# PROTOCOL

# Evaluation of the Acceptability and Safety of the ShangRing Device for Male Circumcision in Shinyanga, Tanzania

## October 22, 2018

*The study protocol was approved by the Ethics Committees of the Tanzanian National Institute for Medical Research (Ref: NIMR/HQ/R.8a/Vol. IX/2995), US Centers for Disease Control and Prevention, Center for Global Health (CGH HSR Tracking #2019-519), and Johns Hopkins School of Public Health Institutional Review Board Office (FWA #00000287).*

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# List of Acronyms

| | |
|---|---|
| AE | Adverse event |
| CDC | U.S. Centers for Disease Control and Prevention |
| CRF | Case Report Form |
| DGHT | Division of Global HIV & TB |
| HIV | Human Immunodeficiency Virus |
| IHI | IntraHealth International |
| MC | Medical Circumcision |
| MoHCDGEC | Tanzanian Ministry of Health, Community Development, Gender, Elderly and Children |
| PEPFAR | U.S. President's Emergency Plan for AIDS Relief |
| PII | Personally Identifiable Information |
| STI | Sexually Transmitted Infection |
| TOT | Trainer of Trainers |
| VMMC | Voluntary Medical Male Circumcision |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| WHO | World Health Organization |

# Investigators, Institutional Affiliations and Roles and Responsibilities

**Tanzanian Ministry of Health & Social Welfare, Community Development, Gender, Elderly and Children (MoHCDGEC):** MoHCDGEC serves as a technical expert on health care and is committed to the provision of basic

health services that are of good, quality, accessible, affordable, and sustainable and gender sensitive to the people of Tanzania. Staff from MoHCDGEC will assist with all aspects of planning to ensure that the evaluation responds to the priorities and information needs of the Government of Tanzania. Staff will be responsible for assisting with oversight of all aspects of the evaluation planning and implementation including protocol development, procedures, results dissemination, and publications.

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**IntraHealth International (IHI):** as the CDC implementing partner working in Shinyanga, Tanzania, IHI clinical staff will provide the training and clinical implementation of the ShangRing at VMMC sites. IHI will support data collection and data management. IHI will also review and provide input on all relevant evaluation documents, tools and reports; develop a data management plan and conduct data quality checks; supervise fieldwork; support data analysis and report writing; support in the dissemination of the final report. IHI will also provide experienced clinical staff for pilot implementation and support monitoring and evaluation activities.

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# Section A: Funding Source

Funding for this evaluation is provided by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under Cooperative Agreement Number 1USGGH001469 with Jhpiego and its Project IQ mechanism. Jhpiego will sub-contract with IHI to perform the in-country work through its Project IQ mechanism.

CDC will collaborate with the Tanzanian Ministry of Health and Social Welfare (MoHCDGEC) and the President's Office – Regional Administration and Local Government (PORALG) who are the custodians of the health facilities in which catchment areas the evaluation will be conducted.

# Section B: Executive Summary

Medical circumcision devices have the potential to accelerate delivery of male circumcision by making the procedure quicker and easier, while remaining as safe as surgical circumcision. In addition, devices may be more acceptable to clients than a surgical approach in some circumstances. Thus circumcision devices may facilitate expansion of adult male circumcision programs for HIV prevention and address some of the common capacity issues in PEPFAR priority countries for male circumcision.

One promising device for adult male circumcision is ShangRing, which was prequalified by the WHO in 2015 for males aged 13 and older. ShangRing has been available for purchase in China since 2005. The ShangRing device has also received approval for use in the European Union and the United States.

ShangRing studies from Kenya, Uganda, and Zambia have demonstrated that ShangRing can be implemented in southern and eastern Africa.

However, because health systems and conditions vary between countries, WHO has created a framework for introducing circumcision devices in a country. This framework recommends countries take a methodical approach to introducing circumcision devices, evaluating acceptability and safety within its health system before making widespread adoption. [1]

**Evaluation Goal:**
To evaluate the safety and acceptability of the ShangRing device for nonsurgical circumcision in routine clinical settings, as a part of a comprehensive HIV prevention program for males in VMMC programs.

**Evaluation Endpoints:**
*Primary Endpoint:* the proportion of males experiencing mild, moderate and severe adverse events (AEs) associated with ShangRing circumcision procedures, including both intra- and post-operative events, and all device-related malfunctions (e.g., early spontaneous detachment).

*Secondary Endpoints:*

- Training needed for proficiency using the ShangRing device, including number of procedures to become fully proficient at applying and removing the ShangRing device.
- Client and provider acceptability, client satisfaction, and duration of procedure.
- The percentage of clients clinically healed 49-52 days post-placement of the ShangRing device, and the time at which point all clients are clinically healed.

**Evaluation Design**

*Training Phase:* this phase will be used to evaluate the training requirements for implementation by mid-level providers, to preliminarily assess acceptability to providers, and to monitor logistical needs. Each clinician will perform no fewer than 10 ShangRing device placements, and 5 ShangRing removals before start of the next phase (implementation pilot).

*Implementation Pilot:* following the training period, 575 male clients will be recruited to undergo circumcision with the ShangRing device in the context of routine service delivery.

Data will be collected at up to at least 5 points in time: at enrollment and device placement (day 0), at device removal (day 7), during a follow-up phone call (day 10), in-depth qualitative interviews for 50 purposefully selected clients (day 28), at an in-person follow-up visit to assess wound healing (day 49), and at subsequent weekly visits to assess healing for those not completely healed at day 49.

Upon completion of the implementation pilot, the data will be analyzed and used to assist with policy decisions and recommendations on ShangRing use in adult male circumcision programs.

# Section C: Protocol

## Introduction

### Voluntary Male Medical Circumcision (VMMC), VMMC Devices and ShangRing

Three randomized controlled trials have demonstrated that Voluntary Medical Male Circumcision (VMMC) reduces the risk of heterosexual HIV transmission from women to men by up to 60%.[2,3,4] For this reason, in 2007 the World Health Organization (WHO) and Joint United Nations Program on HIV & AIDS (UNAIDS) recommended VMMC as part of a comprehensive HIV prevention package in 14 priority countries in sub-Saharan Africa (including Tanzania), each with high HIV prevalence and low male circumcision (MC) coverage. Although each of the 14 priority countries has made progress in implementing and providing VMMC, most fell short of their target number of circumcisions to be performed by 2016.

In August 2016, UNAIDS released the "Fast-Track Commitments to End AIDS By 2030." These commitments included a number of ambitious targets that must be met by 2020 in order to achieve 90% reduction in HIV incidence. Among these targets was an additional 27 million circumcisions in the 14 PEPFAR priority countries.[5]

Circumcision devices can help VMMC programs like Tanzania's meet their ambitious targets in several ways. Depending on their mechanisms of action, devices may have the potential to address up to two major concerns noted by men that affect VMMC program uptake: pain and loss of time from work. As noted below, studies have shown lower pain levels associated with the use of devices, including ShangRing, and this could enable programs to overcome fear of pain as a barrier to circumcision uptake; and it may help convince men if they are able to

return to work sooner following the procedure. Devices could lessen the burden placed on the healthcare system, the shorter procedure time implies that a given number of providers can attend to a larger number of clients. Additionally, the ease of use of devices allows lower cadres of provider to be able to perform circumcision procedures. These facts, in turn, can help decrease overall costs of human resources needed to operate a VMMC program.

The WHO has approved of ("prequalified") two circumcision devices for use. PrePex, which was adopted in several southern and eastern African countries, was discovered to pose increased risk of tetanus because non-viable tissue was left in situ for 7 days after device application; as such, its use has declined in most countries that initially adopted it. With the ShangRing device, the foreskin is removed during placement and tetanus risk is felt to be at the background rate for a country.[6] Multiple countries in southern and eastern Africa are now at various stages of incorporating ShangRing into VMMC programs.

Several studies in China have demonstrated that the ShangRing is safe, easy to use, and enjoys high levels of patient satisfaction. One study of 1,200 ShangRing circumcisions in China found low complication rates; and these findings were corroborated by a second study of 328 Chinese men. [7,8] Both studies found that there were lower pain levels associated with use, and patient satisfaction rates were very high (over 98% in both studies).

A review of ShangRing studies in Kenya, Uganda, and Zambia has demonstrated that ShangRing continues to maintain its low levels of complications and ease of use in African countries.[9] These studies also found that ShangRing had comparable AE rates and pain scores to conventional techniques, that men preferred ShangRing to conventional circumcision, and that patient satisfaction scores were high.[10,11,12,13,14] For these reasons, the authors of the review suggested that ShangRing could assist in expanding VMMC services to more men throughout sub-Saharan Africa.

The procedure time of the ShangRing device across the different studies is faster than conventional circumcision. A study in Kenya found that the average placement time was approximately 5 minutes, and average removal time was approximately 4 minutes (though this study did not compare these times to conventional circumcision). [15] Another study in Kenya comparing ShangRing to conventional circumcision found the ShangRing procedure to take approximately 7 minutes, compared to 21 minutes for conventional circumcision; a similar study in Uganda found the ShangRing procedure to take approximately 6 minutes, compared to 18 minutes for conventional circumcision.[16] The faster ShangRing procedure times have been attributed to the device eliminating the need for placing sutures.

Currently, the WHO is reviewing data from ShangRing studies where the procedure was performed with topical anesthetic cream as opposed to injected anesthesia. If the data review shows that ShangRing circumcisions can be performed without injections this may remove another common barrier – fear of pain and needles – that affects uptake of circumcision among men. The WHO is also reviewing data on a new technique of performing ShangRing circumcisions called the no-flip technique. This technique is an easier procedure to perform, and if approved may allow the ShangRing to be performed by a wider assortment of lower-cadre providers.

## ShangRing and HIV+ Men

A field study of ShangRing, which contained a small number of HIV+ male participants (N=84) found similar outcomes to HIV-negative men receiving ShangRing circumcisions. In the study, the moderate and severe AE rate was 1.2% among HIV+ men and 1.7% among HIV- men (Table 1).[17] Acceptability was high in both groups, with 97.4% and 94.6% of HIV+ and HIV- participants being very satisfied with the appearance, respectively, and 100% and 98.7% of HIV+ and HIV- participants willing to recommend ShangRing MC to a friend or family

member, respectively. Furthermore, time until wound healing was similar at 35-42 days between HIV+ and HIV- men (85.7% vs. 87.3%, respectively).

*Table 1. Adverse events by HIV status during field study in Kenya*[18]

| | HIV+ Men (N = 84)* | HIV-men (N=1065)* |
|---|---|---|
| Mild AEs, n (%) | 1 (1.2) | 0 (0.0)† |
| Moderate AEs, n (%) | 0 (0.0) | 16 (1.5)‡ |
| Severe AEs, n (%) | 0 (0.0) | 2 (0.2) |
| Total AEs, n (%) | 1 (1.2) | 18 (1.7) |
| *Data were available from the researchers on 101 HIV-positive men and 1086 HIV-negative men. Including these additional men increased the AE rate to 3.0% in HIV-positive men (n=3) and 2.6% in HIV-negative men (n=28).<br>†19 (1.7%) males experienced cutaneous pinches, although these were not included in the AE case definition.<br>‡The most common AE was wound dehiscence (n = 9). | | |

## HIV in Tanzania

Based on the 2016/2017 Tanzania HIV Impact Survey (THIS), there are an estimated 1.4 million people aged 15-64 years living with HIV in Tanzania. The prevalence of HIV among adults aged 15-64 is 5% (6.5% for females, and 3.5% for males). The HIV prevalence varies geographically across Tanzania, with a high of 11.4% in Njombe to less than 1% in Lindi and Zanzibar. The Annual incidence of HIV among adults aged 15-64 years in Tanzania is 0.29% (0.4% among females, 0.17% among males). This corresponds to approximately 81,000 new cases annually among adults aged 15-64.[19]

## Male Circumcision in Tanzania

As part of its prevention approach, in 2010 Tanzania adopted a target of 80% VMMC coverage for males aged 10-34, and estimated it needed to reach 2.8 million people by 2015 to meet this goal. As of 2013, 72% of males in Tanzania reported being circumcised, though circumcision coverage varies considerably by region.[20] In regions where traditional male circumcision is practiced, MC prevalence rates are as high as 80% to 99%; in regions that do not practice traditional MC, the prevalence is as low as 26%.[21] As of 2016, program data from PEPFAR indicates that Tanzania has performed 2,361,440 circumcisions since 2010.[22]

## Introducing a New Circumcision Device

The pilot evaluation for ShangRing in Tanzania described in this protocol is designed to meet the standards set by the WHO's *Framework for Clinical Evaluation of Devices for Male Circumcision*.[23] This framework provides the data necessary to assess the safety of device when used by providers in their normal settings. The WHO's framework also provides data related to several other characteristics: client acceptability, provider acceptability, ease of use, cost, and regulatory and marketing.

## Justification for Evaluation

ShangRing can address some of the financial and human resources challenges posed by conventional circumcision techniques. The data from this evaluation will be used to assist the Tanzanian MoHCDGEC with policy decisions and possible recommendations on the use of the device in adult male circumcision programs including provider training, implementation of device circumcision, and messages for male clients and their partners in pre-procedure counseling sessions.

## Evaluation Design and Methods

### Evaluation Goal

To evaluate the safety and acceptability of the ShangRing for device-based circumcision in routine clinical settings, as a part of a comprehensive HIV prevention program for males aged 13 and older in Tanzania.

### Evaluation Objectives

The specific objectives of the proposed implementation pilot is to:

- Describe/assess the safety of the ShangRing device by the occurrence of clinical adverse events (calculated as a rate), when circumcision is performed by trained mid-level providers;
- Ascertain capacity and required clinical capabilities of clinical staff of various cadres to carry out ShangRing procedures;
- Describe/assess male client and provider acceptability of the ShangRing device and process (e.g. need to return to the clinic for device removal, tolerance for leaving device in situ);
- Assess the percentage of clients clinically healed 6 weeks (42 days) following the removal of the device;
- Determine the time at which point all clients are physically healed following the removal of the device.

### Primary Endpoint

The primary endpoint related to the goal and objectives of the evaluation is to:

- Measure the incidence of mild, moderate and severe AEs associated with ShangRing procedures including both procedure and post-procedure events, and all device-related malfunctions such as early spontaneous displacement. The primary endpoint will be assessed at device placement, at device removal, 3-days post removal, at the day 49 post-placement healing assessment, and at any unscheduled visit in that time frame. Adverse events will be measured and described in the following ways:
    - Total numbers and types of known AEs occurring among clients, including all severities of AEs (mild, moderate, severe) and serious AEs (see below), including detailed information about all instances of device displacement/detachment/self-removal/malfunction, need for medical attention or intervention, and final outcomes in those experiencing AEs.
    - Total number of clients with known AEs (may be different from above if clients experience multiple AEs), including all severities of AEs and serious AEs.
    - A description of each adverse event by type, severity, time of detection (days post-application and/or post-removal) captured as date AE is diagnosed, clinical management, and resolution. The likelihood of relatedness to having undergone VMMC and relatedness specifically to the ShangRing device will be determined. AEs will be defined using the definitions in the second edition of the VMMC Adverse Event Action Guide.[24] These are specific to each AE type, but in general:
        - Mild: classification indicates minimal or no intervention is required beyond reassurance and observation;
        - Moderate: classification relates to those AEs that are neither mild nor severe, require intervention, and are usually managed on-site;
        - Severe: classification requires extensive intervention with referral or specialist input.
        - Note: a Serious Adverse Event (SAE) is a standard definition used across many types of interventions. In the context of VMMC, all AEs that meet criteria for severe should also be classified as SAEs. In addition, SAEs also include any event that:
            - Results in death

- Is life threatening
- Requires intervention to prevent permanent disability or incapacitation (including deformity), or results in permanent disability or incapacitation (including deformity)
- Requires hospitalization or referral to a specialist for higher level care or intervention.

  - (Note: device displacement is included as an AE both in the moderate and severe classifications – see Appendix XV).

## Secondary Endpoints

- Determine the training needed for proficiency, including number of procedures required under supervision to become certified as fully proficient. This will involve analyzing AE rates stratified by during training and post-training in addition to overall.
  - Determining whether various cadres are trainable as safe providers. This would involve analyzing AE rates stratified by provider cadre.
- Document client acceptability and satisfaction, to be measured by the following:
  - Time for client to return to normal activity, including work and routine tasks.
  - Clients' opinions of convenience (having device applied, 'wearing' the device for a week, and returning for device removal), acceptability, cosmetic result, and whether they would recommend VMMC, and specifically the ShangRing VMMC option to others.
  - Total number of clients who fail to return to the circumcision site (or site indicated by service providers) for recommended follow-up (whether removal visit or AE follow-up).
  - Proportion of all men receiving VMMC services at the evaluation sites who choose ShangRing method instead of surgical circumcision.
- Document provider acceptability of ShangRing, to be measured by the following:
  - Provider perceived ease of application, ease of removal, ease of clinical management of adverse events, and preferences in comparison to conventional circumcision methods.
- Document duration of procedures, and problems encountered during procedures and post-procedure care, to be measured by the following:
  - ShangRing application time will be measured, including the overall time the client is on the procedure table, and the time required for discreet application activities: client preparation time (including application of local anesthetic and sizing), marking and device application, and clean-up time.
  - ShangRing removal time will be measured, including the overall time the client is on the procedure table, the time required for discreet removal activities, and time for post removal instructions given to the client.
- The percentage of clients determined by a clinician to be clinically healed 49-52 days post-placement of the ShangRing device (42 days post-removal), and the time at which point all clients are clinically healed.
  - Healing will be documented by evaluation staff, who will take photographs of the client's genital area during the follow-up visits.
  - Healing will meet the definition of clinical healing after VMMC, defined as:
    - "Intact epithelium (unbroken skin) covering the wound as judged by the provider on visual inspection, meaning that none of the following are present: sutures, scabbing, drainage, moisture, gaps between epithelial edges or ulceration."[25]

## Evaluation Design

### Overall Design

This implementation pilot is comprised of two phases: a training phase and the main implementation pilot. During the training phase clinicians at the participating sites will be trained in the use of the ShangRing device. Upon completion of the training phase, the main implementation pilot will begin. The implementation pilot is a single arm, open label, prospective cohort evaluation.

### Description of Evaluation Populations and Catchment Areas

*Shinyanga, Tanzania*

Shinyanga is 1 of 31 regions in Tanzania. Shinyanga covers a total of 18,555 square kilometers, which include 3 districts, 6 Local Government Authorities, 15 divisions, 126 wards, and 511 villages.[26]Shinyanga is bordered by Mwanza to the north, Simiyu to the east, Geita to the west, and Tabora to the south. The capital of Shinyanga Region is the municipality of Shinyanga, located in Shinyanga District. As of the 2012 census, the population of the Shinyanga region was 1,534,808. The economy of the region is primarily driven by agriculture. As of 2011, the HIV prevalence of Shinyanga was 7.4%.[27]

According to the Tanzania Demographic Health Survey and Malaria Indicator Survey, 54% of men in Shinyanga reported that they are circumcised.[28] The Tanzania team has proposed the following VMMC static sites in Shinyanga for participation in the evaluation:

- Kahama District Hospital, Shinyanga; this hospital is located in Kahama Town council and serves as referral hospital for three district councils; Ushetu, Msalala and Kahama Town council. It has the catchment population of 270,000 people and offers OPD, IPD, CTC, Reproductive and child health services, Labor and delivery and Laboratory services. The hospital has the bed capacity of 102. VMMC services were integrated in September 2011, and Kahama VMMC static clinic is the busiest MC clinic in Shinyanga region. There are total of 29 VMMC providers and three VMMC National trainers based in this hospital.
- Ushetu Health Centre, Shinyanga; this health center is located in Ushetu district council, about 75 km from Kahama town in Shinyanga region. The facility offers OPD, IPD, Reproductive and child health services, Labor and delivery and CTC services. The facility has a bed capacity of 40 and serves a catchment population of 17,274 people. VMMC static clinic was initiated and integrated in August 2013. There are total of 8 trained VMMC providers.

These sites were selected based on determinations by IntraHealth, CDC-Tanzania, and the Tanzanian MoHCDGEC, that they could meet the inclusion criteria outlined below; and that there was sufficient intrinsic demand for VMMC services in their catchment areas, to offer a sample size large enough to meet the one needed by this evaluation.

### Client Inclusion Criteria

Potential clients will receive a medical history screening and a genital examination conducted by the VMMC provider to determine that they are in overall good physical health. Additional inclusion criteria include the following:

- Male aged 13 years and older
- Uncircumcised following physical assessment
- Seeking medical circumcision at one of the evaluation sites

- Consents to an HIV test.
- Agrees to be circumcised using the ShangRing device
    - Those aged 13-17 years will also require parental/guardian approval in order to be included in addition to providing assent. Parents must also agree to be present at the facility during the circumcision (though not in the operating room unless requested by the client), for the discharge instructions, and for subsequent follow-up visits.
- Penis fits into one of the 18 ShangRing ring sizes
- Able to understand the evaluation procedures and requirements
- Agrees to abstain from sexual intercourse and masturbation, for six (6) weeks post removal, seven (7) weeks total
- Lives within 30 kilometers of the facility in Shinyanga, Tanzania
- Willing to provide valid contact information (i.e. telephone number, address of residence, place of employment and other locator information) and willing to receive communications and/or follow-up visits, clients may also be asked for names of relatives or friends to be contacted in the event that the client cannot be reached
- Has an activated cell/mobile phone or access to a cell/mobile phone
- Agrees to return for a follow-up visit to assess healing day 49 post-placement (42 days post-removal).
- If not healed at the day 49 post-placement visit, agrees to return for weekly follow up visits until healed.
- Agrees to a 10 day post-placement (3 days post-removal) telephone call to assess and detect symptoms of AEs
- Able to communicate in English and/or Swahili
- Capable and willing to provide written informed consent (18 years and older), or written informed consent from a parent guardian (13-17 years) to participate for both HTS and VMMC services.

## Client Exclusion Criteria

Clients who do not meet the inclusion criteria above and who have the following known medical conditions will be excluded from the evaluation:

- Cognitive impairment that prevents the client from providing consent
- Any health condition (reported or observed) that is a contraindication to surgical VMMC in the national program, or that ShangRing providers deem a contraindication. These may include diabetes, peripheral vascular disease, cancer, bleeding disorders, and/or current moderate or severe infectious illness.
- Known **uncontrolled** diabetes, hypertension or tuberculosis (TB)
    - Note: if a client has **controlled** diabetes they may still be eligible for circumcision, but blood sugar should be checked first. If the check reveals blood sugar to be acutely elevated, defer circumcision until blood sugar is better controlled.
- Acute illness, other than colds or other minor complaints
- Active skin infection
- Anatomical variations and anomalies of genitalia:
    - Hypospadias, epispadias, or other urethral anomaly; except for glanular hypospadias, which is not a contraindication if provider is experienced
    - Hydrocele or other scrotal swelling
    - Scrotal hernia
    - Phimosis or paraphimosis
    - Other genital anomaly or disease including infectious or traumatic ulcers, or scarring involving frenulum, foreskin or glans
    - Dermatitis of the penis or foreskin, filariasis or penile cancer

    - Genital warts involving both foreskin and glans (note: genital warts involving only foreskin are not a contraindication if provider is experienced)
    - Urethral discharge
    - Balanitis or posthitis (clients with balanitis should be referred to a specialist, as circumcision is likely to be necessary but should be done by an experienced provider)
- Current sexually transmitted infection (STI) other than HIV (clients with STIs can return for circumcision once STI is treated)
- Other conditions, which in the opinion of the supervising circumcision coordinator, prevents the subject from undergoing a circumcision with the ShangRing device

Clients who do not meet inclusion criteria will be offered standard surgical circumcision if not contraindicated. The number and reasons for such exclusions will be recorded and included in the final evaluation report.

