STUDY PROTOCOL

Uptake of Voluntary Medical Male Circumcision among Men Attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi

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Uptake of Voluntary Medical Male Circumcision among Men attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi

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3 LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
AIM	Acceptability of Intervention Measure
ANOVA	Analysis of Variance
BSC	Bwaila STI Clinic
EMR	Electronic Medical registry
FGD	Focus Group Discussion
FGHF	Fogarty Global Health Fellowship
FIM	Feasibility of Intervention Measure
GHE	Group Health Education
HCWs	Healthcare Workers
HIV	Human immunodeficiency Virus
HTS	HIV testing Services
IDI	In-depth Interview
IHE	Intensified Health Education
LDH	Lilongwe District Hospital
LMICs	Low and Middle-Income Countries
MoH	Ministry of Health
NHSRC	National Health Sciences Research Ethics Committee
NIRN	National Implementation Research Network
ODK	Open Data Kit
PEPFAR	President's Emergency Plan For AIDS Relief
PrEP	Pre-Exposure Prophylaxis
RITE	Re-imbursement, Intensified health education, cell phone Tracing and Escorts
SE Africa	Southern and Eastern Africa
SEM	Structural Equation Modelling
SMS	Short Messaging Service
SOC	Standard of Care
STIs	Sexually Transmitted Infections
UNAIDS	The Joint United Nations Program on HIV and AIDS
UNC IRB	University of North Carolina Institutional Review Board
VMMC	Voluntary Medical Male Circumcision
WHO	World AIDS Organization
WITS HREC	University of Witwatersrand Human Research Ethics Committee

4 DEFINITIONS

Acceptability: the perception among men and healthcare workers that the adaptable RITE intervention is agreeable, palatable and satisfactory.

Appropriateness: the perceived fit of the adaptable RITE intervention to address the problem of low uptake of VMMC among men and healthcare workers.

Clinic escort: the act of escorting/accompanying a participant interested in VMMC from the STI clinic to the VMMC clinic to ensure linkage to care.

Contamination: a situation where the study population become exposed to more than one intervention component

Feasibility: the extent to which the adaptable RITE intervention will be successfully carried out at Bwaila STI clinic.

Intensified health education: consistent and setting-specific education on VMMC incorporated into the routine STI/HIV health education provided at Bwaila STI clinic.

Interference: a scenario where other stakeholders implement an intervention(s) aimed to scale-up the uptake of VMMC at the study sites which may affect attribution.

Seasonality: periodic variation in the uptake of VMMC with calendar time

SMS reminder tracing: the act of reminding participants with a VMMC appointment about their date of procedure through short messaging service.

Time-to-uptake: the number of days from the day a participant is offered VMMC to the day they undergo VMMC

Transport reimbursement: refunding money used for transportation to Bwaila district hospital for participants who undergo VMMC using standard Malawi government rates.

Uptake: the action of undergoing VMMC.

5 INTRODUCTION

5.1 Background Information

Human Immunodeficiency Virus (HIV) infection remains a huge public health burden globally. In 2018, approximately 36.9 million people were living with HIV infection and there were about 940,000 AIDS-related deaths worldwide [1]. In the past decade, the decline in new HIV infections among adults slowed down and has remained static at about 1.9 million people per year world-wide in recent years [2]. Southern and Eastern (SE) Africa is the world's most affected region, accounting for 44% of new infections and with about 52% of the people living with HIV residing in this region [3]. While some countries in the region, such as Uganda and Mozambique, have made great progress in reducing new HIV infections in adults, some, such as Lesotho have been less successful [4]. In Malawi, the HIV prevalence among adults was 9.2% in 2018 [5]

In 2014, the Joint United Nations Program on HIV and AIDS (UNAIDS) developed the fast-track target to reduce the number of global new annual HIV infections among adults to fewer than 200,000 and, in 2016, revised the target to end AIDS as a public health threat by 2030 [2]. As part of achieving this ambitious global plan, UNAIDS called for scale-up of combination prevention strategies [2]. Combination prevention approaches promote simultaneous use of complementary biomedical, behavioral and structural strategies and can be implemented at individual, community and population levels as they are amenable to setting-specific factors such as culture, infrastructure and populations most affected by HIV [2]. One of the immediate goals for UNAIDS is to ensure access to combination prevention options which include pre-exposure prophylaxis, voluntary medical male circumcision (VMMC), harm reduction and condom use to

at least 90% of people by 2020 [6]. However, as the number of new HIV infections remains static at 1.9 million people per year [1], progress in HIV prevention is off-track, highlighting the need for innovative ways to scale-up combination prevention strategies.

One of the existing biomedical prevention methods that is under-utilized in SE Africa is voluntary medical male circumcision [3]. The coverage of VMMC in the region remained below 30% in 2016 compared to other HIV prevention methods such as condom use (83%), HIV testing (76%) and prevention of mother-to-child transmission (89%) [2].

In the mid-2000s, VMMC was confirmed to reduce the risk of HIV transmission by 60% during unprotected heterosexual sex [7]. Three randomized controlled trials in South Africa, Kenya and Uganda contributed overwhelming evidence that VMMC significantly lowers the rate of HIV transmission [8–10]. Consequently, in 2007 the World Health Organization (WHO) and UNAIDS recommended VMMC as a part of the comprehensive HIV prevention strategy for high HIV prevalence and low male circumcision areas – where the greatest public health impact would be realized [11]. As a result, 15 countries in SE Africa, including Malawi, were identified by UNAIDS and WHO as priority countries for expansion of VMMC activities for HIV prevention [2].

Since 2008, VMMC activities for HIV prevention increased in SE Africa [3]. This resulted in an increase in cumulative VMMCs performed between 2008 and 2015. However, by 2016, the coverage of VMMC remained below 30% across the region [3]. In 2016, UNAIDS and WHO set a target to reach 90% of males of 10-29 years in the priority countries with VMMC by 2021 - a target not easy to reach [2].

