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

TABLE OF CONTENTS

LIST OF ACRONYMS

AE	Adverse Event
CRF	Case Report Form
CTC	Care and Treatment Clinic
DC	District Council
HIV	Human Immunodeficiency Virus
IDI	In-depth Interview
MC	Male Circumcision
MOHCDGEC	Ministry of Health Community Development Gender Elderly and Children
NACP	National AIDS Control Program
PEPFAR	United States President's Emergency Plan for AIDS Relief
PORALG	President's Office-Regional Administration and Local Government
PI	Principal Investigator
SD	Standard Deviation
STI	Sexually Transmitted Infection
TMDA	Tanzania Medicines and Medical Devices Authority
TC	Town Council
THIS	Tanzania HIV Impact Survey
ToT	Trainer of Trainers
VMMC	Voluntary Medical Male Circumcision
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

EXECUTIVE SUMMARY

Introduction

Male circumcision (MC) reduces the risk of heterosexually acquired HIV infection in men by 60%. Tanzania is among the 14 sub-Saharan African countries that is scaling up voluntary medical male circumcision (VMMC) for HIV prevention through conventional surgical circumcision. Accelerating the scale up of MC in areas with high HIV prevalence, low MC coverage, and a predominantly heterosexual epidemic is a key component in a comprehensive response for HIV epidemic control. Medical circumcision devices have the potential to speed up the roll out of MC by making the procedure quicker and easier than surgical circumcision, while remaining just as safe. The ShangRing was prequalified by the World Health Organization (WHO) in 2015 as a promising device for circumcision in adolescent and adult males 13 years and older. Based on the WHO's framework for introducing MC devices in countries, IntraHealth International in Tanzania conducted a study to evaluate the acceptability and safety of the ShangRing MC device in Tanzania.

Methods

In Tanzania, we conducted a single arm, open label, prospective cohort evaluation to assess the safety and acceptability of the ShangRing device for nonsurgical circumcision in routine clinical settings. This study was conducted between April and July 2019 in two static MC sites in Shinyanga Region, Tanzania. The recently approved "no-flip" ShangRing circumcision procedure with topical anesthetic was performed on a total of 575 male client study participants aged 13 and older. The primary study outcomes included adverse events (AEs), procedure time, pain, healing, and acceptability of the device in Tanzania. Data on the primary endpoints were collected though observations during placement of the ShangRing device; and through surveys post-procedure (including when the ring was removed, and on the third and 42nd days after removal of the ShangRing). Clinical medical records were completed using routine MC data collection tools. Additional logs were completed tracking placements, removals, and AEs. In-depth interviews were conducted with 50 purposively selected clients on the 28th day after placement of the ShangRing device and with 20 purposively selected service providers to assess the device's acceptability for VMMC. Quantitative data were descriptively analyzed, and qualitative data were thematically analyzed.

Results

AEs were reported for 5% (29) of the 575 ShangRing clients: 22 were mild, five were moderate, and two were severe. Of the total AEs, 24 (83%) were associated with device displacement (20 mild, 2 moderate and 2 severe). None of these AEs were determined to be directly related to the ring malfunctioning. The mean procedure and device removal times were eight minutes (standard deviation [SD] ± 3.98) and six minutes (SD ± 4.5), respectively. Two clients (0.3%) did not respond to the topical anesthesia and were given injectable anesthesia instead. Post-placement pain was not well tolerated in two clients (one self-removed and one was given more topical anesthesia). In total, 572 (99%) of clients had healed by day 49. By day 10, 92% of men had returned to their routine work. Almost all clients (99%) reported that they were satisfied or very satisfied with the appearance of their penis and almost all the clients (99%) would recommend the procedure to others. Use of topical anesthetic, faster recovery, shorter procedure time, and no need for sutures were

common reasons interviewed men opted for ShangRing circumcision. All interviewed clients also reported positive experiences with the ShangRing placement procedure because they did not experience as much pain as expected. Provider acceptability of the procedure was also high (98%), with ease of learning and shorter procedure time as the most frequently cited reasons for acceptability.

Conclusions

Our findings demonstrate that ShangRing device for nonsurgical circumcision is safe in routine clinical settings in Tanzania. With its short procedure times, user friendliness, and high acceptability among clients and providers, ShangRing could facilitate rapid VMMC rollout throughout Tanzania. Lessons learned from Tanzania may inform the implementation of ShangRing in other countries.

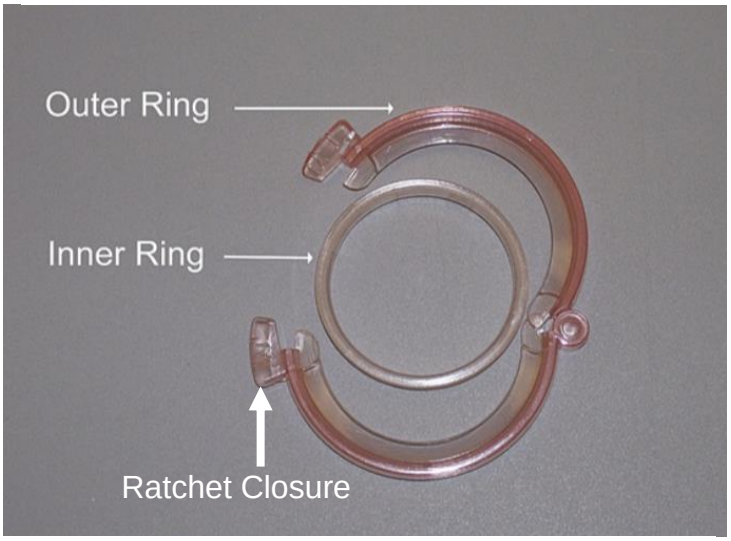
INTRODUCTION

Voluntary Medical Male Circumcision 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%.[i,ii,iii] The 2016-2017 Tanzania HIV Impact Survey (THIS) reported that prevalence of male circumcision is higher in males who were HIV negative (77.4%) than in those who are HIV positive (60.8%). The World Health Organization (WHO) and the Joint United Nations Programme 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 these countries have 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 its *Fast-Track Commitments to End AIDS By 2030*. These commitments included ambitious targets that must be met by 2020 to achieve a 90% reduction in HIV incidence. Among these targets was an additional 27 million circumcisions in the 14 UNAIDS and WHO priority countries.[iv]

World Health Organization (WHO) prequalified two male circumcision devices for use: PrePex and ShangRing. PrePex was adopted in several southern and eastern African countries, but later was discovered to pose an increased risk of tetanus because nonviable tissue was left in situ for seven days after device application; as such, it is no longer manufactured.

Figure 1. The ShangRing device in open position



The ShangRing, manufactured by Wuhu SNNDA Medical Treatment Appliance Technology Co., LTD., Wuhu, Anhui Province, China, is a sterile, single use, disposable MC device that consists of two concentric plastic rings, the inner of which is lined by a silicone pad, which provides a smooth and non-bio reactive surface against the surgical wound (Figure 1). The outer ring consists of two halves which are hinged together at the same end. On each side of the halves there is a locking clasp which allows for locking itself with inner ring. The ShangRing is available in 32 sizes (A4 to Z2), with inside diameters of 40mm to 9mm. Hemostasis is achieved by the pressure applied by the interlocking rings which minimizes bleeding and eliminates the need for sutures.[v]

With the ShangRing device, the foreskin is removed during placement. No tetanus cases have been reported with ShangRing to date.[vi] Multiple countries in Southern and Eastern Africa are now at various stages of incorporating ShangRing into their routine VMMC programs.[vii]

Several studies in China have demonstrated that ShangRing is safe, easy to use, and enjoys high levels of client 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.[viii,ix] Both studies found that there were lower pain levels associated with its use, and patient satisfaction rates were very high (over 98% in both studies) than with conventional surgical circumcision.

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.[x] These studies also found that ShangRing's adverse event (AE) rates and pain scores were comparable to those of conventional techniques, that men preferred ShangRing to conventional circumcision, and that client satisfaction scores were high.[xi,xii,xiii,xiv,xv] 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 ShangRing device placement is faster than conventional circumcision since the device eliminates the need for sutures. A study in Kenya found that the average ShangRing placement time was approximately five minutes, and the average removal time was approximately four minutes (though this study did not compare these times to conventional circumcision).[xvi] Another study in Kenya found the ShangRing procedure to take approximately seven minutes, compared to 21 minutes for conventional circumcision, while in Uganda, the ShangRing procedure was found to take approximately six minutes, compared to 18 minutes for conventional circumcision.[xvii] In Tanzania, a study reported that the total elapsed operating time for conventional circumcisions averaged about 23 and 25 minutes in 2011 and 2012, respectively.[xviii]

A small-scale trial in Zambia comparing the costs of ShangRing versus a standard dorsal slit surgical technique for VMMC found that the direct costs of the two techniques were roughly equivalent. However, with the increased demand for scaling up VMMC services, a ShangRing team could provide services at a substantially lower average total cost due to the potential for more intensive use of staff and other fixed resources.[xix]

In 2019, WHO revised the instructions to add the use of topical anesthetic cream in performing ShangRing circumcisions (as opposed to injected anesthesia), thus removing another common barrier—fear of pain and needles—that affects uptake of circumcision among men. The WHO included use of the "no-flip" technique for performing circumcisions with ShangRing. This technique is easier to perform, and it may allow ShangRing circumcisions to be performed by a wider array of lower-cadre service providers.[xx]

ShangRing and HIV-positive men

In a field study of ShangRing use in Kenya and Zambia, the outcomes for a small number of HIV-positive men (n=84) were similar to those of HIV-negative men receiving ShangRing circumcisions, with moderate and severe AE rates of 1.2% among HIV-positive men and 1.7% among HIV-negative men.[xxi] Acceptability was high in both groups, with 97% and 94% of HIV-positive and HIV-negative participants being very satisfied with penile appearance, respectively, and 100% and 99% of HIV-positive and HIV-negative participants being willing to recommend ShangRing to a friend or family member, respectively. Furthermore, the time until wound healing at 35–42 days was similar between HIV-positive and HIV-negative men (86% vs. 87%, respectively).

HIV in Tanzania

Based on the THIS 2016-2017, there are an estimated 1.4 million people aged 15–64 years living with HIV in Tanzania, with an overall adult HIV prevalence of 4.7% (6.3% for females and 3.4% for males). HIV prevalence varies geographically across Tanzania, from a high of 11.4% in Njombe to less than 1% in Lindi and Zanzibar. The annual incidence of HIV among adults aged 15 and older in Tanzania is 0.24% (0.32% for females and 0.16% for males), corresponding to approximately 72,000 new cases annually. In the Shinyanga Region, where this study takes place, HIV prevalence among men 15 years and older is estimated at 4.3%. Of the same age group of men in Shinyanga, 62.6% were ever tested for HIV and received their results; that percentages falls to 36.6% of men who were tested and received their results in the past 12 months. [xxii]

Male circumcision in Tanzania

As part of its prevention approach, in 2010 the government of 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 2017, 77.6% of males aged 15 years and older in Tanzania reported being circumcised, though circumcision coverage varies considerably by region. In regions where traditional MC is practiced, MC prevalence is as high as 96%; in regions that do not practice traditional MC, the prevalence is as low as 41%.[xxiii] PEPFAR program data from 2016 indicates that Tanzania has performed over 2.3 million circumcisions since 2010.[xxiv]

Introducing a new circumcision device

The pilot evaluation of ShangRing in Tanzania was designed to meet the standards set by the WHO's *Framework for Clinical Evaluation of Devices for Male Circumcision*.[xxv] This framework provides the data necessary to assess the safety of a 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, regulations, and marketing.

Rationale for evaluation

Use of the ShangRing device can address some of the financial and human resource challenges posed by conventional circumcision techniques. ShangRing circumcisions are easier to perform than conventional circumcisions, allowing the procedure to be performed by a wider assortment of lower-care cadres. A new technique for performing ShangRing circumcisions, called the "no-flip technique", whereby the inner ring is placed inside the foreskin, is an alternative to the standard method of everting the foreskin during device placement. The no-flip technique has similar efficacy, safety and acceptability as the standard technique and may offer advantages in terms of ease of placement and removal, and simplicity of training.[xxvi] Data from this evaluation will assist the Tanzanian Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) with policy decisions and possible recommendations on the use of the device in circumcision programs as an additional option for adolescent and adult males, provider training, device implementation, and messages for male clients and their partners in procedure counseling sessions.

Planning and implementation of an evaluation

Implementation timeline. Following the training period, client recruitment and ShangRing circumcision started on May 1, 2019, at both sites and the last follow up visits (i.e., 49 days

post-device placement) ended on July 29, and July 30, 2019, in Kahama District Hospital and Ushetu Health Centre, respectively.

During study implementation clients who undergo the ShangRing procedure also consent to have their data collected at the following points in time to monitor their health outcomes and experience with the procedure:

1. At enrollment and device placement (day 0),
2. At device removal (day 7),
3. During a follow-up phone call (day 10),
4. During in-depth qualitative interviews for 50 purposely selected clients (day 28),
5. At an in-person follow-up visit to assess wound healing (day 49), and
6. At subsequent weekly visits to assess healing for those not completely healed at day 49.

Study management. IntraHealth's current cooperative agreement #NU2GGH001927: Accelerating the Scale-Up of Voluntary Medical Male Circumcision for HIV Prevention for Maximum Public Health Impact in the United Republic of Tanzania under PEPFAR – ToharaPlus – was subcontracted by CDC, through Jhpiego, to conduct the entire ShangRing implementation pilot, supporting all training, procurement, implementation, and data analysis in collaboration with CDC. IntraHealth's home office project support staff also provided technical assistance and operational support to ensure the pilot study was on schedule and met all required payment deliverables (see Appendix 3). CDC Atlanta's technical VMMC leads were closely involved and provided technical support in the creation of the report, including in the development of the ShangRing evaluation study protocol, soliciting ethical approvals, development of data collection tools, data analysis, etc.

Protocol development. CDC provided technical assistance in the protocol and methods development, liaised between key partners and agencies – both locally and internationally – and provided support for preparation and submission of the study protocol for local institutional review committee approval and CDC ethical clearance.

Study implementation. CDC provided expertise and guidance on the completion of the ShangRing study. CDC-Tanzania Principal Investigator, Dr. Daimon Simbeye, and CDC-Atlanta Co-Investigator, Lawrence Hinkle as well as the MOHCDGEC/NACP (Principal Investigator, Dr. Lija Gisenge, and Co-Investigator, Suzan Mbando) conducted a physical visit of the study sites while the study was ongoing. During this visit, they had an opportunity to observe the procedure, data management, handling of waste, and routine reporting procedures as per the evaluation protocol. In addition to this, virtual technical assistance was provided, informed by the weekly service delivery data and AEs reported. Weekly virtual meetings were conducted at the beginning of the study, which were changed to biweekly and later on to monthly calls up to when data collection, analysis and first draft of the report were submitted to CDC and MOHCDGEC/NACP.

Report writing. The CDC Atlanta team was significantly involved in providing inputs to the ShangRing evaluation study report. The VMMC team from the HIV Prevention Branch, at the Division of Global HIV and TB, and CDC Tanzania's Prevention and Science branch staff provided extensive feedback. The report was reviewed by the Science Team and approved by Branch Chief for Science and Surveillance at CDC Tanzania and submitted for e-clearance. The report was approved initially in 2019, with additional comments provided in early 2020 and mid-2021.

Dissemination. This evaluation report will be posted on a publicly accessible website within 90 days of clearance.

METHODS

Study Design

This study was a single arm, open label, prospective cohort evaluation study, with a complementary qualitative study and integrated process evaluation.

Project preparation

During project preparation, we conducted consultative meetings with key government stakeholders at the national, regional, district, facility, and with communities where the study was implemented. Study objectives, design and milestones were first presented to the national VMMC technical working group in October 2018. During initial discussions with stakeholders at the national level, the study's principal investigators, co-investigators, and collaborators were identified, and their roles and responsibilities were established.

Waiver for importation of ShangRing devices and topical cream (EMLA) was sought from the Tanzania medicines and medical devices authority (TMDA) prior to the initiation of research activities. Permits for master trainers to conduct theoretical training for health workers and practical training in the government health facilities were obtained from the chief medical officer. Permissions for service providers to participate in the ShangRing study from the selected public health facilities were obtained from President's Office-Regional Administration and Local Government (PORALG).

