches based on basic behavioral and social scientific concepts such as cognition, emotion, motivation, communication, developmental approaches, social interaction, decision-making, behavioral economics, and structural models are invited. Any descriptive studies should be undertaken with the aim of informing the design or mechanisms of adherence interventions. Interventions should be appropriately tailored to relevant U.S. domestic and foreign populations, and may target individuals, providers, social networks, healthcare clinics, communities, or other groups.

In HIV treatment, ART adherence represents one element of the wider HIV care continuum. Research applications primarily addressing aspects of the HIV care continuum other than ART adherence, such as HIV diagnosis and care engagement, may consider the priorities identified in PA-14-130, and PA-14-132 "Accelerating Improvements in the HIV Care Continuum."

Background

Antiretroviral drugs have spurred numerous breakthroughs in HIV treatment and prevention. The advent of highly active combination ART was a profound turning point that has effectively transformed HIV disease from a fatal disease to a chronic manageable condition in settings where treatment is widely available. The estimated average life-expectancy for individuals who receive timely ART initiation and maintain long-term viral suppression now approaches that of individuals uninfected with HIV.

Antiretroviral drugs have driven a historic expansion of proven HIV prevention strategies in recent years. The landmark HPTN 052 trial determined that HIV transmission risk in serodiscordant couples decreased by 96% through early provision of ART to seropositive partners. A set of large-scale trials conducted with many thousands of participants throughout the world have proven oral and topical antiretroviral PrEP to be safe, well-tolerated, and efficacious for preventing HIV infection.

Achieving maximal benefit from antiretroviral-based HIV treatment and prevention requires excellent adherence. Adherence has been defined as the extent to which patients take medications as prescribed by their health care providers. Although adherence is frequently used as a synonym for medication dose-taking, the construct of adherence is multidimensional. The primary elements of medication adherence behavior are initiation (starting a recommended regimen), implementation (executing the prescribed regimen), and persistence (length of time before discontinuation). Patient implementation of ARV regimens is commonly assessed in terms of the percentage of prescribed doses taken, but it has also been examined in terms of dose-timing, patterns of dose-taking, and brief treatment interruptions.

The determinants of medication adherence behavior are considered multidimensional as well. The World Health Organization (WHO) has categorized medication adherence determinants into factors related to patients, drug regimens, medical conditions, health systems, and social/economic influences. These five domains present a range of opportunities for the development of discrete and combined interventions to support adherence.

Adherence research in HIV treatment and prevention must be addressed distinctly but can inform one another. Scientists and practitioners addressing ART adherence have made significant gains in recent years, but critical gaps remain in our knowledge and abilities for supporting ART adherence. Now that research breakthroughs have expanded the populations to whom ARV-based treatment and prevention is offered, research is additionally needed to create appropriate interventions that support adherence in these new paradigms (e.g., PrEP, treatment as prevention).

Research Scope

This FOA identifies research priorities intended to strengthen adherence to ARV-based HIV treatment and prevention. This review of priority areas is neither comprehensive nor restrictive; it is offered to stimulate critical thinking and innovative approaches on ARV adherence.

PrEP Adherence

Importance of PrEP adherence. The outcomes from major PrEP trials have individually and collectively demonstrated a strong dose-response relationship between greater adherence and reduced HIV transmission. Among trial participants receiving active drug, those evidencing adherence through drug concentration assays achieved notably greater prevention benefits than those who did not. Effective efforts to promote and sustain PrEP adherence should therefore help optimize its preventive impact.

PrEP is intended for use in key populations at high risk for HIV infection, and for time-limited use among particular individuals during intervals of risk. Key populations for further research on PrEP and PrEP adherence in US domestic and international settings include:

- Gay men and men who have sex with men (MSM);
- Heterosexual women;
- HIV serodiscordant couples;
- Transgender individuals;
- Sex workers.