In Malawi, after several years of debate, VMMC was adopted as a HIV prevention strategy in

2012. The prevalence of male circumcision among men aged 15-49 years was 28% in 2016 with only 9% being medical circumcision and 18% traditional circumcision [12]. This coverage is far below the 80% regional target and 60% national target [2,12]. In fact, Malawi has one of the lowest VMMC coverage rates among the priority countries [13]. Since 2008, there has been an increase in the number of VMMCs performed through the Ministry of Health (MoH) VMMC program with support from the President's Emergency Plan for AIDS Relief (PEPFAR), however coverage and uptake have remained low. About 157,504 circumcisions were performed between 2008 and 2014 representing 8% of the target population [14]. Lilongwe, the capital city of Malawi also a PEPFAR supported district, has one of the highest HIV prevalence rates and lowest national circumcision coverage rates (14% in 2015) [2].

Despite the low coverage and uptake of VMMC, early acceptability studies in Malawi showed that VMMC was acceptable among certain communities [15] and recent data show favorable results across different settings in Malawi [16,17]. Some of the most common factors reported to deter men from undergoing VMMC in Malawi include low HIV risk perceptions, especially among older men; fear of pain; lack of support from partner or parent or peers; a preference for traditional circumcision as part of culture in some communities; fear of complications including bleeding, impotence and infections; religious influence; costs associated with accessing VMMC; lack of knowledge on medical benefits of VMMC including myths and misconceptions and unwillingness to be attended to by female healthcare providers [16,18–23].

Carrasco and colleagues conducted a study in three high HIV prevalence districts in southern Malawi and found that only 8% of high-risk group of men accessed VMMC services [13]. Men attending STI clinics are a high-risk population because sexually transmitted infections (STIs) increase the risk of HIV acquisition and transmission by three-fold or more [24]. STI clinics in

Malawi have high HIV prevalence estimated at around 19% in 2018 [25] and low VMMC rates 28% [26]. In the STI setting, VMMC is not only protective against HIV but also against curable STIs [24]. In view of this background, increasing the coverage and uptake of VMMC in men attending STI clinics could potentially result in a greater impact, making STI clinics an ideal setting for scale-up of VMMC services.

Therefore, in an attempt to address the factors outlined above in order to increase the demand and uptake of VMMC, this study proposes to use an adaptable intervention comprising four intervention components that include transport reimbursements **(R)**, intensified health education **(I)**, SMS reminder tracing **(T)** and clinic escorts **(E)** – coined as the **RITE** intervention. This intervention was developed based on literature. Details of the intervention have been outlined in the methods section below.

5.2 Problem statement

Since the inception of VMMC, many countries have fallen below targets resulting in the new fast-track target - to have 90% of males of 10-29 years in priority countries circumcised by 2021 [2]. To achieve this goal, there is need to intensify current efforts and to develop novel strategies in the implementation of VMMC programs [4]. In Malawi, despite efforts to increase the supply of VMMC services in order to improve national coverage, the demand/uptake has remained low [2]. The low demand/uptake poses a great risk of continued HIV and STI transmission.

UNAIDS recommends prioritizing VMMC to sub-populations (for example by age or risk level) to maximize its impact and efficiency [2]. One such sub-population is men attending STI clinics who may have symptomatic or asymptomatic STIs. The Malawi STI guidelines stipulate that VMMC should be offered to all male uncircumcised STI clients, however, this population has

not been prioritized [27]. Recently, the Malawi VMMC program introduced a mobilizer to STI clinics who conduct health education talks on VMMC every morning, however MC rates have continued to remain low – estimated at 28% [26]. Finally, the lack of knowledge on medical benefits of VMMC among the general population may translate to a lack of knowledge on the same among men at STI clinics, which may pose as a major barrier for the demand for VMMC in this population [16,18–23]. In addition, time from when men are offered VMMC to when they undergo the procedure is not well studied and documented. We hypothesize that uptake of VMMC will be higher within the first seven days of exposure to intervention. Obtaining insight on this would help with the design of interventions and programs and the period needed to sustain intervention or program exposure.

Justification

Despite VMMC being a primary focus of the HIV prevention in Malawi, uptake has been far below expected levels due to varied reasons since its inception in 2012. Some of the common reasons include perception of low HIV risk especially among older men, lack of knowledge on medical benefits of VMMC, lack of support from partners or parents or peers and fear of pain and complications of VMMC. Further, the uptake of VMMC has been much lower in men presenting to health facilities with STIs – a high-risk group for HIV acquisition and transmission. Currently, published data on coverage and uptake of VMMC among STI clients in Malawi is unavailable. Further, there are no registered trials of novel strategies for improving the implementation of the VMMC program among men attending STI clinics in Malawi. This study aims to evaluate the RITE implementation intervention implemented systematically to increase the demand and uptake of VMMC among men attending a STI clinic in Lilongwe Malawi.

5.3 The conceptual framework

Creating demand for VMMC is a key strategy for improving uptake in the priority countries [2]. This study is anchored on the theory that knowledge is an integral component of perceptions and that perceptions are a major determinant of behavioral change [28].

Overall, our framework aims to increase the demand of VMMC by first developing insight on the factors that influence decision making whether or not to undergo VMMC among men attending STI clinics then develop health education content and to inform possible modification of the linkage-to-VMMC approaches based on these factors.

Sgaier et al's (2015) framework for demand generation [29], Maibvise and Mavundla (2019) model to promote the uptake of male circumcision [28] and the National Implementation Research Network (NIRN) stages of implementation (2010) by Fixsen et al [30] form the conceptual framework for this study (Figure 1). Sgaier et al's framework focuses on developing insight into reasons for low demand for VMMC in subpopulations and developing innovative solutions to the identified reasons and Maibvise et al's model conceptualizes the processes through which health care workers can promote the uptake of VMMC as an HIV-preventive method in high HIV prevalence and low circumcision settings. NIRN provides a set of systematic stages through which the implementation of an intervention should follow.