*Medical Referral*
Males who present with exclusion criteria for one of the medical reasons listed above will be referred to the appropriate specialist for management of their conditions. Additionally, any men who have an anatomic contraindication but still want circumcision, can be referred to an urologist for further management. In keeping with standard national practice, clients presenting with specific disease conditions such as STIs or TB may be treated on-site or referred for care elsewhere if appropriate services are not available on site. Furthermore, males who are HIV+ will be assessed to determine if they are on antiretroviral therapy (ART). Those not on ART will be referred for ART.

## Client Withdrawal Criteria

A client has the right to withdraw from the evaluation at any time, for any reason, without prejudice to his future medical care by the provider or the health facility (see Appendices V and VI for the client and minor client assent forms). If a client withdraws after consent, but prior to device placement, the client will be replaced until the desired sample size is reached and the data will be excluded from analysis. If a client withdraws after device placement, the client will not be replaced and the existing data will be included in the analysis, but no attempts will be made to collect further data other than that required for clinical documentation of the removal visit. The reason, timing and circumstances of the withdrawal will be documented and analyzed. The client will subsequently not be included among those selected for the day 28 in-person interview, nor will they be asked to return for the day 49 follow-up visit to assess healing. When the client withdraws, they will be informed that they may still return to the clinic for removal of the device as scheduled, and contact the clinic should they have further questions, suffer an AE, or experience other difficulties healing.

**A client will be informed in advance that if he wishes to withdraw from the evaluation after ShangRing placement but before scheduled removal, he must still return to the provider for device removal on day 7 for his own health. The client will also be advised that once applied, it is not safe to remove the device before day 5. If the client requests removal on day 5 or 6, it will be removed as requested.** The number and reasons for client withdrawals will be recorded and included in the final evaluation report (See Appendix XXII).

## Procedure for Handling Clients Lost-to-Follow-Up

Clients who are lost to follow-up after device placement, and therefore do not return to have the device removed, will not be recorded as experiencing an AE, and also will not be included in calculations when measuring AEs.

In the event that a client refuses to return for follow-up, ShangRing has been shown to detach on its own. Studies show that for those clients who do not come in to have the device removed, and wear it for more than

seven days, the ShangRing will eventually spontaneously detach on its own, and healing will progress normally. In one study, complete detachment of the device occurred in 66.7% of men who wore the device for more than seven days, and 14% of men requested removal of a partially detached device 8-14 days after placement. No severe or serious AEs were reported among this group.[29]

A study of delayed removal of ShangRing in Kenya found that in 81.8% of men the ShangRing had completely detached on its own between 10-16 days after circumcision.[30] By 21 days following the circumcision the ring had at least partially detached in 100% of men, and was completely detached in 93.7%. While the ShangRing has been found to be safe if left on, this is not the recommended standard of care for the purposes of this evaluation, and clients will be followed up with for device removal as described in this protocol.

## Provider Participant Inclusion Criteria

Providers meeting the following criteria will be included in the evaluation:

- Adult aged 18 or older
- Employed as a medical doctor, Assistant Medical Officer, Clinical Officer, professional nurse, or enrolled nurse at the participating sites in Shinyanga, Tanzania
- Experienced in providing conventional surgical circumcision
- Trained and certified in ShangRing circumcision techniques for the current evaluation by a trainer who is trained in ShangRing application, and has performed a minimum of 10 placements and 5 removals. The evaluation team will bring in ShangRing master trainers from countries with prior ShangRing experience (i.e. Kenya, Zambia) to train providers based in Shinyanga who will then train mid-level providers to conduct ShangRing circumcision, or send physicians from Tanzania to these countries for training.
    - Trained and competent in identifying and managing complications related to ShangRing circumcision.
    - Trained and competent in screening clients to determine their eligibility for ShangRing circumcision.
- Providers are able to demonstrate competence in ShangRing procedure upon completion of the course as described below.
- Providers are trained and competent in screening clients to determine their eligibility for ShangRing circumcision.
- Agrees to complete evaluation surveys and focus group discussions at midpoint of the evaluation, following at least 4 weeks of client enrollment.
- Ability to communicate in English and/or Swahili.
- Capable and willing to provide written informed consent to participate

## Provider Participant Exclusion Criteria

Providers with the following criteria will be excluded from the evaluation:

- Failure of ShangRing training, as determined by the instructors at the end of the training period
- Failure to comply with universal precautions for infection prevention and control
- Failure to provide written informed consent

## Minimum Site Requirements for ShangRing Pilot Service Delivery

Sites in Shinyanga, Tanzania were selected upon their ability to provide safe male circumcision services and on the basis of meeting minimum readiness requirements necessary to provide ShangRing service delivery. These requirements are as follows:

- Prior to the beginning of the evaluation, at least some providers are trained and competent in conventional surgical male circumcision. This is because there is a risk that ShangRing circumcision will

need to be converted to surgical intervention in the event of certain AEs (e.g., uncontrolled, bleeding), device malfunction or displacement. This criterion may change with further experience demonstrating whether this risk materializes.
- Site is equipped for emergency clinical management of immediate and post-procedure complications.
- Site has an agreed-upon referral plan to a district, sub-district or other facility where providers with skills to manage rare complications are available.
- All supplies for ShangRing placement and removal are reliably available.
- Site is capable of complying with relevant national policies on tetanus immunization for VMMC by both device-based and conventional surgical methods, as applicable.

Sites should provide a brief orientation to other health centers in the catchment area. The purpose of this orientation is to provide these health centers with an overview of the pilot, to offer the health centers guidance on how to provide care for any pilot clients that may present to their clinic, and to request the health centers alert the pilot sites in the event that a client from the pilot seeks follow-up care from the center (i.e. in the case of the AE), and provide the health centers with contact information for implementation pilot staff in order to do so.

## Sample Size, Data Collection and Analysis Timeline

The total sample size for this implementation pilot is 575 male clients at the selected sites in Shinyanga, Tanzania. Both HIV- and HIV+ men will be included in the sample. The sample size of 575 males is consistent with the framework for circumcision device introduction as proposed by the WHO (see appendix I below). Additionally, this sample size is powered to detect the occurrence of adverse events, which is estimated to be 2%. A minimum of 335 males are necessary for 95% confidence that the population proportion is within ±1.5% with an observed adverse event rate of 2%. An additional 240 males will be recruited for further confidence in the results, and to align with the WHO framework. The evaluation teams will enroll males until the 575 sample size figure is achieved. All 575 males to be considered for the data analysis will be enrolled upon completion of the training phase.

All data collection will begin as soon as the first circumcision of an enrolled client occurs. Data will continue to be collected until the country has performed 575 circumcisions with the ShangRing device, and all post-circumcision follow-up data collected from clients as detailed in this protocol is complete. After the 575 circumcisions and all follow-up information is collected, the analysis of data as described per the primary and secondary endpoints will begin. If after the country has finished 575 circumcisions, and wishes to conduct the analysis necessary to inform national policy for the purposes of implementing the ShangRing device on a wider scale, that country may continue to enroll clients, and the first 1000 circumcisions performed should be monitored through active surveillance, as detailed in the WHO framework, and the country should perform its own data analysis as needed. [31]

## Supplies and Logistics

ShangRing devices and medical instruments for placement and removal will be supplied to each partner at the beginning of the evaluation pilot. Partners will be responsible for further distribution to their pilot sites. Depending on actual consumption, disbursed supplies may be recalled for redistribution to match supply with demand at each site. A total of 750 devices will be purchased in various sizes to allow for the 575 procedures to be performed, as well as those performed during the training phase.

## Evaluation Phases

### Training Phase

During the training phase, clinicians at participating sites will be trained in the use of the ShangRing device by "master trainer" clinicians who have previous experience with the ShangRing device. This training phase will be used to evaluate the training requirements for implementation by mid-level providers, and to preliminarily assess acceptability to providers and clients and monitor logistical needs. Each clinician will perform no fewer than 10 ShangRing device placements, and 5 ShangRing removals before the start of the implementation pilot. Between 8 and 12 providers will be trained, meaning the number of clients receiving ShangRing during this time will be approximately 80-120. The clinicians trained in the master trainers will then train midlevel providers at the participating sites (anticipated to be another 2-4 providers at each site). Implementation pilot data will be collected from the clients receiving circumcisions with the ShangRing device during the training phase.

Measures of ShangRing skills following training in the use of ShangRing application including: theoretical tests, practical test of hands-on-skills and clinical test of performing ShangRing on subjects. Indirect measures will focus on the average procedure time of trainees undergoing ShangRing device training. Additional aspects of the training will be explored through qualitative in-depth interviews (See Appendices XIX-XX). Areas of exploration with qualitative data collection will focus on the strengths and weaknesses of the training, effectiveness of training package/materials, satisfaction with training, and suggestions for improvement of training and facilitation. Provider training and acceptability of the ShangRing device will also be assessed through quantitative measures including a Likert scale designed to measure the ease of the procedure, and how willing providers would be to continue performing ShangRing procedures following the conclusion of the implementation pilot (see Appendix XXI).

### Implementation Phase

Following the training phase, a cohort of 575 male clients will be recruited to evaluate the safety of the device, training needs, acceptability and healing time of ShangRing in the context of routine use by clinicians. Detailed CRFs will be maintained for all clients, including those circumcised during the training of mid-level providers. The CRFs and standardized forms will be used to evaluate the three components of the Implementation Phase: safety, acceptability, and healing (Appendices VII-X).

*Safety Component*

The primary aim of the safety component is to monitor clinical adverse events and device-specific adverse incidents according to type and experience of the provider. Data on both general and device-specific adverse events will be monitored using detailed clinical records maintained for all clients and standardized forms completed at specific data collection points. The records and forms will provide information on procedure and removal times and safety, technical difficulty and complications experienced during the procedure and removal process and pain experienced by the male client.

*Acceptability Component*

The primary focus of the acceptability component of the evaluation is to document attitudes towards and experiences with device circumcision (e.g., acceptability during the procedure and post-operatively during healing period while the device remains in situ), effects on activities of daily living, attitudes towards protection from HIV, effects on sexual satisfaction and/or penile sensation and behavior, pain, and satisfaction with cosmetic final result. Perceived acceptability of female partners will be assessed through male clients. The evaluation team will also collect data on reasons for not accepting the device by administering a brief survey to males declining participation in the evaluation (see Appendix XII). Provider acceptability will be assessed by exploring attitudes towards and experiences with device circumcision, impact of offering circumcisions on

clinical practice, barriers and facilitators of clinicians' implementation of device circumcisions (consistency of the final result, simplicity or ease of use).

All men (n=575) who are circumcised during the main implementation phase will be asked to answer a phone call to assess AEs three days post device removal (day 10). All men (n=575) will be asked to return for a follow-up visit on day 49 post-placement to assess healing. All men who are not clinically healed on the day 49 post-placement visit will be asked to return to the clinic at weekly intervals until healed. During the day 49 visit, and subsequent healing visits, men will also have their genital area photographed. A selection of 50 male clients will be asked to participate in private face-to-face qualitative interviews 28 days post-procedure. All clients returning for the day 49 healing assessment, and subsequent healing visits (and for clients under 18 a parent/guardian accompanying them), will be compensated a small amount for their travel costs and time (estimated to be between 7-10 USD/16,000-22,000 Tanzanian Shillings per visit, but not to exceed 30 USD/68,000Tanzanian Shillings) total, as will clients selected for the face-to-face qualitative interviews (see Reimbursements section). As noted above, providers will be interviewed at the evaluations midpoint, at least after four weeks of client enrollment, and this interview will assess provider satisfaction with training, as well as provider acceptability.

*Healing Component*

The primary focus of the healing component is to determine the percentage of men that are clinically healed by day 49-52 following the placement of the ShangRing device (42-45 days post-removal), and to determine the time point post-placement at which all clients are clinically healed. All clients will be asked to return for a day-49 healing assessment, where a provider will review the clients wound to determine healing. As noted above, the wound will be considered healed if it meets the clinical definition of healing after VMMC, and will be indicated as such on the CRF. All clients will also have a photograph of their genital area taken at this visit to document healing. If the client is not clinically healed at the day-49 healing assessment, the client will be asked to return for another assessment in one week's time. Weekly healing assessments will continue until all clients are clinically healed.

## Table 2: Implementation Pilot: Training and Implementation Phases

| Evaluation Component | Sample Size | Endpoints | Methods and Data Collection |
|---|---|---|---|
| Phase 1: Training | Approximately 80-120, depending upon # of providers trained (at least 10 clients per provider) | Primary endpoints:<br>- Provider training needs<br>- Provider acceptability<br>Secondary endpoints:<br>- Procedure and removal times | Administered knowledge and theory based tests<br>Supervisor/doctor observation |
| | | Training Needs Component<br>Primary endpoints:<br>- Provider proficiency with applying and removing the device<br>Secondary endpoints:<br>- Adverse events and device-related incidents<br>- Procedure and removal times<br>- Training satisfaction and needs of providers | Standardized forms to collect data on adverse events and device-related adverse events<br>Client records<br>Qualitative interview with providers<br>Photographs of the client's genital area, to be taken post-device removal (day 7), and at the day 49 healing assessment visit and at subsequent weekly healing visits |
| Phase 2: Implementation Cohort Evaluation | 455-495 (Depending upon # performed during training phase) | Safety Component<br>Primary endpoints:<br>- Adverse events and device-related incidents<br>Secondary endpoints:<br>- Safety of procedure/removal<br>- Provider perception of technical difficulty and complications during procedure and removal process | Standardized forms to collect data on adverse events and device-related adverse events<br>Client records<br>Brief surveys to collect data on reasons to decline participation in the evaluation as indirect measure of acceptability<br>Brief surveys to collect data on client experience with the ShangRing as an indirect measure of acceptability |
| | | Provider Acceptability Component:<br>- Provider acceptability<br>- Practicality of device use<br>- Procedure and removal times<br>Client Acceptability Component:<br>- Client satisfaction<br>- Cosmetic results<br>- Comfort:<br>  - During procedure to place device<br>  - During (nocturnal) erections<br>  - During removal | Qualitative interview with providers<br><br>Qualitative interviews with 50 male clients<br>Qualitative interview with providers<br>Brief surveys to collect data on reasons to decline participation in the evaluation as indirect measure of acceptability<br>Client records – including those recording application and removal times |
| | | Healing Component<br>- Percentage of men clinically healed 49-52 days post placement (42 days post-removal)<br>- Time at which point all men are clinically healed | Client records indicating healing per VMMC healing definition as completed by providers during day 49 healing assessment visit and subsequent weekly healing visits for those not healed at day 49<br>Photographs of the client's genital area, to be taken post-device removal (day 7), and at the day 49 healing assessment visit and at subsequent weekly healing visits |

## Evaluation Procedures and Logistics

### Evaluation Offices

Private spaces in the clinic sites will be used to privately administer interviews and counseling, and provide service referrals. Only evaluation staff, investigators and clients will be granted access to these spaces during the times the evaluation is being conducted. All documents and materials related to the evaluation will be stored in a locked cabinet in a locked office. Electronic data and files will be maintained on password protected computers, used only by the evaluation team.

### Clinic Space and Circumcision Area

The ShangRing procedures will be conducted in a sterile, surgical environment, at sites in Shinyanga, Tanzania.

### Staff Training

*Physician Training*

Physicians from Tanzania will be connected to physicians from countries with previous ShangRing experience (i.e. Kenya, Malawi, Uganda, Zambia) who have been trained and certified as Trainers of Trainers (TOT) at Ningbo Hospital, China, for training to be performed either in Tanzania, or the trainer's home country. The training will follow the framework outlined by expert consultants from the Department of Urology at the Weill Cornell Medical College. Studies suggest that newly trained providers needed to perform a minimum of 7 ShangRing procedures during training in order to be considered competent with the device.[32] Therefore, each trainee physician will perform at least 10 placements of the ShangRing device, and five removals as part of their training. All ShangRing procedures in this group will be closely monitored and tutored by the TOTs. The trainee physicians will act as both operator (the physician applying the ShangRing device) and as assistant alternately. The trainee physicians will also be trained on device removal and AE management. All routine follow-up, including the resolution of any adverse events, will be adhered to based on standard practice. All client data collected during the training phase will be included in the final analysis.

The ShangRing experienced physicians will use a checklist to document each trainee's proficiency. The checklist will include the following proficiencies:

- Determination of suitability for circumcision using ShangRing
- Selection of the correct ShangRing size
- The placement procedure and subsequent removal of the foreskin
- Prevention and management of pain
- Removal of the ShangRing device
- Post-circumcision follow-up of clients, including assessment of wound healing and identification and management of adverse events

When each physician's ShangRing skills are found acceptable by passing a training course and theoretical, practical and clinical tests, s/he will be certified by the training provider as competent. The newly certified Tanzanian physicians will then assist in training mid-level providers (registered and enrolled nurses) in Tanzania.

*Mid-Level Provider Training*

An integrated team, led by the TOTs and assisted by the recently ShangRing trained Tanzanian physicians, will conduct the training for mid-level providers (defined as registered and enrolled nurses) in Tanzania. In this phase of evaluation activities, each trainee mid-level provider will also successfully perform 10 placements and 5 removals before being deemed competent. All ShangRing procedures in this group will be closely supervised and

tutored by the integrated training team described above. When each trainee provider's ShangRing skills are found acceptable by passing a training course and theoretical, practical and clinical tests, s/he will be certified by the integrated training team as competent and permitted to participate in the evaluation as a ShangRing evaluation provider. Additionally, by having the recently trained Tanzanian physicians assist in the training of mid-level providers, the Tanzanian physicians will be better able to conduct future trainings in the event of ShangRing scale-up. All outcomes data during the training phase will be collected per the protocol as part of their training, but will not be included in the analysis.

*Additional Staff Training*

Additional implementation pilot staff will include site coordinators, counselors, and interviewers. All staff will be trained on evaluation implementation including: the protocol, evaluation methods, data management and security, research ethics, safety, human subjects protection and confidentiality. The evaluation staff will also receive basic training on the ShangRing device and appropriate messages to share with clients about the device and circumcision in general. This will help to ensure that implementation pilot staff is able to conduct proper and effective discharge sessions for evaluation subjects after the devices have been placed. The circumcision counselors will participate in a mandatory refresher training on the national guidelines for HIV counseling, testing and referral services. Interviewer training will entail a question by question discussion and consensus-building process on how to ask each question in the surveys and interview guides based on intent and current terms in common usage.

## Recruitment and Enrollment of Clients

### Recruitment

Phase 2 of the implementation pilot will recruit 455-495 male clients, aged 13 and up who are accessing conventional surgical circumcision services in two health facilities in Shinyanga in Tanzania. All male clients, 13 years and older, who arrive at participating clinics seeking VMMC services will be asked if they would like to participate in the evaluation and to receive a ShangRing device-based circumcision. There will be no ShangRing specific recruitment to identify men, instead men recruited through standard programmatic activities, or seeking circumcision on their own initiative, arriving at the clinic will be asked if they would like to participate. Potential clients will be asked until enrollment goals are reached. Clients will be entered into the evaluation in the order in which they enrolled, and therefore will be entered into either phase 1 or 2 depending upon which is ongoing when they enroll. Only subjects who sign an informed consent form (adults), or who have a parent/guardian provide informed consent (those aged 13-17) and provide assent, and meet the eligibility criteria listed below will qualify for enrollment.

Interested males will be informed about: (a) the evaluation requirements, (b) their potential role in the evaluation, (c) the ShangRing circumcision method, and (d) the evaluation procedures. Those males interested in participation will continue with the enrollment process, which includes the following:

- Administration of informed consent
- Confirmation of eligibility through inclusion/exclusion criteria
- Assignment of the client number
- Administration of evaluation questionnaires and case report forms (CRFs) to collect needed information
- Review of medical and medication history
- Completion of a physical examination, including a genital exam, and photography
- Collection of contact information from the client

Males with contraindications for circumcision or device circumcision will not be permitted to participate and they will be referred for standard surgical circumcision, if appropriate.

If a man cannot be circumcised on the day of screening and enrollment, he will be asked to return to the site within seven days to complete the circumcision procedure. Men who do not return within one week of screening will have to undergo re-screening to be enrolled.

Recruitment for the implementation pilot will begin as soon as the providers participating in the ShangRing training are considered competent in its application as demonstrated by passing knowledge and theory based tests, have performed no fewer than 10 placements and 5 removals (approximately 80-120), and deemed ready by the training clinicians to perform ShangRing circumcisions.

## Written Informed Consent

Written informed consent is required by the MoHCDGEC and the National Institute for Medical Research (NIMR). Eligible clients for this evaluation will read and/or have read to them the written consent form in English or the local language. Men aged 13-17 will also have a parent/guardian present to read/have read to them the written consent form in English or the local language. Eligible clients also will have the opportunity to have any questions answered by an evaluation nurse. Informed consent will cover evaluation procedures, potential risks, benefits, and contact persons for reporting complaints or concerns. Procedures will also be put in place to protect confidentiality of the client, and these procedures will be explained to the client prior to their enrollment. Evaluation nurses will explain the procedure and follow-up visits in detail including the need to take confidential photographs of the healing wound at follow-up visits. Evaluation nurses will tell potential clients that the procedure will provide to them safe male circumcision and help the MoHCDGEC to understand the best way to scale-up male circumcision and make it more accessible as one of the prevention strategies for HIV infection. Evaluation nurses also will notify potential clients that they have the right to withdraw from the evaluation at any time; however, if they choose to withdraw after the ShangRing device has been placed, they will need to wait at least 5 days before the device can be safely removed by trained staff. Males who test positive for HIV during screening will still be offered the opportunity to receive a ShangRing circumcision, and these men will receive additional counseling and referral for HIV care and treatment services as described below.

After the contents of the consent form are clearly understood by clients, they (and their parent/guardian, if applicable) will be asked to sign all or part of their name if they accept ShangRing circumcision and agree to follow-up visits. Clients who are unable to sign their name will be allowed to make a digital impression (i.e., thumbprint).

A copy of the signed consent form will be provided to clients and their parent/guardian if applicable (see Appendices III-VI for different consent forms). Another copy of the consent form will be maintained in the site's evaluation files in a locked file cabinet with access limited to evaluation staff.

## Eligibility Screening

The potential client's eligibility will be assessed through a medical history screening and a genital examination, which cover the inclusion criteria listed above and helps to ensure that the client is in overall good physical health. The screening and examination will be documented on evaluation forms (see Appendix VII).

Potential clients who are not eligible to participate in the evaluation will be offered standard surgical circumcision, if their reason for ineligibility does not likewise disqualify them from receiving a standard circumcision. The number and reasons for ineligibility will be recorded and included in the final evaluation report (See Appendix XII).

## HIV Testing Procedures

Serological testing for HIV, which follows national standards established and approved by the Tanzanian MoHCDGEC, is a standard component of male circumcision services globally.

HIV rapid testing will be conducted after receiving written informed consent, and completion of pre-test counseling by certified personnel. Per national guidelines, any person above the age of 18, or any mature minor less than 18 years of age may give informed consent to receive HTC services. A mature minor is defined as any person below 18 years of age who is married, sexually active, or otherwise believed to be at risk for HIV infection. A young person below 18 years of age who does not meet the definition of a mature minor may receive HTC services with the written consent of a parent or legal guardian. Tanzanian national HIV guidelines for HIV counseling, testing and referral services will be followed and pre-test counseling will include an explanation of HIV infection and transmission, the meaning of test results, and risks associated with sexual behaviors. Rapid testing will be conducted using the national algorithm in Tanzania. Clients will be tested using the standard national algorithm and tests. Clients will be informed of the result of their test verbally by a counselor upon its completion.

All potential clients will receive post-test counseling, with specific messages tailored to their test result. Men with negative results will be counseled on strategies for behavioral risk reduction, maintenance of risk reduction and explanation of risk reduction methods (e.g., condom use) before they provide consent for ShangRing circumcision. Men with positive results will be given referral to HIV care services and further counseling and testing, and can receive ShangRing or surgical circumcision that day if still desired and they are otherwise eligible. The counselor will inform them of any additional health assessments required under MoHCDGEC policy for them to access ShangRing or surgical circumcision. If rapid test results are indeterminate, per national guidelines the provider will immediately repeat the test following testing instructions, or another HTC provider/lab technician will repeat the test. If the test is still indeterminate, the client will be retested in two weeks.

All samples and specimens collected as part of routine HIV serological testing will be disposed of in accordance with Tanzanian MoHCDGEC VMMC program guidelines.

## Evaluation Identification Code

This evaluation will use evaluation identification (ID) codes for the various documents related to the evaluation including the CRF, photographs and surveys. The use of evaluation codes will link evaluation documentation with consent forms, which contain client names and signatures. An evaluation ID code will be created for every client. The master list, linking the ID codes with actual clinic records and the client's name, will be maintained by the site coordinator in a locked file cabinet in a locked office separate from all other evaluation files.

The evaluation ID will be an alphanumeric code created by elements related to the evaluation.

- Site location (Initials of site location)
- Date of enrollment
- Client number (consecutive)

In this regard, the first client enrolled at Good Hope Health Center (fictitious example) on September 1 would have the following evaluation ID code: GH0109001.

# Male Circumcision Using ShangRing Device

The ShangRing device contains the following items: two concentric plastic rings, the inner of which is lined by a silicone pad, a measuring tape, and bandages. These must be discarded after each use. The ShangRing device

also requires a removal cutter and removal key to remove the rings, which are sold separately but can be re-used after being thoroughly cleaned and disinfected. The ShangRing device also requires the use of general hospital supplies, local anesthetic, povidone-iodine, and instruments (e.g. hemostatic clamps, surgical scissors). These are not included with the device.

All circumcisions with the ShangRing device will be performed according to the ShangRing Instructions for Use. The current instructions are available online (here: http://www.who.int/hiv/topics/malecircumcision/prequal_mc_devices_2015.pdf ). The current IFU is under review by the WHO. If the WHO updates the IFU based upon its review, pilot providers will be advised to follow the new IFU.

At the end of the application procedure, a photo will be taken of the client's genital with the device in place. Ibuprofen 400 mg (or the equivalent of another non-narcotic analgesic) will be given to the client to use at home if needed. After the procedure the client will take part in a formal discharge and counseling session (as detailed below), where he will be instructed to return at set follow-up visits and to take painkillers in case of discomfort.

On the seventh day following device application, the client returns to the clinic to have the ShangRing device removed. The provider will examine the client's genitals and a photo of the genitals will be taken. After which the provider will clean the area, dress the wound with sterile gauze and secure the bandage with adhesive tape. The client will receive one dressing pad for home to change in case the dressing gets wet. The preparation and procedure time for the device removal will be measured and recorded. The client is instructed to return to the evaluation site in case of any unexpected event, to abstain from sex for six weeks or until the wound is clinically healed (whichever comes later) and to abstain from masturbation. The client will have another counseling session (detailed below) and instructed to return for the healing assessment six weeks later (day 49). Clients that are not clinically healed at day 49 will be asked to return to the clinic at weekly intervals to assess healing, until all clients are clinically healed.

The ShangRing device is intended for single use only and is supplied in a sterile environment. All ShangRing devices removed from clients will be destroyed before disposal. Specifically, the elastic ring is destroyed by cutting it with a scalpel, and the inner ring is destroyed by breaking it with a cutter. Surgical tools used during the ShangRing removal will be sterilized between procedures using an autoclave in accordance with infection prevention and control policies at the clinics.

## Key Post-Placement Procedure Counseling following ShangRing Circumcision

Following each circumcision with the ShangRing device, all clients will receive post-circumcision counseling. This counseling will occur on the day that the circumcision is performed and the ShangRing device is placed, and will stress the following messages:

- When to return for the follow-up visit (day 7) for removal of the ShangRing.
- The importance of abstaining from sex or masturbation for 7 weeks (49 days), following the placement of the ShangRing device, or until the penis is fully healed (whichever comes last).
- The importance of good hygienic practices while the device is in place and the wound heals, and how to keep the penis and wound clean and free of potential infection, and strategies to mitigate the risk of tetanus.
- The client will be instructed to return to the evaluation site in case of any unexpected event, for example if there is difficulty urinating, increasing swelling with discoloration of the penis, signs of infection (purulence), severe or increasing pain, the ring spontaneously detaches before day 7, or any other significant concern that they may have.
- The client will also be advised that painful erections may occur during the night.

- All clients will be provided with a phone number for the facility, and encouraged to call any time with any questions or concerns.
- All clients will be provided with a pamphlet with the above information, as well as with contact information for additional counseling if so desired (see Appendix XIII).

## Key Post-Device Removal Counseling following ShangRing Circumcision

Following the removal of the ShangRing during the day 7 follow-up visit, all clients will receive additional counseling. This counseling will stress the following messages:

- A phone call to the client to take place in 3 days to assess symptoms of AEs.
- When to return for the day 49 (42 days post-removal) visit to assess healing. And the importance of returning for that assessment.
- The importance of good hygienic practices while the wound heals, and how to keep the penis and wound clean and free of potential infection, including the importance of tetanus mitigation strategies.
- The client will be instructed to return to the evaluation site in case of any unexpected event, for example if there is severe discoloration of the penis, signs of infection (purulence), severe or increasing pain, or any other significant concern they may have.
- The client will be advised that painful erections may occur during the night.
- All clients will be provided with a phone number for the facility, and encouraged to call any time with any questions or concerns.
- All sexually active clients will be offered a package of condoms to take home.
- The importance of continued abstention from sex or masturbation for 6 weeks (42 days), following the removal of the ShangRing device, or until the penis is fully healed (whichever comes last).

## Key Post-Device Removal Counseling during AE Assessment Call

Three days following the removal of the ShangRing, all clients will receive a phone call to assess for symptoms of AEs. If the client is determined to be exhibiting signs of an AE, they will be advised to immediately return to the site that performed the circumcision for treatment. During this call, implementation pilot staff will also remind clients of the following:

- The importance of good hygienic practices while the wound heals, and how to keep the penis and wound clean and free of potential infection, including the importance of tetanus mitigation strategies.
- The client will be reminded to return to the evaluation site in case of any unexpected event, for example if there is severe discoloration of the penis, signs of infection (purulence), severe or increasing pain, or any other significant concern they may have.
- The client will be reminded that painful erections may occur during the night.
- All clients will be reminded that they are encouraged to call any time with any questions or concerns.
- The importance of continued abstention from sex or masturbation for 6 weeks (42 days), following the removal of the ShangRing device, or until the penis is fully healed (whichever comes last).
- When to return for the day 49 (42 days post-removal) visit to assess healing. And the importance of returning for that assessment.

## Follow-Up Visits

Active follow-up will be initiated for clients who fail to return on day 7 post-placement to have the device removed, or for other visits (e.g. AE follow-up) recommended by the ShangRing clinician. Each implementing site will assign staff to conduct follow-up telephone calls and home visits as needed. All active follow-up efforts will be documented on the appropriate forms designed for this purpose (Appendix XI). For clients who fail to return for device removal on day 7, active follow-up will start on day 8. Active follow-up will start with telephone calls to the contact number(s) provided by client and recorded on the locator information sheet at enrolment. An

introductory script for contacting clients by phone is attached as Appendix X. If a client is not reachable through direct voice calls, short text message reminders will be sent to his contact phone number. The reminder text message will include client name and specify the name and phone number of the clinic reaching out to him. The text message will not include the purpose of appointment visit for which the reminder is sent. Up to five calls will be made to reach the client; one per day starting on day 8, and continuing over the next 4 days through Day 12 (5 days post-procedure).

Once contact is made, the staff member will reinforce the importance of device removal and encourage the client to return to the circumcision site. If the client states that he is not able to return by day 9 post-placement, or the schedule day, or does not in fact return by day 9 or the schedule day, the staff member will attempt to verify the addresses provided to schedule an appointment at one of the address locations provided for device removal on day 9, or as soon as possible. If the client has not been successfully contacted by day 9 or the scheduled day, home tracing visits to the address he provided will begin. These will total up to 4 visit attempts on different days if necessary to reach the client.

For clients not under follow-up for AEs who miss scheduled visits other than the day 7 visit, follow-up will be done through phone by text messages or voice calls only, except in exceptional circumstances where a clinician deems physical follow-up necessary.

All clients in the evaluation will be followed up at three points in time following ShangRing circumcision, on day 7 (device removal), on day 10 (three day post-removal AE assessment phone call), and day 49 (42 days/6 weeks following device removal). Ten percent of all clients will be brought in on day 28 (21 days/3 weeks following device removal) for in-depth qualitative interviews.

At the day 49 visit, a clinician will assess healing, an evaluation staff will photograph the client's genitals to document healing, and the client will receive counseling that will stress the following messages:

- If the wound is considered to be healed, the client will be informed that they may resume sexual activity and masturbation, but counseled on the need to continue safe sexual practices.
- If the wound is not considered healed, the clinician will offer ask the client to return in one weeks' time to assess healing and ensure the wound is fully healed. The client will also be advised to continue abstention from sexual activity and masturbation.
- If the client is not considered healed, and there is a clinically indicated reason to schedule further follow-up to take place before the next weekly visit, the evaluation staff will schedule such follow-up visits at a medically appropriate time.
- All sexually active clients will be offered a package of condoms to take home.

One week preceding the day 49 healing assessment visit (day 42) the client will receive a short reminder text asking that the client contact the site to confirm the appointment. The reminder text message will include client name and specify the name and phone number of the clinic reaching out to him. The text message will not include the purpose of appointment visit for which the reminder is sent. The client will be asked to confirm the appointment by either calling the clinic, or by replying with a text. If the client does not confirm the appointment within 3 days, (day 45), the client will be sent a second text. If the client still has not confirmed the appointment by day (47), the client will receive one phone call per day from day 47-49 until they have confirmed the appointment or indicated their intent not to come. If the client does not come in on day 49 for the healing assessment visit, and has not indicated his desire to withdraw from the evaluation, then the client will be established as lost to follow up.

## Post Day 49 Healing Assessment Visits

Clients who are not considered healed at the Day 49 healing assessment will be asked to continue returning to the clinic at weekly intervals until they are clinically healed. At each weekly visit, a clinician will assess healing, an evaluation staff will photograph the client's genitals to document healing, and the client will receive counseling that will stress the following messages:

- If the wound is considered to be healed, the client will be informed that they may resume sexual activity and masturbation, but counseled on the need to continue safe sexual practices.
- If the wound is not considered healed, the clinician will ask the client to return again in on weeks' time to assess healing and ensure the wound is fully healed. The client will also be advised to continue abstention from sexual activity and masturbation.
- If the client is not considered healed, and there is a clinically indicated reason to schedule further follow-up to take place before the next weekly visit, the evaluation staff will schedule such follow-up visits at a medically appropriate time.
- All sexually active clients will be offered a package of condoms to take home.

## Unscheduled Visits

Additional visits may occur as needed for complications or adverse events, or for wound healing that is delayed beyond 49 days. Men will be told they should come for an unscheduled visit if they experience medical events such as: any unexpected event, for example if there is severe discoloration of the penis, signs of infection (purulence), severe or increasing pain, or any other significant concern they may have. During unscheduled visits, providers will:

- Review genital health and sexual activity and/or sexual function if applicable
- Examine penis and assess wound healing
- Review device-related events and AE, if applicable
- Review concomitant medications, if applicable
- Take photographs of genital area, if applicable
- Provide HIV risk reduction counseling and condoms (as needed)
- Schedule additional follow-up visits, if necessary
- Refer to a higher level of care, if necessary

**Telephone Calls Initiated By Clients due to AEs:**

The staff member will discuss the clinical course and AE with the client and encourage the client to return for review to the health facility where the circumcision procedure was performed, if deemed medically necessary. If the client does not return for follow-up visits deemed medically indicated, active tracing will be initiated. In situations where clients cannot be reached by telephone or located through physical tracing, after a total of 8 calls and 4 visits on different days, the case will be directed to the attention of the site manager for disposition. In this case, these clients will be considered to have experienced a moderate AE by default, unless follow-up indicating otherwise is able to be completed.

## In-Person Qualitative Interviews

The evaluation staff will select 50 individuals to participate in a more in depth in-person qualitative interview to be held 28 days post-circumcision. Fifty clients were chosen as the sample size, based on prior experience with evaluating acceptability of circumcision devices, which suggests that 50 is sufficient to obtain the necessary range of views and opinions. Only males aged 18 years or older will be eligible to be selected to participate in the qualitative interviews. All clients will be asked when they are enrolled if they are willing to participate in an interview. The first 50 clients, aged 18 years or older, to indicate willingness at enrollment to participate will be asked to interview. If after contacting these men for an interview, not all are able to participate, clinic staff will

continue to proceed down the list of clients in the order in which they enrolled and agreed to an interview, until 50 clients are selected. These interviews will be used to assess client pain, discomfort, and satisfaction with the procedure. Males selected for the qualitative interviews may refuse to participate or withdraw at any time, the reason for their refusal/withdrawal will be recorded and reported. Clients will be offered a small amount to reimburse their travel and time spent for the interview (estimated to be between 20-25 USD/45,000-56,500 Tanzanian Shillings but not to exceed 30 USD/67,900 Tanzanian Shillings).

Interviewers will receive training on the administration of the surveys and questionnaire, question by question in English or Swahili (Tanzania). In order to ensure quality of the interviews training will be provided. Once data collection begins, the site supervisor will also review one out of every ten of the completed surveys conducted by each interviewer. Following each review, the evaluation supervisor and interviewer will meet to discuss areas where the interviewer could improve. Draft interview guides are included in Appendix XVIII.

## Quality Control and Quality Assurance

In order to assure quality of the clinical and surgical procedures, the following has or will be done:

- Sites with previous MC experience and with MoHCDGEC endorsement for MC services will be used for this evaluation.
- All circumcisions with ShangRing will be by adequately trained and certified providers.
- Experienced VMMC providers, trained in surgical and ShangRing circumcision, will be present at each site to monitor and assess the quality of services being provided, including observing surgical procedures and identifying and addressing any quality assurance problems.
- Relevant documentation will be obtained and maintained at evaluation sites.

## Photography

Photographs of the client's penis and genital area will be taken by a clinic staff member, after the ShangRing device is placed, after the ShangRing device is removed, at the day 49 healing assessment visit, and at subsequent healing visits for those clients not healed at day 49. Additional photographs may be taken at the request of the attending clinician as necessary in case of unscheduled medical visits, such as occurrence of AEs. The photographer will take four photographs, presenting a 360˚ view around the glans and showing the frenulum. The photographer will take photographs while a special photo frame is placed around the penis including the subject evaluation number, date of photo, and evaluation day. The photos will not include the client's face. Clients will be asked for consent prior to any photograph, and reserve the right to refuse photographs at any point. Clients will not be removed from the study if they choose not to be photographed.

At the end of each day, all photographs will be downloaded to a password-protected evaluation computer saved in a specific location and backed up on a removable hard drive. The removable hard drive will be kept separate from the computer for ensuring no loss of data. Photographs will not be erased from the camera digital memory card in order to create space on the card. In case the card is full, a new card will be used. The evaluation staff will maintain the removable hard drive and digital memory cards in a secure locked cabinet in a locked office accessible only by evaluation staff. Photographs and digital files will not be kept for more than one year. Upon the conclusion of the evaluation, and the publication of the final report, the digital photographs will be disposed of per Tanzanian MoHCDGEC policies.

The purpose of the photographs is to document complete healing, cosmetic results, complications and adverse events. The photographs collected will be used in part to chart and document healing over time, in order to better understand the healing timeframe. An analysis of healing times will be performed by clinic staff and project investigators in order to better inform the pre-procedure counseling messages clients receive with regard to healing – and when resumption of sexual activity can begin following the procedure. Photographs will

also be used to document and report AEs. When an AE is reported, the photos will be reviewed and verified by project investigators as part of a medical investigation.

## Data Management and Analysis

### Data Collection

Data from the client's surgical and male circumcision medical records will be recorded on CRFs included in the Appendices (see Appendices VII and IX) The CRFs will be used to transfer the information collected in the performance of this evaluation to the clinical database. The original CRF will be kept in the clinic files and a copy will be maintained with additional documentation specifically for this evaluation including photographs, interviewer administered surveys and brief questionnaires. The hardcopy data will be entered into the evaluation database at each site. Corresponding forms, surveys and questionnaires will be completed immediately after each subject's visit. The site coordinator will review the CRFs for completeness and accuracy (signatures, dates, adverse events, serious adverse events, protocol departures) sign/date the forms where indicated. The evaluation team will retain originals of all source documents, subject consent forms, photographs and evaluation data as a permanent record.

The following data will be collected from clients receiving ShangRing circumcision:

***Clinic Visit #1: Enrollment and Circumcision (Day 0)***

- Documentation of general physical screening and medical examination on CRF
- Documentation of medication history on CRF
- Documentation of genital examination on CRF
- Documentation of device-related events and AE on forms, as needed
- Administration of evaluation survey after circumcision
- Collection of contact information from the client

***Clinic Visit #2: Removal Visit (Day 7)***

- Photographs of genitals after device removal
- Documentation of wound healing and genital examination on CRF
- Documentation of device-related events, AE and treatment and resolution of AE, as needed, on forms
- Documentation of changes to medical condition and medication on CRF
- Administration of evaluation survey after device removal

***AE Assessment Phone Call (Day 10)***

- Administration of an interview to determine whether client is experiencing signs and symptoms of an AE

***Follow-Up In-Person Qualitative Interview (Day 28)***

- For 50 clients
- Interview to determine client's feelings about ShangRing circumcision experience

***Follow-Up In-Person Healing Assessment (Day 49)***

- Documentation of wound healing and genital examination on CRF
- Photographs of genitals to document healing
- Documentation of device-related events, AE and treatment and resolution of AE, as needed, on forms
- Documentation of changes to medical condition and medication on CRF

***Additional Wound Healing and Unscheduled Visits***

- Documentation of wound healing and genital examination on CRF
- Documentation of device-related events, AE and treatment and resolution of AE, as needed, on forms
- Documentation of changes to medical condition and medication on CRF
- Photographs of genitals to document healing

The following data will be collected from providers conducting ShangRing circumcision: results from theoretical tests, practical test of hands-on-skills and clinical test of performing ShangRing on subjects following participation in a formal training course; the rate of AE, the rate of device-related incidents and the average procedure time of trainees undergoing ShangRing device training; and strengths and weaknesses of the training, effectiveness of training package/materials, satisfaction with training, and suggestions for improvement of training and facilitation. Providers and select staff working in the facilities where the evaluation is being conducted will also be interviewed about device acceptability.

Source documents for this evaluation include, but are not limited to, staff notes, medical notes, client CRFs and files, screening and interviews and interviewer notes, enrollment logs, informed consent forms, client reimbursement logs, audiotapes and transcripts from qualitative interviews.

Clinic-based data collection will rely on standard clinical forms with data abstracted onto evaluation specific CRF and AE forms. Evaluation providers will complete both standard surgical and evaluation specific forms. The evaluation coordinator, or the site coordinator in the evaluation coordinator's absence, will verify the completeness of forms. Surveys and interviews will be administered by evaluation-hired interviewers. Data collection for this evaluation will be completed using standardized forms for quantitative, clinical data. Providers and interviewers will complete the forms. Once a form is completed, it will be copied and given to site coordinator for data entry. The original form will be retained in the client file at the evaluation site and the copy will be stored in the evaluation office in a locked file cabinet.

Clients and clinic staff/providers interviews will have data collected with digital recordings and interviewer notes. Translations and transcriptions of the digital recordings will be made. Original digital recordings will be destroyed once they have been translated and transcribed. Interviewer notes and transcriptions will be stored in in the evaluation office in a locked file cabinet.

The original client file, normally maintained by the clinic, will contain all source documents. This source file will be maintained at the site and be available for review as needed by the evaluation team. The original CRF will be retained at the evaluation site in the client's file. All subsequent changes to the CRF will be documented on the relevant CRF.

No names or other identifying information will be collected on the various forms other than the clinical record, only client IDs. Completed forms will be given to the site coordinator in an evaluation client folder.

## Adverse Events Management

ShangRing clinicians will be trained on how to detect and manage the known complications of ShangRing circumcision. The responsibilities of the attending clinician in management of AEs will be as follows:

- Manage the AE in a manner consistent with national guidance and the Adverse Event Action Guide for Voluntary Medical Male Circumcision by Device or Surgery, 2nd edition. This may include urgent surgery at the ShangRing facility.
- In the event of a complication that requires client referral to a higher level of care or specialist attention, make sure that the referral is effected and that the client is transferred to the point of care.

- Document and report the event as described in the section below. Moderate, severe and serious AEs should be documented and reported even if they are not apparently related to the procedure.
- Take photographs to document the progression of the AE.
- Notify the lead ShangRing clinician at the site about the event to begin the reporting process describe below.

## Adverse Event (AE) and Other Device-Related Incident Documentation

AE and other incidents that occur as a result of the ShangRing device will be recorded as part of this evaluation. All events and incidents – including mild, moderate and severe AE, expected side effects such as common post-operative findings, occurrences resulting from clients' failure to follow instructions, and device malfunctions – will be documented on the appropriate visit section and device-related events form of the CRF. Events classified according to the definitions provided as mild, moderate and severe based on the PEPFAR AE definitions below should also be recorded on the adverse events form of the CRF. The adverse events form will include a description of the onset, duration, relationship to the procedure, severity, seriousness, and final outcome of the AE. For additional information on severity criteria by type of AE see Appendix XV.

For the purposes of this evaluation AEs that are related to the evaluation device will be graded using the following definitions as guides:

- Definitely related: direct association with the procedure, i.e., follows a reasonable temporal sequence and is a recognized AE of the procedure. Note that this does not imply any error on the part of the provider or client, only that the event would not have happened if the procedure had not been performed.
- Likely/possibly related: more likely explained by the procedure, i.e., follows a reasonable temporal sequence from the procedure and is a plausible AE of the procedure, but could have another cause.
- Likely unrelated: more likely explained by another cause.
- Definitely unrelated: clearly explained by another cause.

A physician will evaluate each AE for severity, seriousness, and relationship to the MC procedure, per the categories and criteria delineated in the *AE Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 2nd Edition* (see Appendix XV for table of AEs and severity). To ensure objectivity, the evaluating physician will be brought in from a site other than where the circumcision was performed. Any evaluating physician should be trained in male circumcision, and have experience evaluating adverse events. Methods to assess the severity, seriousness and relatedness of the AE are detailed in the evaluation SOP manual. Evaluation physicians will be trained to make these assessments in a manner as standardized as possible. The site coordinator will verify that this information will be captured during every evaluation subject visit. AEs will be managed medically as appropriate, and will be followed until resolution or until a clinically stable endpoint is achieved.

The incidence and severity of all AEs related to the circumcision procedure will be documented and collected on the appropriate visit section and device-related events form of the CRF. This form will include a description of the onset, duration, relationship to the procedure, severity, seriousness, and final outcome of the AE. Severe and serious AEs, as well as AEs related to client self-removal of the ShangRing, will also be documented on the ShangRing Device Related Adverse Events form (see Appendix XIV), which must be completed for all AEs that result in hospitalization and all AEs classified as severe per the AE classification guidelines, as well as for those whose severity cannot be classified. The evaluation will compile and analyze mild, moderate and severe AE to determine the AE rate. All other device-related events, including expected side effects and occurrences resulting from clients' failure to follow instructions, will be compiled and summarized to inform program policy related to ShangRing use.

For the purposes of this evaluation, **all** severe AEs must be reported to the CDC **within 24 hours of notification**. Standard reporting procedures for all **notifiable** AEs must be followed per PEPFAR and national guidelines.

## ShangRing and Tetanus

Because the foreskin is removed at the time of device application, ShangRing is not believed to pose increased risk of tetanus when compared to conventional surgical MC. For the purposes of this evaluation, tetanus cases will be treated as a severe AE and must be reported to CDC **within 24 hours of notification**.[33] As tetanus is also a notifiable AE, standard reporting procedures for tetanus must be followed per PEPFAR and national guidelines.

## Data Entry

Once completed and verified, information contained on CRFs and AE forms in client evaluation folders will be forwarded to site coordinator. The coordinator at each site will be responsible for re-confirming the completeness of the forms before giving them to the data entry manager. For each question on the CRFs, the data entry screen will contain a variable name, description, type and code list, if appropriate. Ten percent of the CRFs and AE forms will be checked by the site coordinator for accuracy and quality control. Any inconsistencies will be resolved with the help of the data manager or site coordinator. The data manager or site coordinator will document the item with an apparent error, the original data stored in the data field, a description of the error/omission/inconsistency and revised data (if any). The data manager or site coordinator will note when the revision was made and the rationale for making the revision. The database will be backed up on a daily basis.

Electronic files containing the transcripts from qualitative interviews will be transferred to a qualitative data analysis program such as Atlas.ti.

Quantitative data will be entered using Microsoft Excel, or another standard statistical software. The local data warehouse that contains the electronic evaluation data will be located on a password-protected computer.

Client folders, containing paper-based evaluation forms, will be maintained in a secure locked cabinet in the locked evaluation office. Access to this information and the office will be limited to the circumcision coordinators, site supervisors and investigators.

## Data Management

The electronic files from the local data warehouse will be uploaded by the site supervisor for inclusion in the central data warehouse at the end of each day. The site supervisor will also store a back-up copy of the files on a flash drive and CD-ROMs that will be kept in a locked cabinet. The data manager will upload all local files to a central data warehouse located on a password-protected computer.

The database will be encrypted and maintained by the data manager in a central data warehouse.
The data manager will perform continuous quality assurance checks to ensure that the database is clean and that there are no illogical responses. The data manager will communicate with site staff to resolve the identified issues, if necessary. The data manager will document the item with an apparent error, the original data stored in the data field, a description of the error/omission/inconsistency, revised data (if any), noting who made the revision, when the revision was made, and the rationale for making the data change.

All databases will be password protected and data will be encrypted before transmission over public networks.

As noted above, all photographs will be downloaded to a password-protected evaluation computer saved in a specific location and backed up on a removable hard drive. The removable hard drive will be kept separate from

the computer for ensuring no loss of data. Photographs will not be erased from the camera digital memory card to create space on the card. In case the card is full, a new card will be used. The evaluation staff will maintain the removable hard drive and digital memory cards in a secure locked cabinet in a locked office accessible only by evaluation staff. The digital files will be disposed of in accordance with Tanzanian country policies upon conclusion of the project and the completion of any final analyses and reports.

## Analysis Overview

Quantitative and qualitative data collection will occur during the period comprising the start of evaluation recruitment and the end of the follow-up period of evaluation clients. Data analysis will be conducted in parallel with the recruitment and follow-up process of evaluation clients.

Baseline demographics and client characteristics will be presented in tabular format using descriptive statistics. Binary data such as adverse events will be presented as counts and percentages and the upper limit of the estimate of the AE rate (percent of clients with one or more AE) will be based on a two-sided 95% confidence interval. Adverse event rates will be compared descriptively with the reported rates of similar treatments reported in Tanzania and elsewhere, including: comparison against AE rates found in other studies of ShangRing, comparison against AE rates found in studies of other circumcision devices, and comparison against reported rates of AEs in studies of surgical circumcision. No formal hypothesis tests will be done comparing AE rates in this evaluation to other AE rates.

Adverse event rates will be presented by seriousness, severity, relation to device and outcome by site and by cadre. Continuous data will be represented by a mean, standard deviation, median, minimum and maximum together with 95% confidence intervals for the means. The number and percent of subjects who fail to complete the evaluation will be assessed. Time to withdrawal may also be assessed. The procedure time will be calculated. The first 15 procedures performed by each provider will be compared to the last 15 procedures by that provider with respect to procedure time, to evaluate whether procedure time is shortened with experience. All of the first and last 15 procedures evaluated will take place during the main implementation pilot phase. If a provider does not perform 30 total procedures following the training phase, then the first half of the total number of procedures performed will be compared against the last half. Adverse event rates from the training and post-training phases will also be reported, as well as an overall AE rate. Procedure times during the provider training phase will be tracked, but not used for comparisons. The differences in mean procedure times will be compared with a t-test or a non-parametric equivalent.

Standard statistical software packages R, Stata or SAS will be used for the analysis. No corrections for missing values will be imputed. The data will be analyzed and presented “as-is”.

Client acceptability, time to return to normal activity, and clients’ satisfaction with the post-circumcision cosmetic results will be summarized from data recorded on the evaluation surveys and during qualitative interviews conducted with 10% of randomly selected clients. Similarly, provider acceptability will be summarized from data recorded during qualitative interviews conducted with providers. Qualitative interviews will be digitally recorded and then transcribed by qualified staff. The recordings will transcribed according to the local language used and then to English. The recordings will not be marked with any identifying information but with a unique identifier. Transcriptions will be reviewed electronically, using a qualitative interview analysis software such as Atlas.ti or NVivo, and analyzed for themes. The analysis of the qualitative data will be done through an inductive process where categories are identified as they emerge. Opinions generated by the 10% of clients included in the interviews will be used to tailor the messaging for future program implementation.

The percentage of men healed by day 49, and the time at which all clients are healed, will be reported from data recorded on the client CRFs. The proportion of men unsuitable for ShangRing MC will be extracted from an evaluation log maintained for the purpose of documenting the number of ineligibles and the reasons for their exclusion. Similarly, the number of men who decline ShangRing or who withdrawal will be reported as a proportion.

The photographs taken to document healing and adverse events will be used to supplement the analysis of both endpoints. Photographs will be reviewed only by evaluation project staff, and used to enhance the understanding of different adverse events and as evidence of the duration of the healing process. Photographs of all adverse events (if the client consents) will also accompany the AE reporting, to provide further clarity on these events. The photos will also be used by project staff to better educate ShangRing providers.

### Long-Term Data Storage

Each evaluation site in Tanzania will keep the originally signed informed consent documents for each client, the original CRFs, and originals of all other evaluation documentation (e.g., photographs, surveys product-tracking tools and master logs). The data will be owned by the Tanzanian MoHCDGEC and IntraHealth. The data warehouse will be kept at a location agreed upon by IntraHealth and the Tanzanian MoHCDGEC. The software used for the data warehouse will also be agreed upon by IntraHealth and the Tanzanian MoHCDGEC. Following the completion of evaluation data collection, these documents will be transferred to the Tanzanian MoHCDGEC where it will be maintained for a minimum of five years and will be available for monitoring, audit or inspection as needed. The evaluation database also will be maintained by the MoHCDGEC for a minimum of five years, CDC-Tanzania will keep a copy of the data, which will be stored on a password protected computer and with password protected evaluation files. A process will be established to share data with interested researchers after the publication of evaluation results.

A data transfer agreement will be signed whenever data is taken out of the country. Data available for transfer will include aggregate data from client records data collected through the standardized ShangRing specific data collection forms (device placement and removal times, adverse event forms, etc.), photographs, written data and transcripts from the provider interviews and surveys, and written data and transcripts from the client qualitative interviews. All data will be reviewed to make sure that it is completely de-identified before sharing, and any party interested in obtaining the data must agree to make no effort to identify either clients or providers through their use of the data – and must alert the MoHCDGEC if they inadvertently do so.

## Ethical Considerations

### Potential Harm and Measures to Mitigate Harm

Participation in this evaluation is believed to pose no more than minimal risks. Potential complications of the ShangRing device circumcision include excessive bleeding, hematoma, infection, pain, wound dehiscence, injury to the glans or urethra, excessive or insufficient skin removal, and poor cosmetic results. The use of the ShangRing device has yielded low rates of adverse events in different studies. In a proof of concept evaluation in Kenya, all 40 procedures were completed successfully.[34] Only three mild adverse events, all cutaneous injuries of the skin of the penis, was reported among the 40 clients (7.5%) and mean pain scores were low. A second evaluation in Kenya enrolled 197 men, each of whom received successful ShangRing circumcisions, these were compared against 201 men who received conventional surgical circumcisions.[35] The ShangRing group experienced AEs at a similar rate to the conventional surgical circumcision group, with 14 moderate and one severe AE in the ShangRing group (7.6%) and 10 moderate AEs in the conventional surgical circumcision group (5.0%). The severe AE was a case of pain that occurred in the ShangRing group during the circumcision. The other AEs included: wound dehiscence, post-procedure pain, and an anesthetic complication. All AEs were

treated and resolved without problems. The pain scores between the two groups were similar at most points of time, with the exception that the pain during an erection while the device is in place was significantly higher for the ShangRing group. A comparative evaluation in Uganda found that a majority of men chose ShangRing over the dorsal slit method when asked to choose a preferred procedure, 508 chose ShangRing compared to 113 (though four men who chose ShangRing had to receive conventional circumcision when the ShangRing procedure failed, these failures occurred early in the evaluation and were attributed to provider inexperience).[36] There were no differences in the rate of moderate and severe AEs between the two groups – five total (1%) in the ShangRing group, and one (.9%) in the conventional surgical circumcision group. The AEs included post-operative pain, bleeding, infection, wound dehiscence, and insufficient skin removal. Additional studies in Kenya and Zambia have found similar rates of AEs between ShangRing procedures and conventional circumcision.[37]

Clients will be reminded during the device placement and removal visits to come into the clinic for follow-up care should any complications arise for example if there is severe discoloration of the penis, signs of infection (purulence), severe or increasing pain, or any other significant concern they may have. If clinical care is required after evaluation close-out, care will be provided at the evaluation site as part of their regular activities. If necessary, men may be referred to a hospital near the evaluation site for additional care. To assist in locating clients who do not return for scheduled follow-up, personal contact data such as addresses, cell phone numbers, and contact information of friends and family members will be collected. If clinical care is required after evaluation close-out, care will be provided at the evaluation site as part of their regular activities.

Potential conventional surgical complications of male circumcision include excessive bleeding, hematoma formation, infection, pain, injury to the glans or urethra, excessive or insufficient skin removal, and poor cosmetic results. It is expected that at least some of these complications will be decreased with the ShangRing, or will at minimum occur with similar frequency as with conventional male circumcision. There are, however, AEs specific to the ShangRing method of circumcision, such as device displacement or malfunction.

Research studies performed on this topic have found no association between circumcision status and increased risky sexual behaviors. One such study was performed in Kisumu, Kenya, between 2009-2013. In that time, the circumcision prevalence increased from 30% to 60%, but despite this increase there was no or minimal sexual risk compensation.[38] A second research study performed in Nyanza Province, Kenya (where Kisumu is located), found similar results. This study followed 3299 males, aged 18-35, for two years. Half of this group was circumcised at enrollment in the study, the other half was not. The males in the study were surveyed on their sexual behaviors several times over the two years. The study found that not only was there no evidence of risk compensation among circumcised men but both circumcised and uncircumcised men significantly reduced their HIV risk behaviors.[39] Recently, separate studies in Kenya, South Africa, and Zambia further corroborated these results. Each study found no evidence that circumcised men are more likely to engage in risky sexual behavior than uncircumcised men.[40]

Although clients will be asked to sign a written consent to participate in this evaluation, several procedures will be taken to minimize the risks associated with participation. All clients will be provided with photocopies of their signed consent and assent forms.

1. Counselors and interviewers will reiterate that participation in the evaluation and circumcision are voluntary. They will conduct all counseling and interviews in a private area.
2. All adverse events will be immediately treated and clients will be followed to resolution. AE will be clinically managed according to 2nd edition of the Adverse Event Action Guide. Clients will be entitled for continuation of clinical follow-up and treatment until their evaluation related clinical problem has been resolved, even beyond the six week follow-up period.

3. Consistent with standard clinic procedures and MoHCDGEC policy, surgical and male circumcision medical records and evaluation instruments (i.e., consent forms and paper-based surveys) will be stored in a secured, locked file cabinet in a locked office with access limited to select evaluation staff.
4. All electronic files will be kept on an encrypted and password-protected computer with access limited to select evaluation staff.
5. All evaluation staff interacting with clients will be required to sign an Employee Confidentiality Agreement (see Appendix XXIII for this form*)*.
6. Sites with previous MC experience and with MoHCDGEC endorsement for MC services will be used for this evaluation. Relevant documentation will be obtained and maintained in the central evaluation files.
7. All providers who will perform the ShangRing procedures will be trained by others experienced with the device. Training certificates will be on file.

## Potential Benefits

Regardless of the circumcision procedure performed, research studies have shown that circumcised men are at a reduced risk for acquiring urinary tract infections and sexually transmitted infections, including HIV. In addition, available data on ShangRing suggests that it is associated with shorter procedure times, similar pain scores, similar AE rates, and similar or higher client satisfaction scores than standard MC.[41]

Additional potential individual benefits associated with participating in this evaluation include the following:

- Enhanced counseling for HIV and other STIs
- Condoms, health information, and referrals for HIV prevention services

## Social Harm Events

Social harm events will be reported to the Tanzanian Bioethics Committees and all other ethical review boards including to the Bioethics Committee, and CDC ADS. Potential incidents may include protocol noncompliance, breach of confidentiality, loss of privacy, stigmatization, relationship difficulties, physical or verbal abuse, interference with gainful employment, and coercion. Social harms may be identified during interviews with the clients or by other evaluation staff. All social harm events (i.e., events potentially related to evaluation participation) should be brought to the attention of the site coordinator. Clients who report social harm events will be referred to speak with an evaluation staff person. **The site coordinator or his/her designee will report the event on the device-related events form to the Principal Investigator within 24 hours** of becoming aware of the event in the same way that severe AE are reported (above). Social harm events will then be reported to all ethical review boards. The device-related events form for this evaluation is located in Appendix XIV.

Protocol noncompliance may be identified by the evaluation staff or the investigators during the periodic and closeout monitoring visits as well as during in-house monitoring. The procedures for capturing, recording and reporting protocol noncompliance will be specified in the evaluation manual and data management plan. Non-emergency noncompliance from the protocol must be approved by the investigators. If these changes might affect the scientific soundness of the protocol or the rights, safety, or welfare of human subjects, IRB approval is also required prior to implementation. Deviations from the protocol by clients will not be considered protocol noncompliance (e.g., not following wound care instructions; missing a follow-up visit, etc.). Evaluation staff will provide continued counseling of and education for the clients who do not adhere to the prescribed evaluation procedures.

An emergency departure from protocol that eliminates an apparent immediate hazard to a client and is deemed crucial for the safety and well-being of that client may be instituted for that client only by the site coordinator or his/her designee. In those cases, the site investigator will **notify the IRBs in writing** as soon as possible, no later

than **five working days** after the emergency occurred, and document on the Protocol Violation form reasons for non-compliance and ensuing events.

Generally, non-emergency non-compliance is the result of simple human error by site staff. In all such cases, the non-compliance event must be documented. If protocol non-compliance events persist, refresher training in evaluation procedures will be undertaken.

## Approvals and Consultations

This evaluation is being submitted for approval from the National Institute for Medical Research, and the Centers for Disease Control and Prevention Office of the Associate Director of Science (OADS).

## Data Security and Confidentiality

Clients will be identified by name only on their client CRF, but not on any survey questionnaire, photograph, or any other documentation. All evaluation records will be kept in a locked file cabinet with access limited to evaluation staff only. Client identifiers, such as names and faces, will not be shown in or written on any photograph taken during this evaluation. Client identifiers will be entered on a master client log that links names and identification numbers; that log will be stored in the locked file cabinet with restricted access.

Clients' evaluation files at the site, including informed consent and CRF, will be kept in a locked file cabinet with access limited to evaluation staff. Clients' information will be filed by client ID number, with names written in a discrete location (e.g., on the inside cover of the client's file folder) in order to reduce the chance of an inadvertent breach of confidentiality. Clients will not be reported by name in any report or publication resulting from data collected in this evaluation.

All computerized database records will identify clients by identification numbers only. Electronic data files will be maintained on password-protected computers accessible only by site coordinators and investigators.

## Potential Risks

While medical male circumcision is generally a safe procedure, clients are at risk for a number of adverse events including pain, injury to the penis, risk of excessive bleeding, and infection, among others. Some of these adverse events have resulted in death in the past. As noted above, the rate of adverse events in circumcision programs, and through previous ShangRing trials, is very low. All men will be counseled on the risk of adverse events when enrolling in the evaluation, and will have the option to withdraw from the procedure until the device is placed.

## HIV Notification Policy

All men enrolling in this evaluation must consent and agree to receive an HIV test. Men not wishing to receive an HIV test will be offered conventional surgical circumcision. Men who do receive an HIV test, and test positive, will be notified of their status per Tanzanian Voluntary Medical Male Circumcision Program guidelines. Additionally, men who test positive will be actively linked to HIV care and treatment, also per program guidelines.

## Sponsor Monitoring

As the evaluation sponsor, the Centers for Disease Control and Prevention (CDC) may conduct monitoring or auditing of evaluation activities to ensure the scientific integrity of the evaluation and to ensure the rights and protection of evaluation clients. Monitoring and auditing activities may be conducted by:

- CDC staff ("internal")
- authorized representatives of CDC (e.g. a contracted party considered to be "external")
- both internal and external parties

Monitoring or auditing may be performed by means of on-site visits to the MMC clinic or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of CDC. During the visit, any evaluation-related materials may be reviewed and the Investigator along with evaluation staff should be available for discussion of findings. The evaluation may also be subject to inspection by regulatory authorities (national or foreign) as well as the IECs/IRBs to review compliance and regulatory requirements.

### Conflicts of Interest

The project investigators and co-investigators report no conflicts of interest.

### Reimbursements

Reimbursement for evaluation participation will be offered to compensate clients for the substantial commitment of time and effort required to complete surveys and interviews and to return to the clinic for follow-up visits (Day 7, Day 49, and subsequent follow-up healing visits). It is anticipated that clients will receive transportation and time reimbursement only for their follow-up clinic visits (not for the initial placement visit), transportation and time reimbursement for the qualitative interview, and a HIV prevention kit for participation in the evaluation. Based on an analysis of transportation costs in Shinyanga, and considering the length of times the clients are in the clinic for the VMMC procedure, the value of time and transportation reimbursement is estimated to be between 7-10 USD per visit (16,000-22,000 TZS). If the cost of transportation within Shinyanga, Tanzania increases, the reimbursement may increase to keep pace with the economic environment. However, the reimbursement value will not exceed 12 USD (27,000 TZS) per visit. Reimbursements will be paid to the client upon the conclusion of the visit. For clients under 18, the time and transportation reimbursement will be paid to the client's guardian accompanying them to the clinic upon the conclusion of the visit.

Some benefits offered for participating in this evaluation (e.g., the provision of condoms and educational materials) may be perceived as additional incentives. During the qualitative interviews conducted with all providers trained to use ShangRing and a random sample of clients, a snack valued at approximately 3 USD (6,500 Tanzanian Shillings) will be offered.

## Projected Timeline

The estimated time needed to complete the evaluation, including ethical approvals and report dissemination, is 12 months.

During the preparatory phase, # mid-level providers will participate in a (length in days TBD) training course in good clinical practice. All providers who successfully complete this course will receive formal training on ShangRing device application and removal. The training will be conducted by the trained doctors from countries with previous ShangRing experience (Kenya, Zambia, Uganda).

The detailed timelines for both the preparatory and implementation phases of the evaluation are provided in Tables 2 and 3. Additional details about interactions with clients, including the application and removal of the device and client follow-up, are provided in Table 4.

## Dissemination of Findings

Throughout the course of the evaluation pilot key stakeholders in Tanzania will receive a monthly update on the status of the pilot. In Tanzania, key stakeholders include the following: MoHCDGEC, PORALG, RCHMT VMMC TWG, Tanzania PEPFAR TWGs, IntraHealth, and Jhpiego. A monthly update will be provided by IntraHealth. The purpose of these updates is to ensure that all parties that will ultimately assume responsibility for transitioning the pilot to active surveillance under the Ministry are involved. As enrollment approaches completion, discussions will include the transition from evaluation pilot to active surveillance oversight.

Upon completion of primary data analysis and prior to finalizing a final report, findings will be shared with leadership at MOHCDGEC and the national VMMC TWG to ensure the involvement of key stakeholders in the report writing process. Feedback gathered will be used to complete the final evaluation report, which is intended to inform and shape MoHCDGEC policies regarding the use of devices for adult male circumcision in Tanzania. Other means of dissemination will include presentations at international meetings and workshops, and submission of manuscripts to peer reviewed journals. The primary manuscript of the main evaluation results (primary evaluation objectives) will be a project shared by MoHCDGEC, PORALG, CDC, Jhpiego, IHI, and other implementing partners. The final report will be produced in alignment with PEPFAR requirements, and will also be posted in English on a publically accessible website within 90 days of clearance, per PEPFAR regulations. Any presentations/manuscripts on the main evaluation results will assign proper credit and acknowledgment to the contributions of all partners. Presentations/manuscripts on secondary analyses of evaluation data may be undertaken by each partner who has the capability to utilize the data properly and professionally. Requests for data will be made to MoHCDGEC in writing and all collaborating partners will review all presentations or manuscripts for accuracy. No data collected in this evaluation may be published without prior written agreement of relevant staff.

## Table 3: ShangRing Implementation Pilot Timeline – Preparatory Phase

| **Activities** | **Quarter 4 (July – September 2018)** | | | **Quarter 1 (October – December 2018)** | | | **Quarter 2 (January – March 2019)** | | |
|---|---|---|---|---|---|---|---|---|---|
| | July | August | September | October | November | December | January | February | March |
| ***Preparatory Phase*** | | | | | | | | | |
| Protocol Development | X | | | | | | | | |
| Human Subjects review and clearance | X | X | | | | | | | |
| Hire manager and interviewers | | X | X | | | | | | |
| Interviewer training | | X | X | | | | | | |
| Data collection: qualitative interviews with clinicians | | | X | X | | | | | |
| Training of clinicians in Tanzania | | | X | X | | | | | |
| Data collection: qualitative interviews with clinicians and surveys with ShangRing circumcised males | | | | X | X | | | | |
| Client follow-up and documentation of outcomes | | | | X | X | X | | | |
| *Implementation Activities* | | | | → | → | → | → | → | |

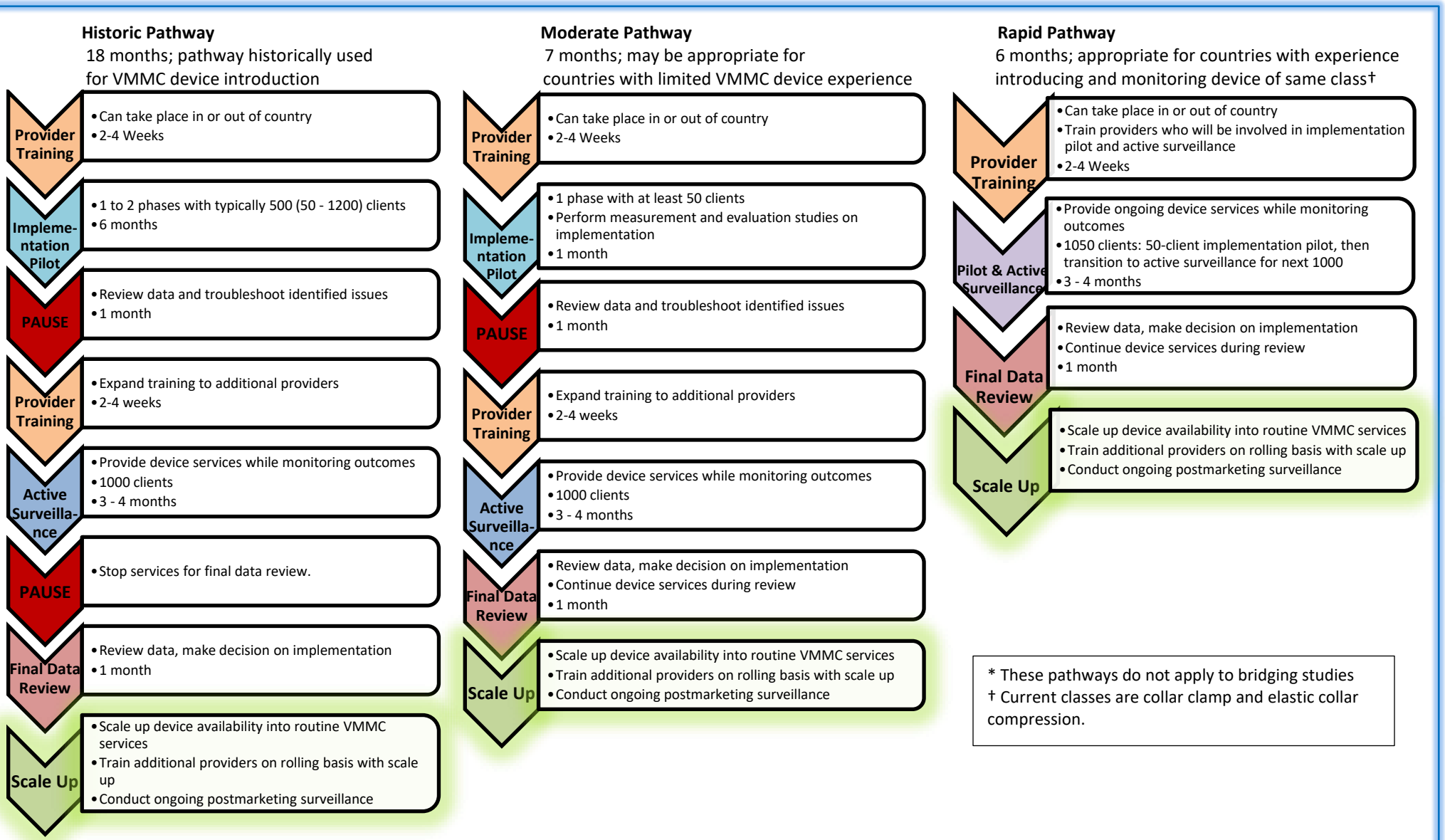
## Table 4: ShangRing Implementation Pilot Evaluation Timeline – Implementation Phase

| Activities | Quarter 4 (July – September 2018) | | | Quarter 1 (October – December 2018) | | | Quarter 2 (January – March 2019) | | | Quarter 3 (April – June 2019) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | July | August | September | October | November | December | January | February | March | April | May | June |
| ***Implementation Phase*** | | | | | | | | | | | | |
| *Preparatory Activities* | → | → | → | | | | | | | | | |
| Mid-level provider training in Tanzania | | | X | X | | | | | | | | |
| Counseling and messaging training | | | | X | | | | | | | | |
| Data collection: qualitative interviews with doctors and mid-level providers | | | | X | | | | | | | | |
| Site Preparation | | | X | X | | | | | | | | |
| Client follow-up and documentation of outcomes from practice | | | | X | X | | | | | | | |
| Recruitment of clients for evaluation and device placement | | | | X | X | | | | | | | |
| Client follow-up and documentation of outcomes | | | | X | X | X | | | | | | |
| Data collection: all men at 4 points (immediately after circumcision, at device removal, 49 days post circumcision) | | | | X | X | X | X | | | | | |
| Data collection: 10% of men 28 days after device placement | | | | | X | X | X | | | | | |
| Data cleaning and merging | | | | | | X | X | X | | | | |
| Write preliminary report | | | | | | | | X | X | | | |
| Discuss report and findings with key stakeholders | | | | | | | | | X | X | X | |
| Present final report to TWG | | | | | | | | | | | | X |

# Appendices

## Appendix I - Pathways for Introduction of VMMC Devices

This schematic shows three potential alternative pathways for introducing a new prequalified device into voluntary medical male circumcision programs, based on extent of previous experience with device introduction. All are consistent with the WHO Framework for Clinical Evaluation of Devices for Male Circumcision, 2012, designed to ensure appropriate safety monitoring in introduction.*




Regardless of pathway, preparation for introduction and implementation of a new technology should follow a participatory planning process that includes all key stakeholders. *Beginning with the end in mind: planning pilot projects and other programmatic research for successful scaling up* (WHO 2011) provides a framework on how to design pilot projects with scaling up in mind to increase the likelihood that they can be implemented on a large scale if proven successful.

## Appendix II – Consent form for Male Circumcision by ShangRing

What you should know about this program:

- This consent form explains the requirements for circumcision by the ShangRing device.
- Please read it carefully and take as much time as you need. Someone is available to read the material to you, if you are not able to read by yourself.
- A device called ShangRing is now available as an alternative method of circumcising males 13 years and above who are HIV-negative. The ShangRing device has been used to perform large numbers of circumcisions in China and other countries and has been researched in Kenya, Uganda, and Zambia. You are being offered the opportunity to choose between being circumcised by the ShangRing device or through the conventional surgical method.

## Purpose of the implementation pilot

You are being offered the opportunity to take part in a program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device in selected health facilities. Although ShangRing has been successfully used in other countries, the purpose of this program is to learn more about using this method of circumcision for large numbers of males in Tanzania to decide whether to begin offering it all over the country.

ShangRing circumcision differs from surgical circumcision because it is done without stitching, which makes the procedure much faster, but the device must stay on the penis for 7 days before removal. However, most men and boys who have been circumcised using the device are not bothered while wearing the device.

## Why you are being asked to participate

You are being asked if you want to take part in this implementation pilot evaluation because you have come to the clinic for circumcision, you are 13 years or more, and have indicated that you are willing to take an HIV-test .If you choose to take part in this activity, you will be assessed to determine if you are eligible for circumcision using the ShangRing device. This will include HIV testing.

## Procedures

If you are eligible and agree to ShangRing circumcision, the health care team will give you anesthetic by [injection/topical cream] in your penis to prevent pain during the procedure. The ShangRing will be placed on your foreskin, compressing it to prevent bleeding. The rest of your penis is protected and will not be compressed. Then your foreskin will be removed and the ShangRing will be left in place to protect the wound while it heals.

You will be asked to return to the clinic on the seventh day to have the device removed. It is important not to try to remove the device yourself, as this can cause bleeding and infection, and to contact the clinic immediate if the device comes off or moves.

You will also be asked to return 6 weeks (42 days) after the device is removed in order to review healing. If you are not healed 6 weeks after the device is removed, you will be asked to return to the clinic once a week until you are completely healed.

You will be asked to answer some questions by telephone three days after the device has been removed. During this call you will be asked questions to assess how well you are recovering from the procedure. You will also be asked if you are willing to participate in an interview three weeks (21 days) after the device is removed. If you agree and are selected to participate in an in-person interview, you will be reimbursed for your time and transportation to the interview site and provided a snack during the interview.
To receive ShangRing circumcision, you must also provide your contact information and alternative information for contacting you, including a physical address, and you must consent to being contacted by text, phone and visits if needed, to make sure you get the ShangRing removed in case you are unable to return to the clinic. Alternative contact information may include workplace, school or cell number belonging to a friend or relative through whom you can be reached. If you do not return to the clinic to have it removed in time, we will need to use your contact information to reach or visit you. If we send you a text message, it will include your name and specify the name and phone number of our clinic. But the purpose of appointment visit will not be included in the text message reminder.

You may come to the clinic at any time if you have concerns or a problem related to circumcision. You will be given instructions for how to care for your wound. For any care needed after normal clinic hours, or any concerns at any time, please call the 24-hour clinic phone number provided:

Primary #+_____(Site specific or assigned to the clinician on call)

Secondary #_____(Site specific)

In the unlikely event of a complication, the medical team would also like to request your permission to take photographs of your penis. This will help us to learn about possible complications so that we can better prevent them. It is up to you to decide whether or not to allow photographs, and you can still participate and receive ShangRing surveillance activity whether or not you agree to have photographs taken. If you agree, your permission will still be asked before any photograph is taken. There are no risks to you related to the pictures taken because your name will not be attached to the photograph but only your program identification number. Your face or other body parts will not be photographed. Any photographs of your penis that may be taken, as well as all information collected from you in the surveillance, will be kept in your file in a locked cabinet at the clinic to be accessed only by clinic staff responsible for your care.

## Risks/discomforts

There are some risks and discomforts with ShangRing circumcision.

- You may have some pain during the week you are wearing the ShangRing device because of the pressure on the penis. You may also have some pain when you have erections before the ring is removed.
- As with any circumcision, there are risks of infection, delayed healing, and other complications. Rarely, these can be serious, requiring more surgery or hospitalization to treat. Very rarely, there can be death or deformity due to the procedure. In order to

minimize these risks, your providers follow careful quality standards and you will be educated about correct wound care.

## Benefits

The benefits of being circumcised include lowered risk of HIV infection for men who are currently HIV-negative; lowered risk of some sexually transmitted infections, and improved hygiene. The benefit of circumcision from the ShangRing device compared to surgical circumcision may include less time and less pain from the procedure, the ability to return to work or your regular activities sooner, and a better appearance of the penis after the circumcision has healed because no stitches are used. By participating in this surveillance activity, you will provide additional information about ShangRing that the MOH will use to guide further and more widespread use of this device for circumcision. You will also be compensated for your time, including reimbursement for time and travel to all ShangRing related follow-up visits to the clinics, and for the qualitative interview, if applicable. The value of compensation will be determined based upon the cost of transportation, and is expected to be between 16,000-22,000 Tanzanian Shillings. You will be reimbursed at the clinic, upon the conclusion of your visit, for each visit after the initial placement visit (device removal, healing assessment, and interview, if applicable).

**Alternatives:** You can choose not to be circumcised, or you can choose to be circumcised using the surgical method.

Do you have any questions?

## What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this program's purpose, procedures, and possible benefits and risks of the procedure.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this program and to return for device removal.
- You agree to be contacted by phone, through friends, at your workplace, home or any other place for device removal or any other necessary follow ups.
- You have been informed that you will not be charged for the treatment received.
- You have been informed that you will not be given monetary compensation for participating, except for reimbursement for time and travel.

I understand and accept the benefits and risk for taking part in this program as stated above.
I have decided on my own free will to take part (or allow my child to take part) in this program.

Name of client:_____

Name of guardian if applicable: _____

Signature of client, or guardian if client is a minor:_____

_____
Day Month Year

**If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:**

I was present throughout the entire informed consent process with the volunteer. All questions from the volunteer were answered and the volunteer freely decided whether to accept the benefits and risk for taking part in this program.

**Signature of Witness** **Date**

**Printed Name of Witness**

I certify that I have explained to the client (and volunteer if applicable) the nature and purpose, the potential benefits, and possible risks associated with participating in this program.

**Signature of Clinic Staff Person Who Obtained Consent** **Date**

**Printed Name of Clinic Staff Person Who Obtained Consent**

## Appendix III – Additional Informed Consent Form for Photography

## Additional Informed Consent Form for Photography

## Volunteer Agreement for Photography

This Additional Informed Consent Form for Photography during the program has been read and explained to me. I have had a chance to ask questions about the program. I have agreed to take part as a volunteer. I have freely decided to allow clinic staff to take pictures of my penis during this program. I also understand that if I agree, the clinic staff will still ask my permission before pictures are taken at any contact.

☐ YES, **I also agree** to have clinic staff take photographs of my penis during this program.

☐ NO, **I do not agree** to have program staff take photographs of my penis during this program.

_____ _____

**Signature or Thumb Print of Volunteer** **Date**

_____

**Printed Name of Volunteer**

**If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:**

I was present throughout the entire informed consent process with the volunteer. All questions from the volunteer were answered and the volunteer freely decided whether to permit photography of his penis during this review. If he agrees, the volunteer also understands that he will be asked for his permission before photographs are taken at each visit/before each occurrence.

_____ _____

**Signature of Witness** **Date**

_____

**Printed Name of Witness**

## Appendix IV – Additional Informed Consent Form for Qualitative Interview

# Additional Informed Consent Form for Qualitative Interview

## Purpose of the Qualitative Interview

You are being asked to participate in an interview meant to evaluate your experience with the ShangRing device. The purpose of this interview is to gauge the attitudes of men who have received a ShangRing device-based circumcision, in order to evaluate its acceptability to clients. Information derived from these interviews will be used to inform the use of the ShangRing device in the Tanzania voluntary medical male circumcision program.

## Why you are being asked to participate

You are being asked if you want to take part in this qualitative interview because you received a ShangRing circumcision as part of the program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device in selected health facilities.

## Procedures

If you are one of the 50 clients selected to take part in this activity, you will be asked a series of questions by an interviewer that are designed to assess your feelings and attitudes about your ShangRing circumcision. All of your answers are confidential, and you will not be quoted by name in any report that is produced as a result of this program. The interview will last for approximately one hour (60 minutes). You will be reimbursed for your time and for transportation costs to and from the interview site, and provided a snack during the interview. You may choose not to participate in this interview, not to answer certain questions, or to end the interview whenever you wish.

Do you have any questions?

## Volunteer Agreement for Qualitative Interview

This Additional Informed Consent Form for Qualitative Interview has been read and explained to me. I have had a chance to ask questions about the interview. I have agreed to take part as a volunteer. I have freely decided to participate in this interview.

☐ YES, **I agree** to participate in a qualitative interview.

☐ NO, **I do not agree** to participate in a qualitative interview.

_____ _____

**Signature or Thumb Print of Volunteer** **Date**

_____

**Printed Name of Volunteer**

**If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:**

I was present throughout the entire informed consent process with the volunteer. All questions from the volunteer were answered and the volunteer freely decided whether to participate in this interview.

_____ _____

**Signature of Witness** **Date**

_____

**Printed Name of Witness**

## Appendix V - Assent Form for Male Circumcision by ShangRing (For Ages 13-17)

What you should know about this program:

- This form explains what will happen if you get circumcised using the ShangRing device.
- Please read it carefully and take as much time as you need. Someone can read the material to you, if you are not able to read by yourself.
- A device called ShangRing is now available as a new method of circumcising males who are 13 years old or older and who do not have HIV. The ShangRing device has been in China and other countries and has been studied in Kenya, Uganda, and Zambia You have the chance to choose whether to be circumcised by the ShangRing device or through the normal surgical method.

## Purpose of the implementation pilot

You have the chance to take part in a program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (/MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device.

The purpose of this program is to learn more about using the ShangRing in Tanzania to decide if it should be offered all over the country.

ShangRing circumcision is different from surgical circumcision because the client does not need stitches after the procedure. It is faster, but the device must stay on the penis for 7 days before it is taken off. But, most men and boys who have been circumcised using the device are not bothered while wearing the device.

## Why you are being asked to participate

You are being asked if you want to take part in this program because you have come to the clinic for circumcision, you are 13 years old or older more, and have agreed to take an HIV-test.

If you choose to take part in this activity, you will be checked to see if you are eligible for circumcision using the ShangRing device. This will include taking an HIV test.

## Procedures

If you are eligible and agree to ShangRing circumcision, the health care team will apply a cream to your penis to prevent pain during the procedure.

The ShangRing will be placed on your foreskin, squeezing it tightly to prevent bleeding. The rest of your penis is protected and will not be squeezed. Then your foreskin will be removed and the ShangRing will be left in place to protect the wound while it heals.

Do not to try to remove the device yourself, because it can cause bleeding and infection. Contact the clinic immediate if the device comes off or moves.

You will be asked to come back to the clinic on the seventh day to have the ring taken off. You will also be asked to return 6 weeks (42 days) after the device is removed in order to look at healing. If you are not healed 6 weeks after the device is removed, you will be asked to return to the clinic once a week, until you are completely healed.

You will be asked to answer some questions by telephone three days after the ShangRing is taken off. You will be asked questions about how well you are recovering from your circumcision.

To receive ShangRing circumcision, your parents must also provide:

- A telephone number and backup number
- Your physical address
- Your parents must agree to being contacted by text, phone and in-person visits. This information is needed to make sure you get the ShangRing removed in case you are unable to return to the clinic
- Your parents must also agree to come back to the clinic with you when you have the device taken off, and when you come back for your healing visit

The backup number may be a number at your workplace or school, or a cell number belonging to a friend or relative where we can reach them. If you do not return to the clinic to have the ShangRing removed in time, we will need to use this contact information to reach or visit you. If we send your parents a text message, it will include your name and the name and phone number of our clinic. But the reason of the visit will not be included.

You may come to the clinic at any time if you have concerns or a problem related to circumcision. You will be given instructions for how to care for your wound. For any care you need when the clinic is closed, or any concerns at any time, please call the 24-hour clinic phone number provided:

Primary #+_____(Site specific or assigned to the clinician on call)

Secondary #_____(Site specific)

It is unlikely, but if you have a problem because of the circumcision, the medical team will ask for your permission to take photographs of your penis. This will help us to learn about possible problems so that we can better stop them from happening. It is your choice whether or not to allow photographs. You can still participate even if you do not want to have photographs taken.

If you agree, your permission will still be asked before any photograph is taken. There are no risks to you related to the pictures taken because your name will not be attached to the photograph. Your face or other body parts will not be photographed. Any photographs of your penis that may be taken, as well as all information collected from you, will be kept in your file in a locked cabinet at the clinic, and only clinic staff taking care of you will be able to open it.

You and your family will not be charged for your circumcision as part of this program, this also includes treatment if you need to return to the clinic for any reason after your surgery. You and your family will also not be paid to participate in this program, but your family will be given money to cover the cost of travel to and from the clinic.

## Are there risks or discomforts?

There are some risks and discomforts with ShangRing circumcision.

- You may have some pain during the week you are wearing the ShangRing device because of the pressure on the penis. You may also have some pain when you have erections before the ring is removed.

- As with any circumcision, there are risks of infection, delayed healing, and other complications. Rarely, these can be serious, and you may need more surgery or hospitalization to treat. Very rarely, there can be death or permanent damage to the penis due to the procedure. In order to reduce these risks, your health care team follows careful quality standards and you will be taught correct wound care.

## What are the benefits?

The benefits of being circumcised include:

- Less risk of HIV infection for males who are HIV-negative right now
- Less risk of some sexually transmitted infections
- Improved hygiene.

The benefits of circumcision from the ShangRing device compared to surgical circumcision may include:

- Less time and less pain from the procedure
- The ability to return to work or your regular activities sooner
- And the penis may look better after it has healed because no stitches are used.

By participating in this program, you will provide additional information about ShangRing that the MoHCDGEC will use to guide further and more widespread use of this device for circumcision.Your family will also be paid back for its time and travel costs, including for time and travel to all ShangRing related follow-up visits to the clinics (16,000-22,000 Tanzanian Shillings per visit, depending upon cost of travel).

## What are my other choices?

You can choose not to be circumcised, or you can choose to be circumcised using the surgical method.

Do you have any question?

## What does your guardian's signature on this form mean?

Your signature on this form means:

- You know about this program's purpose, procedures, and possible benefits and risks of the procedure.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this program and to return for device removal.
- You agree to be contacted by phone, through friends, at your workplace, home or any other place for device removal or any other necessary follow ups.
- You have been informed that you will not be charged for the treatment received.
- You have been informed that you will not be paid for participating, except for reimbursement for transportation costs to the clinic to have the device removed.

| **Parent/Guardian Assent:** |
|---|

I understand and accept the benefits and risk for taking part in this program as stated above.
I have decided on my own free will to allow my child to take part in this program.

Name of client:_____

Name of guardian if applicable: _____

Signature of client, or guardian if client is a minor:_____

_____
Day Month Year

**Client Assent:**

Your parent/guardian has given parental consent because you are below the age of consent according to the law. However, the decision to be circumcised or not is yours and you have the final decision. If you sign below, it means that you agree to be circumcised using the ShangRing method.

Client Assent signature: _____

**If Parent/Guardian Cannot Read the Form Himself, A Witness Must Sign Here:**

I was present throughout the entire informed consent process with the volunteer and their guardian. All questions from the volunteer were answered and the volunteer and parent/guardian freely decided whether to accept the benefits and the risk of participating in this program.

_____ _____
**Signature of Witness** **Date**

_____
**Printed Name of Witness**

I certify that I have explained to the volunteer and their parent/guardian the nature and purpose, the potential benefits, and possible risks associated with participation in this program.

_____ _____
**Signature of Clinic Staff Person Who Obtained Consent** **Date**

_____
**Printed Name of Clinic Staff Person Who Obtained Consent**

## Appendix VI – Informed Consent Form for Photography (For Ages 13-17)

# Additional Informed Consent Form for Photography (For Ages 13-17)

## Parent/Guardian Agreement for Photography

This Additional Informed Consent Form for Photography during the program has been read and explained to me. I have had a chance to ask questions about the program. I have agreed that my child may participate as a volunteer. I have freely decided to allow clinic staff to take pictures of my child's penis during this program. I also understand that if I agree, the clinic staff will still ask both my child's and my permission before pictures are taken at any contact.

☐ YES, **I also agree** to have clinic staff take photographs of my child's penis during this program.

☐ NO, **I do not agree** to have program staff take photographs of my child's penis during this program.

_____ _____

**Signature or Thumb Print of Volunteer** **Date**

_____

**Printed Name of Volunteer**

**Client Assent:**

Your parent/guardian has given parental consent because you are below the age of consent according to the law. However, the decision to be agree to be photographed is yours and you have the final decision. If you sign below, it means that you agree to allow clinic staff to take pictures of your penis as part of this program.

Client Assent signature: _____

**If Volunteer Cannot Read the Form Himself, A Witness Must Sign Here:**

I was present throughout the entire informed consent process with the volunteer and their parent/guardian. All questions from the volunteer and their parent/guardian were answered and the volunteer and their parent/guardian freely decided whether to permit photography of his penis during this review. If he agrees, the volunteer and their parent/guardian also understands that they will be asked for permission before photographs are taken at each visit/before each occurrence.

_____ _____

**Signature of Witness** **Date**

_____

**Printed Name of Witness**

## Appendix VII – Case Report Form (CRF) – Screening

# CASE REPORT FORM – SCREENING

Evaluation of the safety and acceptability of the ShangRing device for male circumcision in Tanzania

Site Code: ☐☐☐

Client ID # (CID): ☐☐☐☐☐☐☐☐☐

*A copy of the full SOP Manual is available upon request.

## INSTRUCTIONS FOR THE PROPER COMPLETION OF THE CRF

Please follow the instructions below:

1. Use a ball-pen, DO NOT use a pencil, a marker or a fountain pen.
2. Make sure to place the separator provided under the last copy of each page so that data recorded on one page does not copy to the next.
3. Subject initials will be comprised of the first letter of the first name followed by the first letter of the surname.
4. Fill in the form in a clear, concise and readable way. Use common medical terminology.
5. Correct wrong data by crossing out the information with a single line and writing the correct data next to it. The evaluation coordinator, or the site coordinator in the evaluation coordinator's absence, will initial and date the correction.
    a. Example: ~~07/03/1969~~ corrected to 09/03/1969 (with initials and date of the correction)
6. Complete all the available boxes, DO NOT leave empty fields.
    a. For evaluations not performed record ND (not done).
    b. For data not relevant to the subject or stage of evaluation record NA (not applicable).
    c. If you do not know the data, please use the initials UNK (unknown).
    d. Use leading zeroes if necessary (e.g.: 15 mg = 0 1 5 mg).
    e. Make sure to complete every header on each page.
7. Please make sure to **circle the correct option** whenever it is requested.
8. Please DO NOT add wording to CRF pages unless required. For any additional comments please use the Comments Sheet at the end of the CRF modules.
9. Dates (e.g., date of birth, date of visit) will be recorded in the DD/MM/YYYY format.
    a. Example: 19 June 2017 will be recorded as 19/06/2017
10. CID is the Client Identification Number. It comprises the initials of the site followed by the four digit enrollment date and the three digit subject consecutive number. Example: Subject number 1 in Good Hope Health Center enrolled on July 21 will be GH2107001.
11. Time will be recorded in 24:00 format.
    a. Example: 6:15 pm will be recorded as 18:15

Client's CID:

## ELIGIBILITY CONFIRMATION

| Inclusion Criteria | (check appropriate box) | |
|---|---|---|
| Male 13 years or older | Yes ☐ | No ☐ |
| Wants to be circumcised | Yes ☐ | No ☐ |
| Is uncircumcised | Yes ☐ | No ☐ |
| HIV sero-negative | Yes ☐ | No ☐ |
| Able to communicate in English or Swahili | Yes ☐ | No ☐ |
| Lives within 30 km of the facility | Yes ☐ | No ☐ |
| Agrees to be circumcised using the ShangRing device | Yes ☐ | No ☐ |
| Capable and willing to provide written informed consent (18 years and older), or written informed consent from parent (13-17 years) | Yes ☐ | No ☐ |
| If 13-17 years old, parent/guardian agrees to be present during circumcision (skip if client is older than 17) | Yes ☐ | No ☐ |
| Penis fits into one of the 18 ShangRing ring sizes | Yes ☐ | No ☐ |
| Able to understand the evaluation procedures and requirements | Yes ☐ | No ☐ |
| Agrees to abstain from sexual intercourse and masturbation, for six (6) weeks post removal (i.e., seven (7) weeks total) | Yes ☐ | No ☐ |
| Willing to provide valid contact information (i.e., telephone number, address of residence, place of employment and other locator information) | Yes ☐ | No ☐ |
| Has an activated cell/mobile phone or access to a cell/mobile phone | Yes ☐ | No ☐ |
| Agrees to complete brief evaluation surveys to assess satisfaction: post-placement and post-removal | Yes ☐ | No ☐ |

**Any "NO" answer disqualifies the subject from participating in the evaluation**

| **Exclusion** Criteria | (check appropriate box) | |
|---|---|---|
| Male below 13 years | Yes ☐ | No ☐ |
| Correct fitting ShangRing size is not available | Yes ☐ | No ☐ |
| Has the following diseases: hypospadias, hydrocele, scrotal hernia, balanitis, epispadias | Yes ☐ | No ☐ |
| Known bleeding/coagulation abnormality | Yes ☐ | No ☐ |
| Is cognitively impaired | Yes ☐ | No ☐ |
| Has a serious chronic illness, which is not well-controlled (subject not feeling well or has significant medical complaints) | Yes ☐ | No ☐ |
| Has an active genital infection, current urethral discharge, or other STI symptom | Yes ☐ | No ☐ |
| Has another condition, which in the opinion of the supervising circumcision coordinator (a medical doctor) prevents the subject from undergoing circumcision with the ShangRing device | Yes ☐ | No ☐ |

**Any "YES" answer disqualifies the subject from participating in the evaluation**

Client's CID:

## INFORMED CONSENT VERIFICATION

| | | |
|---|---|---|
| Has the client been informed according to the protocol? | Yes ☐ | No ☐ |
| Has the consent been obtained **before** any evaluation related procedures? | Yes ☐ | No ☐ |
| Has the client signed the photography consent form? (Declining photography does not exclude the client from participating) | Yes ☐ | No ☐ |
| Has the client provided a phone number and agreed to be contacted by evaluation staff | Yes ☐ | No ☐ |
| Has the client signed the consent form? | Yes ☐ | No ☐ |
| Consent Date: _____ | | |
| Has the client been provided with a photocopy of the signed consent form? | Yes ☐ | No ☐ |
| Does the client agree to participate in the in-person qualitative interview three weeks post-removal? (If yes have client complete in-person interview consent during post-MC counseling) | Yes ☐ | No ☐ |
| Does the client agree to return for a healing assessment 6 weeks post-removal, and subsequent weekly healing visits if not healed at 6 week post-removal visits? | Yes ☐ | No ☐ |

Date of Birth (day/month/year): _____

Age in Years: _____

***Include a copy of the signed consent with this form in client evaluation file***

Client's CID:

## CLIENT CONTACT INFORMATION

**First Name:**_____ **Surname:**_____

**Contact number(s) Home:**_____ **Mobile:**_____

**Work:** _____

**Preferred time to receive evaluation calls:**_____

**Address and description of area of residence:** _____

_____

_____

**Place of employment:** _____

**Family member/friend name:** _____

**Contact number(s):** _____

## Appendix VIII – Tanzania MoHCDGEC Male Circumcision Client Form

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

VOLUNTARLY MEDICAL MALE CIRCUMCISION

INDIVIDUAL CLIENT RECORDS

## CLIENT PROFILE

1. Name of health facility or MC site _____
2. Service Delivery Approach Static / routine ☐ Outreach/mobile/campaign ☐
3. Client's Name: _____ Phone _____
4. Client ID Number _____
5. Client's Address:
   Region _____
   District _____
   Ward _____
   Village _____
   Age years _____
6. Marital status: Married ☐ Single ☐ Cohabiting ☐ Not applicable (minor) ☐
7. Visit Date: ☐☐ ☐☐ ☐☐☐☐
   d d m m y y y y

## COMING FROM

| | |
|---|---|
| Self-referred | |
| VCT | |
| PITC | |
| Other (please describe) | |

## MEDICAL HISTORY

8. Has the client had any STIs in the last 3 months? Yes ☐ No ☐
9. Does the client currently have any of the following complaints?
   a. Urethral discharge: Yes ☐ No ☐
   b. Pain on erection: Yes ☐ No ☐
   c. Pain on urination: Yes ☐ No ☐
   d. Genital warts: Yes ☐ No ☐
   e. Genital sore (ulcer): Yes ☐ No ☐
   f. Swelling of the scrotum: Yes ☐ No ☐
   g. Difficulty in retracting foreskin: Yes ☐ No ☐
   h. Others: _____

10. Is client under treatment for any of the following?

| CONDITION | DIAGNOSED (Y/N) | ON MEDICATION (Y/N) |
|---|---|---|
| Hypertension | Yes ☐ No ☐ | Yes ☐ No ☐ |
| Diabetes | Yes ☐ No ☐ | Yes ☐ No ☐ |
| HIV/AIDS: | Yes ☐ No ☐ | Yes ☐ No ☐ |
| Others (eg. TB)_____ | | |

11. Has client ever had any surgical operation? Yes ☐ No ☐

12. Any complications related to previous surgery? Yes ☐ No ☐ (If yes specify)

    a. Infection ☐

    b. Excessive bleeding ☐

    c. Other _____

13. Any history of bleeding problems in self or family members? Yes ☐ No ☐

14. Any known allergies to any of these medications:

    a. Local Anesthetics: Yes ☐ No ☐

    b. Antiseptics: Yes ☐ No ☐

    c. Any other medications (specify) _____

15. Any history of Tetanus vaccination? Yes ☐ No ☐ Don't Know ☐

    d. Date of most recent tetanus booster _____

    e. Verified by vaccination record? Yes ☐ No ☐

**PHYSICAL EXAMINATION**

16. Any significant physical abnormality on general examination? Yes ☐ No ☐

    If yes, specify_____

17. Weight_____Kg: Vital signs before procedure: Pulse rate: _____beats/min

    Blood pressure: _____/_____mmHg Temperature _____(°C)

18. Penile examination (tick):

    a. Urethral discharge Yes ☐ No ☐

    b. Smegma under the foreskin Yes ☐ No ☐

    c. undescended testicles Yes ☐ No ☐

    d. Condylomata lata/ acuminate Yes ☐ No ☐

    e. Hydrocele Yes ☐ No ☐

    f. GUD Yes ☐ No ☐

    g. Phimosis / paraphimosis Yes ☐ No ☐

    h. Adhesion of Prepuce to glans Yes ☐ No ☐

    i. Balanitis/redness/swelling of foreskin/ glans/ shaft Yes ☐ No ☐

    j. Chordae (banana shaped penis) Yes ☐ No ☐

    k. Other (specify)

19. Client medically cleared for MC procedure? Yes ☐ No ☐ If no, why? _____

## HIV TESTING

20. Client tested for HIV as part of MC service Yes ☐ No ☐

21. Date of testing: ☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

a. Test result: Negative ☐ Positive ☐ Indeterminate ☐

## CLIENT REFERRED TO

22. a. STI ☐ b. Other surgical/medical ☐ c. CTC ☐ d. psychosocial support ☐ e. client not referred ☐

**INFORMED CONSENT FOR MALE CIRCUMCISION PROCEDURE**

I _____ have agreed and consented for you to do the operation of Circumcision (removal of the foreskin) on me/my child. I understand that Male Circumcision is a surgical procedure and with any medical or surgical procedure there are risks involved.

I have read/ had it read and understood this consent form. I have been given enough information and a chance to ask questions and all my questions about male circumcision have been answered in a satisfactory manner.

I am the parent ____legal guardian____ (*tick the relationship for MC procedure on minor).
My signature below indicates that I have freely given permission for me/my child to have Male Circumcision performed.

| _____ | _____ | _____ |
|---|---|---|
| Thumbprint/signature of client/parent/guardian | Signature MC provider/counsellor | Date |

## MC PROCEDURE

23. MC procedure conducted Yes ☐ No ☐

24. Date of MC procedure ☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

Time Started _____ Time Finished _____

25. Anaesthesia Used: Lignocaine_____ml ____% Bupivicaine: _____ ml_____%
Other _____ml _____%

26. Method: Forceps-guided ☐ Dorsal Slit ☐ Sleeve Resection ☐
Surgeon's Name:_____Cadre: _____
Assistant's Name:_____ Cadre: _____
Additional Notes (if needed):_____

27. Intraoperative AE: Any adverse event occurrence during procedure? Yes☐No ☐ If yes tick type of AE below..

a. excessive skin removal Yes☐No☐
b. damage to penis Yes☐No ☐
c. excessive bleeding Yes☐No ☐
d. anesthetic-related event Yes☐No ☐
e. other

28. Severity of intraoperative AE:

a. Mild ☐ b. Moderate ☐ c. Severe ☐

## POST-OP AND DISCHARGE

29. Please describe the condition of the bandage in relation to bleeding:

a. Bandage clear ☐ b. Blood spot on bandage ☐ c. Bandage soaked ☐

30. Vital Signs after procedure:

Pulse rate: _____beats/min c. Blood pressure: ___/___mmHg d. Body temperature_____ (°C)

31. General condition at discharge:

Satisfactory ☐ b. Needs follow up ☐ c. Not discharged ☐

32. Analgesics given Yes ☐ No ☐ Type and dosage given. Specify_____

## FOLLOW-UP NOTES

Date of first follow up visit: ☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

Days post-op:_____

Notes: _____

Did a post-operative AE occur? Yes ☐ No ☐

If AE occurred, date of AE

☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

Condom given Yes ☐ No ☐

Quantity given _____

Date of Second follow up visit: ☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

Days post-op:_____

Notes: _____

Did a post-operative AE occur? Yes ☐ No ☐

If AE occurred, date of AE

☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

Condom given Yes ☐ No ☐

Quantity given _____

## POST OPERATIVE AE BY TYPE

Type of AE at first follow up visit:

(i) a. Bleeding or blood soiling of the BANDAGE Yes ☐ No ☐

b. Swelling of the penis or scrotum Yes ☐ No ☐

c. Persistent pain Yes ☐ No ☐

d. Infection Yes ☐ No ☐

e. Failure to pass urine Yes ☐ No ☐

f. Other: Specify_____

(ii) Severity, post-operative adverse event

Mild ☐ Moderate ☐ Severe ☐

Type of AE at Second follow up visit:

(i) a. Bleeding or blood soiling of the BANDAGE Yes ☐ No ☐

b. Swelling of the penis or scrotum Yes ☐ No ☐

c. Persistent pain Yes ☐ No ☐

d. Infection Yes ☐ No ☐

e. Failure to pass urine Yes ☐ No ☐

f. Other: Specify _____

(ii) Severity of post-operative adverse event

Mild ☐ Moderate ☐ Severe ☐

**Other AEs Occurred after 7 days Date:** _____

## Appendix IX – Case Report Form (CRF) – ShangRing Device

# CASE REPORT FORM – ShangRing DEVICE

Evaluation of the safety and acceptability of the ShangRing device for male circumcision in Tanzania

Site Code: ☐☐☐

Client ID # (CID): ☐☐☐☐☐☐☐☐☐

INSTRUCTIONS FOR THE PROPER COMPLETION OF THE CRF

Please follow the instructions below:

1. Use a ball-pen, DO NOT use a pencil, a marker or a fountain pen.
2. Make sure to place the separator provided under the last copy of each page so that data recorded on one page does not copy to the next.
3. Subject initials will be comprised of the first letter of the first name followed by the first two letters of the surname.
4. Fill in the form in a clear, concise and readable way. Use common medical terminology.
5. Correct wrong data by crossing out the information with a single line and writing the correct data next to it. The evaluation coordinator, or the site coordinator in the evaluation coordinator's absence, will initial and date the correction.
    a. Example: ~~07/03/1969~~ corrected to 09/03/1969 (with initials and date of the correction)
6. Complete all the available boxes, DO NOT leave empty fields.
    a. For evaluations not performed record ND (not done).
    b. For data not relevant to the subject or stage of evaluation record NA (not applicable).
    c. If you do not know the data, please use the initials UNK (unknown).
    d. Use leading zeroes if necessary (e.g.: 15 mg = 0 1 5 mg).
    e. Make sure to complete every header on each page.
7. Please make sure to **circle the correct option** whenever it is requested.
8. Please DO NOT add wording to CRF pages unless required. For any additional comments please use the Comments Sheet at the end of the CRF modules.
9. Dates (e.g., date of birth, date of visit) will be recorded in the DD/MM/YYYY format.
    a. Example: 19 June 2017 will be recorded as 19/06/2017
10. CID is the Client Identification Number. It comprises the initials of the site followed by the four digit enrollment date and the three digit subject consecutive number. Example: Subject number 1 in Good Hope Health Center enrolled on July 21 will be GH2107001.
11. Time will be recorded in 24:00 format.
    a. Example: 6:15 pm will be recorded as 18:15

## Ministry of Health, Community Development, Gender, Elderly and Children

## ShangRing Device Case Report Form

(Attach form to VMMC Client Form)

## Part 1 – Client Eligibility and Consent

**Client ID Number:_____** **Date of Visit (dd-mm-yyyy):_____**

**Client is eligible for ShangRing circumcision (circle one)?** Yes No If No, Specify Reason:_____

_____

**Confirmation of client's eligibility (circle one):**

1. **In good health:** Yes No
2. **Counseled:** Yes No
3. **Consented:** Yes No N/A (13-17 years old)
4. **If 13-17 year-old client, consent by parent/guardian and assent by client:** Yes No N/A

   **If 'No' for any of the above, explain: _____**

---

## Part 2 – ShangRing Device Placement Procedure

**Device size: _____** **Expiration Date (dd-mm-yyyy):_____**

**If the device application is not the same day as the screening report, has there been a change in the genitals (compare to screening visit report)?** Yes No

**Time placement procedure began (e.g. 14:30):_____**

**Time placement procedure ended (e.g. 14:45): _____**

**Comments: _____**
**_____**
**_____**

**Was the device applied according to its Instructions for Use (circle one)?** Yes No

**If "No," explain in detail:_____**

_____
_____
_____

**Was the penis disinfected before applying the device (circle one):** Yes No

**What form of anesthesia was used? Indicate injection/cream, what kind for each, and for injection provide dosage:_____**

**Please Attach ShangRing Label Here:**

**Was there an Adverse Event during placement (circle one)?** Yes No

**If yes, how would you rate the AE (circle one, refer to definitions below):** Mild Moderate Severe

Severity cannot be classified (if problem with placement or device malfunction)

*Adverse Event Definitions:*

Mild: classification indicates minimal or no intervention is required beyond reassurance and observation

Moderate: classification relates to those AEs that are neither mild nor severe, require intervention, and are usually managed on site

Severe: classification requires extensive intervention with referral or specialist input

NB: If any Moderate, Severe, or Severity not classified adverse events above are checked, complete the AE form.

**Full name and surname of clinician placing device: _____**

**Signature: _____** **Cadre (e.g. physician, nurse): _____**

**Full name and surname of assistant: _____**

**Signature: _____** **Cadre (e.g. physician, nurse): _____**

## Part 3 – Post-Application Evaluation and Assessment (Before Discharge)

**Dressing intact and holding penis against abdomen (circle one)?** Yes No

**Client given post-procedure written instructions (circle one)?** Yes No

**Clinical disposition of client, including AE management: _____**

**Oral analgesia given (circle one)?** Yes No **Drug (name, dose, quantity dispensed): _____**

**Scheduled removal date (dd-mm-yyyy): _____**

**Discharged by (Full name and surname): _____**

**Signature: _____** **Cadre (e.g. physician, nurse): _____**

## Appendix X – ShangRing Post-Placement Survey

## ShangRing Post-Placement Survey

**[Table to be completed by Evaluation Staff]**

| | |
|---|---|
| **Date (dd/mm/yyyy):** | |
| **Client ID:** | |
| **Name of Survey Administrator:** | |
| **Facility:** | |

**Introduction:** Thank you for agreeing to complete this survey to evaluate your experience with the ShangRing circumcision device. This survey asks a few brief questions about your experience in having the ShangRing device placed. Your name will not be recorded anywhere on this survey, and your replies will be kept completely confidential. In this survey there are no right or wrong answers. We are most interested in your honest opinions and reactions to these questions. You may also refuse to answer any question you wish for any reason. The information that you provide will help to determine the future use of ShangRing in Tanzania. If you have any questions about the survey, please do not hesitate to follow up with evaluation staff. If you have difficulty reading or understanding any of the questions, evaluation staff are on hand to read and help you interpret the questions.

**1. Why did you choose to have a ShangRing circumcision instead of surgical circumcision (circle answer option below)?**

| | | | | |
|---|---|---|---|---|
| I thought ShangRing would be less painful | I didn't want an injection | I had heard about ShangRing before | No Reason | Other (comment below) |

Comment:_____

**2. How did you find the placement process for the ShangRing device (circle answer option below)?**

| | | | | |
|---|---|---|---|---|
| It was about what I expected | It was easier than I expected | It was harder than I expected | I did not have any expectations for the placement | Other (comment below) |

Comment:_____

**3. How did you find the pain of your circumcision during the ShangRing device placement (circle answer option below)?**

| | | | | |
|---|---|---|---|---|
| It was about what I expected | It was less painful than I expected | It was more painful than I expected | I did not have any expectations about pain | Other (comment below) |

Comment:_____

**4. At this point, would you recommend the ShangRing to someone you know who is considering circumcision (circle answer option below)?**

| | | | |
|---|---|---|---|
| Yes | No | I don't know at this time | Other (Comment below) |

Comment:_____

## Appendix XI – ShangRing Post-Removal Survey

## ShangRing Post-Removal Survey

**[Table to be completed by Evaluation Staff]**

| | |
|---|---|
| **Date (dd/mm/yyyy):** | |
| **Client ID:** | |
| **Name of Survey Administrator:** | |
| **Facility:** | |

**Introduction:** Thank you for agreeing to complete this survey to evaluate your experience with the ShangRing circumcision device. This survey asks a few brief questions about your experience with ShangRing now that the device has been removed. Your name will not be recorded anywhere on this survey, and your replies will be kept completely confidential. In this survey there are no right or wrong answers. We are most interested in your honest opinions and reactions to these questions. You may also refuse to answer any question you wish for any reason. The information that you provide will help to determine the future use of ShangRing in Tanzania. If you have any questions about the survey, please do not hesitate to follow up with evaluation staff. If you have difficulty reading or understanding any of the questions, evaluation staff are on hand to read and help you interpret the questions.

**1. How much discomfort did you experience while wearing the ShangRing device over the past seven days (circle answer option below)?**

| | | | | |
|---|---|---|---|---|
| I had no discomfort while wearing the ring | I had minor discomfort while wearing the ring | I had moderate discomfort while wearing the ring | I had a lot of discomfort while wearing the ring | Other (comment below) |

Comment:_____

**2. How much did the ring affect you while performing day-to-day activities (circle answer option below)?**

| | | | | |
|---|---|---|---|---|
| It did not affect me at all | It only affected me while performing certain activities | It affected me during all activities, but I could still do them | It prevented me from performing certain activities | Other (comment below) |

Comment:_____

**3. After having worn the ring for a week, would you still choose to do ShangRing for circumcision, or would you choose surgery (circle answer option below)**

| | | | | |
|---|---|---|---|---|
| I would definitely choose ShangRing again | I would probably choose ShangRing again | I would probably choose surgery | I would definitely choose surgery | I don't know |

Comment:_____

**(Survey is continued on next page)**

**4. How satisfied are you with the appearance of your circumcision (circle answer option below)?**

| | | | | |
|---|---|---|---|---|
| I am very satisfied | I am satisfied | I am dissatisfied | I am very dissatisfied | I don't know |

Comment:_____

**5. At this point, would you recommend the ShangRing to someone you know who is considering circumcision (circle answer option below)?**

| | | | |
|---|---|---|---|
| Yes | No | I don't know at this time | Other (Comment below) |

Comment:_____

## Appendix XII – ShangRing Case Report Form: Client Follow-Up Form

# CASE REPORT FORM – ShangRing DEVICE FOLLOW-UP

Evaluation of the safety and acceptability of the ShangRing device for male circumcision in Tanzania

Site Code: ☐☐☐

Client ID # (CID): ☐☐☐☐☐☐☐☐☐

INSTRUCTIONS FOR THE PROPER COMPLETION OF THE CRF

Please follow the instructions below:

1. This form is to be used for ALL follow-up visits, including the removal visit, and unscheduled visits.
2. Complete a new form at each follow-up visit.
3. Use a ball-pen, DO NOT use a pencil, a marker or a fountain pen.
4. Make sure to place the separator provided under the last copy of each page so that data recorded on one page does not copy to the next.
5. Subject initials will be comprised of the first letter of the first name followed by the first two letters of the surname.
6. Fill in the form in a clear, concise and readable way. Use common medical terminology.
7. Correct wrong data by crossing out the information with a single line and writing the correct data next to it. The evaluation coordinator, or the site coordinator in the evaluation coordinator's absence, will initial and date the correction.
    a. Example: ~~07/03/1969~~ corrected to 09/03/1969 (with initials and date of the correction)
8. Complete all the available fields, DO NOT leave empty fields.
    a. For evaluations not performed record ND (not done).
    b. For data not relevant to the subject or stage of evaluation record NA (not applicable).
    c. If you do not know the data, please use the initials UNK (unknown).
    d. Use leading zeroes if necessary (e.g.: 15 mg = 0 1 5 mg).
    e. Make sure to complete every header on each page.
9. Please make sure to **circle the correct option** whenever it is requested.
10. Please DO NOT add wording to CRF pages unless required. For any additional comments please use the Comments Sheet at the end of the CRF modules.
11. Dates (e.g., date of birth, date of visit) will be recorded in the DD/MM/YYYY format.
    a. Example: 19 June 2017 will be recorded as 19/06/2017
12. CID is the Client Identification Number. It comprises the initials of the site followed by the four digit enrollment date and the three digit subject consecutive number. Example: Subject number 1 in Good Hope Health Center enrolled on July 21 will be GH2107001.
13. Time will be recorded in 24:00 format.