The study team also conducted participatory meetings with regional, district officials and service providers from the selected study sites as part of early stakeholder engagement. The study protocol was presented to them and their role in the pilot study was established. During these meetings, the regional, council and facility management teams provided guidance on selection of possible study sites, establishment of acceptable compensation rates for study participants, and advised on proper client recruitment methods to enhance quick enrolment of study participants. Updates on the study progress were presented during quarterly VMMC performance review and data analysis meeting in January and April 2019, which brought together the regional medical officer, district medical officers, and health facility in-charges from the selected study areas, among other participants.

Study region and sites

The ShangRing pilot study was conducted in Shinyanga region within two health facilities, Kahama District Hospital and Ushetu Health Centre, that were supported by IntraHealth, the recipient of pilot study funds, and was supporting the implementation of the ongoing VMMC project in Shinyanga region (Figure 2). These sites were purposefully selected to participate in this study because they had well established static sites and had large demand for VMMC services to offer a large enough sample size to meet the evaluation needs.

In early February 2019, the study coordinator conducted an assessment in the two selected study sites to establish their eligibility for the study. This assessment was conducted using the national VMMC site selection assessment checklist (Table 1). The two selected sites were deemed ready for ShangRing study (readiness >90%), with a few modifications that were

implemented prior to implementation including:

- Additional medical tents—with beds, emergency kits, and infection prevention tools and equipment—were mounted outside the main VMMC sites to add a private space for conducting postoperative surveys and a waiting area for clients who chose conventional surgical circumcisions.
- Additional research assistants and data collection tools were provided to assist with assessment of client eligibility, conducting post-procedure exit interviews, and offer additional ShangRing device-related information to study participants (Table 2).

Figure 2: ShangRing Study Area (Ushetu DC & Kahama TC)

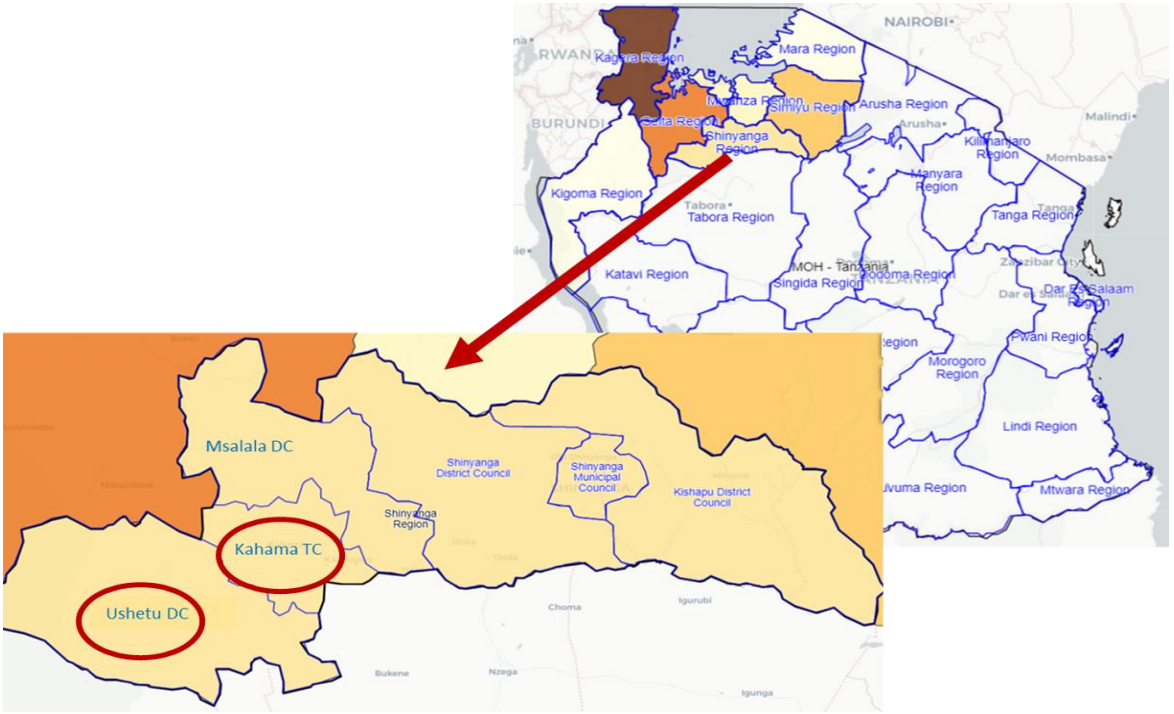


Table 1: Description of site characteristics from the site selection assessment, ShangRing Evaluation, Tanzania, 2019

Areas of assessment	Kahama H	Ushetu HC	Expected score
Organization of VMMC services	6	6	6
Infrastructure capacity	3	3	3
Surgical room	16	14	16
Privacy and outfit of surgical rooms	4	2	4
Recovery and documentation area	5	5	7
Human resources	6	6	6
Availability and use of current guidelines	8	8	8
Availability of personal protective equipment	18	18	18
Availability of waste management and disposal mechanisms	14	12	14
Availability of antiseptics	10	10	10
Total Score	**90**	**84**	**92**
% Score	**98%**	**91%**	**100%**

Phases of implementation

The study was structured in two phases. In the first phase, the health workers were trained on ShangRing circumcision using both theoretical and practical training methods. As part of the training, each of the service providers was required to circumcise a minimum of ten clients using ShangRing devices and accomplish at least five removals. All the trained health workers were certified to be ShangRing circumcision providers. The second phase included recruitment of study participants, conducting ShangRing circumcision and removals as well as related follow ups and qualitative assessments (Table 2).

Table 2: Data collection methods and tools used to obtain data during training and implementation phases, ShangRing Evaluation, Tanzania, 2019

Endpoints	Method	Data Collection tools
Phase 1: Training		
Training Needs Components Primary endpoints: • Provider training needs • Provider proficiency (placement and removal) • Provider acceptability	Surveys	• Knowledge and theory-based pre- and post-tests
	Observations	• Trainer observation checklist during practicum training
Training Needs Components Secondary endpoints: • Training satisfaction • Procedure and removal times • Adverse events and device-related incidents	Documents and records	• Standardized forms to collect data on adverse and device-related events. • Client clinical records signed by providers
	Interviews	• Qualitative interviews with providers
	Photographic records	• Photographs of the client's genital area (on day 0, 7, 49, and at subsequent weekly healing visits)
Phase 2: Implementation Cohort Evaluation		
Safety Component **Primary endpoints:** • **Adverse and device-related events** **Secondary endpoints:** • Adverse events during placement/removal • Providers' technical difficulty and complications during placement/removal	Documents and records	• Standardized forms to collect data on adverse and device-related events. • Client records
	Surveys	• Client acceptability log to collect data on reasons to participate or not participate in the study, as an indirect measure of acceptability
Acceptability Component **Provider acceptability** • Practicality of device use • Placement and removal times **Client Acceptability** • Comfort during placement and removal • Experience while wearing the ring. • Penile appearance after healing	Interviews	• Qualitative interviews with providers • Qualitative interviews with clients
	Surveys	• Brief surveys on reasons to decline participation in the evaluation as an indirect measure of acceptability
	Documents and records	• Client records, including those recording placement and removal times
Healing Component • Percentage of men clinically healed 49–52 days post-placement (42 days post-removal) • Time points at which all men are clinically healed	Documents and records	• Client records indicating healing per the VMMC healing definition, as completed by providers during the day 49 healing assessment visit and subsequent weekly healing visits for those not healed at day 49
	Photographic records	• Photographs of the client's genital area, taken post-device removal (day 7) and at the day 49 healing assessment visit and subsequent weekly healing visits

Training Phases

The training curriculum included two full days of in-classroom lectures (April 29–30, 2019), followed by 15 days of supervised clinical practical exercises (May 1–15, 2019). Four "lead trainers"[1] who were engaged by Akeso Associates as consultants to facilitate training of trainers (ToTs) and service providers trained a total of 20 service providers of different cadres on ShangRing circumcision. Trained service providers included six national VMMC ToTs from Shinyanga Region, 12 VMMC providers from Kahama and Ushetu, and two IntraHealth's VMMC project continuous quality improvement officers (Table 3).

Table 3: Provider cadres trained, ShangRing evaluation, Tanzania, 2019

Provider cadre	Number	Percent
Clinical officers	1	5
Enrolled nurses	9	45
Medical doctors	4	20
Registered nurses	6	30
Total	20	100

In-class theoretical training

The in-class theoretical training was conducted in accordance with the latest WHO recommendation (2019) on the device, including information about (1) the "no-flip" technique, (2) inclusion of adolescents 13 years or older, and (3) use of topical anesthetic cream as an alternative to injectable anesthetic. Knowledge acquisition was measured using pre- and post-test assessments (before and immediately after the training practicum) and practicum mentorship observations. The providers were also informed about the pilot study protocol and the standard operating procedures.

Training practicum

After the in-classroom training, the practicum session began with master trainers demonstrating ShangRing device placements on three clients, while participating service providers were observing. Next, each provider trainee assisted a trainer in placing a device, for a total of 20 devices placed. Then, each provider trainee was assisted by a trainer in placing one device, for a total of 20 devices placed. Provider trainees were then allowed to start placing ShangRing devices in pairs, as per the study protocol. Each provider trainee was required to conduct a minimum of ten ShangRing device placements and five removals, under close supervision of the trainers, during which each of the distinct steps was assessed. A ring placement checklist was provided to the provider trainees, and each placement was given a score ranging between zero and two[2]. The tenth placement was supposed to have the highest score for the provider trainee to be certified. As part of this training, it was our objective to identify possible trainees who could be future ShangRing trainers of trainers after they gained substantial experience with ShangRing. All 20 trainees were certified as ShangRing providers after passing a written assessment and having acquired the required skills in ShangRing device placement and removal. They were then eligible to continue to the implementation phase of the study.

The assessment of trained service providers was conducted using two approaches: A pre- and post-test was administered before the training began and during the second week of the

[1] Physicians, nurses, and clinical officers experienced in conventional surgical circumcision who were either trained in China or trained locally by those trained in China to conduct Shang Ring circumcisions

[2] A score of zero = not able to place the ring; a score of one = adherence to 50% and above of the protocol; a score of two = adherence to 100% of the protocol.

training, respectively, and an evaluation was conducted on a case-by-case basis for each of the trainees using a detailed clinical scoresheet.

Data collected from the training phase, including average training time and average procedure time during ShangRing device training, were included in the final analysis. Other aspects of the training, including its strengths and weaknesses, the effectiveness of the training package/materials, provider satisfaction, and suggestions for its improvement, were explored through qualitative in-depth interviews. Provider training and acceptability of the ShangRing device were also assessed via a Likert-scale questionnaire, with responses designed to measure the ease of performing the procedure and how willing providers would be to continue performing ShangRing procedures following the conclusion of the implementation pilot.

Providers were interviewed at the evaluation's midpoint, at least four weeks after client enrollment, and this interview assessed provider satisfaction with training and acceptability using ShangRing for circumcisions.

Recruitment and enrollment of study clients

Upon arrival at the study health facility, clients were grouped by age for routine group counseling, with separate information sessions provided for adults and adolescents. Service providers informed interested males about the general facts regarding VMMC and HIV; the two circumcision methods offered at the facility—the conventional surgical method and the ShangRing method; the evaluation requirements and procedures, which follow national VMMC guidelines; and their potential role in the evaluation. Clients interested in conventional surgical circumcision proceeded through the normal client flow. Those interested in ShangRing were taken through the eligibility screening and consent procedure before ring placement.

Clients were compensated for their travel costs and time on day 7 (for the ring removal), on day 49 (for the healing assessment) and on subsequent healing visits, if necessary. The compensation ranged from 20,000 Tanzanian Shillings (approximately $8.70 USD) per visit and 30,000 (approximately $13 USD) per visit for clients younger than 18 who were accompanied by an adult. Clients selected for face-to-face interviews on day 28 post-removal were also compensated. This compensation cost was estimated based on the prior agreement in a meeting with the regional, district and community stakeholders to account for regional transport costs for clients residing within 30 km around the study site.

Client eligibility screening

Potential clients were screened according to inclusion/exclusion criteria, as follows:

Client inclusion criteria

A potential client's eligibility was assessed through a medical history screening and a genital examination conducted by the VMMC provider to ensure that the client was in overall good physical health. As additional inclusion criteria, clients needed to:

- Be an uncircumcised male aged 13 years or older (as determined during the physical assessment)
- Be seeking medical circumcision at one of the study sites

- Consent to an HIV test, unless they were known to be HIV-positive[3]
- Agree to be circumcised using the ShangRing device[4]
- Have their penis fit into one of the ShangRing ring sizes available during the study
- Be able to understand the evaluation procedures and requirements
- Agree to abstain from sexual intercourse and masturbation for six weeks after ring removal, for a total of seven weeks
- Live within 30 kilometers of the facility in Shinyanga Region, Tanzania
- Be willing to provide valid contact information (i.e., telephone number, address of residence, place of employment, and other locator information) and be willing to receive communications and/or follow-up visits[5]
- Have an activated mobile phone or access to a mobile phone
- Agree to return for a follow-up visit to assess healing at day 49 (42 days post-removal)[6]
- Agree to a ten-day post-placement (three days post-removal) telephone call to assess and detect symptoms of AEs
- Be able to communicate in English and/or Kiswahili
- Be capable and willing to provide written informed consent (18 years and older) or written informed consent from a parent guardian (13–17 years old) to participate for both HIV testing services and VMMC services.

Client exclusion criteria

Clients who did not meet the inclusion criteria above and/or who had any of the following known medical conditions were excluded from the evaluation:

- A cognitive impairment that prevented the client from providing consent
- Any health condition (reported or observed) that was a contraindication to surgical VMMC in the national program or that ShangRing providers deemed a contraindication. These may include diabetes, peripheral vascular disease, cancer, bleeding disorders, and/or current moderate or severe infectious illness.
- A current sexually transmitted infection (STI) other than HIV (clients with STIs were advised to return for circumcision once the STI was treated); and/or other conditions, which in the opinion of the site supervisor, prevented the client from undergoing a circumcision with the ShangRing device.

Screening and examination results were documented on evaluation forms. Clients who did not meet the inclusion criteria were offered a standard surgical circumcision, if not contraindicated. The number and reasons for exclusions were recorded and are reflected in this report. Serological testing for HIV is a standard component of MC services globally. All clients were offered HIV testing and only those who consented for HIV testing were included in the study. HIV seropositivity was not part of the study exclusion criteria. This permitted

[3] Men who were known to be HIV-positive could forgo the test if they were able to provide proof of their status (i.e., a positive test result) or show that they were on treatment. If unable to provide proof, the men were tested to confirm their status.

[4] Those aged 13–17 years were required to have parental/guardian approval, in addition to providing assent. Parents/guardians also needed to agree to be present at the facility during the circumcision (though not in the operating room, unless requested by the client), during delivery of discharge instructions, and during subsequent follow-up visits.

[5] Clients may have also been asked for the names of relatives or friends to be contacted if the client could not be reached.

[6] Clients who had not healed by the day 49 post-placement visit had to agree to return for weekly follow-up visits until they were healed.

enhanced understanding of healing among HIV-positive males circumcised with the ShangRing.

Client consent

Research assistants were trained for two weeks on obtaining written or thumb-printed informed consent from consenting clients after providing information about the study procedures, benefits and risks as written in the study information sheet in Kiswahili. Eligible clients for this evaluation were guided through the consent process, where they read and/or had read to them the written consent form in Kiswahili. Minor client study participants (males aged 13–17) received complete information regarding the study procedures, risks, and benefits, then were asked for their assent. A parent/guardian of the minor clients was also present to read/have read to them the study information sheet and written consent form in Kiswahili. All questions and clarifications were provided to the clients when needed by the study nurse or research assistants. Informed consent covered evaluation procedures, potential risks, benefits, and contact persons for reporting complaints or concerns. After the contents of the consent form were clearly understood by clients (and their parent/guardian, if applicable), they were asked to sign all or part of their name if they accepted ShangRing circumcision and agreed to follow-up visits. Clients who were unable to sign their name could make a digital impression (i.e., a thumbprint). A copy of the signed consent form was provided to clients and their parent/guardian, where applicable.