Adequacy of PrEP adherence. Inadequate study product adherence contributed to early discontinuation of certain PrEP trials. Although randomized placebo-controlled trials provide a different context for adherence compared to open-label use of a proven drug, trials indicating low to modest product adherence have raised questions about the potential adequacy of PrEP adherence under less-controlled conditions. Demonstration projects are underway to investigate PrEP uptake, adherence, and persistence in real-world use by key populations. Priority research in this area includes:

- Studies designed to characterize rates and patterns of PrEP uptake, adherence, and persistence under open-label use.
- Research to advance scientific understandings about PrEP adherence requirements for reducing HIV transmission risk, and how to effectively communicate these understandings in the course of PrEP delivery.
- Studies that aim to help individuals and clinicians make informed decisions regarding intervals when PrEP initiation and discontinuation is indicated, based upon HIV risk.

Assessment and monitoring of PrEP adherence. Apart from drug concentrations, PrEP lacks a ready biomarker associated with behavioral adherence that is analogous to viral load in HIV treatment. Prevention trial data have raised questions about the validity of adherence measures such as self-report and pill counts in trial settings. In the context of clinical care, feasible and valid approaches for monitoring PrEP adherence are needed to address clinical guidelines emphasizing regular adherence monitoring and to identify individuals needing additional support for adherence. There is an additional challenge of examining PrEP adherence concurrently with risk behavior, since PrEP will not have preventive utility unless its use appropriately encapsulates risk behavior. Priority research in this domain may include:

- Research that provides clinicians with feasible and effective methods for monitoring patient adherence to PrEP in open-label use.
- Studies to test technologies or assays that facilitate prospective or "real-time" monitoring of PrEP adherence.
- Research examining patterns of PrEP adherence in relationship to patterns of risk behavior.

Determinants of PrEP adherence. Scant knowledge exists regarding PrEP use outside of the context of closely controlled, randomized double-blinded trials. Trial findings indicate a number of individual-level adherence determinants including age, alcohol use, and sexual activity. Perceived risk has been proposed as a driver of PrEP uptake and adherence, and relationship factors and social support may also have a role to play. Research designed to advance scientific understandings of determinants of open-label PrEP uptake, adherence, and persistence will be critical to developing effective adherence interventions that will strengthen its preventive impact. Related work includes:

- Research to assess determinants of PrEP adherence and persistence in key populations.
- Studies examining the role of perceived risk as a motivator and determinant of PrEP uptake, adherence, and persistence.
- Research to understand multilevel determinants of PrEP adherence, including individual, provider, and healthcare system factors.

Interventions for PrEP adherence. Proven interventions to promote and sustain adherence to PrEP are entirely lacking at this time. The strong relationship between PrEP adherence and PrEP efficacy means that efforts that promote and sustain PrEP adherence should help limit new infections among PrEP users. In an adherence sub-study nested within the Partners PrEP trial, electronically monitored adherence was nearly-perfect (~99%) under conditions where adherence counseling was provided to individuals evidencing <80% adherence during unannounced pill counts; at this exceptionally high adherence level no HIV infections were observed among individuals receiving active drug and 14 infections were found among those receiving placebo.

PrEP adherence interventions are likely to be delivered in conjunction with risk-reduction counseling, HIV testing, and other clinical monitoring accompanying PrEP. Among many possible approaches, the development of technologic approaches to monitor PrEP adherence and help deliver adherence support could be highly beneficial. Studies to develop and test PrEP adherence interventions will include, but are not limited to:

- Research to develop and test interventions to promote and sustainPrEP adherence. To assure sound measurement and triangulation of intervention effects, PrEP adherence intervention trials should whenever possible include (1) a self-report measure of adherence, (2) at least one additional non-self-report measure of adherence (e.g., pharmacy refill, electronic monitoring, unannounced telephone pill counts, etc.), and (3) a biomarker expected to be affected by changes in adherence behavior (e.g., drug concentrations).
- Research to integrate PrEP adherence and behavioral risk reduction counseling for PrEP users.
- Studies designed to improve adherence to PrEP regimens as well as other guidelines for PrEP use such as regular HIV testing and clinical monitoring.
- Studies testing technology-based or -enhanced interventions to support PrEP adherence and persistence.
- Studies to improve peer-, couple-, social network-, or community-based social support for PrEP use and adherence.
- Research to develop and test interventions that improve awareness, address misconceptions, or target structural barriers regarding PrEP use to facilitate uptake when indicated.