The main features of the framework are related and are in two iterative steps. The two steps illustrate the transition from improved demand towards improved uptake of VMMC.

Steps of the conceptual framework: The overall approach for this study will be in two steps detailed below:

Step A: Insight Development, Exploration and Installation–

The aim of this step is to develop insight on the factors that influence decision making for circumcision among men in STI clinics. This step was guided by Sgaier et al's, and Maibvise and Mavundla's frameworks; and have been combined with the exploration and installation stages of the NIRN framework.

To develop insight, we will conduct key stakeholder consultations. Key stakeholders will include the ministry of health VMMC program, the Centers for Disease Control (CDC) VMMC program, Population Services International (PSI) VMMC program, Johns Hopkins Program for International Education in Gynecology and Obstetrics (Jhpiego) and healthcare workers at Bwaila VMMC clinic and STI clinic. The aim of the meeting will be understand the views of men of VMMC from the experts and identify the best way to conduct health education and the appropriate content to include in health education material in a STI clinic setting. This is the NIRN 'exploration' stage.

The identified factors will inform the development of health education material for demand creation and the best way to deliver the material. Education sessions will be interactive to allow a continuum of insight development and improvement processes. Sustained education is aimed to create a sustained social support system for the men, from peers and sexual partners. Healthcare workers and Bwaila STI clinic and VMMC clinic will be trained on the final intervention. This is the NIRN 'installation' stage.

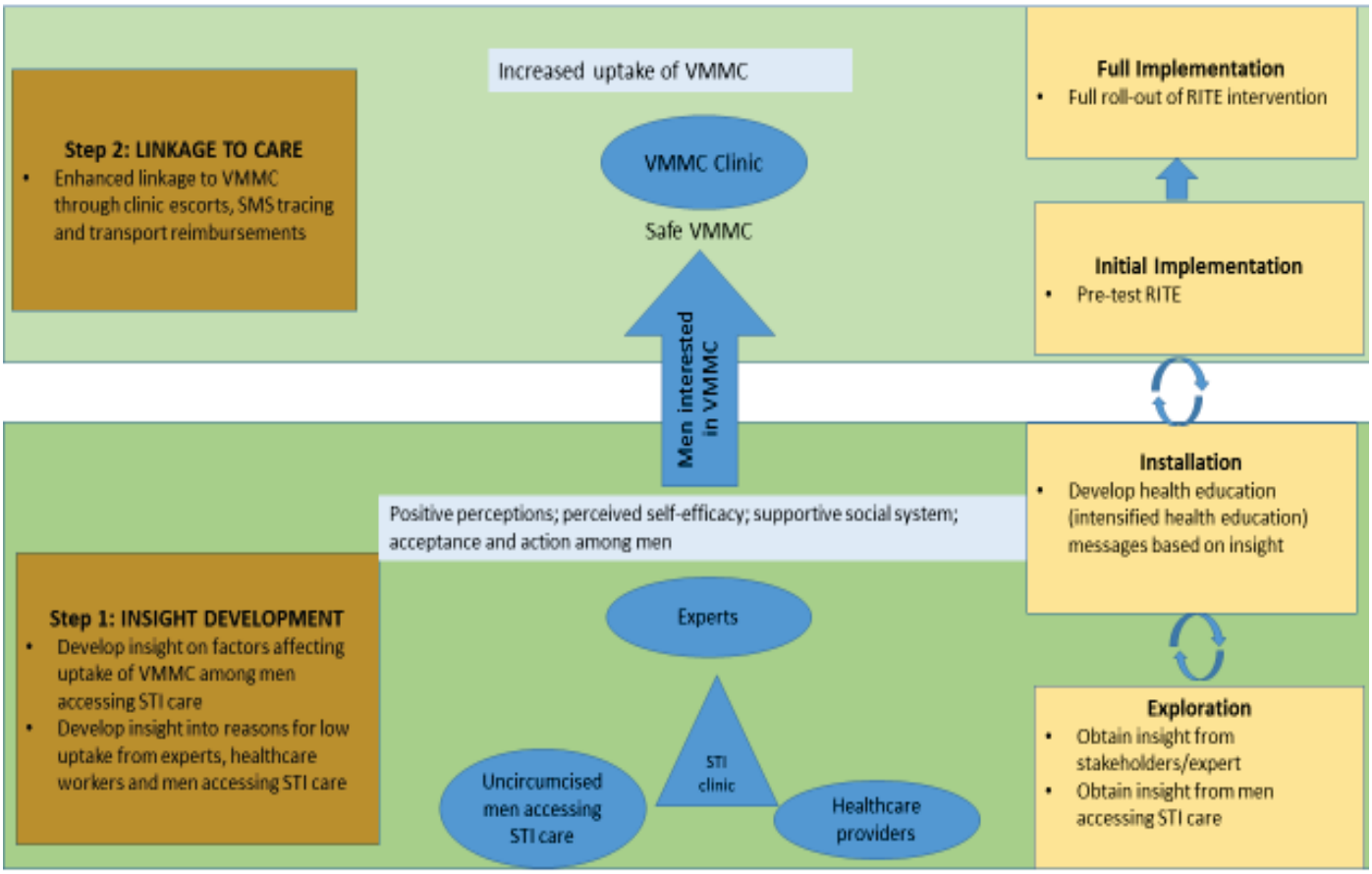

Figure 1: Conceptual Framework for Scale-up of VMMC - Adapted from Maibvise, 2019, Sgaier 2015 and Fixsen 2010

Step B: Linkage to care, Initial Implementation and Full Implementation

The aim of this step is to improve uptake of VMMC by improving linkage and access to VMMC. Healthcare workers (HCW) at the STI clinic will facilitate access and utilization of safe VMMC services using different intervention components. However, before fully implementing the intervention, we will pilot the intensified health education among men and healthcare workers

delivering the education. This is the 'initial implementation' stage of the NIRN framework. Once our intervention is piloted, we will proceed with full implementation, the final NIRN stage.