Client sample size

The sample size of 575 males was consistent with the framework for circumcision device introduction, as proposed by the WHO.[xxvii] This sample size was powered to detect the occurrence of AEs, which is estimated to be 2%. A minimum of 335 males was necessary for 95% confidence that the population proportion is within ±1.5%, with an observed AE rate of 2%. An additional 240 males were recruited to provide further confidence in the results and to align with the WHO framework. The evaluation teams enrolled consenting clients on a rolling-basis until the sample size of 575 was achieved.

Provider eligibility screening

Provider inclusion criteria

To be included in the evaluation, providers needed to:

- Be an adult, aged 18 or older
- Be employed as a medical doctor, an assistant medical officer, a clinical officer, a professional nurse, or an enrolled nurse at a participating site in Shinyanga Region, Tanzania
- Be experienced in providing conventional surgical circumcisions
- Be trained and certified in the ShangRing circumcision technique by a trainer who was trained in the ShangRing procedure and who has performed a minimum of ten placements and five removals[7]
- Demonstrate competence in the ShangRing procedure upon completion of the course
- Be trained and competent in screening clients to determine their eligibility for ShangRing circumcision
- Agree to complete interviews following the training, at the midpoint of the evaluation, and following at least four weeks of client enrollment

[7] Master trainers from Kenya trained providers based in Shinyanga, who then trained mid-level providers.

- Agree to complete an evaluation survey after all ShangRing circumcisions were performed
- Be able to communicate in English and/or Kiswahili
- Be able and willing to provide written informed consent to participate.

Provider exclusion criteria
Providers who did not meet the inclusion criteria above and/or met either of the following criteria were excluded from the evaluation:
- Failure of ShangRing training, as determined by the instructors at the end of the training period.
- Failure to comply with infection prevention and control throughout as determined by the VMMC Infection Prevention and Control Guidelines, including handling of medical waste during and after the procedure.

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).

Ring size assessment
Globally, the ShangRing device is available in 32 sizes (A4 to Z2), with inside diameters of 40mm to 9mm. In this study, only ten ring sizes were available. Service providers were trained to switch one or two ring sizes below the tape measurement based on their judgement on the measured size of the sub coronal shaft in relation to the thickness of the foreskin. While ordering for the first time, we used historical data from Kenya to make decisions on quantities of devices by size.

Duration of placement and removal of ShangRing
We separately documented the amount of time taken for the topical anesthetic to take effect and the time for actual device placement, including foreskin removal. The duration of topical anesthetic was counted as the length of time from when the provider completed applying the cream to the full shaft of the penis to when it was confirmed that the foreskin was numb and ready for incision. In this process EMLA® cream, 10 mg 5% (2.5% lidocaine, 2.5% prilocaine) was applied around and inside of the foreskin, covering the full shaft of the penis. The penis was then covered with a surgical glove and the client could leave the procedure room for approximately 20 minutes and then called back and checked if the anesthesia had taken effect. If the area was not yet numb, it was rechecked every two to five minutes, for up to an additional 30 minutes. If the topical anesthetic had not taken effect by the end of the additional 30-minute period (i.e., 50-55 minutes post-application), injectable anesthesia was used (upon client consent). The anesthetic cream was then wiped off the penis shaft before ring placement.

The device placement duration was counted from when the foreskin was held by forceps for insertion of the inner ring to when the foreskin was removed. In this process, the foreskin was held by forceps and the inner ring slipped under the foreskin to the level of the coronal

sulcus. The outer ring was then clamped around the inner ring, squeezing the foreskin in-between. The foreskin was then adjusted at a proper position and cut. The device removal

Figure 3: Client data workflow and data collection points, ShangRing Evaluation, Tanzania, 2019

duration was counted from when the outer ring was opened until the inner ring was removed.

Assessment of pain

Pain was measured using the Visual Analog Scale only among clients who reported moderate and severe AEs; with scores ranging from "does not hurt" to "hurts a whole lot".

Post-placement interview

Before being discharged, clients were interviewed about their experience to determine their acceptability and satisfaction with the ShangRing procedure.

Continuous monitoring

During study implementation clients who undergo the ShangRing procedure also consent to have their data collected at the following points in time to monitor their health outcomes and experience with the procedure:

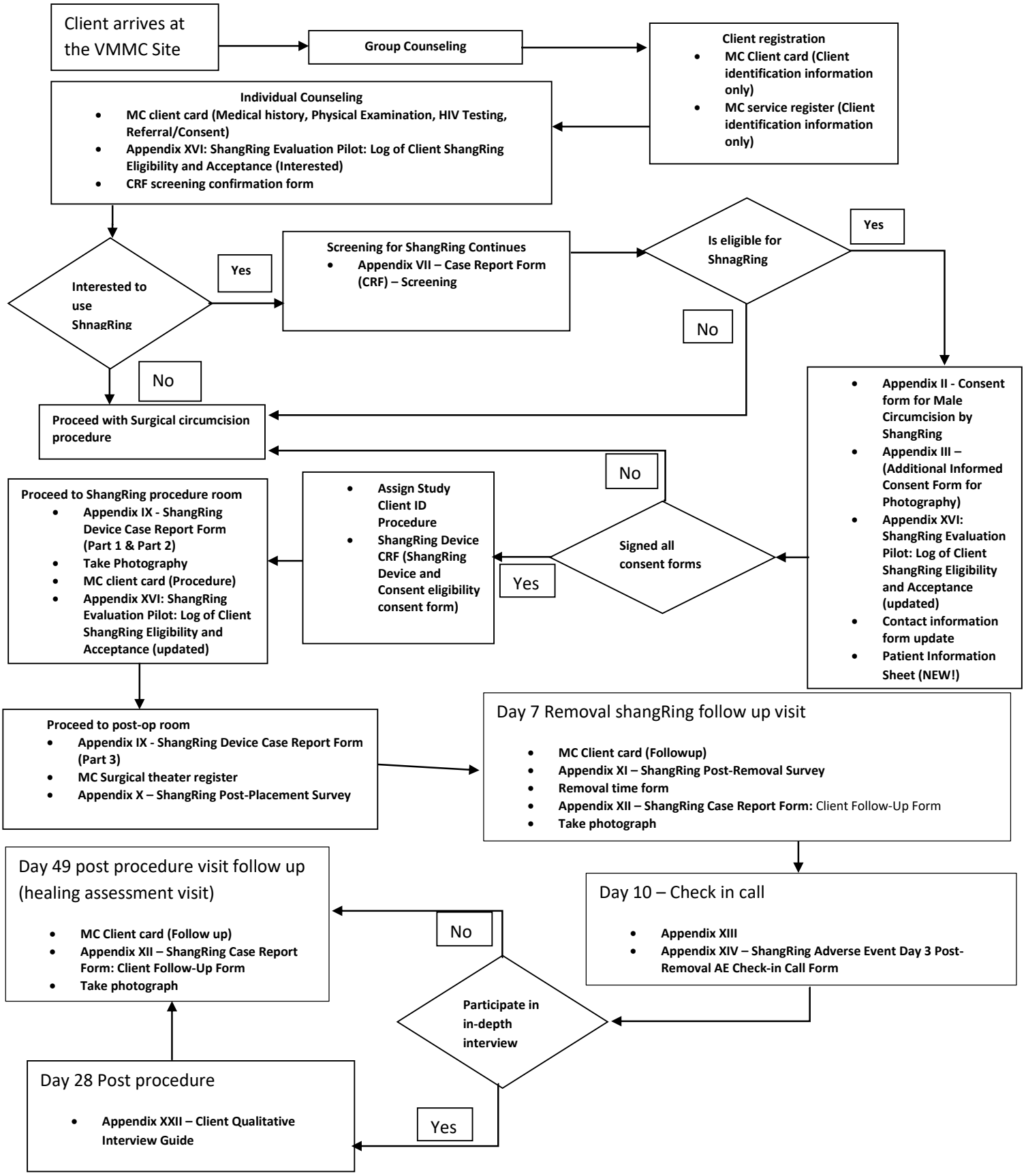
- at enrollment and device placement (day 0) - before being discharged, clients were interviewed about their experience to determine their acceptability and satisfaction with the ShangRing procedure.
- at device removal (day 7) - clients were interviewed about their physical comfort while wearing the ShangRing device for seven days, how circumcision using ShangRing device affected their performance of day-to-day activities, and satisfaction with their penile appearance after circumcision.
- during a follow-up phone call (day 10) - all circumcised men were asked to answer a phone call to assess AEs three days post device removal.
- during in-depth qualitative interviews (day 28) - fifty adult males were purposively selected from the clients enrolled in the ShangRing evaluation study to participate in private face-to-face in-depth interviews.
- at an in-person follow-up visit to assess wound healing (day 49) - all men were asked to return for a follow-up visit on day 49 post-placement to assess healing and have their genital area photographed.
- at subsequent weekly visits after day 49 - all men who were not clinically healed on day 49 post-placement visit were asked to return to the clinic at weekly intervals until healed.

Data collection

Data were collected at different points along the client flow continuum: client screening and individual counseling, consent, procedure room, post-operative room, and post-operative follow-up visits (Figure 3).

All service providers were trained on how to capture data at different points. Research assistants were trained for two weeks on administering the survey questionnaires and conducting in-depth interviews (IDIs) in Kiswahili. Data were collected at up to five points in time for each enrolled client: at enrollment and device placement (day 0), at device removal (day 7), during a follow-up phone call (day 10), during in-depth qualitative interviews for 50 purposely 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 (Figure 3).

Figure 3: Client engagement timeline



IDIs were conducted by trained study personnel, all of them degree holders with background training on research methodologies and ethics in human research. The interviewers were trained by a senior on how to moderate IDIs, taking consent, taking notes and recording using digital recorders. Each of these IDIs were conducted by two personnel, i.e., one

moderator and one note taker who also regulated the tape recorder during interviews. Prior to field work, the interviewers were trained by the senior research scientist on how to conduct interviews using the respective guides, that were translated from English to Kiswahili and back translated to ensure the meaning of each interview guide was retained. The translated interview guides were pre-tested amongst IntraHealth staff to assess if the questions asked are clear and provide the expected responses. A total of 50 clients were interviewed with the assumption this would obtain the necessary range of views and opinions. In cases where the questions were not clear or provided unexpected responses, revisions were made to ensure they capture expected responses. Only males aged 18 years or older were selected to participate in the qualitative interviews. A separate written consent was also obtained for clients willing to participate in an interview. These interviews gathered information on clients' experience from placement to healing, discomfort, and satisfaction with ShangRing circumcision. Source documents for this evaluation included, but were not limited to, staff notes; medical notes; client case report forms (CRFs) and files; screenings, interviews, and interviewer notes; enrollment logs, informed consent forms; client reimbursement logs; and audiotapes and transcripts from the qualitative interviews.

Data entry and management

On a daily basis, a summary of the number of clients circumcised and AEs were recorded in a customized database in Microsoft Excel (version 2019) and submitted to the MoH/NACP and all PIs on a weekly basis.

All client-level quantitative data from the paper-based forms were manually entered in EpiInfo. Once evaluation forms were completed and verified, the data clerks forwarded the CRFs and AE forms to the site coordinators. For qualitative data, after all the recorded interviews were transcribed and translated into English, the original digital recordings were destroyed. Transcripts were saved in a de-identified format and stored in password protected laptops, interviewer notes were stored in the evaluation office in a locked file cabinet.

As per the AE reporting guidance for this evaluation study, AE forms for the two severe AEs were scanned and submitted to the study PI Dr. Lija Gissenge, who was the head of the prevention unit at NACP/MOHCDGEC and copied to all study investigators at PORALG (Mathew Emmanuel Mganga), WHO (Bhavin Jan), CDC-Atlanta (Jonas Hines, Lawrence Hinkle, Carlos Toledo), CDC-Tanzania (Kokuhumbya Kazaura, Daimon Simbeye, Amuri Mbaraka), and to the manufacturer of ShangRing through Akeso Associates to describe the nature of the AEs, management, and results. The site coordinators reconfirmed that the forms were complete and accurate (including signatures, dates, AEs, serious AEs, and protocol departures).

The local data warehouse containing the de-identified electronic evaluation data was located on a password-protected computer and encrypted to avoid un-authorized access. Client folders, containing paper-based evaluation forms were secured in a locked cabinet, and access to this information was limited to the study coordinators, site supervisors, and investigators at the supported health facilities. Throughout the study period, original client files were maintained at the health facility in accordance with the national VMMC data management protocol. Hard copies of study materials (survey, consent form, AE forms, etc.) were maintained at the site's evaluation files in a locked file cabinet with access limited to evaluation staff. After completion of data entry at the site level, client cards, AE forms, and other hard copies of study tools were kept in locked trunks and transported for storage at IntraHealth offices in Dar es Salaam. All databases were password-protected and encrypted

before transmission over public networks. Photographs were encrypted and downloaded to a password-protected evaluation computer, saved in a specific location, and backed up on a password protected removable hard drive. Five years following completion of final analyses and reports, all files with data collected solely for the purpose of this study including photos and qualitative transcripts will be disposed in accordance with the Tanzanian country policies upon conclusion of the project. Client files remained at the study sites as part of routine client records.

Clients were identified by name only on their client CRF, but not on any survey questionnaire, photograph, or any other documentation. Client identifiers, such as names and faces, were not shown in or written on any photograph taken during this evaluation. Client identifiers were entered on a master client log that links names and identification numbers; that log was stored in the locked file cabinet with restricted access. Clients have not been reported by name in any report or publication resulting from data collected in this evaluation.

Quantitative data analysis

Means, standard deviations, and percentages were used to describe quantitative variables. The largest group was used as the reference to compare time to anesthetic effectiveness, the durations of device placement and removal procedures, and duration of clinical wound healing between the different age categories. Client acceptability, time to return to normal activity, and clients' satisfaction with the post-circumcision cosmetic results were summarized from data recorded on the evaluation surveys. Student's t-test was used to determine the level of significance; the alpha level was set to 0.05. No formal hypothesis test was performed comparing AE rates in this evaluation to other AE rates. Stata version 15[8] was used to conduct the quantitative analysis. No corrections for missing values were imputed.

Qualitative data analysis

NVivo 12[9] qualitative data analysis software was used for the analysis of IDI data. Thematic analysis was used to inductively code the transcripts to identify emerging themes. An iterative approach was used to develop the codebook and index the transcripts by categories, themes, and patterns that emerged from the data. Two analysts developed the coding scheme using the English translated transcripts. After coding ten transcripts and discussing the codes, the codebook was revised, and the themes finalized for coding of the remaining transcripts. Coding was conducted by three trained project staff who harmonized new codes as they emerged.

HIV notification policy

To be eligible to participate in this evaluation, all men approached for enrollment were asked to provide consent and agree to receive an HIV test. Only men who consented to HIV testing were enrolled in the evaluation. Out of the those who consented and enrolled, the newly identified HIV-positive clients were escorted to a care and treatment clinic (CTC) and were successfully enrolled in care. All were circumcised afterwards using the ShangRing device as per their preference.

Ethical approval

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) and Johns Hopkins School of Public Health Institutional Review Board Office (FWA # 00003428). This project was

[8] StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC.
[9] NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2018.

