Voluntary Medical Male Circumcision (VMMC) Procedures **Tool H – ShangRing**

External Quality Assurance (EQA)

Injected anesthesia, Flip Technique, and No-Flip Technique

Site Name:_____ Reviewer's Name:_____ Date:_____

This Tool (H) aims to objectively assess resources and activities related to:

- Screening patients and preparation for ShangRing
- ShangRing procedures for adults and adolescents
- Prevention of infection
- Surgical backup and training

Reviewer Guidance:

The reviewer will record observations by marking "Y" for Yes (wholly adequate), or "N" for No (not wholly adequate) as noted on the form. In cases where the "N" is checked, the reviewer is asked to explain in the Notes section as appropriate.

Any additional general comments may also be recorded in the Comments/Notes section at the end.

For ShangRing services and clinical management there are many considerations for each of the indicators. Several key elements are identified for the reviewer as a guide during observations. An indicator may be judged adequate overall, with comments identifying the strongest areas as well as problematic components, even though the overall performance may be within acceptable standards. When judged partially or not wholly adequate (N) overall, the specific component(s) that require change should be identified, as well as affirmation of those elements that are sound.

Please obtain permission from the clinical staff to observe the procedure. Then obtain verbal consent from the client (and from the parent/guardian if the client is a minor) to observe.

For each item below, please check the correct box in the first column to indicate whether the provider asked about the item (NOT whether the answer was "Yes"). In the second column indicate whether the provider documented the result.

Medical History			Did provider ask about or perform?		Did provider document the results correctly?	
Does the client currently have or did he recently have any of the following:		N/A	Y	N	Y	N
For post-pubescent clients only	H1. **Medical History –** Any discharge from the tip of penis?					
	H2. **Medical History –** Any pain or burning on urination?					
	H3. **Medical History –** Frequent urination?					
	H4. **Medical History –** Any swelling/redness of the foreskin or penis?					
	H5. **Medical History –** Any ulcer or warts anywhere on penis?					
	H6. **Medical History –** Any problems with sexual function					
H7. **Medical History** – Does the client have allergies to any medication?						
H8. **Medical History** – Has the client had any previous surgeries?						
H9. **Medical History** – If client has had previous surgeries, has he had any complications, including prolonged bleeding? (Please write 'NA' if NO previous surgeries).						
H10. **Medical History** – Has the client ever had prolonged bleeding after cuts, dental extractions, or nosebleeds?						
H11. **Medical History** – Does the client have diabetes?						
H12. **Medical History** – Does the client have any history of anemia?						
H13. **Medical History** – Does the client currently have any other serious chronic illness? (It is NOT necessary to ask about HIV status).						
H14. **Medical History** – Does the client have a history of keloid scarring? (a history of keloids is a contraindication to circumcision at the VMMC site)						
Physical Exam						
H15. **Physical Exam** – Was the weight obtained? *If NO, skip to J17.*						
H16. **Physical Exam** – What was the weight (kg)?						
H17. **Physical Exam** – Was the temperature obtained?						
H18. **Physical Exam** – Was the blood pressure obtained?						
H19. **Physical Exam** – Was the penis examined, lifting and moving as needed to visualize all sides (done to rule out current STIs and anatomic abnormalities)?						

H20. **Physical Exam** – Did the examiner ask the client to point out any scars from previous surgery or injury? (The examiner should look at any scars to ensure there are no keloids which would be a contraindication to circumcision)				
H21. **Physical Exam** – Was an attempt made to retract the foreskin and visualize the urethra? (For phimosis, adhesions, hypospadias/epispadias).				
H22. **Physical Exam** – Was the scrotum examined, lifting and moving as needed to visualize all sides? (Done to rule out disorders such as hydrocele).				
H23. **Physical Exam** – Was eligibility for VMMC assessed by VMMC provider? (the operating provider should always personally examine to confirm eligibility prior to beginning the procedure)				

Sources: PEPFAR Operational Guide for Voluntary Medical Male Circumcision Services: *A service guide for site operations*; Uganda Standard MC Record; WHO Manual for Male Circumcision under Local Anesthesia.