ART Adherence

Importance of ART adherence. Striving to achieve and maintain the highest possible level of ART adherence remains important for optimizing HIV treatment outcomes. Among many factors that can influence ART treatment success or failure, research has long identified adherence as a central determinant of viral suppression, improved CD4+ T-cell count, delayed progression to AIDS, and patient survival. Although the development of highly potent and boosted drug regimens may allow viral suppression despite imperfect ART adherence, adherence remains strongly predictive of viral suppression and long-term mortality even with contemporary antiretroviral regimens. There are indications that the relationship between ART adherence and risk of virologic failure may vary by drug class and can evolve in the context of durable viral suppression, and the significance of different forms of adherence behavior may vary over the course of treatment as a result.

Adequacy of ART adherence. Meta-analyses indicate that ART adherence remains sub-optimal in many patient groups and regions around the world. In the US, large patient samples evidence disparities in ARV initiation, adherence, and viral suppression along racial/ethnic, age, and gender lines. In sub-Saharan Africa, brief interruptions of ARV treatment adherence have been observed and predict the development viral failure.

Assessment and monitoring of ART adherence. There remains no gold standard for behavioral assessments of ARV adherence. Many assessment methods have been examined in the context of HIV treatment, including self-reports, pharmacy refill, announced and unannounced pill counts, and electronic drug monitoring. The validity and precision of these tools vary, and each contains advantages and disadvantages. Any assessment approach for ART adherence would be made more useful if it could be configured to systematically provide prospective or real-time monitoring of adherence behavior. Routine monitoring of ART adherence could empower patients through timely feedback, and could offer healthcare providers actionable information for the delivery of targeted adherence support interventions. Related studies may include:

- Studies to test technology-assisted monitoring approaches that provide feedback loops to patients regarding their ART adherence and triage those demonstrating persistent non-adherence to adherence support interventions.
- Research testing technology-delivered or assay-based point-of-care ART adherence assessments to facilitate targeted delivery of interventions to individuals in need of adherence support.
- Studies to develop and test predictive models that use monitored ART adherence levels, patterns, and other factors to produce actionable information regarding the future likelihood that a given individual may experience viral failure.

Determinants of ART adherence. The conduct of formative research and the articulation of theoretical models are critical for designing effective adherence interventions. Theory-based and empirical studies have elaborated many important determinants of adherence to ART, particularly within general clinic populations in highly developed countries, and primarily at the level of patient- and regimen-related factors. Fewer studies have systematically investigated various social-contextual, healthcare system, and structural factors, despite evidence that ART adherence can be affected by factors such as care team composition, food insecurity, and experiences of discrimination and stigma. Further research to understand social and structural determinants of ART adherence in both domestic and international settings will be needed to inform the design and mechanisms of novel adherence interventions. Priority research in this domain may include:

- Research to understand novel determinants of ART treatment adherence and persistence.
- Research to understand how the "treatment as prevention" concept may influence ART treatment uptake and adherence in key populations.
- Studies to understand factors contributing to disparities in ART adherence and treatment outcomes along racial/ethnic, age, and/or gender lines.
- Studies to understand provider, clinic, healthcare system, and other structural factors that may impact ART treatment adherence.
- Descriptive studies to inform the development of ART adherence interventions for resource-limited care settings.

Interventions for ART adherence. Regimen simplification has benefitted ART adherence but has not eliminated the challenge. Further studies are needed to expand available interventions to support ART adherence and enhance their efficacy. Research to date has generated a small but growing set of interventions with demonstrated efficacy in improving ART adherence. The US Centers for Disease Control and Prevention (CDC) maintains a list of rigorously-tested and evidence-based ART medication adherence interventions for dissemination here. Documented intervention effects to date have generally been modest and with greater impact on behavioral adherence than viral load. Key research gaps exist in the development and testing of interventions addressing youth living with HIV, interventions in resource-limited settings globally, and structural and systems-level interventions with broad impact on ARV treatment adherence.

ART adherence intervention trials should be mindful of rigor and should assess impact on both behavioral adherence and biological outcomes such as viral suppression. Related research will include, but is not limited to, the following:

- Research on novel ART adherence interventions designed to achieve a strong and sustained impact on behavioral adherence and biologic treatment outcomes. To assure sound measurement and triangulation of intervention effects, ART adherence intervention trials should include (1) a self-report measure of adherence, (2) at least one additional non-self-report measure of adherence (e.g., pharmacy refill, electronic monitoring, etc.), and (3) a biomarker expected to be affected by changes in adherence behavior (e.g., viral load, drug concentrations).
- Studies that implement adherence interventions in response to prospective monitoring of adherence behavior.
- Research using behavioral economic approaches to encourage or incentivize adherence and/or viral suppression.
- Adherence intervention research that targets depression and mental health as important co-factors related to ART adherence.
- Studies to develop and test approaches for improving ART adherence and treatment outcomes by addressing upstream social and structural determinants (e.g., economic factors, food security, HIV stigma).
- Research to develop and test interactive computer/tablet, internet, smart-phone, or other technology-based or technology-enhanced adherence interventions designed to augment outpatient HIV clinic capacity to address ART adherence with patients.
- Research designed to evaluate clinic-level or systems-level approaches to patient antiretroviral adherence.

Key populations and junctures to be targeted by ART interventions may include but are not limited to:

- Research to develop and test ART adherence interventions delivered within the first year following ARV initiation, to improve treatment outcomes and establish a strong foundation for a lifetime of ARV adherence.
- Research to develop and test culturally appropriate HIV treatment adherence interventions among racial and ethnic groups evidencing disparities in ART adherence and HIV treatment outcomes.
- Studies to develop and test culturally appropriate interventions for supporting ART adherence within resource constrained settings globally.
- Studies to improve ART adherence among women in the post-partum period.
- Studies on interventions designed to improve ART adherence among children and adolescents.
- Research on ART adherence intervention approaches for people coping with co-morbid conditions that may complicate ART adherence, such as depression.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Resubmission Revision The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.
Award Project Period	The total project period may not exceed 2 years.

NIH grants policies as described in the *NIH Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct

eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

NIH will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months (as described in the *NIH Grants Policy Statement*), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements

in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, required and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date. If a Changed/Corrected application is submitted after the deadline, the application will be considered late.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement*.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

> **Important reminders:**
> All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.
>
> The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.
>
> See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

NEW Important Update: See NOT-OD-16-006 and NOT-OD-16-011 for updated review language for applications for due dates on or after January 25, 2016.

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3)Genome Wide Association Studies (GWAS).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate National Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.

- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement*.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements as noted on the Award Conditions and Information for NIH Grants website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the annual Non-Competing Progress Report (PHS 2590 or RPPR) and financial statements as required in the *NIH Grants Policy Statement*.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available atwww.fsrs.gov on all subawards over $25,000. See the *NIH Grants Policy Statement* for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Finding Help Online: http://grants.nih.gov/support/index.html

TTY: 301-451-5939
Email: commons@od.nih.gov

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact CenterTelephone: 800-518-4726

Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone: 301-435-0714
TTY: 301-451-5936
Email: GrantsInfo@nih.gov

Scientific/Research Contact(s)

Michael J. Stirratt, Ph.D.
National Institute of Mental Health (NIMH)
Telephone: 240-627-3875
Email: stirrattm@mail.nih.gov

Vanessa Elharrar, M.D.
National Institute of Allergy and Infectious Diseases (NIAID)

Telephone: 240-292-4787
Email: elharrarva@niaid.nih.gov

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Rita Sisco
National Institute of Mental Health (NIMH)
Telephone: 301-443-2805
Email: siscor@mail.nih.gov

Ann Devine
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: (240) 669-2988
Email: adevine@niaid.nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Appendix B: External Reviewer Form

External Reviewer Template

Grant Proposal Thesis - External Reviewer Feedback Template

Please use this template as a basis for providing feedback on the grant proposal you are reviewing to the student PI.

1. Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
○	○	○	○	○

2. How could the submission have been more responsive to the call for proposals?

3. Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
○	○	○	○	○

4. What improvements could be made to the theory and structure of the proposal?

5. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
○	○	○	○	○

6. What would have improved the argument that the proposed activities are necessary?

7. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
○	○	○	○	○

8. What changes would improve the perceived feasibility of the proposed activities?

9. Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
○	○	○	○	○

10. What changes would improve the perceived feasibility of the proposed activities?

What additional comments and suggestions do you have for the