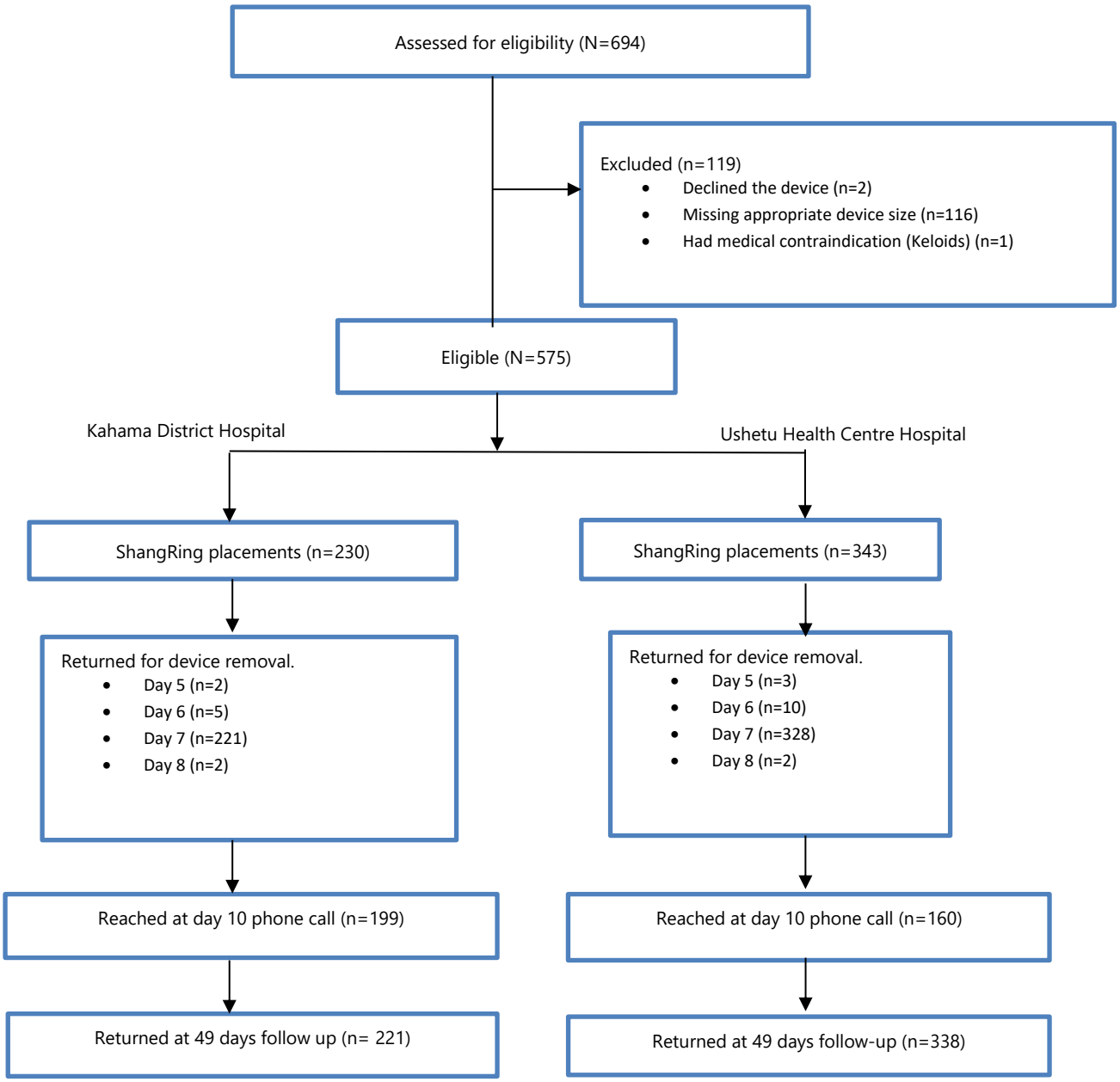
reviewed in accordance with CDC human research protection procedures and was determined to be research, but CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes.

FINDINGS

Client Enrollment

Among the 694 men who sought MC services at the two study sites during the study period (between May and June 2019), 692 opted for the ShangRing circumcision and the remaining two clients preferred conventional surgical circumcision because they were not ready to opt for a new technology. All the 692 clients who opted for ShangRing circumcision were screened for eligibility, with 575 (83%) being enrolled in the study. This included 43 (7%) who were enrolled during the training phase, 345 (60%) who were enrolled at Ushetu Health Centre, and 230 (40%) who were enrolled at Kahama District Hospital. The remaining 117 clients who opted for the ShangRing device were not enrolled in the study because they were not eligible: one client was considered unsuitable for circumcision because he had keloids and 116 clients were not enrolled because correct-fitting ShangRing sizes were unavailable for them at the time of the procedure. Of the 575 clients who were enrolled in the study, 573 (99.6%) were successfully circumcised using the ShangRing device. Device placement was not completed in two clients (due to intraoperative AEs), and both were removed from the rest of the analysis, except for their AE information (Figure 4).

Figure 4: Tanzania ShangRing Pilot Study Clients Flow Chart, 2019



Demographics of ShangRing pilot study participants

The median age of the clients circumcised using the ShangRing device was 25 years (SD 9.9, interquartile range was 11 years). Among them, 217 (38%) were adolescents aged 13–19 and 358 (62%) were adults aged 20 years and above (Table 5). A total of 241 (42%) clients were married and the remaining 334 (58%) were unmarried. Of the unmarried clients, 90 (27%) were unmarried minors (i.e., aged below 18 years).

Table 5: Demographics of ShangRing pilot study participants and interquartile range calculations, ShangRing Evaluation, Tanzania, 2019

Age group	Frequency (N)	CF	LCB
10–14	12	12	9.5
15–19	205	217	14.5
20–24	129	346	19.5
25–29	104	450	24.5
30–34	41	491	29.5
35–39	31	522	34.5
40–44	23	545	39.5
45–49	18	563	44.5
50+	12	575	49.5

Upper Quartile (Q3)

$$L + \left(\frac{\frac{3N}{4} - f_c}{f_Q}\right) \times \omega$$

$L=24.5$
$f_C=346$
$f_Q=104$
$W=5$

$$24 \cdot 5 + \left(\frac{431 - 346}{104}\right) \times 5$$

$$24 \cdot 5 + \left(\frac{85}{104}\right) \times 5$$

$24 \cdot 5 + 4.1$
$Q3 = 28.6$
IQR =Q3-Q1
=28.6-17.7
=10.9~11

Lower Quartile (Q1)

$$L + \left(\frac{\frac{N}{4} - f_c}{f_Q}\right) \times \omega$$

$L=14.5$
$f_C=12$
$f_Q=205$
$W=5$

$$14 \cdot 5 + \left(\frac{144 - 12}{205}\right) \times 5$$

$$14 \cdot 5 + \left(\frac{132}{205}\right) \times 5$$

14·5 +3.2
Q1 = 17.7

Medical history and physical examination

All clients received health education and HIV prevention messages, including reminders that VMMC does not provide 100% protection against new HIV infections. Medical histories were taken and medical checkups done for all clients before enrolment in the study. Five clients were diagnosed with contraindications as follows: three had an active STI; therefore, they were referred to the STI unit for treatment before circumcision; one had very high fever and was referred to the outpatient department for further medical check-up and treatment; and the last one had keloids and was advised to visit a specialized hospital. All three clients with an STI and the one with fever were treated and returned later for circumcision. The client with keloids was not circumcised but was instead referred to specialized services to avoid lifetime disability or disfigurement of the glans.

All clients attending the VMMC clinic were required to be tested for HIV; those who did not consent for HIV testing were excluded from the study. A total of 560 clients (97%) were tested for HIV and received their test results. The remaining 15 (3%) provided evidence of their known HIV-positive status at the study site. Of the 560 clients who were tested, six (1%) were newly identified as HIV-positive, making the total of HIV-positive clients to be 21.

Duration of placement and removal of ShangRing

The average time for topical anesthesia to take effect was 29.6 minutes, at a standard deviation of ±2.6 minutes. The meantime for device placement was eight minutes, at a standard deviation of ±4 minutes. The meantime for device removal was six minutes, at a standard deviation of ±4.5 minutes (Table 6).

Table 6: Duration of steps in the ShangRing device procedure, ShangRing Evaluation, Tanzania, 2019

Duration of steps in the ShangRing device procedure	Mean time in minutes
Topical anesthesia to take effect	29.6 minutes (SD ± 2.6)
Device placement	8 minutes (SD ± 4.0)
Device removal	6 minutes (SD ± 4.5)
Overall time of placement procedure	35.4 minutes (SD ± 3.5)

Experience with topical anesthesia

Although most of the clients who participated in qualitative interviews preferred the topical anesthesia to avoid pain from an injection, injectable anesthesia was also used in seven clients. Of the seven clients with injectable anesthesia, two of them were injected because they did not respond to the topical anesthesia after two applications and one hour of waiting. The remaining five clients wanted to minimize the waiting time before procedure (topical anesthesia takes up to approximately 30 minutes to take effect, while injectable anesthesia takes up to four minutes). This choice reduced the procedure time to 12–14 minutes instead of 38–42 minutes.

Post-operative follow-up visits

Two clients were switched to conventional surgical circumcision following unsuccessful device placement; they later returned for post-circumcision follow-up 48 hours and seven-days post circumcision as per the conventional VMMC guideline. The remaining 573 ShangRing circumcised clients were scheduled to return for device removal on day 7 post-placement.

Generally, all devices were successfully removed by day 8. Of these, 571 were removed by the health workers at the VMMC clinic, one self-detached on day 4 due to slippage of the ring and one was a self-removal due to unbearable pain following nocturnal erection. All clients returned at the ShangRing site where they were assessed by the trained service providers on the progress on wound. A total of 547 (95%) clients had the devices removed at a facility on day 7 post-placement as per the ShangRing circumcision guidance; 20 devices (3%) were removed on day 5 or 6 when clients returned with partial spontaneous detachment that caused discomfort and/or pain during movements or erection; one device (0.2%) was self-removed by the client on the third day due to unbearable pain; and one (0.2%) self-detached by sliding off on the fourth day. The remaining four clients (0.7%) had their rings removed on day 8 post-placement.

Occurrence and classification of adverse events

A total of 29 (5%) AEs were reported during the ShangRing pilot study. None of these AEs were directly related to the ring malfunctioning. The occurrence of these AEs was classified in terms of time of occurrence and severity.

Classification of adverse events by timing of occurrence

Three of the reported AEs occurred during placement, 25 while the device was in situ, and one during removal (Table 7).

i) Two out of three AEs that happened during placement were classified as displacements that were attributed to provider errors. On one of these two cases, inner surfaces of the prepuce slipped from the ShangRing immediately after placement. On the second case, the provider excised the foreskin with incomplete locking of the device outer ring. In both cases the device was removed, and the circumcision was completed with sutures instead. The third intraoperative AE was classified as pain due to removal of adhesions.
ii) Twenty-five AEs that happened while the device was in situ included 20 displacements due to partial spontaneous detachment prior to scheduled removal on post-placement day 7; one displacement that resulted in bleeding, one due to self-removal following unbearable pain on day 4 post placement; one due to slippage of the ring on day 4 during nocturnal erection, one due to infection and one due to pain.
iii) One AE occurring during removal was classified as pain.

Classification of adverse events by type and severity

Of the 29 adverse events, 22 were classified as mild, five moderate, and two severe (Table5). Mild AEs included 20 early spontaneous detachments and two due to pain. For clients who experienced early spontaneous detachments, devices were removed by the trained service providers before day 7. Once the foreskin trapped in between the inner ring and outer ring heals, the ring starts to detach in parts. In that process, the remaining parts start to be pulled forcefully especially during movements, this causes pain. Once the client presented at the facility, the device was removed, and no additional interventions were done.

Five moderate AEs included one post-operative pain due to removal of adhesions (a small amount of topical anesthesia was added to calm the pain), one intra-operative bleeding (the bleeding vessel was ligated), one spontaneous detachment due to ring slippage on day 4 (no intervention was done apart from wound care messaging), one self-removal done by the client on day 3 (no intervention was done apart from wound care messaging) and one infection after removal of the device (a dose of antibiotics was supplied).

The remaining two AEs were classified as severe AEs, including one incomplete placement and one slippage of the inner skin during placement. For these two severe AEs, bleeding was controlled, the device was removed, and sutures were placed like conventional surgical MC. These two clients were requested to return for 48 hours, and seven-day post circumcision follow up visits. All the remaining AEs were well managed as per the AE action guide by trained health workers to resolution without major challenges.

Table 7: Occurrence and type of adverse events, ShangRing Evaluation, Tanzania, 2019

Occurrence of adverse event	Number	Percent	
During placement	3	10%	
While in situ	25	86%	
During removal	1	4%	
After removal	0	0	
Type of adverse event	**Mild (n=22)**	**Moderate (n=5)**	**Severe (n=2)**
Pain	2	1	0
Bleeding	0	1	0
Device displacement	20	2	2
Infection	0	1	0

Adverse events by age groups

AEs were distributed among clients aged 15- to 36-years-old. No AEs were reported for clients under 15 or above 36 years of age (Table 8).

Table 8: Number/percentage of clients experienced AE by age, ShangRing Evaluation, Tanzania, 2019

Age (years)	N	Percent
15	3	10%
16	6	21%
17	2	7%
18	1	3%
19	4	14%
20	1	3%
21	3	10%
22	1	3%
23	4	14%
24	2	7%
36	2	7%

Among the nine clients who reported moderate and severe AEs, the median score from the visual analog pain scale was 1 on a scale of 0 (does not hurt) to 4 (hurts a whole lot). Nearly half (44%) of the clients who responded to this question said it does not hurt, the remaining 33% said it hurts just a little bit, and 22% said it hurts a little more (Table 9).

Table 9: Visual Analog Scale pain scores, ShangRing Evaluation, Tanzania, 2019

Visual Analog Scale pain score	Number	Percent
Does not hurt	4	44.4
Hurts just a little bit	3	33.3
Hurts a little more	2	22.2
Hurts even more	0	0
Hurts a whole lot	0	0

Ring size assessment

A total of 51 (9%) clients were switched to a different ring size, 23 clients placed with sizes above the recommended size and the remaining 28 clients placed sizes below the recommended size. Of these clients, one client was among the 20 clients who had early device removals due to partial spontaneous detachments, classified as a mild AE (Table 10).

Table 10: ShangRing sizes recommended and placed, ShangRing Evaluation, Tanzania, 2019

Recommended ring size	Available ShangRing size placed										
	A4	A3	C	D	E	F	G	H	I	K	Total
A3	0	18	1	0	0	0	0	0	0	0	**19**
B	0	0	1	0	0	0	0	0	0	0	**1**
C	0	0	54	4	0	2	1	0	0	0	**61**
D	0	0	0	60	0	0	2	0	0	0	**62**
E	0	0	1	0	71	1	4	0	0	0	**77**
F	0	0	0	0	0	66	6	0	0	0	**72**
G	0	0	0	3	1	3	114	1	1	1	**124**
H	0	0	0	0	1	0	4	54	2	0	**61**
I	0	0	0	0	0	0	6	2	52	1	**61**
K	0	0	0	0	0	0	1	0	1	35	**37**
Total	**0**	**18**	**57**	**67**	**73**	**72**	**138**	**57**	**56**	**37**	**575**

Ring sizes by age groups

The most used ring sizes were G (24%), followed by F (13%), E (13%), and D (12%). Nearly half of all clients used sizes E, F and G. Sizes F and G were most common for adult clients aged 20–29, while sizes G through K were most common among adolescent clients aged 13–19 (Table 11).

Table 11: ShangRing sizes by age group, ShangRing Evaluation, Tanzania, 2019

	ShangRing size									
Client age	A3	C	D	E	F	G	H	I	K	Total
13–14	0	0	0	0	1	0	1	1	9	**12**
15–19	1	12	16	26	16	54	25	34	21	**205**
20–24	4	13	16	20	21	32	13	6	4	**129**
25–29	8	14	15	8	16	33	5	4	1	**104**
30–34	2	6	6	6	5	7	3	4	2	**41**
35–39	3	4	4	7	2	5	4	2	0	**31**
40–45	0	5	3	2	3	3	3	4	0	**23**
45–49	0	3	5	3	3	3	1	0	0	**18**
50+	0	0	2	1	5	1	2	0	1	**12**
Total	**18**	**57**	**67**	**73**	**72**	**138**	**57**	**55**	**38**	**575**

Client satisfaction and acceptability post-placement of ShangRing (day 0)

Table 12 describes clients' experience post-procedure. The belief that ShangRing circumcision was less painful than conventional surgical circumcision was reported by nearly 40% of all clients. Nearly three in every five clients (59%) reported that the device placement process was easier than expected and 36.1% reported it to be as expected. Only 0.5% found it harder than expected, and 4% did not have any expectations related to pain. Clients were also asked to gauge the pain experienced during placement of the device. More than half (57%) reported the pain to be easier than what they expected, 25% about what they expected, and 0.7% more than what they expected. The remaining 5% did not have any expectations in relation to the device placement pain. Immediately after placement, 99% of the clients stated that they would recommend the ShangRing device to someone they knew.

Table 12: Acceptability and satisfaction with ShangRing circumcision post-placement, Tanzania, 2019

	N = 573*	Percent
Why did you choose to have a ShangRing circumcision instead of surgical circumcision?		
I thought ShangRing would be less painful	228	39.8
I have heard about ShangRing before	180	31.4
I did not want an injection	81	14.1
No reason	17	3.0
Other	67	11.7
How was the placement process for the ShangRing device?		
It was about that I expected	207	36.1
It was easier than I expected	337	58.8
It was harder than I expected	3	0.5
I did not have any expectation for placement	20	3.5
Other	6	1.0
How did you find the pain of your circumcision during the placement of the ShangRing?		
It was about that I expected	143	25
It was easier than I expected	328	57.2
It was harder than I expected	4	0.7
I did not have any expectation for placement	30	5.2
Other	68	11.9
At this point would you recommend ShangRing to someone you know who is considering circumcision?		
Yes	570	99.5
No	1	0.2
I do not know	2	0.4

*Two clients were not engaged in the survey due to incorrect placement

Client satisfaction and acceptability post-removal of ShangRing

While wearing the ShangRing device, just under half (49%) of the clients experienced no discomfort at all, 44% reported minor discomfort, and 5% reported moderate discomfort. A total of 13 clients (2%) reported a lot of discomfort while wearing the device.

Approximately 83% of the clients reported that wearing the device did not affect them at all, while 5% were affected while performing certain activities. Only 0.2% of the clients reported discomfort while performing all activities, although they could still do them; 11% reported discomfort that prevented them from performing certain activities.

After the device was removed, clients were asked about their level of acceptability and satisfaction with the device; 98% responded that they would choose the ShangRing device again; 71% of the clients were very satisfied; and an additional 29% were satisfied with the procedure. Only one client (0.2%) was dissatisfied due to pain upon removal, and three (1%)

were neither satisfied nor dissatisfied. At this stage, 98% of all ShangRing circumcised clients would recommend the procedure while four clients (1%) would not because of pain experienced during the removal of the device or wanting to wait until they had healed completely before recommending the procedure to other males (Table 13).

Table 33: Acceptability and satisfaction with ShangRing circumcision at post-removal

	Frequency (N=573)	Percent
How much discomfort did you experience while wearing the ShangRing device over the past seven days?		
I had no discomfort while wearing the ring	281	49
I had minor discomfort while wearing the ring	253	44
I had moderate discomfort while wearing the ring	26	5
I had a lot of discomfort while wearing the ring	13	2
How much did the ring affect you while performing day-to-day activities?		
It did not affect me at all	473	82
It only affected me while performing certain activities	34	6
It affected me during all activities, but I could still do them	1	0.2
It prevented me from performing certain activities	65	11
After having worn the ring for a week, would you still choose ShangRing for circumcision, or would you choose surgery?		
I would definitely choose ShangRing again	562	98
I would probably choose ShangRing again	4	1
I would probably choose surgery	1	0.2
I would choose surgery	5	1
I don't know	1	0.2
How satisfied are you with the appearance of your penis?		
I am very satisfied	405	71
I am satisfied	164	29
I am dissatisfied	1	0.2
I am very dissatisfied	0	0
I don't know	3	1
At this point would you recommend ShangRing to someone you know who is considering circumcision?		
Yes	568	98
No	4	1
I don't know	1	0.2

Follow-up healing assessment post ShangRing removal

Of the 573 ShangRing-circumcised clients, 559 (98%) were seen and 14 (2%) did not return for additional follow ups. The seen clients returned to the facility 49 days post-device placement, and their wound healing was assessed by trained providers. Of the clients who returned for follow-up, 99.5% had fully healed by day 49. Three clients had not healed by their day 49 follow-up visit. During interviews with these clients, they revealed that instead of following instructions from trained service providers, they abided by information from peers who had been circumcised using the surgical method that they were not allowed to take showers or wet the wound until it was healed. The clients were cleaned and treated at the facility, and they returned seven days later for another review. By day 56, they all had fully healed. Data from the 21 HIV-positive clients were reviewed to assess their healing. All had returned for follow-up on day 49, and their healing was found to be like that of the HIV-negative clients.

Quantitative Data from Providers

Training immediate outcomes

From the pre- and post-training assessment, we observed a 61% increase (pre- vs. post-training scores – p=0.000) in provider knowledge of the ShangRing circumcision procedure. Post-training provider opinion scores regarding the ShangRing theoretical and practical training components averaged between 4.56 and 5.0 for the theoretical training and between 4.8 and 5.0 for the practical training (Table 14).

Table 14: Providers' opinions on ShangRing training and practice post-training, ShangRing Evaluation, Tanzania, 2019

Do you agree or disagree with the following statements? (5=Strongly Agree; 4=Agree; 3=Neither Agree nor Disagree; 2=Disagree; 1=Strongly Disagree)	Mean Score (SD)
Theoretical Training	**N=20**
The trainers possessed strong subject matter expertise	5 (0)
The trainers had the ability to explain and illustrate concepts	4.94 (0.2)
The trainers successfully and completely answered participant questions that arose	4.94 (0.2)
The information received during training was useful and applicable:	4.56 (0.5)
The pace of the training was appropriate	4.94 (0.2)
The training was appropriate for your level of experience	4.78 (0.4)
The training materials were useful and applicable	5 (0)
The training adequately prepared you for performing male circumcision with the ShangRing	4.9 (0.2)
Practical Training	**N=20**
I found ShangRing circumcisions to be easy to perform	4.9 (0.2)
Compared to surgical circumcision, ShangRing circumcisions were easier to perform:	5 (0)
Compared to surgical circumcision, ShangRing circumcisions were faster to perform:	4.9 (0.3)
Compared to surgical circumcision, I find ShangRing to be a safer procedure:	5 (0)
I prefer performing ShangRing procedures over surgical circumcision	4.8 (0.4)
Clients receiving ShangRing appear happier with their circumcision than clients receiving surgical circumcision	4.9 (0.3)
I would advise that clients select ShangRing circumcision over surgical circumcision	5 (0)
If possible, I would like to continue offering ShangRing circumcision to clients	5 (0)

Adverse events by service provider cadre

More than 60% of the clients were circumcised by nurses: 243 (42%) by enrolled nurses and 140 (24%) by registered nurses, while the remaining 34% were circumcised by upper cadres (Table 13). A review of AEs by service provider cadre showed that all service provider cadres had similar proportions of AEs. The AEs documented in this study were not associated with provider cadres (SD ±4.6, p-value = 0.1398). The 43 circumcisions performed by the participating nursing officer were done under guidance of the trainers as part of the demonstration during practical training. There was one AE among the 43 procedures performed by the nursing officer (Table 15).

Table 15: Proportion of VMMC clients reporting adverse events by service provider cadres, with statistical test of association, ShangRing Evaluation, Tanzania, 2019

Provider cadre	Number of clients circumcised	Proportion of clients circumcised (%)	Adverse events	Proportion of VMMCs resulting in an adverse event (%)
Medical doctors	91	16	7	7.7

Clinical officers	58	10	2	3.4
Nursing officers	43	8	1	2.3
Registered nurses	140	24	5	3.6
Enrolled nurses	243	42	14	5.8
Total	575	100	29	5

Mean ($\bar{x}$)	5.8
Standard deviation	4.6
N	5
Standard error of the mean (SEM)	2.06688
Degree of freedom	4
Hypothesized mean (μ)	2
t-statistic	1.838852
p-value	0.13984

Qualitative Data from Clients

Fifty adult males were purposively selected from the clients enrolled in the ShangRing evaluation study to participate in in-depth interviews (IDIs). Of these IDI clients, 20 (40%) had completed primary school, eleven were still in secondary school (20%), nine (18%) did not attend formal school, eight (16%) did not complete primary school, and two had completed secondary school. Of these, 34 (68%) were in a relationship.

Reasons for selecting ShangRing circumcision

The most common reasons clients cited for selecting ShangRing over conventional circumcision included: less pain with the procedure, no stitches, does not disrupt daily activities, faster recovery, and the short procedure time. Other reasons less commonly mentioned were attractive appearance of the penis observed from friends, wanting to try something new, and others were interested in the more frequent follow-ups done to clients who were circumcised using the ShangRing device.

Less painful or no pain. Most men reported that circumcision with the ShangRing device is less painful or causes no pain at all because the procedure is short and does not involve injection or stitches.

> *"Ah, I said, why should I not use ShangRing than do minor surgery? Why not try it as well? What will it be like? In fact, my spirit inspired me to choose a ShangRing device, I decided to choose it, myself, without being influenced by anyone, that device, I was happy, first it is a device that is painless, you do your daily routine, without pain." (Age 30, KH0105011)*

> *"I think personally I considered the fact that I was making the procedure simple, which includes not experiencing extreme pain because it takes a short time, so I decided to use this method because I thought it is better." (Age 40, KH2205287)*

> *"First they said there is no pain when you are circumcised by using the ShangRing device, then you can carry on with your daily activities since after seven days the device can be removed" (Age 42, KH0405028)*

No stitches. Narratives from the interviews revealed that most men decided to opt for the ShangRing device for circumcision because the procedure, unlike surgical circumcision, does

not involve stitches—information that was relayed to them during health education at the facility. The men believed that stitches are usually more painful, especially during erections and that wound healing takes a long time. This may have made the men fearful of surgical circumcision.

> *"After I was told about it I liked it because I saw that there is no stitching and it took a short time just seven days and I saw that my condition is good and until now I feel fine and there is no pain, just some mild pains and a small wound" (Age 39, KH1005151)*

> *"The stitching method is very painful, but this method even if you get an erection you do not feel a lot of pain or you do not feel pain at all" (Age 18, UH0105001)*

Does not disrupt daily activities. Most men reported that they chose ShangRing because it does not disrupt their daily activities. The device allowed them to proceed with daily activities without pain and without other people noticing, during wound healing, that they had been circumcised.

> *"My daily work, [pause] my daily routine, I think I'm on the buses, and the day I left here, when I went for a ShangRing circumcision, I went to work straight after that, I worked as usual, without feeling any kind of pain, or any difference, I felt like, normal, like no circumcision had been done at all. That device, well, I urge, Tanzanian citizens, it is a good device, that makes you be good without anyone noticing it" (Age 30, KH0105011)*

> *"I used this device after I was told that I will continue doing my normal daily activities" (Age 45, KH0605029)*

Perceived quick recovery. Faster recovery, i.e., fast wound healing, was also reported as one of the main reasons for choosing the ShangRing device. Men reported that their wounds had healed faster than they had expected.

> *"The good thing is that you recover in a short time" (Age 49, KH2305176)*

Short procedure time. The respondents also reported that they decided to try ShangRing circumcision because it is a short procedure. Men reported that the ShangRing procedure took a very short time compared to other circumcision methods because it does not involve stitches.

> *"It is after were told about the characteristics of this device that when circumcised by this method it does not take a long time like in the stitching method, the stitching method has delays, so we decided to go for this method because it seems to be easy" (Age 40, KH2205287)*

Experiences with anesthesia. During the interview, client experiences with anesthesia before the ShangRing procedure were also discussed. Men shared their experiences and knowledge regarding two types of anesthesia, injection, and topical cream, available at the facility during the study implementation period. However, all men who participated in the interviews reported to use topical anesthesia and not an injection. They reported using the topical anesthesia was a positive experience because it prevented them from feeling pain and it took several hours before wearing off.

> *"I was given applied cream anesthesia, I think it is only that they applied and then a short time later, I was circumcised, I was happy, first I didn't feel anything" (Age 30,*

KH0105011)

"Any pain, I did not feel any pain [pause] until they told me that they were done and that I was okay, first I wanted to ask, um, have you really done this work? When did you do it? Because, it was like, they were just there loosely" (Age 30, KH0105011)

"I think the applied anesthesia is better because it takes a long time and you do not feel pain even during the procedure" (Age 40, KH2205287)

Clients' experiences with ShangRing circumcision

Sharing their experience with ShangRing circumcision during IDIs, most clients reported that they did not experience as much pain as they had anticipated during the procedure and for the majority, staying with the ring around their penis did not affect their daily lives. Some of them did experience painful erections that they had been informed of during counseling.

Perceived less pain during placement. All interviewed clients reported positive experiences with the ShangRing placement procedure because it took a short time, and they did not experience much pain as expected. The following quotes from clients provide illustrative examples about their common experiences:

"It wasn't painful, so the procedure was very good" (Age 18, UH0105001)

"I didn't feel any pain, I did not see any challenges, it's like they are playing around, it took like a few minutes, and they told me to go home, I could walk properly, I walked a long distance then I went home and even at home I walked a lot, so the important thing is to know what the body has gone through" (Age 26, KH2305176)

"When I saw that they have inserted the device and there is no pain I realized that the procedure is good, because I thought that I might experience excruciating pain, but it was different from what I thought" (Age 35, UH0405049)

Did not affect their lives while the ring was on situ. The majority of interviewed clients were very positive about their experiences with the ShangRing device during the seven-day period when it was around their penis, before ring removal. They reported that having the ShangRing around their penises did not affect their lives because they experienced less pain than expected or no pain at all. They also reported that even with the ShangRing around their penises, they were able to continue with their daily activities, which was different from their expectations.

"In fact within seven days, I think there were never a problem, I kept seeing myself, that is, I am as I was at the beginning, as though I had not had any circumcision, as if I had no device even though I had it, and I would take a shower as usual, when I wake up I start with, my daily routine work, there was no even a feeling of fever, no bleeding anywhere, it's really, really, really cool" (Age 30, KH0105011)

"I did not experience any pain at all." (Age 18, UH0105001)

"My condition was just good after placement, the condition changed on the fourth day…it became very painful on fourth and fifth day" (Age 45, KH0605029)

Temporary pain during erections. Although most men reported that they did not experience challenges during this period, some men did report experiencing temporary pain,

especially during erections at night.

> *"The feelings cause erection, and honestly you experience excruciating pain" (Age 41, KH1705137)*

> *"Yes, at night, I experienced mild pain during erection, but after urinating the pain stops….yes, just moderate, at night when I experience an erection but, in the afternoon, it is not painful at all".(Age 18, UH0105004)*

Clients' experiences with removal of ShangRing device

The experience of removing the ShangRing device was also discussed during the interviews and most clients reported that device removal was painful but lasted only for a short time. Others cited that the most painful moment was during the removal of the inner ring and not the outer ring.

> *"I experienced pain during the removal but immediately after removing it the pain did not go on for long, it just took a few minutes, and the pain was gone then they placed the bandage, and I was given other bandages to go with at home. So, the pain stopped and after that I felt better than when I had the ShangRing device on, I just felt good after it was removed" (Age, KH2205287)*

> *"The procedure for removal of the device, the device was just removed but there was a little pain while removing the inner ring, the outer ring did not cause any pain, but the inner ring had been a little stuck somewhere so removing it caused some mild pain" (Age 37, UH1005146)*

The healing processes

When asked about their wound healing after ring removal, the majority of men reported that their wounds were in good condition. They reported no complications with their wounds and they were not experiencing pain because the wounds had healed quickly.

> *"It has dried up, some parts have not yet dried up as you know a wound cannot dry all at once, but I can say it's doing well, it's not bad." (Age 41, KH1705137)*

> *"I don't have any complications with my wound at all, it is doing well, I do not experience any problem." (Age 58, KH2305178)*

Client satisfaction with ShangRing circumcision

Interviewed clients reported satisfaction with ShangRing circumcision for reasons detailed below.

Provider's good services. The findings revealed that most of the interviewed clients were very satisfied with the services provided at the health facilities, noting that the providers had been very kind and caring and had provided detailed information regarding VMMC services. The clients also expressed satisfaction that they had been given the opportunity to choose the circumcision method they preferred. They were also satisfied with the phone calls they had received from the service providers checking on their progress, as well as the willingness of the providers to visit them in case of challenges, which showed the providers' concern for their health.

> *"I liked the fact that the service itself is good, it has no complications, the service providers are very understanding, they welcome you well, first they educate you before the*

circumcision, then you accept and you enter voluntarily knowing what is going to happen, and after the circumcision I must adhere to certain things, I felt good and that's why I chose it." (Age 49, KH2305176)

"Generally, the stage that I liked most is when they said that I could make a phone call if I experienced any difficulty, and if you cannot come, we can come to your place. This means that it is a good thing and I personally realized that even if a person could not manage to come here, they could visit him at home, I liked it because they care about their clients because everyone has to write the place where they come from so, they analyze your location, so I realized that they are serious with what they do, and the services provided. So, these are some of the things that personally made me happy." (Age 34, UH2405288)

No complications. The majority of interviewed clients reported that they liked the ShangRing circumcision because it did not cause complications. They reported not encountering any complications that disrupted their daily activities.

"This service has made me feel normal, it doesn't have any complications or delays, even if the device is inserted you can still do some light activities, you just have to understand that you have a device placed in your body." (Age 49, KH2305176)

"I can say that I am 100 percent satisfied and if we are told to choose between this device and other methods, I would choose the ShangRing device, and I will advise a lot of people to use this especially for adult men, so for now it's better to use it because it is not complicated, and the healing process is fast." (Age 39, KH1005151)

Less or no pain. The majority of interviewed clients liked ShangRing circumcision because they did not experience pain at all or experienced less pain than expected during and after the procedure.

"I liked it because I did not experience any pain, and I will even advice my friends to use this device." (Age 35, UH0405049)

"Because it is just a short minor surgery which does not involve any pain." (Age 37, UH1005146)

Does not disrupt daily activities. The interviewed clients also reported that they liked ShangRing circumcision because it allowed them to continue their daily activities, unlike other circumcision methods that require the cessation of daily activities to allow for proper wound healing.

"I liked the stage that involved inserting the device because after that I could continue doing my normal activities." (Age 45, KH0405029)

"Doctor, I have to say that I was attracted to use the ShangRing device because I witnessed that those that were circumcised using the stitching method experienced a lot of pain. For instance, for us men, when it comes to trauma, a man is always in a certain state of being, a physical condition during erection. They experience excruciating pain during erection because the stitches become tight so when they told me about this method even though I had not used it, I thought it is better than the other one." (Age 41, KH1705137)

Good penile appearance. The majority of interviewed clients reported being very satisfied with ShangRing circumcision because its lack of stitches results in an appealing penile appearance.

> *"Well, I can only say that since this service started until now, I am very satisfied. Considering that if I look at my body part it appears better than those who have undergone circumcision by using the normal surgery method." (Age 41, KH1705137)*

Short procedure time. The majority of the interviewed clients also reported liking ShangRing circumcision because its procedure time is short compared to other circumcision methods. They reported that the procedure took a much shorter time than expected.

> *"The step that I liked the most during the insertion of the ShangRing device, first it does not take much time, even if, during when they are inserting it, even if you were in a rush to go somewhere, you will still go in time, they insert it in a short time, and, and you go on, unlike the traditional one, that one takes time, stitching, it takes time until they finish, actually, very long." (Age 30, KH0105011)*

No injection or stitches. Not having injections or stitches during the procedure was reported as one of the main reason men prefer the ShangRing circumcision. They reported that men fear local anesthetic injections and stitches, which are necessary with other circumcision methods.

> *"And following the procedure that are not as much, different from the other one you have to go through injection, then stitching and other procedures but in this one it just takes a short while and you are done." (Age 49, KH2305176)*

Confidentiality. Confidentiality of the ShangRing device circumcision method was also reported as one of the major reasons men liked ShangRing circumcision. It was reported that unlike other circumcision methods, the ShangRing procedure allowed clients to walk feeling little or no pain, therefore no one suspected that they had just been circumcised. Most older men preferred that other people did not notice that they had been circumcised, which would be difficult with other circumcision methods. The ShangRing method thus provided them with the opportunity to keep their circumcision a private matter

> *"What I liked most about this modern circumcision is the secrecy, if you do not tell someone that I have been circumcised, they cannot know that I have been circumcised, so I liked this method a lot." (Age 28, UH0905127)*

> *"I am satisfied with this method since it is painless and I healed after a short time, I used to walk and go for social activities and socialize with my fellows in weddings* (while wearing the device) *without them knowing….other methods you cannot socialize and go to weddings and other social activities."* (*Age 52, UH1005151)*

Resumption of sexual intercourse and masturbation

During the interview, the issue of resuming sexual activity or masturbation was discussed. Most clients reported not to have started sexual activity because the wound had not yet healed, and they were following health care provider instructions (resuming sex seven weeks post-placement). However, a few clients reported to have resumed sex and/or masturbation within three weeks after removal.

"I had sex, not less than once, even seven times… I feel good there is no problem I did not even finish the seven weeks." (Age 32, UH2405285)

"…when you insert it and the wound is not completely healed, you feel some kind of pain and when it is inside you experience itchiness in the wound…but there is a force that compels you to do it so you keep penetrating but you feel the itchiness and when you ejaculate you remove it quickly. You feel as if there is no pleasure, but you are just done..." (Age 40, KH2205287)

One client reported masturbating more than seven times; the first time was done while wearing the device, on the fifth day after placement, and he reported experiencing a lot of pain. As narrated below:

"…I really got hurt…It was on day 5. I really missed my fiancée it was at night when I was trying to get some sleep….yes the pain was severe." (Age 21, UH1505214)

Qualitative Data from Providers

We also conducted 31 IDIs with service providers who had participated in the ShangRing training. A two-phase approach was used: 18 interviews were conducted with the providers immediately after the in-classroom training and 13 interviews were conducted with the providers who participated in the actual implementation of the study.

Provider knowledge of the ShangRing device before training
Most of the service providers reported not having much knowledge regarding ShangRing device placement. The providers who had reported hearing about the ShangRing device before the training had only limited knowledge, e.g., they did not know what the device looked like or how it was used.

"Honestly when they came to introduce this project, that is when I first heard about ShangRing, I had never heard anything about ShangRing." (Enrolled Nurse, UHP1005014)

"During the training in Kahama, they just gave an overview of ShangRing, but I did not know what it was. When we went for the 2 days training that is where I knew what the ShangRing device entails and what it is." (Enrolled Nurse, UHP1005017)

Provider opinions on the training
All the service providers interviewed regarded the training very positively. They reported that the training taught them different aspects of the ShangRing procedure that they did not know before.

"In my opinion the training was good, we enjoyed it, the preparation was good, from the venue, as for the teachers and the teaching condition was also good and what we learnt is the same thing that we applied practically, although while learning you might see it as something new but during the practical sessions I understood more, when you come to the reality during executing my responsibilities." (Enrolled Nurse, UHP1005012)

Most service providers also mentioned that they liked the training topics and found them all to be very valuable. Providers noted that the trainings on how to apply topical anesthesia and how to place and remove the ring were very important because these were new skills for them.

"Frankly, I could say that all stages were important because I didn't have any knowledge about the ShangRing device, so just saying that the theory or practical was important it's not right because in there are things to learn in the theory sessions and after that you can move on to the practical sessions, so as for me generally everything was important." (*Assistant Medical Officer, KHP1005002)*

"Applying the ELMA cream and measuring the penis with a tape measure was also important to me because at first I did not know that the penis is also supposed to be measured." (Enrolled Nurse, UHP1005017)

"The topic about ShangRing, the way it was made, its parts and their names, but also the ShangRing procedure, the way of inserting and removing the device, and I was surprised that if something has already been tightened how do you remove it, then I came to realize that there is a key and when you use that key to open the ShangRing comes out easily." (Enrolled Nurse, UHP1005012)

Adequacy of training in preparing the providers

All service providers reported that the training was enough to prepare them to perform the ShangRing procedure and that they felt competent in performing the procedure after the training.

"Very well, I feel capable even when I am alone at the facility, I can insert the device properly and remove it after seven days, I don't think I will encounter any challenge that can't be fixed." (Medical Officer, UHP1005011)

"Honestly, it [the training] has prepared me to a great extent and this is why now I can perform the procedure without any problem, and we have understood it for a short time, even after our teachers had left, we have been doing well." (Enrolled Nurse, UHP1005012)

"Yes, the training was good because I have not experienced any problem, ever since I got the training, I have not faced any challenge in any aspect." (Enrolled Nurse, UHP1005017)

Provider opinions on performing the ShangRing procedure

Providers who were interviewed at the evaluation midpoint (after 250 ShangRing placements) reported that they liked performing the ShangRing procedure because the device is easy to use; the procedure time is short; there are fewer AEs; there is less blood during the procedure, which reduces the risk of infections transmitted by blood; the procedure is less painful for clients and does not disrupt their daily routine; the procedure results in good penile appearance; and the procedure reduces the work of the providers.

"It's not hard, as I said earlier it isn't hard for someone that is used to providing the normal circumcision service that we used to provide. But if you recruit a new person and just request them to come and learn about ShangRing it might be hard for them." (Registered Nurse, UHP1005013)

"In short, it is not hard if you will do it carefully while following the instructions provided and the more we do it, we realize we do not have to do it carelessly but if you are careful and working in coordination with your partner, you will do a good job." (Enrolled Nurse, UHP1005012)

"The first thing that I really like about this device is that it is very difficult to cause any harm to the client like hurting the penis because during the whole process of cutting the

foreskin, you can see the penis clearly so it's very difficult to cause any harm there. Secondly, the possibility of encountering a lot of blood to the service provider is low, you will not have to deal with a lot of blood while providing the service. The time you spend on one client is short. So, for me that is what I consider to be a great advantage, it takes a short time, So, there are many clients in a short time, also you will encounter less blood compared to the other conventional method." (Assistant Medical Officer, KHP1005002)

"My opinion is that the benefits of the ShangRing device outweigh the older methods because it uses a short time, it reduces the possibility of losing a lot of blood during the procedure and the results of the surgery using the ShangRing device are more attractive in appearance more than the older methods, I advise that it should be used more than the older methods, maybe if the clients personally prefers the old procedure but I think as service providers, the device is more beneficial and it reduces the burden, personally I would prefer the ShangRing method more than the old method." (Medical Officer, UHP1005011)

"After receiving this training, personally I think it helps more, I would advise that it should be used even to the 10- or 12-year old, if possible we should use it to all age groups because I have seen it is simple that it reduces time, clients do not stay for long at the facility, also it helps when the client undergoes the procedure they can resume their normal duties in a short while, they can take a shower. Also, the other thing that I noticed is that it helps service providers on the issue of injuries because as we are using local applied cream anesthesia it means you will not have to use injections that may sometimes be at risk, this is different from the first one, also you will not encounter a lot of blood as it was in Dorsal Slit, so I think this is better than Dorsal slit." (Registered Nurse, UHP1005013)

Except for one provider who was concerned with the waiting time for topical anesthesia to take effect, the remaining 17 providers preferred topical to injectable anesthesia. As explained by one of the providers:

"The client doesn't get tired and because we use applied cream anesthesia and not injection, the clients like it because they don't experience pain when placing it, they just sit comfortably with happy faces and after a short while they are surprised that the procedure is done and there is no blood in the operated area." (Medical Officer, UHP1005011)

During interviews at the end of the pilot all of the service providers reported that they were very satisfied with the use of ShangRing device. They all preferred the ShangRing circumcision, reporting that they found it "much easier" to learn and perform, and resulted in a more cosmetic penis appearance compared to the conventional circumcision. Some of their recommendations and suggestions regarding the ShangRing procedure and VMMC in general.

"The ShangRing service is very good, should continue being provided and not only by partners also the government should consider how this service will be sustained." (Assistant Medical Officer, KHP1005002)

"In my opinion, I think it is good because it will help men in reducing the spread of HIV/AIDS by 60% but what I see is that we have not reached many people, especially now when we were providing the ShangRing services here, when we used to do Dorsal slit it seemed as if some areas might not have enough clients but when we introduced this method, I have seen that many of them are still coming so my opinion is we should continue advocating and improving the ShangRing service in order to get more clients,

that's my opinion, we should encourage and give them education so that they can come hence reaching more men." (Registered Nurse, UHP1005013)

"While attending on the clients I noticed that if the education is provided, I have seen that many are afraid of injection, so if we provide the education while telling them that we applied cream anesthesia, I have noticed that most of them are more inspired, so it seems that men are still afraid of being injected in their penis, so maybe if we tell them that there is anesthesia, they might be more interested to come." (Registered Nurse, UHP1005013)

DISCUSSION

This study is the first to evaluate the implementation, safety, and acceptability of ShangRing circumcision for adolescents aged 13 years and older, and adult men in Tanzania. Like other ShangRing studies in Sub-Saharan African countries, findings from this study suggest that ShangRing circumcision is safe and acceptable among adolescents and adult men aged 13 years and above[xxviii]. The device placement process was considered easier than expected and experienced pain levels were considered more tolerable than expected by nearly three in every five clients, and 99% of the clients would recommend the ShangRing circumcision to others. Also, most of the study participants —570 (99%)—were satisfied with the appearance of the healed penis and all of them would recommend the ShangRing circumcision to others.

Like findings from other studies in Kenya and Zambia, we found that HIV status had no apparent impact on the rate of wound healing.

The majority of clients, 409 (71.2%), chose to have a ShangRing circumcision because they perceived it to be less painful compared to surgical circumcision. Twenty-two percent of the clients circumcised with the ShangRing device in this study were 30 years of age and above. Based on these results, ShangRing circumcision is a promising technique for attracting adult men for circumcision, considering less than 10% of the males circumcised using conventional surgery through the routine VMMC program in the same facilities around the same time were aged 30 years and above. Should further research and active surveillance confirm our results, the use of ShangRing would accelerate both scale up of the country's VMMC efforts towards achieving 90% saturation targets within a shorter time and attain more immediate impact on HIV incidence reduction as per the recommendations in the WHO VMMC guideline[xxix] and THIS results[xxx].

This study reports a total AE rate of 5%, with only 1.2% of these being moderate and severe AEs. These findings are similar to those reported in a Uganda study among adolescents 13–17 years old with a moderate AE rate of 1.3%[xxxi]. In Kenya, a study using the no-flip ShangRing circumcision technique among boys below 18 years of age showed a 5% moderate AE rate[xxxii]. Compared to other ShangRing studies in Sub-Saharan Africa, device displacement was commonly recorded in this study, including partial or complete displacements, due to spontaneous or non-spontaneous displacements caused by provider errors or client intentions, both during placement and while the device was in situ as part of the early healing process. For example, 22 (83%) of all AEs were classified as displacements, including 20 of the devices that were removed on day 5 or 6 due to partial spontaneous detachment that caused discomfort and/or pain during movements or erection. Once the client presented at the facility, the device was removed, and no additional interventions were

required or done. For the first time, both a spontaneous device detachment following an extended painful nocturnal erection and a non-spontaneous client self-removal outside of the facility were reported. Although none of the observed device displacements appeared to be associated to the device malfunctioning, there is need for VMMC programs implementing ShangRing circumcision to continue monitoring device displacements to better understand the associated scenarios and health outcomes.

We also reported two device placement failures: one due to early excision of the foreskin with incomplete locking of the device and another with slippage of the inner skin immediately after device placement and removal of the foreskin. As in the two studies one in Uganda and another one in Kenya, where four device failure cases happened, circumcision was completed using sutures as in conventional technique[xxxiii xxxiv]. With these occurrences, all sites offering ShangRing circumcision should also ensure presence of providers who are competent in conventional surgical technique to address the complication if arises.

We based our procurement of ShangRing devices for the study on the device usage experience established from Kenya and Uganda ShangRing implementation studies. However, adolescent and adult clients in our study used more of the smaller ShangRing devices (i.e., sizes G, F and E) than the larger ShangRing sizes (i.e., C and D) that were commonly used for adolescent and adult clients in the Kenya and Uganda studies. This resulted in some clients not getting the most appropriately sized device. Should further studies confirm our results on device size usage, countries should consider establishing an appropriate inventory of ShangRing device sizes for their own target male populations to avoid wastage of unused devices. No cases of device malfunction were recorded in this study as a result of using a sub-optimally sized device or any other reason.

There was considerable interest in the use of topical over injectable anesthesia in this study by clients. Only five clients (0.9%) opted for injectable anesthesia in order to shorten the waiting time for their circumcision while two clients (0.3%) were non-responsive to the topical anesthesia and required the injectable. Responses from our client interviews indicate that the acceptability of ShangRing circumcision was influenced by the use of non-injectable anesthesia. It is thus unclear if participants favored ShangRing circumcision for reasons more specific to the device (e.g., short circumcision procedure time and better cosmetic results) or for reasons related to the use of topical over injectable anesthesia.

Although this study did not compare conventional surgery versus no-flip technique ShangRing circumcision, the time required for the actual ShangRing procedure was shorter (8 minutes (SD ± 4)) than the 20–30 minutes required for conventional surgical male circumcision[xxxv]. However, when waiting time for the topical anesthetic to take effect was included, the ShangRing procedure time was longer than conventional surgery procedure time in other studies reporting a comparison of ShangRing circumcision with conventional surgery.

Most VMMC providers in the study expressed that the ShangRing placement and removal procedures were easy to carry out and that ShangRing circumcision caused less bleeding, was faster and easier to perform and yielded better cosmetic results, with fewer complications than surgical circumcision. Some providers noted the following disadvantages with ShangRing circumcision: the long waiting time for the topical anesthesia to act, the need for careful measurement and selection of ring sizes (a client placed with too small a device may experience greater pain); and the challenge of ensuring availability of all needed ring

sizes. In general, providers commented that the ShangRing should be endorsed for widespread use, and all noted that it should be made available as an alternative method for adolescents and adult men aged 13 years and above. While one provider was concerned with the waiting time for the topical anesthesia to take effect, the remaining 17 VMMC providers involved in the study preferred topical to injectable anesthesia. Based on our study results, the no-flip ShangRing circumcision is simple for VMMC providers to learn and to be used in VMMC programs.

STUDY LIMITATIONS

There are limitations to this study worth noting. The pilot study was conducted in only two sites in Shinyanga region; therefore, findings are limited to a smaller geographical coverage. In this pilot study, men self-selected for ShangRing circumcision, therefore the study lacked the benefits of randomization, including the reduction of selection bias, and minimalization of confounding factors, among others. A double-blind experiment (of clients and providers) was not considered due to the observable differences in the procedure and tools used. It is possible that the two clients who declined ShangRing circumcision may have done so because they only wanted to receive conventional surgical circumcision. An additional limitation is that only male clients aged 13 years and older were enrolled; thus, we cannot generalize the findings to boys younger than 13 years of age. Lastly, the unavailability of some smaller ShangRing device sizes may have resulted in the enrollment of more older men than younger clients.

RECOMMENDATIONS

Based on our findings, below we present specific recommendations to guide the way forward for consideration on adoption of the ShangRing device by the Tanzania VMMC program.

- Complete the recently initiated active AE surveillance among 1,000 clients to review results and inform the way forward for the Government of Tanzania. The ShangRing device offers an opportunity to increase the efficiency and acceptability of VMMC services.
- Conduct a comparative costing study of the ShangRing versus surgical circumcision to provide data to inform recommendations on the possible adoption and roll out of ShangRing circumcision in Tanzania.
- Should the ShangRing be approved for use in the Tanzania VMMC program:
    - Register the ShangRing device and topical anesthesia for use and sale in Tanzania.
    - Collect additional data on Tanzania-specific "device size by age" needs. Size forecasting for the evaluation study was based on the experience of other countries, the results of which were not adequately generalizable to Tanzania.
    - Ensure quality, reliable and adequate local inventory for both the ShangRing device in the needed sizes as well as the topical anesthetic cream to meet client demand.
    - Provide additional training and certification of national ShangRing circumcision trainers.
    - Increase the number of providers that are trained and certified in the ShangRing procedure to meet client demand.
    - Update, produce and distribute sufficient supplies of national client cards, client registers, surgical registers, and national MC reporting forms to accommodate the use of the ShangRing method and topical anesthesia.

- Compare results from this study on acceptability, wound healing, surgical difficulties, and AEs with the use of the ShangRing for early infant male circumcision.
- Update guidelines, materials, and supplies to incorporate ShangRing circumcision information in data collection, reporting tools, counseling, and demand creation.
- Continue monitoring device displacements to better understand the associated scenarios and health outcomes.

CONCLUSIONS

Our results suggest that the no-flip technique and topical anesthesia for performing circumcisions with ShangRing device are safe and acceptable for males aged 13 years and older in Tanzania. Back-up surgical circumcision and injectable anesthesia are needed in cases of ring placement failure, topical anesthesia unresponsiveness, and when clients prefer conventional surgical circumcision. ShangRing circumcision with topical anesthesia is easier than conventional surgical circumcision for task shifting among different cadres of providers. Furthermore, it offers the benefits of reduced procedure time, minimal blood loss and pain during the procedure, no injected anesthesia or suturing, and low rate of infection. Although the evaluation findings strongly suggest that ShangRing is safe and acceptable by both clients and providers, the ongoing active AE surveillance coupled with a costing study comparing ShangRing against conventional surgical circumcision are critical components to determine a national scale-up through the VMMC program.

ACKNOWLEDGMENTS

This study was conducted jointly between the National AIDS Control Programme (NACP) of the MOHCDGEC and the PORALG in collaboration with IntraHealth International, Inc. The study was funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Centers for Disease Control and Prevention (CDC) under the Project IQ mechanism implemented by Jhpiego.

We would like to express our gratitude to members of the Shinyanga regional and districts authorities including the regional administrative secretary, regional health management team and council health management teams of the Ushetu and Kahama town councils, who are the custodians of the service providers and health facilities whose catchment areas were the source of the clients recruited for this study. The authors also thank the providers and static site managers from Ushetu Health Center (Enock Ngasa) and Kahama Town Council District Hospital (John Otieno) who invaluably assisted with staff coordination and implementation. We appreciate the training support received from the master trainers and support staff from Akeso Associates Quentin Awori and Jairus Oketch.

Finally, the authors would like to thank the participants and parents who volunteered to take part in the study, without them, this study would not have been possible.

AUTHORS

This report was written by Kija Nyalali, Daimon Simbeye, Veronica Selestine, Carolina Mejia, Johnson Joachim, Paul Mwakipesile, Lucy Mphuru, Pastory Sekule, Shawn Aldridge, Andrew Durkin, Anne Vinluan, Suzan Mmbando, Gissenge Lija, Bhavin Jani, Quentin Awori, Amuri Mbaraka, Kokuhumbya Kazaura, Todd Lucas, and Carlos Toledo.

We also appreciate the other valuable contributors during the conception, design, and implementation of this pilot study, including Zaynab Lweno, Msafiri Swai, Peter Mlacha, Angela, Ramadhani, James Juma McOllogi, Boniface Marwa, Mathew Emmanuel Mganga, Cate Laube, Lawrence Hinkle, and Jonas Hines.

CONFLICT OF INTEREST STATEMENT

This study was a multi-country evaluation study funded by PEPFAR through CDC-Project IQ Mechanism and was implemented by VMMC Implementing Partners at CDC Namibia (Jhpiego) and CDC Tanzania (IntraHealth) with technical assistance from the SI units at IntraHealth, NACP and CDC. The impartiality of this study was overseen by Jhpiego through the reviewing of deliverables and processing payment based on invoice documentation. All investigators and co-authors have seen and agree with the contents of the report and there is neither financial nor any other conflict of interest that had been reported or we are aware of.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies.

APPENDIX 1: KEY INVESTIGATOR CVS

Name	Surname	Affiliation	SEV (CDC Staff Only)	Qualifications*
Lija	Gissenge	Head, HIV Prevention Unit, Tanzania Ministry of Health, Community Development, Gender Elderly and Children	--	• MD
Boniface	Nguhuni	Division of Health, Social Welfare & Nutrition Services, President's Office – Regional Administration and Local Government (PORALG)	--	• MD • MsC
Lucy	Mphuru	IntraHealth International	--	• MD
Kija	Nyalali	IntraHealth International	--	• MPH
Catharine	Laube McDonald	Jhpiego	--	• BA
Mainza	Lukobo-Durrell	Jhpiego	--	• DrPH
Stephanie	Davis	CDC-Atlanta	13563	• MD • 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	• MD • MPH
Koku	Kazaura	CDC-Tanzania	18317	• DDS • MPH
Mbaraka	Amuri	CDC-Tanzania	2740	• MD • MPH

*Complete CVs are available upon request

APPENDIX 2 – CONSENT FORM FOR MALE CIRCUMCISION USING 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 immediately 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?

We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

   Dr. Lija Gissenge
   Head of the Prevention Unit/National AIDS Control Program
   Ministry of Health & Social Welfare, Community Development, Elderly and Children
   Building No. 11
   P.O.Box 743
   40478 - Dodoma. Tanzania
   Phone: + 255 784 284148| Email: j.lija@hotmail.com

2. Dr. Lucy Mphuru (Co-Investigator of this study) and the Project Director at IntraHealth International in Tanzania through the following contact address:

   Dr. Lucy Mphuru
   IntraHealth International
   Plot #446, Golf Street, Kawe Area –
   P.O.Box 12007
   Dar Es Salaam, Tanzania
   Phone: +255 282 501155/Mobile | lmphuru@intrahealth.org

If at any time you have any questions regarding your rights as a participant in this research study; you many directly contact the ethics review committee through the following contact details:

Secretariat,
Physical Address:
National Institute for Medical Research
3 Barack Obama Drive, 11101 Dar es Salaam, Tanzania.

Postal Address:
National Institute for Medical Research
P.O. Box 9653,
Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

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.

Client Consent:

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:_____

_____
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 3 – ADDITIONAL INFORMED CONSENT FORM FOR PHOTOGRAPHY

Additional Informed Consent Form for Photography

_____

Purpose of the Photography
The purpose of the photographs is to document healing over time, to better understand the healing timeframe. When an AE is reported, the photos will be reviewed and verified by project investigators as part of a medical investigation. Information derived from these photos will complement other study related data to inform the use of the ShangRing device in the Tanzania voluntary medical male circumcision program.

Procedures
Photographs of your 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.

Each time a photograph is taken (placement, removal, healing assessments, or possible 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 your face. You will be asked for oral consent prior to any photograph, and you reserve the right to refuse photographs at any point. You will not be removed from the study if you choose not to be photographed.

Do you have any questions?
We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

   Dr. Lija Gissenge
   Head of the Prevention Unit/National AIDS Control Program
   Ministry of Health & Social Welfare, Community Development, Elderly and Children
   Building No. 11
   P.O.Box 743
   40478 - Dodoma. Tanzania
   Phone: + 255 784 284148| Email: j.lija@hotmail.com

2. Dr. Lucy Mphuru (Co-Investigator of this study) and the Project Director at IntraHealth International in Tanzania through the following contact address:
   Dr. Lucy Mphuru

IntraHealth International
Plot #446, Golf Street, Kawe Area –
P.O.Box 12007
Dar Es Salaam, Tanzania
Phone: +255 282 501155/Mobile | lmphuru@intrahealth.org

If at any time you have any questions regarding your rights as a participant in this research study; you many directly contact the ethics review committee through the following contact details:

Secretariat,
Physical Address:
National Institute for Medical Research
3 Barack Obama Drive, 11101 Dar es Salaam, Tanzania.
Postal Address:

National Institute for Medical Research
P.O. Box 9653,
Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

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 4 – 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). The interview will be recorded in order to better accurately capture your opinions, but in order to preserve your anonymity, your name will not be used during the interview, and your name will not be attached to the recording in any way.
You will be reimbursed the amount not exceeding Tanzanian Shillings 50,000/- 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 and this will not affect your participation in the study.

Do you have any questions?
We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:
   Head of the Prevention Unit/National AIDS Control Program
   Ministry of Health & Social Welfare, Community Development, Elderly and Children
   Building No. 11
   P.O.Box 743
   40478 - Dodoma. Tanzania
   Phone: + 255 784 284148| Email: j.lija@hotmail.com

2. Dr. Lucy Mphuru (Co-Investigator of this study) and the Project Director at IntraHealth International in Tanzania through the following contact address:

    Dr. Lucy Mphuru
    IntraHealth International
    Plot #446, Golf Street, Kawe Area –
    P.O.Box 12007
    Dar Es Salaam, Tanzania
    Phone: +255 282 501155/Mobile | lmphuru@intrahealth.org

If at any time you have any questions regarding your rights as a participant in this research study; you many directly contact the ethics review committee through the following contact details:

Secretariat,
Physical Address:
National Institute for Medical Research
3 Barack Obama Drive, 11101 Dar es Salaam, Tanzania.

Postal Address:
National Institute for Medical Research
P.O. Box 9653,
Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

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, and I understand that the interview will be recorded. I have freely decided to participate in this interview.

☐ YES, **I agree** to participate in a qualitative interview, and allow for it to be recorded.

☐ 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 5 – 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?
We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

   Dr. Lija Gissenge
   Head of the Prevention Unit/National AIDS Control Program
   Ministry of Health & Social Welfare, Community Development, Elderly and Children
   Building No. 11
   P.O.Box 743
   40478 - Dodoma. Tanzania

Phone: + 255 784 284148| Email: j.lija@hotmail.com

2. Dr. Lucy Mphuru (Co-Investigator of this study) and the Project Director at IntraHealth International in Tanzania through the following contact address:

   Dr. Lucy Mphuru
   IntraHealth International
   Plot #446, Golf Street, Kawe Area –
   P.O.Box 12007
   Dar Es Salaam, Tanzania
   Phone: +255 282 501155/Mobile | lmphuru@intrahealth.org

If at any time you have any questions regarding your rights as a participant in this research study; you many directly contact the ethics review committee through the following contact details:

Secretariat,
Physical Address:
National Institute for Medical Research
3 Barack Obama Drive, 11101 Dar es Salaam, Tanzania.

Postal Address:
National Institute for Medical Research
P.O. Box 9653,
Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

Your parent/guardian will also give a 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: _____

What does parent/guardian's signature on this form mean?

Your parent/guardian will give a 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.

Your guardian's signature on this form means:

- They know about this program's purpose, procedures, and possible benefits and risks of the procedure.
- They have been given the chance to ask questions before you sign.
- They have voluntarily agreed to be in this program and to return for device removal.
- They 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.
- They have been informed that you will not be charged for the treatment received.

- They 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 Consent:

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 parent/guardian:_____

Signature of parent/guardian: _____

_____

Day Month Year

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 6 – CLIENT ASSENT FORM FOR PHOTOGRAPHY (FOR AGES 13-17)

Purpose of the Photography
The purpose of the photographs is to document healing over time, in order to better understand the healing timeframe. When an AE is reported, the photos will be reviewed and verified by project investigators as part of a medical investigation. Information derived from these photos will complement other study related data to inform the use of the ShangRing device in the Tanzania voluntary medical male circumcision program.

Procedures
Photographs of your 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 your face. You will be asked for oral consent prior to any photograph, and you reserve the right to refuse photographs at any point. You will not be removed from the study if you choose not to be photographed.

Do you have any questions?
We would like to answer all your questions. If you have any questions now, please ask us. If you will have any questions later, you can also contact the following:

1. Dr. Lija Gissenge (Principal Investigator of this study and the head of prevention unit at the Ministry of Health Community Development Gender Elderly and Children - National AIDS control program (NACP)) through the following contact address:

   Dr. Lija Gissenge
   Head of the Prevention Unit/National AIDS Control Program
   Ministry of Health & Social Welfare, Community Development, Elderly and Children
   Building No. 11
   P.O.Box 743
   40478 - Dodoma. Tanzania
   Phone: + 255 784 284148| Email: j.lija@hotmail.com

2. Dr. Lucy Mphuru (Co-Investigator of this study) and the Project Director at IntraHealth International in Tanzania through the following contact address:

   Dr. Lucy Mphuru
   IntraHealth International
   Plot #446, Golf Street, Kawe Area –
   P.O.Box 12007
   Dar Es Salaam, Tanzania
   Phone: +255 282 501155/Mobile | lmphuru@intrahealth.org

If at any time you have any questions regarding your rights as a participant in this research study; you many directly contact the ethics review committee through the following contact details:

Secretariat,
Physical Address:
National Institute for Medical Research
3 Barack Obama Drive, 11101 Dar es Salaam, Tanzania.