Surgical Backup	**Y**	**N**	**Notes**
H24. **Surgical Backup** – Is <u>immediate</u> skilled surgical backup available in the same facility?			
H25. **Surgical Backup** – Is surgical backup in a different department?			
H26. **Surgical Backup** –Is there a protocol for converting device placement failures to surgical procedures? **(Discuss plan with staff).**			
H27. **Surgical Backup** – Is a written plan in place for surgical backup?			
H28. **Surgical Backup** – Is the surgical backup adequately skilled in performing complex VMMC surgical procedures to address potential adverse events? **(Discuss skill of surgical backup with staff).**			

Comments on the surgical backup plan (specify feasibility and the adequacy of experience of surgical backup):

Training	**Y**	**N**	**Notes**
H29. **Training** – Have the clinical personnel in health facilities in the site's catchment area been oriented on ShangRing?			
H30. **Training** – Have the clinical personnel in health facilities in the site's catchment area been oriented on the recognition of potential complications from ShangRing?			
H31. **Training** – Have the clinical personnel in health facilities in the site's catchment area been oriented on client management and referral policy for ShangRing?			

Additional Comments/Notes:

All questions should be answered Yes if the item is fully complete, and No if any part is not.			
Topical Anesthesia (if client did not receive topical anesthesia, please skip to Pre-Placement Steps section)			
Question	**Y**	**N**	**Notes**
H32. **Topical Anesthesia** – Was 2.5% lidocaine, 2.5% prilocaine cream used for topical anesthesia? (if not, please write what was used in the notes section)			
H33. **Topical Anesthesia** – Was the topical cream applied to the inner foreskin, glans, outer foreskin, and skin of the full length of the penile shaft (for best effectiveness)?			
H34. **Topical Anesthesia** – Was the penis covered with an impermeable barrier (e.g. the provider's glove) after application of the cream? (this ensures cream stays in contact without being wiped off)			
H35. **Topical Anesthesia** – Did the provider allow at least 25 minutes after applying the cream before checking for anesthetic effect?			
H36. **Topical Anesthesia** – Did the provider check all 4 quadrants of the foreskin gently with forceps and ensure adequate anesthesia before the procedure?			
If adequate anesthesia not accomplished with topical cream, the client will require injectable anesthesia. Please progress to **Pre-Placement Steps** and ensure completion of the section on **Anesthetic Injection.**			
Pre-Placement Steps			
Client	**Y**	**N**	**Notes**
H37. **Pre-Placement Steps –** Was the client's name and age verified?			
H38. **Pre-Placement Steps –** Was consent verified?			
H39. **Pre-Placement Steps –** Did the provider measure the flaccid penile shaft circumference just below the coronal sulcus (proximal to the body)?			
	Y	**N**	**Notes**
H40. **Pre-Placement Steps –** Did the provider select the appropriate size ShangRing?			
Aseptic technique			
H41. **Aseptic technique** – Did the provider perform all surgical scrub elements correctly?			
H42. **Aseptic technique** – Did the provider remove all jewelry (If no jewelry worn, comment N/A in notes section)?			
H43. **Aseptic technique** – Did the provider first wash his/her hands and arms up to the elbow with non-medicated soap?			
H44. **Aseptic technique** – Did the provider scrub with medicated soap or alcohol including all sides of each finger?			
H45. **Aseptic technique** – Did the provider keep his/her hands above the elbows until gloved?			