5.4 Study Objectives

5.4.1 Main Aim

The aim of this study is to evaluate the RITE intervention for improved uptake of VMMC among men attending Bwaila STI clinic in Lilongwe, Malawi between May 2020 and October 2020.

5.4.2 Specific objectives

1. To compare uptake of voluntary medical male circumcision between the RITE intervention and the standard of care among men attending Bwaila STI clinic in Lilongwe Malawi
    a. To compare time-to-uptake of voluntary medical male circumcision between the RITE intervention and the standard of care among men attending Bwaila STI clinic in Lilongwe Malawi
    b. To assess factors affecting uptake of voluntary medical male circumcision among men attending Bwaila STI clinic in Lilongwe Malawi
2. To develop STI clinic setting-specific voluntary medical male circumcision educational material at Bwaila STI clinic in Lilongwe Malawi
3. To assess the acceptability, appropriateness and feasibility of the RITE intervention among men and healthcare workers at Bwaila STI clinic in Lilongwe, Malawi.

a. To assess the acceptability and appropriateness of the RITE intervention among men at Bwaila STI clinic in Lilongwe, Malawi

6 METHODOLOGY

6.1 Study design

This is a pragmatic, pre- and post-interventional quasi-experimental study combined with a prospective observational study design. The primary aim is to determine the effectiveness of the RITE intervention in increasing the uptake of VMMC at Bwaila STI clinic. The implementation science aim is to determine the potential utility (feasibility, acceptability and appropriateness) of RITE intervention in an STI clinic setting [31]. We will use a sequential mixed methods approach, starting with formative qualitative study to refine the proposed intervention (RITE), followed by a pragmatic, mixed-methods quasi-experimental study with one pre-exposure and four distinct exposure groups [7]. This stand-alone intervention will be implemented at a practical STI clinic setting without random allocation to the intervention. We will observe for the standard of care (SOC) in the pre-intervention phase and introduce our intervention in a step fashion of different intervention combinations with four different intervention groups. This approach will allow us to assess the effect of the intervention while assessing the effect of different combinations of the intervention components, building up to the full intervention. Since the STI clinic is an outpatient clinic and STIs are generally acute infections that resolve quickly with treatment, it is not possible to randomize intervention components and follow the same participants over time as a cohort hence the different exposure groups. The key outcome of interest, VMMC uptake, will be measured at the VMMC facility.

6.2 Study setting

The study setting is the Bwaila STI Clinic (BSC) and Bwaila VMMC clinic at Bwaila District Hospital (BDH). BDH is a public secondary level facility in Lilongwe and the only facility offering specialized STI care situate in a busy central town area of the Lilongwe district. Approximately 80 patients visit BSC per day. The VMMC clinic and BSC are about 300 meters apart within the BDH campus. Twenty (20) people comprising nurses, clinicians, HIV testing services (HTS) counsellors, receptionists and support staff run BSC. As standard of care, all STI patients at BSC receive group health education (GHE) and are offered opt-out provider initiated HIV testing as standard of care, before receiving care for their STIs. We propose to integrate intensified health education to the GHE. About two to three GHE sessions are conducted per day with different cohorts of patients based on their time of arrival at the clinic however only one GHE includes education on VMMC. The clinic receptionist assisted by a nurse or counsellor conducts GHE. The first GHE session includes a mobilizer from the VMMC clinic who conducts an educational talk on VMMC every morning at the STI clinic and refers men to the VMMC clinic using referral slips. The additional GHE sessions do not have educational talks by the mobilizer. We will train the clinic receptionist, counselors, nurses and the mobilizer to conduct intensified health education. As standard of care, uncircumcised men with STIs are supposed to be offered VMMC at the STI clinic by clinicians however this is not reinforced. Data on demographics, HIV testing and treatment, sexual history and STIs are collected routinely through an electronic medical registry.

The VMMC clinic has a director, administrator, program officers, clinicians (male and female), nurses (both male and female), data clerks, mobilizers and support staff. A team consisting of one clinician, an assisting nurse and other support staff conduct circumcisions. Circumcisions are

done at the VMMC clinic and in the community through outreach clinics and mobile vans. Data such as demographics, referral source, date and outcome of VMMC are recorded in registers. We will use these registers to track men referred from the STI clinic who will undergo circumcision. Men attending the STI clinic may either be index cases (symptomatic) or sexual partners (symptomatic or asymptomatic). Men with symptomatic STIs will not undergo VMMC on the same day of their STI clinic visit until they complete treatment for their current STI.

6.3 Study population

The study population is uncircumcised men ≥ 18 years accessing STI care regardless of their HIV status, at Bwaila STI clinic between April and September 2020 in Lilongwe Malawi. The population will also include healthcare workers at Bwaila STI and VMMC clinics and other key stakeholders. The other key stakeholders will MoH VMMC program officials, and the private sector such as the CDC, PSI and Jhpeigo.

6.4 Inclusion Criteria

The inclusion criteria will be as follows:

- Uncircumcised men ≥ 18 years accessing STI care regardless of their HIV status
- Willingness to participate in the study
- Willingness to provide informed consent

6.5 Exclusion criteria

Men with prior exposure to research activities who come for repeat STI visits

6.6 The RITE Intervention

The RITE intervention was developed solely based on literature. As such, based on results from the formative research, the content of the intensified health education will be designed to make it more setting specific.

6.6.1 Composition

The RITE intervention has been guided by the conceptual framework (figure 1) and Powell et al's refined compilation of implementation strategies [32].

Intensified Health Education (I)

Intensified health education will be more consistent and setting-specific education on VMMC incorporated into the routine STI/HIV health education provided at Bwaila STI clinic. Currently, health education on VMMC at Bwaila STI clinic is offered once in the morning session – leaving out patients who come later to the clinic. The health education session combines education on HIV and STIs, usually offered by HIV testing counselor or clinic receptionists, and education on medical circumcision, offered by a VMMC mobilizer from the Bwaila VMMC clinic.

In this PhD study, we intend to make health education more setting specific and delivered better by conducting formative research to understand the views of men on VMMC with emphasis on men accessing STI care. In addition, we intend to intensify the education by conducting additional (more than one educational talk as per current standard) educational talks. The health talks will be delivered at Bwaila STI clinic – the recruitment point. The current format of the educational talks will be maintained but in addition, educational material on medical circumcision will be developed based on results from the formative research. The VMMC

mobilizer including the clinic receptionist and counselors will be trained on the educational material. We anticipate that the content of the health talk may involve the following fundamental information: description of VMMC, medical benefits of VMMC and addressing myths and misconceptions around VMMC among other topics. After the group education, men will be asked of their interest in circumcision individually by counsellors (during standard HIV testing) and clinicians as they receive care at the STI clinic.

Clinic Escorts (E)

Clinic escorts will be the act of escorting/accompanying a participant interested in VMMC from the STI clinic to the VMMC clinic to ensure linkage to care. We propose to use clinic escorts who will accompany men interested in VMMC from the STI clinic to the VMMC clinic to ensure that men are not lost in transit. Men may either undergo same day VMMC (if asymptomatic) or have an appointment for VMMC on a later date if symptomatic or if they have other viable reasons. Escorting patients is beneficial in linkage and retention in care and is policy in varied clinical settings [32]. Clinic escorts will be data clerks and clinic aides.

SMS Tracing (T)

SMS reminder tracing will be the act of reminding participants with a VMMC appointment about their date of procedure through short messaging service. This PhD study proposes to use SMS tracing to remind men who could not have same day VMMC of their appointment for VMMC. The content and frequency of the SMS messages will be guided by the findings from formative research however we have included a modifiable guide of the messages. Cell phone tracing is also a proven strategy for minimizing loss to follow-up and improving retention [33–35]

Transport Reimbursement (R)

Transport reimbursement will be refunding money used for transportation to the Bwaila district hospital for participants who undergo VMMC using standard Malawi government rates. Transport reimbursement equivalent to US$10 as stipulated by the National Health Sciences Research Ethics Committee (NHSRC) in Malawi, will be offered to all men who will undergo VMMC on the day of the procedure to minimize the opportunity cost. Incentives also have been shown to improve many medical outcomes [40, 41]. Eligible men will receive transport reimbursement when they undergo VMMC. Men who cannot have same day circumcision will receive a coupon to present on the day of the procedure for reimbursement. Documentation of the VMMC procedure will be confirmed in the VMMC clinic's procedures register before payment.

6.6.2 Implementation

The implementation will be guided by the NIRN stages of implementation framework.

Exploration

As detailed under the conceptual framework, we will conduct expert consultation meetings with key stakeholders including MoH, CDC, PSI, Jhpeigo and healthcare workers from Bwaila STI and VMMC clinics. The aim of the meeting will be understand the views of men of VMMC from the experts and identify the best way to conduct health education and the appropriate content to include in health education material in a STI clinic setting. This stage may last for one week.

Installation

This stage will be used for developing and endorsing educational material and the delivery methods. Necessary resources for the study will be mobilized. All staff (STI clinic and VMMC

clinic) will be trained by the investigator on the intervention. The clinic receptionist, VMMC mobilizer, counsellors and nurses will be specifically trained on the intensified health education material. This stage will be one week.

Initial Implementation (Pre-test)

This stage will be used to pre-test the intensified health education. We will use the lessons learnt from the pre-test to refine the educational material. This stage will also allow HCWs at the two clinics to internalize the intervention. Support to healthcare workers will be provided through supervision, retraining and constructive feedback. This stage may last about two weeks – one week for pre-testing and another week for making necessary modifications if necessary.

Full implementation

This will be full roll-out of our intervention. The intervention will have four implementation blocks (Appendix 1) that will be different combinations of the intervention components in an incremental manner. There will be one week of no intervention between interventions as a wash-out period. The implementation will be as follows: First we will observe the SOC VMMC referral process. In **block one**, we will introduce IHE which will then be maintained throughout the implementation period. Clinic escorts combined with IHE in **block two**. **Block three**, IHE, clinic escorts and SMS tracing will be combined. In **block four**, all intervention components will be combined including transport reimbursement to form the full intervention. Supportive supervision and constructive feedback will be maintained throughout the implementation period. Based on the sample sizes detailed below, we anticipate that each intervention block will last about 3-4 weeks.

6.1 Sampling

We will use purposive sampling to select experts or stakeholders involved in VMMC programs (MoH officials, HCWs and private sector officials) to attend the consultative meeting. Men who will participate in the surveys and focus group discussions will be purposively recruited and segmented by meaningful characteristics, such as age, marital status, religion or other factors that the experts think are vital. We will also use purposive sampling to select healthcare workers (HCWs) to participate in the in-depth interviews (IDIs) and surveys. No sampling techniques will be required for measurement of uptake of VMMC. The sample sizes and time points of measurements have been outlined in the sections below.

6.2 Data Collection

Overall, we will collect demographic characteristics for our study population. Among men accessing STI care, we will collect demographic data such as age, marital status, educational status and socioeconomic status. Additional data collected may include sexual history, HIV and ART status. Data will be collected using the routine electronic medical registry at Bwaila STI clinic and exported into a Microsoft Excel spreadsheet.

Objective 1: To compare uptake of voluntary medical male circumcision between the standard of care and the different combinations of the RITE intervention among men attending Bwaila STI clinic in Lilongwe Malawi

Uptake in this study will be the action of undergoing VMMC. Uptake of the intervention will be measured for each implementation block. Data on demographic characteristics including contact information, HIV history, sexual history and STI data will be collected for all participants from

the STI clinic using a routine clinical form through the electronic medical registry (EMR) (Appendix 2). We will collect data on the number of uncircumcised men offered VMMC and the number of men referred to the VMMC clinic from the STI clinic using study specific data collection form (Appendix 3). In addition the number of men who underwent VMMC will be collected from routine VMMC clinic registers using a study specific data collection form (Appendix 4). Data clerks and the VMMC mobilizer will collect these data on a daily basis from both clinics. SMS tracing attempts will be collected separately on a study-specific SMS tracing form (Appendix 5). The content of the SMS will be designed during the pre-test but we have included a draft of what the content may include (Appendix 5). The data will be collected and collated daily by a data clerk. Data will be entered into a Microsoft Excel spreadsheet by a data assistant.

Objective 1a: To compare time-to-uptake of voluntary medical male circumcision between the pre- and post-intervention periods among men attending Bwaila STI clinic in Lilongwe Malawi

Time-to-uptake will be the number of days from the day a participant is offered VMMC to the day they undergo VMMC. Data clerks will collect data on the date the participant is offered VMMC from the STI clinic using a study-specific data collection form (Appendix 3) while the date the participant undergoes VMMC will be collected from routine VMMC clinic registers on a daily basis and entered into Microsoft Excel.

Objective 1b: To assess factors affecting uptake of voluntary medical male circumcision among men attending Bwaila STI clinic in Lilongwe Malawi

We will collect data on demographic, sexual and HIV/ART will be collected from the Bwaila STI clinic electronic medical registry and exported to Microsoft excel spreadsheet. Data will be

exported on a weekly basis by a data assistant. We will use these covariates to assess factors affecting uptake of VMMC among men who will undergo VMMC.

Objective 2: To develop STI clinic setting-specific voluntary medical male circumcision educational material at Bwaila STI clinic in Lilongwe Malawi

To achieve this objective, firstly, we will collect data from the consultative meeting with key stakeholders outlined in the above sections as notes. The notes will be collected by the investigator and another note-taker. Data will be analyzed in real-time. The suggested content and delivery methods will be identified. Secondly, we will conduct a pilot of the intensified health education material and methods on men accessing care at Bwaila STI and collect more notes on possible ways to refine intensified health education. Any necessary refinements will be done and the intensified health education material and methods will be endorsed.

Objective 3: To assess the acceptability, appropriateness and feasibility of the RITE intervention among men and healthcare workers at Bwaila STI clinic in Lilongwe, Malawi.

Acceptability will be defined as the perception among men and HCWs that the RITE intervention is agreeable, palatable and satisfactory [36]. **Appropriateness** will be the perceived fit of the RITE intervention to address the problem of low uptake of VMMC among men and HCWs [36]. **Feasibility** will be the extent to which the RITE intervention will be successfully carried out at Bwaila STI clinic [36]. Acceptability, appropriateness and feasibility will be measured quantitatively using surveys and qualitatively using in-depth interviews (IDIs) and focus group discussions (FGDs). Acceptability and appropriateness will be measured before (at

baseline) and during implementation of our intervention for each implementation block. Feasibility will be measured during implementation for each implementation block because it cannot be measured before exposure to the intervention [36]. A vignette (embedded in the data tools) on the RITE intervention will be read out to respondents to describe the intervention. Data on acceptability, appropriateness and feasibility will be collected using the following methods:

Surveys*:* For acceptability, we will use the acceptability of intervention measure (AIM), a tool designed by Weiner et al [37], to collect quantitative data for acceptability. The AIM uses Likert scales of four constructs which assess if an intervention is appealing, likeable, welcome and approved. For appropriateness, we will use the intervention appropriateness measure (IAM) to collect quantitative data for appropriateness [37]. The IAM uses a Likert scales of constructs which assess if an intervention is fitting, suitable, applicable, and a good match. For feasibility, we will used the feasibility of intervention measure (FIM) for feasibility Surveys [37]. The FIM uses a Likert scales of constructs which assess if an intervention is implementable, possible, doable, and easy to use. These tools have been slightly modified to suit the study setting.

Acceptability and appropriateness will be conducted at baseline and for each implementation block except for feasibility which cannot be assessed before exposure to the intervention (Appendix 6 - 9). Surveys data will be collected on electronic tablets through open data kit (ODK). Data clerks will administer surveys on an electronic tablet for the men while HCWs will self-administer the surveys. Each survey will to last approximately 10 - 20 minutes. Survey data will be downloaded from the tablets to a Microsoft Access password-locked database. IDIs and FGDs will complement the surveys.

***In-depth interviews*:** IDIs will be conducted with HCWs from Bwaila STI clinic only. IDIs will

be ideal for HCWs because they are fewer in number, easier to reach and will provide a platform to explore in more detail if our intervention is practical for the clinic. IDIs will be conducted in the local language (Chichewa) by the investigator with the help of a qualitative researcher. We will conduct interviews with HCWs before implementation (baseline) and during implementation (during the last implementation block with the full RITE intervention) to explore implementation issues until saturation is reached. Each interview will last approximately 45 – 60 minutes. IDIs will be administered using an interview guide developed by the investigator in consultation with qualitative researchers are the University of North Carolina Project (UNC Project) in Malawi (Appendix 10).

Focus Group Discussions: FGDs will be conducted with the men only. FGDs will be ideal for the men because they will allow us to collect opinions from more men at one time compared to IDIs. Men will be purposively recruited and segmented by meaningful characteristics, such as age, marital status, religion or other factors that the experts think would influence what and how men may share information. FGDs will be conducted in Chichewa by the investigator with help from qualitative researchers. The FGDs will be administered using a guide developed by the investigator and qualitative researchers from UNC project (Appendix 11). Each FGD will have between 8 to 12 men. We will conduct two FGDs before implementation at baseline (appendix 11) and another two FGDs during implementation of the full RITE intervention only (appendix 11). Each FGD will be approximately 60 – 90 minutes. The IDIs and FGDs will complement the quantitative methods by exploring factors identified in surveys.

We will take notes and record the IDIs and FGDs. IDIs and FGDs will be translated to English during transcription. The investigator and one qualitative researcher will conduct the transcription and coding using Nvivo 14 S.E. in preparation for thematic analysis. We will

ensure intra-coder and inter-coder consistency by comparing codes. In case of inter-coder inconsistencies, a third person (socio-behavioural scientist) will conduct the coding (tiebreaker). We will collect demographic data from all respondents. A summary of methods is available in Table 1, Appendix 12.

6.3 Sample Size Calculation and Justification

Data on the incidence of VMMC among men with STIs is unavailable. Based on routine data, the Bwaila STI clinic sees about 60 patients per day. Of these, 27 patients are men. Using the prevalence of circumcision from the MoH integrated HIV Program third quarter report of 28% among men with STI, we estimate that at least 19 uncircumcised men will visit the STI clinic per day and at least 380 uncircumcised men per month. Since the project implementation period is expected to be about 6 months, we expect that a minimum of 2280 uncircumcised men will be exposed to our intervention and observed for VMMC uptake.

We will offer all men who express interest in VMMC to participate in a survey. We anticipate between 5-15% of the men will decline participation in the survey. All (approximately 12) healthcare workers will be offered to take the surveys. All available experts (approximately 10) will be offered to take a survey.

Sample size for surveys

Based on the total sample size of 80 men indicated below, we calculated that 67 surveys are required for each intervention component to achieve 95% confidence level with 5% margin of error [38]. We will offer all men who express interest in VMMC to participate in a survey. We anticipate between 5-15% of the men will decline participation in the survey. All (approximately

12) healthcare workers will be offered to take the surveys. All available experts (approximately 10) will be offered to take a survey.

Data Analysis

Overall, we will use descriptive statistics such as mean, median and proportion to describe the demographic characteristics of the study population by implementation block. Demographic characteristics will include but not limited to age, marital status, educational status and socio-economic status. These characteristics will be compared with the SOC group using Student's T-test or Chi-squared test at $\alpha=0.05$ and 95% confidence interval, assuming normal distribution.

Objective 1: To compare uptake of voluntary medical male circumcision between the standard of care and the different combinations of the RITE intervention among men attending Bwaila STI clinic in Lilongwe Malawi

Uptake will be calculated as a proportion - the number of men who will undergo VMMC divided by the number of uncircumcised men offered VMMC at the STI clinic. Uptake will be calculated for each implementation block. Uptake for each block will be compared against SOC using Student's T-test at $\alpha=0.05$ significance level and 95% confidence interval, assuming normal distribution.

Objective 1a: To compare time-to-uptake of voluntary medical male circumcision between the standard of care and intervention period among men attending Bwaila STI clinic in Lilongwe Malawi

Time-to-uptake of VMMC will be calculated as the number of days taken for an individual to undergo circumcision at the VMMC clinic from the day they were offered circumcision at the STI clinic. To compare time-to-uptake between SOC and the intervention blocks, we will conduct time-to-event analysis to estimate duration to circumcision and Kaplan Meier curves will be plotted and compared between SOC and implementation blocks. We will also study factors affecting time-to-uptake using cox regression.

Objective 1b: To assess factors affecting uptake of voluntary medical male circumcision among men attending Bwaila STI clinic in Lilongwe Malawi

We will assess factors affecting uptake of VMMC using logistic regression modeling. We will use univariate models to assess association. Covariates with $P<0.05$ and those based on expert knowledge of this topic will be fit into multivariate logistic regression models to control for confounders.

Objective 2: To develop STI clinic setting-specific voluntary medical male circumcision educational material at Bwaila STI clinic in Lilongwe Malawi

We will use thematic analysis approach for qualitative analysis of the consultative meeting notes. The notes will be coded and salient themes will be identified. The content and delivery methods will be deduced from the salient themes.

Objective 3: To assess the acceptability, appropriateness and feasibility of the adaptable RITE intervention among men and healthcare workers at Bwaila STI clinic in Lilongwe, Malawi.

We will use mixed methods to assess acceptability, appropriateness and feasibility. For acceptability, appropriateness and feasibility quantitative surveys, these outcomes will be

calculated as a median score and percentages for each of the survey questions. The results will be compared between SOC and each implementation block using Wilcoxon sign-ranked test, analysis of variance (ANOVA) and test of proportions as required. We propose to use structural equation modelling to assess predictors of acceptability, appropriateness and feasibility. The latent variables will be acceptability, appropriateness and feasibility. We assume that the constructs measuring each of these latent variables are correlated, we will conduct principal component analysis and calculate factor loadings and error variance to estimate the true effect of the constructs. We also assume that the latent variables will be correlated. Therefore, we will conduct confirmatory factor analysis to assess how the latent variables will affect the impact of our intervention on uptake of VMMC.

Qualitative data will be analyzed using a thematic approach (thematic framing and coding, indexing, and charting). We will conduct data analysis concurrent with interviews to identify salient themes and areas that may require further exploration in the subsequent interviews. Salient themes will be deduced from codes identified from the IDIs and FGDs.

6.4 Ethical Considerations

Using the informed consent forms, the study will be explained to all participants and written informed consent (Appendixes 13 - 15) will be obtained from respondents for participating in the study. Informed consent for audio recordings will be obtained as part of the main informed consent form based on the Malawi ethics board requirements. Permission was obtained from the Lilongwe District Health Officer (appendix 16) to conduct the study at the STI and VMMC clinics. All data forms, informed consent forms, interview notes and voice recorders will be stored under a double-lock system at the UNC Project during the study period. Electronic data

will be stored in a password-protected database. Both paper and electronic data will not contain identifiable information. Ethics approvals have been obtained from the National Health Sciences Research Ethics committee of Malawi (NHRSC) (appendix 17) and the University of North Carolina at Chapel Hill Internal Review Board (appendix 18). Final ethics approval will be obtained from the University of the Witwatersrand Human Research Ethics Committee (HREC)

6.5 Limitations and anticipated challenges

Contamination may be challenge in this implementation study however, we believe we have partly addressed this by using wash-out periods of one week between interventions. Selection bias may be a potential limitation if men with certain common characteristics enroll to a specific intervention block and affect the uptake of VMMC. Seasonality (circular trends) is a well-known confounding factor in VMMC research. Men in LMICs prefer to undergo circumcision in the cold season [39]. Our study will recruit participants during a period that will transition through the cold season however, we will monitor circular trends by measuring the prevalence of circumcision among men at Bwaila STI clinic. Interference in this study will be defined as a stakeholder implementing any intervention aimed to scale-up the uptake of VMMC at the study sites.

6.6 Proposed publications

1. Study designs paper with a description of how the intensified health education and RITE were developed and the implementation science research methodology
2. The impact of the RITE intervention on uptake of VMMC among men at Bwaila STI clinic in Lilongwe Malawi. This will include results on time-to-uptake of VMMC and factors affecting uptake of VMMC

3. The acceptability, appropriateness and feasibility of the RITE intervention for improve uptake of VMMC among men attending a STI clinic in Lilongwe Malawi

6.7 Timeline of proposed scope of work (Work Plan)

The timeline and scope of work have been detailed in Appendix 19.

6.8 Study Budget

This PhD will be funded by National Institute of Health; Fogarty Global Health Fellowship (FGHF) grant and the D43 training grant number; D43 TW01 0060-01 under the Malawi HIV Implementation Research Scientist Training Program (M-HIRST). Details are in Appendix 20.

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7 APPENDIXES

7.1 Appendix 1: Schema of the Implementation Stages

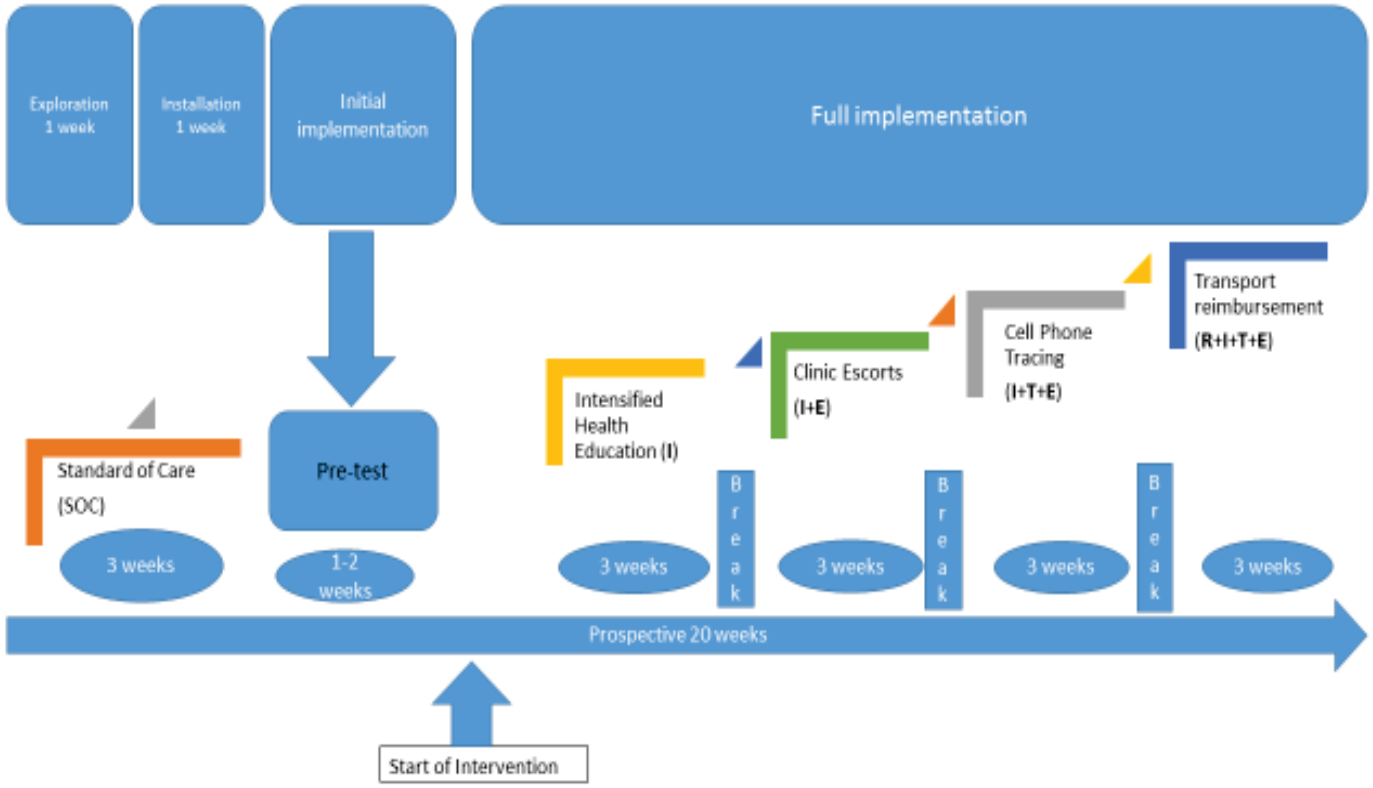

Figure 1: Stages of Implementation of the RITE intervention