Postal Address:
National Institute for Medical Research
P.O. Box 9653,
Dar es salaam, Tanzania.
Tel.: +255 22 2121400
Mobile: +255 758 587885
Hotline: +255 22 2130770
Email: ethics@nimr.or.tz

Your parent/guardian will also give a parental consent because you are below the age of consent according to the law. However, the decision to 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: _____

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 Parent/Guardian **Date**

_____

Printed Name of Parent/Guardian

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 7 – 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 ☐
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 ☐
Consents to an HIV test, or shows proof of HIV-positive status	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) or until healed	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 8: 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: _____

MC Client Health History Card Page 1

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 ☐

RIDHAA YA KUFANYIWA TOHARA

Mimi _____ nimekubali nifanyiwe/ mwanangu afanyiwe upasuaji wa kuondoa govi. Nimeelezwa na kutambua kwamba upasuaji huu ni kwa ajili ya afya yangu/ ya mtoto wangu na kwamba unaweza kuwa na madhara.

Baada ya kupatiwa maelezo ya kina na kupatiwa muda wa kuuliza maswali, nimeridhika na majibu niliyopatiwa.

Mimi ni **mzazi_____mlezi_____**. Sahihi yangu chini ni kuashiria kuwa kwa idhini yangu mwenyewe bila kushurutishwa nimetoa kibali cha upasuaji huu kwangu/ kwa mwanangu.

_____ _____ _____

Sahihi ya Mteja/Mzazi/Mlezi Sahihi ya Mtoa huduma / Mshauri Tarehe

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 9– CASE REPORT FORM (CRF) – SHANGRING DEVICE PLACEMENT

CASE REPORT FORM – ShangRing DEVICE Placement

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):**_____

Type of anesthesia used (circle one): EMLA Cream Injectable Lignocaine

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): _____

If EMLA used, time waiting for it to take effect (in minutes): _____

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 10 – 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 11 – 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 don't know

I would definitely choose ShangRing again	I would probably choose ShangRing again	I would probably choose surgery	I would definitely choose surgery

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 12 – 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 13 – 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 14 – 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 15 – SHANGRING ACTIVE SURVEILLANCE: DEVICE PLACEMENT AND FOLLOW-UP LOG

ShangRing Active Surveillance: Device Placement and Follow-up Log

Client ID	**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

APPENDIX 16: 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 ID	Interested in ShangRing? (Y/N)	Eligible after medical screening? (Y/N) If no, why?	Consents to ShangRing? (Y/N) If no, why?*

*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 17 – 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.

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 18 – 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

<table>
<tr><td>Device Event
(Indicate type)</td><td>Evaluation Phase</td><td>Start/Onset</td></tr>
<tr><td rowspan="11">☐ Anesthetic Related Problem
☐ Bleeding
☐ Pain
☐ Scarring/Disfigurement Poor cosmetic result or excess skin removal
☐ Device Displacement
☐ Device detachment
☐ Infection
☐ Injury to penis
☐ Sexual effects/ undesirable sensory changes
☐ Wound Disruption
☐ Excess swelling of penis/scrotum
☐ Hematoma
☐ Difficulty with removal
☐ Difficulty urinating
☐</td><td>☐ During placement ☐ While in place
(before discharge)
☐ During removal ☐ After removal</td><td>Date:

Time:</td></tr>
<tr><td>Severity
(Consult definitions for grading classification)</td><td>Events/AE Code
(Consult definitions for codes)</td></tr>
<tr><td>☐ Mild
☐ Moderate
☐ Severe</td><td></td></tr>
<tr><td>Moderate or Severe AE</td><td>Relationship to Device</td></tr>
<tr><td>☐ Yes ☐ No

If “Yes,” complete adverse events form</td><td>☐ Unrelated
☐ Possibly
☐ Definitely</td></tr>
<tr><td>Action</td><td>Pain VAS (see below)</td></tr>
<tr><td>☐ None ☐ Pharmaceutical
☐ Surgical ☐ Non-surgical
☐ Evaluation termination
☐ Other Specify: _____</td><td></td></tr>
<tr><td colspan="2">Complete when resolved or at final visit</td></tr>
<tr><td>Outcome</td><td>End/Termination</td></tr>
<tr><td>☐ ☐</td><td>Date:</td></tr>
</table>

Excessive skin removal ☐ Other	Resolved ☐ Resolved with sequel ☐ Persistent ☐ Unchanged ☐ Unknown	Time:

Visual Analog Scale (VAS):

0

Very happy, no hurt

2

Hurts just a little bit

4

Hurts a little more

6

Hurts even more

8

Hurts a whole lot

10

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.

Adverse Event	**Start/Onset**	**Status**	**Device Event Number**
	Date: Time: Date/time observed (if different):	☐ New ☐ Ongoing	
	Action	**Severity** *(Consult definitions for grading classification)*	**AE Code** *(Consult definitions for codes)*

	☐ None ☐ Pharmaceutical ☐ Surgical ☐ Non-surgical ☐ Evaluation termination Other ☐ Specify: _____	☐ Moderate ☐ Severe *If severe, complete information below*	
	Date of SAE report to evaluation investigators:	Was the SAE a result of protocol departure? Yes ☐ No ☐ If "Yes," please specify:	
	Date of last visit and last visit number:	Date the device was applied:	
	Please describe the SAE in block letters (use following page if additional space is needed):	Choose criteria for SAE: ☐ Death ☐ Permanent disability ☐ Life threatening ☐ Hospitalization or prolongation of inpatient hospitalization ☐ Required intervention to prevent one of the above ☐ Other:	
	Outcome	**End/Termination**	
	☐ Resolved ☐ Resolved with sequel Persistent ☐ Unchang ☐ Unkn ☐ n	Date: Time:	

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 19: 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* A1-SD: *Injury to penis*–limited superficial injury not requiring additional intervention.	*Excess skin removal–NA* A1-SD: *Injury to penis*–abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	*Excess skin removal–NA* A1-SD: *Injury to penis*–injury that requires surgical intervention to stop bleeding or repair.
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	A2/B/C-PA: Pain serious enough to result in disability (as evidenced by	A2/B/C-PA: Pain serious enough to result in disability (as evidenced by

	standard postoperative analgesics and considered within normal thresholds associated with surgery	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).	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 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.	*Scarring*-Discernible but re-operation not required. Usually noticed first by the client and reported to the 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.	*Scarring*-Discernible and requires reoperation or referral/transfer to another facility. *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. *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 20 - SHANGRING EVALUATION PILOT: EMLA APPLICATION TIME FORM

ShangRing Evaluation Pilot: EMLA Application Time Form
(Enter time in 24 hour form, e.g. 18:00)

Client ID #	Date (DD/MM/YYYY)	Time for EMLA (if applicable)*	Overall Time[µ]		
			Begins	Ends	Total time (in minutes)

***Time for EMLA:** For those clients circumcised using EMLA cream, record amount of time (in minutes) spent from when the cream is applied, to when it takes effect and the placement procedure begins.

[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 21 - 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)

***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 22 – 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. During your circumcision, were you given EMLA cream for anesthetic, or did you receive an injection?

10. 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.].

11. How was the process of having the ShangRing device put on your penis?

12. 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]

13. How was the removal process?

14. 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*].

15. Did you resume sexual activity or masturbation before you returned for your healing assessment?

16. 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].

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

18. Are you satisfied with the result?

19. What did you like about the procedure?

20. What did you dislike?

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

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

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

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

25. 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 23 – 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 asked to interview at two points in time, and asked to complete one survey. If you choose not to participate in the ShangRing evaluation, you will not be interviewed, nor will you be asked to complete the survey. Additionally, refusal to participate in the ShangRing evaluation will not impact your employment in any way.

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. Refusal to participate in the ShangRing evaluation program will not impact your employment in any way.

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 24 – 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 25 – 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 26 – 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 27: 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 28 – SHANGRING EVALUATION CLIENT WITHDRAWAL LOG

ShangRing Client Withdrawal Log

Client ID	Date Enrolled	Date Withdrawn	Reason(s) for Client Withdrawal

APPENDIX 29: RESOURCES AND BUDGET

Deliverable and Payment Schedule

Deliverable	Description of Deliverable	Required Deliverable	Deliverable Completion Date	Amount
1	Signing of sub-agreement	Fully executed agreement	October 15, 2018	$34,125
2	Complete hiring of study coordinator and research assistants	Signed employment contracts of recruited personnel	November 1, 2018	$49,617
3	Complete training of 12 providers	1.Training report 2. List of trained providers with signatures and details of their phone numbers, regions/districts, facility they work for, and job titles	30th April 2019	$9,581
4	Procurement of needed equipment, ShangRing device and Topical cream	Delivery and Goods Received	25th April 2019	$37,474
5	Complete enrolment of study	573 study participants enrolled in the study completed follow up visits	July 30, 2019	$16,860
6	Complete data analysis and final study report	Final study report	September 29, 2019	$22,968
TOTAL				**$170,625**

REFERENCES

[i] Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med*. 2005;2(11): e298.

[ii] Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. *Lancet*. 2007;369(9562):657-666.

[iii] Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. *Lancet*. 2007;369(9562):643-656.

[iv] The Joint United Nations Programme on HIV/AIDS (UNAIDS). Fast track commitments to end AIDS by 2030. August 15, 2016. Retrieved from: http://www.unaids.org/sites/default/files/media_asset/fast-track-commitments_en.pdf.

[v] WHO Prequalification of Male Circumcision Devices Public Report. Product: ShangRing. WHO reference number: PQMC 0003-003-00. March 2019, version 3.0.

[vi] Tetanus and voluntary medical male circumcision: risk according to circumcision method and risk mitigation. Report of the WHO Technical Advisory Group on Innovations in Male Circumcision – consultative review of additional information, 12 August 2016. Geneva: World Health Organization. 21 September 2016. Available at: http://www.who.int/hiv/pub/malecircumcision/tetanus-vmmc-report/en/.

[vii] Project IQ Webinar series. Virtual Roundtable on ShangRing for VMMC: Country perspectives. September 9th 2019. https://www.malecircumcision.org/resource/introduction-virtual-roundtable-shangring-vmmc-country-perspectives

[viii] Peng YF, Chang Y, Wang GY, et al. Clinical application of a new device for minimally invasive circumcision. Asian J Androl 2008 ;10:447-54.

[ix] Cheng Y, Peng YF, Liu YD, et al. A recommendable standard protocol of adult male circumcision with the Chinese ShangRing™: outcomes of 328 cases in China. Zhonghua Nan Ke Xue 2009; 15:584-592.

[x] Barone MA, Li PS, Awori QD, Lee R, Goldstein M. Clinical trials using the ShangRing™ device for male circumcision in Africa: a review. *Transl Androl Urol* 2014;3(1):113-124.

[xi] Barone MA, Ndede F, Li PS, et al. The Shang Ring device for adult male circumcision: a proof of concept study in Kenya. J Acquir Immune Defic Syndr 2012; 60:e82-9.

[xii] Barone MA, Awori QD, Li PS, et al. Randomized trial of the Shang Ring for adult male circumcision with removal at one to three weeks: delayed removal leads to detachment. J Acquir Immune Defic Syndr 2012; 60:e82-89.

[xiii] Sokal DC, Li PS, Zulu R, et al. Randomized controlled trial of the Shang Ring versus conventional surgical techniques for adult male circumcision: safety and acceptability. J Acquir Immune Defic Syndr 2012; 60:e82-9.

[xiv] Barone MA LP, Zulu R, Awori QD, et al. A Field Study of Male Circumcision Using the Shang Ring, a Minimally Invasive Disposable Device, in Routine Clinical Settings in Kenya and Zambia.

7th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention; Kuala Lumpur, Malaysia, 2013.

[xv] Kigozi G, Musoke R, Watya S, et al. The acceptability and safety of the Shang Ring for adult male circumcision in Rakai, Uganda. J Acquir Immune Defic Syndr 2013;63:617-21.

[xvi] Barone MA, Li PS, Awori QD, Lee R, Goldstein M. Clinical trials using the ShangRing™ device for male circumcision in Africa: a review. *Transl Androl Urol* 2014;3(1):113-124.

[xvii] Barone MA, Li PS, Awori QD, Lee R, Goldstein M. Clinical trials using the ShangRing™ device for male circumcision in Africa: a review. *Transl Androl Urol* 2014;3(1):113-124.

[xviii] Rech D, Bertrand JT, Thomas N, Farrell M, Reed J, Frade S, et al. (2014) Surgical Efficiencies and Quality in the Performance of Voluntary Medical Male Circumcision (VMMC) Procedures in Kenya, South Africa, Tanzania, and Zimbabwe. PLoS ONE 9(5): e84271. https://doi.org/10.1371/journal.pone.0084271

[xix]Bratt JH, Zyambo Z. J. Comparing direct costs of facility-based Shang Ring provision versus a standard surgical technique for voluntary medical male circumcision in Zambia. Acquir Immune Defic Syndr. 2013 Jul 1;63(3):e109-12. doi: 10.1097/QAI.0b013e31828e9526.

[xx] WHO Prequalification of Male Circumcision Devices Public Report. Product: ShangRing. WHO reference number: PQMC 0003-003-00. March 2019, version 3.0.

[xxi] Sokal DC, Li PS, Zulu R, et. al. Field Study of Adult Male Circumcision Using the ShangRing in Routine Clinical Settings in Kenya and Zambia. *JAIDS J Acquir Immune Defic Syndr*. 2014;67(4):430-437. Doi:10.1097/QAI.0000000000000321.

[xxii] Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC). Tanzania HIV Impact Survey (THIS) 2016-2017: Final Report. Dar es Salaam, Tanzania. December 2018.

[xxiii] The United Republic of Tanzania, Voluntary medical male circumcision country operational plan: 2014-2017. November 2014.

[xxiv] PEPFAR Dashboards. Country and Regional Program Results, FY 2010-2016: Tanzania. May 5, 2017. Retrieved from: https://data.pepfar.net/country/impact?country=Tanzania&indicatorGroup=HIV%20Prevention&year=2004&yearTo=2016.

[xxv] World Health Organization. Framework for clinical evaluation of devices for male circumcision. September 2012. Retrieved from: http://apps.who.int/iris/bitstream/10665/75954/1/9789241504355_eng.pdf?ua=1.

[xxvi] WHO Prequalification of Male Circumcision Devices Public Report. Product: ShangRing. WHO reference number: PQMC 0003-003-00. March 2019, version 3.0.

[xxvii] World Health Organization. Framework for clinical evaluation of devices for male circumcision. September 2012. Retrieved from: http://apps.who.int/iris/bitstream/10665/75954/1/9789241504355_eng.pdf?ua=1.

[xxviii] Barone MA, Awori QD, Li PS, et al. Randomized trial of the Shang Ring for adult male circumcision with removal at one to three weeks: delayed removal leads to detachment. J Acquir Immune Defic Syndr 2012; 60:e82-89.

[xxix] World Health Organization. Preventing HIV through Safe Voluntary Medical Male Circumcison for Adolescent Boys and Men in Generalized HIV Epidemic: Recommendations and Key considerations (2020)

[xxx] Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC). Tanzania HIV Impact Survey (THIS) 2016-2017: Final Report. Dar es Salaam, Tanzania. December 2018.
[xxxi] Kigozi G, Musoke R, Kighoma NGR. The acceptability and safety of the ShangRing for adolescent male circumcision in Rakai, Uganda. International AIDS Society Conference; 2014; Melbourne, Australia. TUPE148 p.
[xxxii] Awori QD et al. Journal of the International AIDS Society 2017, 20:21588 http://www.jiasociety.org/index.php/jias/article/view/21588 | http://dx.doi.org/10.7448/IAS.20.1.21588
[xxxiii] Ibid
[xxxiv] Kigozi G, Musoke R, Kighoma NGR. The acceptability and safety of the ShangRing for adolescent male circumcision in Rakai, Uganda. International AIDS Society Conference; 2014; Melbourne, Australia. TUPE148 p.
[xxxv] World Health Organization. Manual for male circumcision under local anesthesia and HIV prevention services for adolescent boys and men (2018). https://www.who.int/hiv/pub/malecircumcision/chapter_9.pdf