Example: 6:15 pm will be recorded as 18:15

## ShangRing Client Follow-Up Form

**Client ID Number: _____ Date of visit (dd-mm-yyyy): _____**

**Date of ShangRing Device Placement (dd-mm-yyyy): _____**

**Contact Type (select one):**

- **On-site visit (specify name of facility/site): _____**
- **Off-site visit (specify location, i.e. work, home, school): _____**
- **Phone contact (number called): _____**

**Type of Visit (select one):**

- **Removal visit (specify days since device placement): _____**
- **Day 42 post-placement healing assessment (specify day if client comes in on different day): _____**
- **Post day 42 follow-up healing assessment (specify days since device placement): _____**
- **Unscheduled visit (specify days since device placement): _____**

**Is there a photographer present to take pictures of the procedure (circle one):** Yes No
(If 'No,' do not proceed until a photographer is available. Photos must be taken with the photo frame, including client ID number, date and pain score before and after device removal).

**Has there been a change to the client's medication since device placement (circle one):** Yes No
(If 'Yes,' please record the medication on the medications CRF page).

**Summary of Follow-Up:**

**Clinical course leading to client's visit today: _____**

**_____**

**_____**

**Care/advice provided: _____**

**_____**

**_____**

**Medication given (circle one)?** Yes No

**If yes, drug (name, dose and total quantity dispensed):_____**

**For removal visit, was anesthesia required during removal (circle one):** Yes No NA (not removal visit)

**If "Yes," what?_____**

**For removal visit, were there any device-related events or AEs that occurred during the removal (circle one):**

Yes No NA (Device not removed this visit)

If "Yes," please record on Adverse Events form.

**For removal visit, provider evaluation from 1 to 10 (1 being worst): _____**

**Name of provider who removed the ShangRing device: _____**

**Healing status observed by clinician (select one):** Healed Not Healed NA (pre-day 42 visit)

Clinical healing defined as: clinical healing after MC by any method is intact epithelium (unbroken skin) covering the wound as judged by the provider on visual inspection, meaning that none of the following are present: sutures, scabbing, drainage, moisture, gaps between epithelial edges or ulceration.

**Was client instructed not to masturbate until completely healed (select one)?** Yes No NA (client healed)

**Was client reminded to abstain from sexual intercourse until completely healed (select one)?**

Yes No NA (client healed)

**Was client reminded to return to the site in the event of any unexpected situation, in case of pain, or if client has not yet had ring removed, if ring is displaced (select one)?** Yes No

## Adverse Events

**Was there an Adverse Event seen/reported during follow-up (select one):** Yes No

**If yes, how would you rate the AE (circle one, refer to definitions below):** Mild Moderate Severe

Severity cannot be classified (if problem with placement)

*Adverse Event Definitions:*

Mild: classification indicates minimal or no intervention is required beyond reassurance and observation

Moderate: classification relates to those AEs that are neither mild nor severe, require intervention, and are usually managed on site

Severe: classification requires extensive intervention with referral or specialist input

NB: If any Moderate, Severe, or Severity not classified adverse events above are checked, complete the AE form.

**For unscheduled visits, has the client experienced a device-related event or AE since his last visit (select one):**

Yes No NA (not an unscheduled visit)

**For unscheduled visits, please describe the reason for the unscheduled visit:**_____
_____
_____
_____

**Is circumcision progressing as expected (select one)?** Yes No

**If "No," please explain:**_____
_____
_____

## Assessment (Before Discharge)

**Clinical disposition and AE management:** _____

**Next visit date, if applicable (dd-mm-yyyy):** _____

**Discharged by (Full name and surname):** _____

**Signature:** _____

## Appendix XIII – Introductory script for contacting ShangRing clients by phone

**Introductory script for contacting ShangRing clients by phone**

May I please speak to _____?
If yes, proceed to next paragraph
If no, is there better time to call you later? If yes, schedule appointment follow another call

My name is _____ and I am calling from _____ (*name of health facility*) to follow up on your appointment to visit our clinic on _____ (*date*) for_____ (*purpose of missed appointment).* At your last visit to our clinic you indicated that you would come for _____ *(purpose of missed visit e.g. review or device removal).* May I ask if you may be available for this appointment at a different time?

*Schedule another appointment for clinic visit or for home visit by providers depending on his availability.*
*If the client is not at home, but another person answers the phone, a message will not be left for the person who answers the phone. Proceed as follows;*

My name is_____.
May I know when he is likely to be back for me to call him on this same number or can you guide me on how else I can reach him?

*Depending on the response, schedule another call or follow guidance given on how to reach him.*

## Appendix XIV – ShangRing Adverse Event Day 3 Post-Removal AE Check-in Call Form

**ShangRing Adverse Event Check-in Call Form**

**Client ID:**

## Instructions

This form is to be used during the call with clients to check for signs of adverse events three days following the removal of the ShangRing device. The questions below are meant to evaluate whether the client is potentially experiencing an adverse event in the aftermath of their circumcision. After introducing yourself, and informing the client of the purpose of the call, ask the client each question on the list. For any 'yes' answers, probe for more information. If any of the information the client offers suggests an adverse event, advise that the client come to the clinic immediately for further evaluation.

## Questions

1. Are you experiencing pain that keeps you from doing anything you normally do? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____
2. Has swelling, tenderness or pain around the wound gotten worse since your circumcision? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____
3. Have you noticed any expanding redness around the wound area, or red streaking spreading from the wound? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____
4. Have you noticed any pus or fluid coming from the wound area? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____
5. Have you felt like you have had a fever in the past few days, or experienced chills, shaking, breaking into sweats more than usual? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____

6. Are you still bleeding from the wound area? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____
7. Are you experiencing any difficulty urinating? **Y N**
    a. **If yes:** Advise the client to visit the clinic to be evaluated
    **Note any comments:**_____
    _____
    _____
    _____
8. Are you experiencing any other new problems since the surgery? **Y N**
    a. **If yes:** Ask the client to describe the symptoms, and record below. If the symptoms are concerning advise the client to visit the clinic to be evaluated.
    **Note any comments:**_____
    _____
    _____
    _____

Upon conclusion, thank the client for their time and remind them of their visit for the healing assessment in 39 days' time. If the client is one of those selected to participate in the qualitative interview, remind them of the date of the interview.

## Appendix XV – ShangRing Active Surveillance: Device Placement and Follow-up Log

## ShangRing Active Surveillance: Device Placement and Follow-up Log

| **Client Full Name and Surname** | **Chart #** | **Date of SR placement (dd/mm/yy)** | **Returned for Day 7 Removal? Y/N)** | **Follow-up attempts if client did not return on Day 7** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Attempt 1: date, type, outcome | Attempt 2: date, type, outcome | Attempt 3: date, type, outcome | Attempt 4: date, type, outcome | Attempt 5: date, type, outcome | Attempt 6: date, type, outcome | Attempt 7: date, type, outcome |
| | | | | | | | | | | |
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## Appendix XVI: ShangRing Evaluation Pilot: Log of Client ShangRing Eligibility and Acceptance

# ShangRing Evaluation Pilot: Log of Client ShangRing Eligibility and Acceptance

For all clients eligible on initial intake for ShangRing circumcision please fill out a line below.
To be completed during pre-MC counseling.

| Date (dd/mm/yy) | Client Name | Interested in ShangRing? (Y/N) | Eligible after medical screening? (Y/N) If no, why? | Consents to ShangRing? (Y/N) If no, why?* |
|---|---|---|---|---|
| | | | | |
| | | | | |
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| | | | | |

*If client gives a reason for declining ShangRing that can fall into these categories give the corresponding number if applicable: 1 – I don't want to try a new procedure, 2 – I heard about someone else's negative experience, 3 – I don't want to have to get an HIV test, 4 – I'm afraid it will hurt too much. If the client gives a different reason for refusing ShangRing, write the client's reason in the comment box.

## Appendix XVII – ShangRing Post-Operative Care Instructions

**Post-Operative Instructions**

*These post op care instructions will be included in pre-and post-procedure counselling for each client. For minors, the same guidance will be given to parents or guardians. A copy will also be given to clients or parents/ guardians to carry home.*

**Wearing the ShangRing**

1. It is recommended that, back at home, you rest until you have gotten used to the ShangRing being in place.

2. Do not try to remove or reposition the ShangRing yourself, and keep the penis clean and dry.

3. After the day of circumcision, you may shower or use clean bottled water to rinse the wound while the ShangRing is in place as long as you carefully dry the penis and ShangRing afterwards. Do not go swimming or wash in a bathtub.

4. Do not take part in any intensive activities (e.g. playing soccer or other strenuous manual work in construction sites or farms) to avoid dislocation of the ring. In the case of heavy sweating, be sure to clean and dry the body immediately to keep the wound from being infected, which would delay healing.

5. DO NOT HAVE SEX (INCLUDING MASTURBATION) while the ShangRing is in place. This can damage the wound, displace the device, and increase risk of infection and transmitting diseases.

6. Try not to allow your penis to dangle freely. Tightly fitted briefs are recommended in order to keep the penis from drooping downward and to keep the ring in place and avoid skin abrasion.

7. In the event that you experience mild pain (including during an erection), especially in the first few days after the circumcision, over-the-counter pain medications such as paracetamol (acetaminophen), naproxen or ibuprofen can be used for pain relief. If the pain is excessive, contact your health care provider for further advice. Urinating may help to quickly end an erection.

8. Keep the circumcised area clean and dry. This will promote proper healing. When urinating, use a piece of toilet paper or cloth to prevent urine from seeping into the circumcision area, possibly resulting in infection.

9. Do not apply ointment or cream on or around the circumcised area. Also you should not apply traditional remedies or any other substances (e.g. herbs, soil, cow dung). This may slow the healing process, and can also increase risk for infection, including tetanus, which can be fatal.

10. You may experience slight swelling around the ShangRing. This is normal as long as it does not cause you too much discomfort. Wearing tightly fitted briefs to keep the penis facing up should help prevent swelling.

Post-operative Care instructions

11. Seven days after your circumcision, return to the clinic to have the ShangRing removed. Do not try to remove or reposition the ShangRing yourself. This can cause serious bleeding or infection. If the device does come off or gets moved, contact the clinic immediately

**After Removal of the ShangRing**

1. Keep the bandage clean and dry and remove the bandage before going to sleep. In the event that the bandage does get wet, replace the bandage immediately. Replace the bandage in the morning after removal and repeat for one additional day. Starting on the third day, you can wash the penis and the wound area normally and leave the bandage off.

2. Do not apply ointment or cream on or around the wound. Also you should not apply traditional remedies or any other substances (e.g. herbs, soil, cow dung). This may slow the healing process, and can also increase risk for infection, including tetanus, which can be fatal.

3. DO NOT HAVE SEX (INCLUDING MASTURBATION) within the 6 weeks after your circumcision or until the wound has healed completely. Early sex can damage the wound and increase risks of disease transmission. If you absolutely cannot avoid having sex before 6 weeks, masturbation is safest, and sex with condoms is safer than unprotected sex. After six weeks, you should use condoms to protect the circumcision wound (as well as to reduce the transmission of HIV and other infections) for three months, even after it appears completely healed. 4. Expect the complete healing of the wound may take 3 to 4 weeks, or longer.

**When to come to clinic or call your doctor**

While wearing the ShangRing or after removal, contact your health care provider at cell phone #: _____or _____, or visit the clinic:

1. If you notice bleeding from around the ShangRing or from the wound after the ShangRing surgery or the ShangRing removal.
2. If you experience difficulty passing urine.
3. If you experience seriously painful swelling, increasing redness, bruising, elevated temperature around the wound, fever, or the discharge/appearance of pus.
4. If there is severe swelling around the ShangRing, or around the area in which the ShangRing was placed which causes you discomfort.
5. If you experience excessive pain (including during an erection) while the ring is still in place.
6. If the ShangRing is damaged or comes off accidentally (partially or completely).
7. If you have any other inquiries or concerns.

## Appendix XVIII – Adverse Event Reporting Form

Client ID:

### Device Related Events Form

Has the participant experienced a device related event per protocol? This includes mild, moderate and severe AE, expected side effects such as common post-operative findings, occurences resulting from participants' failure to follow instructions, and device malfunctions. Please consult the *Adverse Event Classifications and Definitions: During Device Placement or Wearing and During or After Device Removal* for clarification and definition of adverse events. If the client is determined to have experienced an adverse event, please complete below.

If this is an AE defined as moderate or severe, also fill in the corresponding AE form. Note, that notifiable adverse events must also be reported also per PEPFAR and national guidelines.

Client ID:

**Device Events Form**

| **Device Event** *(Indicate type)* | **Evaluation Phase** | **Start/Onset** |
|---|---|---|
| ☐ Anesthetic Related Problem<br>☐ Bleeding<br>☐ Pain<br>☐ Scarring/Disfigurement Poor cosmetic result or excess skin removal<br>☐ Device Displacement<br>☐ Device detachment<br>☐ Infection<br>☐ Injury to penis<br>☐ Sexual effects/ undesirable sensory changes<br>☐ Wound Disruption<br>☐ Excess swelling of penis/scrotum<br>☐ Hematoma<br>☐ Difficulty with removal<br>☐ Difficulty urinating<br>☐ Excessive skin removal<br>☐ Other | During placement ☐ While in place ☐ (before discharge)<br>During removal ☐ After removal ☐ | Date:<br>Time: |
| | **Severity** *(Consult definitions for grading classification)* | **Events/AE Code** *(Consult definitions for codes)* |
| | Mild ☐<br>Moderate ☐<br>Severe ☐ | |
| | **Moderate or Severe AE** | **Relationship to Device** |
| | Yes ☐ No ☐<br>If "Yes," complete adverse events form | Unrelated ☐<br>Possibly ☐<br>Definitely ☐ |
| | **Action** | **Pain VAS (see below)** |
| | None ☐ Pharmaceutical ☐<br>Surgical ☐ Non-surgical ☐<br>Evaluation termination ☐<br>Other ☐ Specify: _____ | |
| | *Complete when resolved or at final visit* | |
| | **Outcome** | **End/Termination** |
| | Resolved ☐ Resolved with sequel ☐<br>Persistent ☐ Unchanged ☐<br>Unknown ☐ | Date:<br>Time: |

**Visual Analog Scale (VAS):**

| 0 | 2 | 4 | 6 | 8 | 10 |
|---|---|---|---|---|---|
| **Very happy, no hurt** | **Hurts just a little bit** | **Hurts a little more** | **Hurts even more** | **Hurts a whole lot** | **Hurts as much as you can imagine** |

**I have checked all data introduced to this form until this point and verified that they are complete, correct and reconcilable with the original documentation.**

Evaluation Coordinator's Signature: _____ Date:_____

Client ID:

## Adverse Events (AE) Form

Has the participant experienced a moderate or severe AE per protocol? If "No", do not enter information on this form. If the AE is defined as severe, notify the principal investigators based on the evaluation protocol.

<table>
<tr><th>Adverse Event</th><th>Start/Onset</th><th>Status</th><th>Device Event Number</th></tr>
<tr><td rowspan="6"></td><td>Date:<br>Time:<br>Date/time observed (if different):</td><td>New ☐<br>Ongoing ☐</td><td></td></tr>
<tr><td>Action</td><td>Severity<br>(Consult definitions for grading classification)</td><td>AE Code<br>(Consult definitions for codes)</td></tr>
<tr><td>None ☐ Pharmaceutical ☐ Surgical ☐<br>Non-surgical ☐ Evaluation termination ☐<br>Other ☐ Specify: _____</td><td>Moderate ☐<br>Severe ☐<br>If severe, complete information below</td><td></td></tr>
<tr><td>Date of SAE report to evaluation investigators:</td><td colspan="2">Was the SAE a result of protocol departure? Yes ☐ No ☐<br>If “Yes,” please specify:</td></tr>
<tr><td>Date of last visit and last visit number:</td><td colspan="2">Date the device was applied:</td></tr>
<tr><td>Please describe the SAE in block letters (use following page if additional space is needed):</td><td colspan="2">Choose criteria for SAE:<br>☐ Death<br>☐ Permanent disability<br>☐ Life threatening<br>☐ Hospitalization or prolongation of inpatient hospitalization<br>☐ Required intervention to prevent one of the above<br>☐ Other:</td></tr>
<tr><td>Outcome</td><td colspan="2">End/Termination</td></tr>
<tr><td>Resolved ☐ Resolved with sequel ☐<br>Persistent ☐ Unchanged ☐ Unknown ☐</td><td colspan="2">Date:<br>Time:</td></tr>
</table>

**Please add any additional comments related to this AE. Please write in block letters and sign and date your comments.**

**I have checked all data introduced to this form until this point and verified that they are complete, correct and reconcilable with the original documentation.**

Evaluation Coordinator's Signature: _____ Date: _____

## Appendix XIX: Adverse Event Classifications and Definitions: During Device Placement or Wearing and During or After Device Removal*

| Adverse Event | Mild | Moderate | Severe |
|---|---|---|---|
| ***During Device Placement or Wearing*** | | | |
| AN: Anesthetic Related Problem (A1-AN) | Mild localized swelling allergic reaction at injection site without swelling and systemic reaction. | Reaction to anesthetic including light-headedness, nervousness, dizziness that resolves spontaneously and **not** requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital. | Symptoms of severe systemic allergic reaction to local anesthetic including rash, urticaria, angioedema, and shortness of breath, or symptoms of overdose of local anesthetic including light-headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, bradycardia, or hypotension requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities or hospitalization to manage. |
| BL: Bleeding | A1/A2-BL: Bleeding during placement or wearing that is more significant than usual or spotting of the bandage or clothing with blood; both easily controlled | A1/A2-BL: Bleeding during placement or wearing that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device. | A1/A2-BL: Bleeding during placement or wearing that requires blood transfusion, transfer to another facility, or hospitalization; or bleeding that requires surgical exploration, removal of device, placement of sutures, hospitalization, or transfer to another facility. |
| PA: Pain | A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. | A1-PA: Client expresses discomfort and is not able to cooperate well with procedure. | A1-PA: Client rates pain as very severe. |
| SD: Scarring/disfigurement/ poor cosmetic result; excess skin removal; injury to penis | *Excess skin removal–NA*<br><br>A1-SD: *Injury to penis*–limited superficial injury not requiring additional intervention. | *Excess skin removal–NA*<br><br>A1-SD: *Injury to penis*–abrasion or small laceration of the glans or shaft | *Excess skin removal–NA*<br><br>A1-SD: *Injury to penis*–injury that requires surgical intervention to stop bleeding or repair. |

| | | | |
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| | | requiring pressure dressing, but surgical repair is not required. | |
| ***During or After Device Removal*** | | | |
| BL: Bleeding | B/C-BL: Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure. | B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure or requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound. | B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary. |
| DD: Device Displacement | A2-DD: NA | A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal that does not require surgical intervention to correct, either because the device can be removed, repositioned, or replaced with a new device. | A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that requires surgical intervention to correct, or requires hospitalization or transfer to another facility to clinically manage. |
| IN: Infection | B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene. | B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics. | B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics. |
| PA: Pain | A2/B/C-PA: Client complaints of pain, not requiring more than standard postoperative analgesics and considered within normal thresholds associated with surgery | A2/B/C-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting for at least 1 day after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5–7 (on a 1–10 scale). | A2/B/C-PA: Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting 2 or more days after device placement or removal. For programmes that utilize a visual analogue scale (VAS) for rating severity of pain, a VAS score of 8–10 (on a 1–10 scale). |
| SD: Scarring/disfigurement/ Poor cosmetic result; excess skin removal (C-SD) | *Scarring*-complaints by client in the absence of discernible abnormal scarring/disfigurement. *Torsion of* | *Scarring*-Discernible but re-operation not required. Usually noticed first by the client and reported to the | *Scarring*-Discernible and requires reoperation or referral/transfer to another facility. |

| | | | |
|---|---|---|---|
| | *penis*–torsion present but does not cause pain or discomfort. *Insufficient skin removal*–prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state. | provider. *Torsion of penis*–torsion present that causes mild pain or discomfort with erection but does not require surgery to correct. *Insufficient skin removal*–prepuce partially covers glans when flaccid but surgical correction is not necessary. | *Torsion of penis*–torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction. *Insufficient skin removal*–prepuce covers most of the glans when flaccid and surgical correction is necessary. |
| Injury to Penis | A2/B/C-SD: *Injury to penis*-limited superficial injury not requiring additional intervention. | A1-SD: *Injury to penis*-bruise or abrasion of the glans or shaft requiring pressure dressing, but surgical repair is not required. | A1-SD: *Injury to penis*-injury that requires surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, injury to urethra or development of a fistula is also considered a severe AE. |
| Excess Skin Removal | C-SD: *Excess skin removal*-slight tightening of the skin observed; no surgical correction needed. | C-SD: *Excess skin removal*-pulling of scrotal skin onto the penile shaft and wound disruption. | C-SD: *Excess skin removal*-wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation. |
| SX: Sexual Effects/Undesirable Sensory Changes | C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioral consequences. | C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery. | C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery. |
| WD: Wound Disruption | C-WD: Wound disruption but not extensive enough to require suturing for wound closure. | C-WD: Muco-cutaneous gap > 1.0 cm in width, but no exposure of deeper tissue | C-WD: Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement. |
| OA: Other AEs, Excess swelling of penis/scrotum including hematoma; other | *Excess swelling*–mild swelling without signs of on-going bleeding. | *Excess swelling*–symptoms/signs that require clinical intervention, but not surgical exploration. *Other*–other adverse events related to surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 4 days after surgery but not more than 7 days. | *Excess swelling*–surgical exploration required to control bleeding or remove haematoma or symptoms/signs so extraordinary as to cause disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal as pertinent. |

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| | | | *Other*–other AE(s) related to the surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal, or result in hospitalization or referral/transfer to another facility. |
| Difficulty Urinating | N/A | A2/C-OA: Symptoms that resolve with removal/repositioning of the device or dressing (transient difficulty urinating that resolves on its own would not be considered an AE). | A1/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct. |

***Adapted from Appendix 3 of *Adverse Event Action Guide For Voluntary Medical Male Circumcision (VMMC) by Surgery or Device, 2nd Edition, 2016***

## Appendix XX - ShangRing Evaluation Pilot: Application Time Form

# ShangRing Evaluation Pilot: Application Time Form

(Enter time in 24 hour form, e.g. 18:00)

| Client ID # | Date (DD/MM/YYYY) | Overall Time[µ] | |
|---|---|---|---|
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[µ]**Overall Time:** Begins upon the arrival of client in operating room, concludes once procedure is complete and client is released from operating room.

## Appendix XXI - ShangRing Evaluation Pilot: Removal Time Form

# ShangRing Evaluation Pilot: Removal Time Form

(Enter time in 24 hour form, e.g. 18:00)

| Client ID # | Date (DD/MM/YYYY) | Device Removal Begins* (Time) | Device Removal Ends* (Time) |
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***Begin/End Time:** Time begins when client is admitted to the room for device removal. Time ends when device is removed and client is ready to be released.

## Appendix XXII – Client Qualitative Interview Guide

**In-Depth Qualitative Interviews**

| | |
|---|---|
| **Date (dd/mm/yyyy):** | |
| **Name of Moderator:** | |
| **Name of Note-Taker:** | |
| **Facility:** | |
| **Start Time:** | |
| **End Time:** | |

**Introduction**

Thank you for agreeing to participate in this interview. The purpose of this interview is to discuss your opinions around circumcision and ShangRing. In order to do this, I will ask you questions about your experience with the ShangRing device for male circumcision. This interview, and your replies will be kept completely confidential. I will not record your name or link anything you say in a way that will make it easy to identify you. In this interview there are no right or wrong answers. We are most interested in your honest opinions and reactions to these questions. You may also refuse to answer any question you wish for any reason. The interview should last approximately one hour, though you may end it at any time. The interview will be recorded, but your name will not be included on the recording, and we will not store the recording in a way that can be used to identify you. You may request a break should you need one. Please feel free also to help yourself to the provided snack. And if you need them, the rest rooms are located [provide directions]. The information that you and others provide will help to determine the future use of ShangRing in Tanzania.

Are there any questions before we begin?

1. How old are you in complete years?
2. Where do you currently reside?
3. What is the highest level of formal schooling you completed?
4. Are you currently in a relationship with someone such as a spouse or partner? [Note for interviewer: if yes ask question 5, if no, skip to question 6].
5. What is your relationship with this person?
6. What was the primary reason you decided to get circumcised?
7. What made you decide to try the ShangRing device?
8. What made you choose to try the ShangRing device instead of surgical circumcision?
9. Did you tell anyone that you had a ShangRing circumcision? If so, what was their reaction? [Note for interviewer: probe for who the person was, gender, relationship to the client, etc.].
10. How was the process of having the ShangRing device put on your penis?

11. What was it like during the seven (7) days that you had the device on? [Note for interviewer: probe for issues related to pain including with erections, limits on activities including sex and masturbation, hygiene].

12. How was the removal process?

13. What have you been told about the healing process? [Note for interviewer: probe for things they have been told to do and what not to do until healing is complete. *Clarify any information that is not correct regarding abstinence until healing is complete and future condom use*].

14. How would you describe your experience since the ShangRing device was removed? [Note for interviewer: probe for perceptions regarding how the healing process is progressing].

15. How would you describe your satisfaction with your circumcision?

16. Are you satisfied with the result?

17. What did you like about the procedure?

18. What did you dislike?

19. Was the information about the circumcision process with the ShangRing device clear and accurate?

20. In your opinion, what kind of messages could make VMMC more appealing to men?

21. In your opinion, are there messages that could make ShangRing an appealing option for VMMC for men who may not want to have surgery?

22. Is there anything else related to ShangRing that you would like to comment on or ask?

23. Do you have any comments related to ShangRing or medical male circumcision in general?

*Note for Interviewer:* Thank the client for their time, and provide the following reminders:

- When/where to return for the day 49 (42 days post-removal) healing assessment.
- The importance of good hygienic processes while the wound continues to heal, and how to keep the penis and wound clean and free of potential infection, including the importance of tetanus mitigation strategies.
- That the client should return to the evaluation site in case of any unexpected event, for example if there is severe discoloration of the penis, signs of infection (purulence), severe or increasing pain, or any other significant concern they may have.
- Painful erections may continue to occur during the night as the wound heals.
- The client is encouraged to call any time with any questions or concerns.
- The importance of continued abstention from sex or masturbation for 6 weeks (42 days), following the removal of the ShangRing device, or until the penis is fully healed (whichever comes last).

## Appendix XXIII – Consent form for Provider Interviews and Surveys

## Consent Form for Provider Interviews and Surveys

What you should know about this program:

- This consent form explains the purpose and requirements of the provider interviews and surveys
- Please read it carefully and take as much time as you need.

### Purpose of the Provider Interviews and Surveys

You are being asked to participate in these interviews because you have been selected to take part in a program being done by the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and its partners to offer 575 circumcisions using the ShangRing device in selected health facilities. Although ShangRing has been successfully used in other countries, the purpose of this program is to learn more about using this method of circumcision for large numbers of males in Tanzania to decide whether to begin offering it all over the country. This includes evaluating the opinions of providers who have experience performing the ShangRing procedure. Specifically, it is important to learn your honest opinion on the ShangRing device on a number of topics including:

- The value of the ShangRing training
- The technical ease or difficulty in performing ShangRing circumcisions, including length of time, and safety for both the provider and the client
- Your preference in performing ShangRing or surgical circumcisions
- Whether or not ShangRing will appeal to men compared to surgical circumcision

### Procedures

If you agree to participate in the ShangRing program, you will be interviewed at two points in time, and asked to complete one survey.

The first interview will take place upon the completion of your ShangRing training. At this time you will be asked for your thoughts on the training process – including the curriculum; and for your preliminary thoughts on the ShangRing device – both in terms of your opinions on performing the procedure, and how you believe potential clients will feel about the procedure.

The second interview will take place about halfway through the program, after you have had a chance to perform ShangRing circumcisions on clients for some time. This interview will be used to evaluate your opinions on performing the procedure as part of clinical practice, what you like and dislike about using the device, anything you have observed from the men receiving the procedure, and your opinions on the future use of ShangRing within Tanzania's VMMC program.

The survey will be administered upon the completion of the program. It is meant to evaluate your feelings both on the training prior to the start of the program, and you experience using the device throughout the duration of the program.

The interviews are expected to last 30 minutes to an hour each. The survey is 20 questions long, including 16 multiple-choice questions, and 4 questions with written responses, and is expected to take 15-20 minutes to complete.

## Confidentiality

We wish to learn your honest opinion through the interviews and survey, there are no right or wrong answers, and all of your answers are confidential. Your name will not be written on any notes taken by the note-taker or moderator. And no comments or quotes that you give in the interview or in the written answers on the survey that could potentially be used to identify you will be included in any evaluation report. You will also not be asked to provide your name on the survey.

## Risks

While the above steps will be taken to ensure your confidentiality, there is always a chance, however small, that somehow evaluation staff or others reviewing your answers will be able to discern your identity. This could be due either to human error, or based on information available in the answers you give. As we indicate, however, we desire your honest opinion – and we anticipate the risk to you professionally, even if you are identified, to be very small.

## Benefits

The benefits of your participation in the interviews and the survey are that your opinion will be strongly considered by decision-makers when evaluating the findings of the program, and determining the future of the ShangRing device in Tanzania. You will not be paid for your participation, but you will be offered a snack during the interviews.

**Alternatives:** You can choose not to participate in the ShangRing evaluation program, and subsequently will not be trained in its use.

Do you have any questions?

## What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this program's purpose, procedures, and possible risks and benefits and the steps taken to ensure your confidentiality
- You have been given the chance to ask questions before you sign.
- You agree to complete the interviews at the conclusion of the ShangRing training and halfway through the program
- You agree to complete the survey upon the conclusion of the program
- You have been informed that you will not be given monetary compensation for participating

I understand and accept the benefits and risk for taking part in this program as stated above.
I have decided on my own free will to take part this program.

Name of Provider:_____

Signature of Provider:_____

_____
Day Month Year

## Appendix XXIV – Phase 1 Provider Interview Guide

**Provider Interview Guide – Phase 1 to be Administered Upon Completion of Provider ShangRing Training**

| | |
|---|---|
| **Date (dd/mm/yyyy):** | |
| **Name of Moderator:** | |
| **Name of Note-Taker:** | |
| **Facility:** | |
| **Start Time:** | |
| **End Time:** | |

**Introduction**
In this interview, I will ask you questions about your experience and thoughts about the ShangRing device for adult male circumcision now that you have been trained in its use. To protect your confidentiality, I will not record your name or link anything you say in a way that will make it easy to identify you. The interview will be recorded, but your name will not be included on the recording, and we will not store the recording in a way that can be used to identify you. In this interview there are no right or wrong answers. Thus, I would like your honest opinion and reaction to the questions that I ask. The information that you and others provide will help to determine the future use of ShangRing in Tanzania.

Are there any questions before we begin?

1. What is your role/position?
2. What are your thoughts about medical male circumcision for HIV prevention?
3. Prior to the training, what had you heard about the circumcision device called ShangRing?
4. Now that you have been trained in its use, what are your thoughts about this method of circumcision?
5. Do you think males will be interested in ShangRing circumcision?
6. How was the training?
7. Do you feel the training adequately prepared you to perform circumcisions using the ShangRing device?
8. What aspect of the training was the most valuable?
9. What was the least helpful part of the training?
10. Are the procedures around the ShangRing device and its use clear and easy to understand?
11. Do you have any additional thoughts or comments related to the ShangRing device that you would like to share?
12. Do you have any final comments on ShangRing or medical male circumcision in general?

## Appendix XXV – Phase 2 Provider Interview Guide

**Provider Interview Guide – Phase 2 to be Administered At Evaluation Halfway Point (After 250 total ShangRing circumcisions)**

| | |
|---|---|
| **Date (dd/mm/yyyy):** | |
| **Name of Moderator:** | |
| **Name of Note-Taker:** | |
| **Facility:** | |
| **Start Time:** | |
| **End Time:** | |

**Introduction**
In this interview, I will ask you questions about your experience with the ShangRing device, now that you have used it to perform medical male circumcisions as part of this evaluation. To protect your confidentiality, I will not record your name or link anything you say in a way that will make it easy to identify you. The interview will be recorded, but your name will not be included on the recording, and we will not store the recording in a way that can be used to identify you. In this interview there are no right or wrong answers. Thus, I would like your honest opinion and reaction to the questions that I ask. The information that you and others provide will help to determine the future use of ShangRing in Tanzania.

Are there any questions before we begin?

1. What feedback have you heard from males circumcised with the ShangRing? [Note for interviewer: probe for positive and negative aspects]

2. What kind of services or support that are not currently being offered would need to be provided if Tanzania is to increase the use of ShangRing?

3. Do you think males would be interested in receiving ShangRing circumcisions?

4. What do you like about performing circumcisions with ShangRing?

5. What do you dislike?

6. What has changed since you performed your first ShangRing circumcision?

7. Are the standard procedures for use of the ShangRing device clear and easy to understand?

8. What is your experience talking with men about ShangRing? [Note for interviewer: probe for what is easy and difficult, and what the provider likes and dislikes]

9. In your opinion, what factors will impact the ability to use ShangRing in more sites and offer this type of circumcision to more men? [Note for interviewer: follow up about structural/managerial/organizational factors in the health clinic, as well as individual patient factors].

10. What aspects of providing medical male circumcision with the ShangRing device do you find personally difficult? [Note for interviewer: follow up with questions on what could help address these difficulties, and what personal strategies the provider used to address them].

11. What issues do you think most impact a man's decision to have a ShangRing circumcision?

12. What are your thoughts on providing ShangRing circumcision compared to using conventional surgical circumcision techniques? [Note to interviewer: probe to see if provider feels very strongly about one technique or the other, and if yes follow up to inquire why provider feels this way]

13. What are your thoughts on what kinds of messages that could make VMMC more appealing to men? Are there messages related to Shang Ring in particular that you think would resonate in men who are reticent to go for a standard surgical circumcision?

14. Which men do you think would be most interested in ShangRing? Do you have any suggestions on strategies for reaching these men? (I.e. where to find these men, what medium should be used to deliver the message, etc.).

15. Is there anything else related to ShangRing that you would like to comment on or ask?

16. Do you have any final comments related to ShangRing or male circumcision in general?

## Appendix XXVI – ShangRing Evaluation Provider Survey

**ShangRing Evaluation Provider Survey**

**Introduction**

You are receiving this survey because you participated in the {insert project name} as a provider. This survey is meant to gauge your opinions on the ShangRing circumcision device. Your opinions will be used to inform the acceptability of the ShangRing device among providers, and will guide further implementation of the ShangRing device in Tanzania's voluntary medical male circumcision program.

All opinions expressed in this survey are anonymous and confidential. Your words may be used in future reports and analyses created as part of this program, but they will not be attributed to you.

Please answer all questions below per the directions provided. Many questions are rated on a 1 – 5 scale. Some questions are open ended and offer you the chance to expand upon your answers.

When complete, please return this survey to:

**Section 1 – ShangRing Training**

This section is meant to evaluate the training you received on the ShangRing device prior to the beginning of the program. Please select the rating for each question based upon the following criteria:

5=Strongly Agree 4=Agree 3=Neither Agree nor Disagree 2=Disagree 1=Strongly Disagree

1. The trainers possessed strong subject matter expertise:
   ☐5 ☐4 ☐3 ☐2 ☐1
2. The trainers had the ability to explain and illustrate concepts:
   ☐5 ☐4 ☐3 ☐2 ☐1
3. The trainers successfully and completely answered participant questions that arose:
   ☐5 ☐4 ☐3 ☐2 ☐1
4. The information received during training was useful and applicable:
   ☐5 ☐4 ☐3 ☐2 ☐1
5. The pace of the training was appropriate:
   ☐5 ☐4 ☐3 ☐2 ☐1
6. The training was appropriate for your level of experience:
   ☐5 ☐4 ☐3 ☐2 ☐1
7. The training materials were useful and applicable:
   ☐5 ☐4 ☐3 ☐2 ☐1

8. The training adequately prepared you for performing male circumcision with the ShangRing device:
   ☐5 ☐4 ☐3 ☐2 ☐1
9. What did you like most about the training? _____
   _____
   _____
   _____
10. What recommendations do you have for improving the training? _____
    _____
    _____
    _____

**Section 2 – Performing ShangRing Circumcisions**

This section is meant to evaluate your feelings on using the ShangRing device to perform voluntary medical male circumcisions. Please select the rating for each question based upon the following criteria:

5=Strongly Agree 4=Agree 3=Neither Agree nor Disagree 2=Disagree 1=Strongly Disagree

11. I found ShangRing circumcisions to be easy to perform:
    ☐5 ☐4 ☐3 ☐2 ☐1
12. Compared to surgical circumcision, ShangRing circumcisions were easier to perform:
    ☐5 ☐4 ☐3 ☐2 ☐1
13. Compared to surgical circumcision, ShangRing circumcisions were faster to perform:
    ☐5 ☐4 ☐3 ☐2 ☐1
14. Compared to surgical circumcision, I find ShangRing to be a safer procedure:
    ☐5 ☐4 ☐3 ☐2 ☐1
15. I prefer performing ShangRing procedures over surgical circumcision:
    ☐5 ☐4 ☐3 ☐2 ☐1
16. Clients receiving ShangRing appear happier with their circumcision than clients receiving surgical circumcision:
    ☐5 ☐4 ☐3 ☐2 ☐1
17. I would advise that clients select ShangRing circumcision over surgical circumcision (if they are eligible for ShangRing):
    ☐5 ☐4 ☐3 ☐2 ☐1
18. If possible, I would like to continue offering ShangRing circumcision to clients:
    ☐5 ☐4 ☐3 ☐2 ☐1

19. Is there anything in particular you would like to comment on in comparing conventional surgical circumcision with ShangRing circumcision? _____

_____

_____

_____

20. Do you have any final comments on ShangRing or male circumcision in general?_____

_____

_____

_____

## Appendix XXVII: Employee Confidentiality Agreement

**Evaluation of the Acceptability and Safety of the ShangRing Device for Male Circumcision in Tanzania**

**Employee Confidentiality Agreement**

I recognize that in carrying out my assigned duties as a staff member on the ShangRing Pilot Evaluation in Tanzania, I may obtain access to private information about persons in this evaluation that was provided with the assumption of confidentiality. I understand that I am prohibited from disclosing or otherwise releasing any personally identifying information, either directly or indirectly, about any individual in the evaluation. If I am responsible for any breach of confidentiality, I understand that civil and/or criminal penalties may be brought against me. I acknowledge that my responsibility to ensure the privacy of protected health information contained in any electronic records, paper documents, or verbal communications to which I may gain access shall not expire, even after my employment or affiliation with this evaluation has terminated.

By my signature, I acknowledge that I have read, understand, and agree to comply with the terms and conditions of this Confidentiality Agreement.

Employee name (printed): _____

Employee signature: _____

Date: _____

Supervisor name (printed): _____

Supervisor signature: _____

Date: _____

## Appendix XXVIII – ShangRing Evaluation Client Withdrawal Log

**ShangRing Client Withdrawal Log**

| Client Name | Client ID | Date Enrolled | Date Withdrawn | Reason(s) for Client Withdrawal |
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## Appendix XXIX – WHO ShangRing Prequalification

World Health Organization

# WHO list of prequalified male circumcision devices

Last updated: 18 August 2016

| Product name | Manufacturer | Type of circumcision device | Catalogue number(s) | Packaging | Manufacturing site(s) | Year prequalified |
|---|---|---|---|---|---|---|
| ShangRing | Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd. | Collar clamp | ShangRing (4.0cm) A4 SR-II-40<br>ShangRing (3.9 cm) A3 SR-II-39<br>ShangRing (3.8 cm) A2 SR-II-38<br>ShangRing (3.7 cm) A1 SR-II-37<br>ShangRing (3.6 cm) A SR-II-36<br>ShangRing (3.5 cm) B SR-II-35<br>ShangRing (3.4 cm) C SR-II-34<br>ShangRing (3.3 cm) D SR-II-33<br>ShangRing (3.2 cm) E SR-II-32<br>ShangRing (3.1 cm) F SR-II-31<br>ShangRing (3.0 cm) G SR-II-30<br>ShangRing (2.9 cm) H SR-II-29<br>ShangRing (2.8 cm) I SR-II-28<br>ShangRing (2.6 cm) K SR-II-26<br>ShangRing (2.4 cm) M SR-II-24<br>ShangRing (2.2 cm) O SR-II-22<br>ShangRing (2.0 cm) Q SR-II-20<br>ShangRing (1.8 cm) S SR-II-18 | Size A4 (4.0 cm), 1 unit<br>Size A3 (3.9 cm), 1 unit<br>Size A2 (3.8cm), 1 unit<br>Size A1 (3.7cm), 1 unit<br>Size A (3.6 cm), 1 unit<br>Size B (3.5 cm), 1 unit<br>Size C (3.4 cm), 1 unit<br>Size D (3.3 cm), 1 unit<br>Size E (3.2 cm), 1 unit<br>Size F (3.1 cm), 1 unit<br>Size G (3.0 cm), 1 unit<br>Size H (2.9 cm), 1 unit<br>Size I (2.8 cm), 1 unit<br>Size K (2.6 cm), 1 unit<br>Size M (2.4 cm), 1 unit<br>Size O (2.2 cm), 1 unit<br>Size Q (2.0 cm), 1 unit<br>Size S (1.8 cm), 1 unit<br>Measuring tape x1<br>Bandages, removal cutter, and removal key opener sold separately. | 4F Overseas Student Pioneer Park Science Innovation Center Economic & Technology Zone North Yinhu Road Wuhu, China | 2015 |

## Appendix XXX – Data Use Agreement

# Data use agreement

**DATA SOURCE**

| | |
|---|---|
| Name of study | |
| Data description | |

**NAME AND ORGANSIATION'S DETAILS OF PERSON REQUESTING DATA**

| | |
|---|---|
| Name | |
| Organisation | |
| Email address<br>Cell number | |

**DETAILS OF DATA USE**

| | |
|---|---|
| Purpose | |
| Period | From / /201 to / / 201 |
| Ethics regulatory authority approving study:<br><br>Study Approval Number:<br><br>Title of study:<br><br>Aim of study: | |

**CONDITIONS OF USE (TICK EACH ITEM AGREED TO)**

☐ I will not attempt any linkage or combination of the study data to identify individuals for any purpose

☐ I agree to make no attempt to learn the identity of any persons included in these data. If I should discover the identity of a person inadvertently, I will advise the Tanzanian Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) of any such discovery in writing within 2 business days.

☐ I agree to utilize data officially received from MoHCDGEC authorized staff person I will also not send data via email attachments.

☐ I will not carry individual-level data on hardcopy listings or forms

☐ I will keep all hard copies of analysis and locked in a secure location.

☐ Within seven (7) business days from the end of my authorized period of data use, defined above, I agree in consultation with Tanzania MoHCDGEC, to destroy the study encrypted data file and notify the MoHCDGEC data manager that this file has been destroyed.

☐ I agree to notify the MoHCDGEC in writing if I will be changing positions within seven (7) business days prior to my planned change or exit date. I agree not to take copies of the data, data analysis, printouts, runs, graphs, etc. with me when I change positions.

☐ I will only access data on secured computers or through secure connections. A computer or connection is considered secure if access is through my site's secure data network, which typically is a VPN (virtual private network) at the institution.

☐ I will review all data documentation provided by the MoHCDGEC data manager for the analysis datasets prior to using the data to ensure that I am correctly using the variables in the datasets. I will contact the MoHCDGEC, if I have any questions about the correct use of data.

☐ I will promptly inform the MoHCDGEC, of any deviation from these guidelines.

☐ I will acknowledge the contribution of MoHCDGEC by including its contributors as an author, the PIs, the funders and study participants in any publication of this data. (Example below)

> The researchers acknowledge the contribution of all study participants and the XXX study team. Protocol: XXX funded by XXX under terms of the cooperative agreement xxx.

☐ I will not copy data or share data with persons other than those identified in the official proposal.

☐ I will submit all reports based on ShangRing evaluation study data to the MoHCDGEC for clearance, in accordance with MoHCDGEC and Funder guidelines prior to public release for review and comment.

I understand that I am responsible for agreed upon costs incurred in the preparation and delivery of data and MoHCDGEC will be reimbursed for those costs within 30 days of notification.

This agreement may be amended by mutual written agreement of the Parties. Additionally, this agreement may be terminated immediately upon mutual written consent of both Parties or unilaterally by either Party with sixty (60) days' written notice to the other Party.

| _____ | _____ | _____ |
|---|---|---|
| Name (Print) | Signature | Date |

_____

Mailing address, email address, or fax number to receive copy of this signed agreement

List other data user (add list of other users)

Approved by:

Print Name: _____ Title: _____

Signature: _____ Date: _____

## Appendix XXXI – Investigator Qualifications

| Name | Surname | Affiliation | SEV (CDC Staff Only) | Qualifications* |
|---|---|---|---|---|
| Gissenge | Lija | Head, HIV Prevention Unit, Tanzania Ministry of Health, Community Development, Gender and Children | -- | • MD |
| Boniface | Nguhuni | Division of Health, Social Welfare & Nutrition Services, President's Office – Regional Administration and Local Government (PORALG) | | • MD<br>• MsC |
| Lucy | Mphuru | IntraHealth International | -- | • MD |
| Catharine | Laube McDonald | Jhpiego | -- | • BA |
| Mainza | Lukobo-Durrell | Jhpiego | -- | • DrPH |
| Stephanie | Davis | CDC-Atlanta | 13563 | • MD<br>• MPH |
| Melissa | Habel | CDC-Atlanta | 19100 | • MPH |
| Jonas | Hines | CDC-Atlanta | 6212 | • MD |
| Lawrence | Hinkle | CDC-Atlanta | 8564 | • MSPH |
| Carlos | Toledo | CDC-Atlanta | 7632 | • PhD |
| Daimon | Simbeye | CDC-Tanzania | 6320 | • MPH |
| Koku | Kazaura | CDC-Tanzania | 18317 | • DDS<br>• MPH |
| Mbaraka | Amuri | CDC-Tanzania | 2740 | • MD<br>• MPH |

*CVs available upon request

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