H46. **Aseptic technique** – Did the provider avoided touching anything, except drying towel, until gloved?			
H47. **Aseptic technique** – Did the provider put on gloves without letting their skin touch the outer surface?			
H48. **Aseptic technique** – Did the provider replace gloves if punctured (comment N/A in notes section)?			
H49. **Aseptic technique** – Was the client asked whether they were allergic to iodine antiseptic prior to applying povidone-iodine (7.5% - 10%), and if allergic, was or chlorhexidine gluconate (2% - 4%) used instead?			
H50. **Aseptic technique** – Did provider check for physiological adhesions and if adhesions are detected, does provider administer anesthesia before continuing cleaning? *In case of adhesions with administration of injectable anesthesia first, SKIP to question H59, follow anesthesia questions, then return to H51. Adhesions can usually be separated easily by applying gentle pressure on them using a moist gauze swab or a blunt probe.*			
H51. **Aseptic technique** – Was antiseptic applied to client moving outward from the glans and inner foreskin, to the outer foreskin, shaft and scrotum, and peripheral genital area, including lower thighs and suprapubic area, without letting cleaned skin touch uncleaned skin?			
H52. **Aseptic technique** – Did the provider apply antiseptic three times?			
H53. **Aseptic technique** – Did the provider wait ≥2 minutes before initiating placement for disinfectant action?			
H54. **Aseptic technique** – Was the client draped correctly (draping extends up to mid-chest, down to mid-thighs, and laterally over sides of the bed)?			
H55. **Aseptic technique** – Did the provider remove and replace gloves after skin preparation?			
H56. **Aseptic technique** – Did the provider wear a face mask and protective eyewear throughout device placement?			
H57. **Surgical Preparation and Procedures** – If the provider wore protective eyewear, were the lenses clean and clear and remain so throughout the procedure? (poor visualization of the operative field can lead to poor operative technique and increased risk for adverse events.)			
H58. **Surgical Preparation and Procedures** – Did the operative field have adequate lighting during the entire procedure? (poor lighting can increase the risk of adverse events)			
Anesthetic Injection			
H59. **Anesthetic –** Were early symptoms of anesthetic overdose explained **to client** e.g., metallic taste in the mouth, numbness, light-headedness, dizziness, itching, or shortness of breath?			
H60. **Anesthetic –** Did the provider open a NEW vial of anesthetic for the observed client?			

H61. **Anesthetic –** Was only lidocaine <u>without</u> epinephrine, with or without bupivacaine used?			
H62. **Anesthetic –** For clients receiving lidocaine alone, what was the volume (ml) AND strength of the lidocaine injected (%)?	ml		
	%		
H63. **Anesthetic –** Does this equate to no more than 3.0 mg/kg based on the weight recorded in H16? (Indicate N/A in the notes if client did not receive lidocaine alone).			
H64. **Anesthetic –** For clients receiving lidocaine with bupivacaine, what was the volume (ml) AND strength of the lidocaine injected (%)? (Write N/A in notes if client did not receive lidocaine with bupivacaine).	ml		
	%		
H65. **Anesthetic –** Does this equate to no more than 2.0 mg/kg and 0.5 mg/kg of lidocaine and bupivacaine, respectively? (Indicate N/A in the notes if client did not receive lidocaine with bupivacaine).			
H66. **Anesthetic –** Was a 23-gauge (or higher) needle inserted at the 11 and 1 o'clock positions?			
H67. **Anesthetic –** Was aspiration performed with each movement of the needle?			
H68. **Anesthetic** – If client expressed pain during the VMMC procedure, did the provider wait for drug to take effect if applicable, then give additional anesthetic if needed (up to max safe dose)? (If no pain, indicate N/A in notes).			
H69. **Anesthetic** – Did the provider use a NEW needle AND syringe (no 'double-dipping') to withdraw the additional anesthetic? If additional anesthetic was not required, ask the provider what technique would be used in this situation, and answer this question based on description.			
	Y	**N**	**Notes**
ShangRing Placement Steps (flip technique) – if no-flip technique used, please skip to that section			
H70. **Placement Steps** – Was the inner ring placed below or proximal to the level of the coronal sulcus, and with clamps at the 3, 6, 9, and 12 o'clock positions, the foreskin everted the foreskin (turned it inside out) over the inner ring?			
H71. **Placement Steps** – If necessary due to tight foreskin or frank phimosis, was a 1 cm dorsal incision made to permit eversion of the foreskin over the inner ring (indicate N/A in notes if not necessary)			
H72. **Placement Steps** – Was the outer ring secured ring over the inner ring, placing the foreskin between the two rings?			

H73. **Placement Steps** – After engaging the first ratchet of the outer ring, was the foreskin adjusted as needed to ensure the proper placement of the device?			
H74. **Placement Steps** – Did the provider ensure there were no extra folds of skin caught between the two rings and check that rings were in proper location before engaging second ratchet of the outer ring?			
H75. **Placement Steps** – Was excess foreskin excised using a scalpel?			
H76. **Placement Steps** – Were 6 to 10 nicks made perpendicular to the incision line using the scalpel to prevent formation of a constricting circumferential scab?			
H77. **Placement Steps** – After excising the foreskin, did the provider inspect the underside of the ShangRing to identify any extraneous skin that may be pinched between the rings, and pulled to release from pinch as necessary?			
H78. **Placement Steps** – Was the presence or absence of AEs assessed and documented, including pain?			
ShangRing Placement Steps (no-flip technique)			
H79. **Placement Steps** – Was the foreskin fully retracted to include bluntly freeing any adhesions between the glans and inner foreskin?			
H80. **Placement Steps** – Was the inner ring placed within the foreskin and adjusted to sit on the coronal sulcus at a horizontal position near the frenulum?			
H81. **Placement Steps** – If necessary due to tight foreskin or frank phimosis, was a 1 cm dorsal incision made to permit eversion of the foreskin over the inner ring (indicate N/A in notes if not necessary)			
H82. **Placement Steps** – Was the outer ring placed securely over the inner ring, with the foreskin between the two rings?			
H83. **Placement Steps** – After engaging the first ratchet of the outer ring, was the foreskin adjusted as needed to ensure the proper placement of the device?			
H84. **Placement Steps** – Did the provider ensure there were no extra folds of skin caught between the two rings and check that rings were in proper location before engaging second ratchet of the outer ring?			
H85. **Placement Steps** – Was the foreskin excised with scissors taking caution to avoid injuring the glans? (a scalpel should not be used to excise the foreskin)			
H86. **Placement Steps** – Was the presence or absence of AEs assessed and documented, including pain?			
Dressing material and application			
H87. **Dressing Material and Application** – Did the provider first ensure there was no bleeding?			
H88. **Dressing Material and Application** – Was the wound cleaned with antiseptic?			

H89. **Dressing Material and Application** – Was dry dressing applied to the wound?			
Disinfection			
H90. **Disinfection** – Did the staff dispose of personal protective equipment correctly?			
H91. **Disinfection** – Were all needles and syringes disposed of safely? (in sharps container, no two-handed recapping, no reuse, no disassembling before disposal, without overstuffing)			
H92. **Disinfection** – If disposable instruments were used, were they placed in high-level chemical disinfection after the case? (if reusable instruments were used, please complete the instrument reprocessing tool)			
Complete H93 & 94 only if injectable anesthesia was used.	**Y**	**N**	**Notes**
H93. **Disinfection** – Was lidocaine vial disposed of? *If YES, skip question H94.*			
H94. **Disinfection** – Ask provider how opened lidocaine vials are handled after first use. Does the procedure ensure that no vial which might have had 'double dipping' is later used for another client?			
Removal			
H95. **Removal –** Did staff wash their hands prior to removing the ShangRing device?			
H96. **Removal** – Was the presence or absence of AEs while the ring was in place, assessed and documented?			
H97. **Removal** – Was 1%-2% lidocaine, sterile water, or saline applied to the area around the wound and left for approximately 1-2 minutes to take effect?			
H98. **Removal** – Did the provider insert and twist the tip of the removal key opener into the 'key hole' (located on the hinge of the outer ring)?			
H99. **Removal** – Did the provider use a clamp to gently pull the inner ring back from the edge of the wound?			
H100. **Removal** – Did the provider cut the inner ring at two points opposite each other, e.g., the 6 and 12 o'clock positions, using the removal cutter? (not necessary if ring had been applied using the no-flip technique)			
H101. **Removal** – Was the ring properly disposed of in a receptacle for infectious waste?			
H102. **Removal** – Was a bandage applied to wound?			
H103. **Removal** – Was the presence or absence of AEs during removal correctly documented, including pain?			

Additional Comments/Notes: