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| **Voluntary Medical Male Circumcision (VMMC) Continuous Quality Improvement (CQI)**    **Level 1 – Safety of Procedure – SHANGRING PROCEDURE (INJECTED ANESTHESIA/FLIP)**  **Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reviewer’s Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | |
| **Male Circumcision Procedure** | | | | | | | |
| This section assesses standards to ensure:   * The procedure room is suitable for male circumcision by ShangRing * Materials and supplies for male circumcision procedure are in stock * The providers prepare the client for male circumcision procedure * The providers administer topical anesthetic and perform device placement correctly * The provider gives client appropriate post-placement care instructions * Client records are updated and completed prior to discharge * Device is removed in alignment with manufacturer instructions for use * Post-removal instructions are provided on wound care, potential complications and danger signs, return visits, and abstinence/resumption of sexual activity, and post-removal adverse events are recorded   All assessments should be determined through direct observation. Select “yes” if the item being assessed is present/adequate; select “no” if the item being assessed is not adequate; select N/A only if the item being assessed is not applicable. If an item is not available for observation but otherwise necessary, select “no”. | | | | | | | |
| **Placement** | | | | | | | |
| *Observe the procedure room for the following:* | | | **Y** | **N** | **N/A** | **Notes** | |
| L1-SR-IJ-FL-1. **Male Circumcision Procedure** – Availability of operating/strong lights. | | |  |  |  |  | |
| L1-SR-IJ-FL-2. **Male Circumcision Procedure** – Restriction of access (signage is sufficient). | | |  |  |  |  | |
| L1-SR-IJ-FL-3. **Male Circumcision Procedure** – Privacy is available to each patient (doors with handles & locks separating procedure room from rest of clinic; beds enclosed by curtains; at least 1m between patient beds – if services are provided in tents, beds should at least be enclosed by curtains and 1m apart). | | |  |  |  |  | |
| L1-SR-IJ-FL-4. **Male Circumcision Procedure** – The procedure rooms have adequate temperature control, ventilation, and space. | | |  |  |  |  | |
|  | | | **Y** | **N** | **N/A** | **Notes** | |
| L1-SR-IJ-FL-5. **Male Circumcision Procedure** – There is a designated space for surgical scrub with clean running water, soap, and access to sterile towel and PPE. | | |  |  |  |  | |
| L1-SR-IJ-FL-6. **Male Circumcision Procedure** – Use of PPE by all personnel, at all times (at a minimum: masks, caps, shoe covers). | | |  |  |  |  | |
| *Physically verify that:* | | |  | | | | |
| L1-SR-IJ-FL-7. **Male Circumcision Procedure** – MC instrument set contains necessary instruments to perform the ShangRing procedure:   * Instrument tray wrapped with sterile drape * “o” drape (80 cm x 80 cm, with ~ 5 cm hole) * Examination gloves (for placement and removal) * Povidone iodine (50 mL 7.5–10% aqueous-based solution)a * Gallipot * Measuring tape * Syringe, 10 or 20 mL * Anesthetic(s) in one of the following concentrations:   + 1% plain lignocaine/lidocaine (without epinephrine) alone   + 1% plain lignocaine/lidocaine (without epinephrine) and 0.25% bupivacaine   + 2% plain lignocaine/lidocaine (without epinephrine) alone   + 2% plain lignocaine/lidocaine (without epinephrine) and 0.5% bupivacaine * ShangRing devices with all components (outer ring, inner ring) * Hemostatic clamps * Metzenbaum scissors * Scalpel * Kidney dish * Removal cutter * Removal key   a It is important to have available alternative solutions for skin disinfection, such as chlorhexidine gluconate (2% ‐ 4%), for patients allergic to povidone iodine. | | |  |  |  |  | |
| *Please obtain permission from the clinical staff to observe procedures. Then obtain verbal consent from the client (and from the parent/guardian if the client is a minor) to observe.*  *Observe in the care of two clients whether the providers do the following:* | | | | | | | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-8. **Male Circumcision Procedure** – Prepare the necessary equipment. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-9. **Male Circumcision Procedure** – At least one provider participating in the procedure periodically speaks with client to detect difficulty speaking or confusion (due to anesthetic toxicity); responds to client questions and provides reassurance when prompted. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-10. **Male Circumcision Procedure** – Verify client’s name and age. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-11. **Male Circumcision Procedure** – Check for consent. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-12. **Male Circumcision Procedure** – Flaccid penile shaft circumference is measured just below the coronal sulcus (proximal to the body). | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-13. **Male Circumcision Procedure** – Select correct size ShangRing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-14. **Male Circumcision Procedure** – Scrub and put on protective clothing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-15. **Male Circumcision Procedure** – Ask client whether they are allergic to iodine antiseptic prior to applying povidone‐iodine (7.5% ‐ 10%), and if allergic, use chlorhexidine gluconate (2% ‐ 4%) instead. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-16. **Male Circumcision Procedure** – Check for physiological adhesions and if adhesions are detected, administer anesthesia before *continuing cleaning. In case of adhesions, SKIP to question L1-SR-IJ-FL-21, follow anesthesia questions, then return to L1-SR-IJ-FL-16. Adhesions can usually be separated easily by applying gentle pressure on them using a moist gauze swab or a blunt probe.* | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-17. **Male Circumcision Procedure** – Clean genitalia and surrounding area (from umbilicus to mid-thigh) with **three applications** of povidone-iodine (7.5% - 10%) or chlorhexidine gluconate (2% - 4%), and allow it to dry for at least two minutes. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-18. **Male Circumcision Procedure** – Ensure proper positioning of the client. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-19. **Male Circumcision Procedure** – Drape the client exposing the genitalia only. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-20. **Male Circumcision Procedure** – Re-wash hands and replace gloves after skin preparation | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-21. **Male Circumcision Procedure** – Describe early symptoms of anesthetic overdose, e.g., metallic taste in the mouth, numbness, light-headedness, dizziness, itching, or shortness of breath to the client before administering anesthetic. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-22. **Male Circumcision Procedure** – Use safe dose of anesthetic  *Note: Maximum safe doses of anesthetic*   * *Lidocaine alone: 3mg/kg* * *Lidocaine with bupivicaine: lidocaine 2.0 mg/kg; bupivicaine 0.5 mg/kg* | **Y** |  | | |  | | *Enter volume and concentrations as applicable:*  **Client 1**  **\_\_\_\_\_\_\_\_ml \_\_\_\_\_\_\_\_%**  **\_\_\_\_\_\_\_\_ml \_\_\_\_\_\_\_\_%**  **Client 2**  **\_\_\_\_\_\_\_\_ml \_\_\_\_\_\_\_\_%**  **\_\_\_\_\_\_\_\_ml \_\_\_\_\_\_\_\_%** |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-23. **Male Circumcision Procedure** – Administer anesthetic at the base of the penis (at eleven and one o’clock followed by a ring block). | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-24. **Male Circumcision Procedure** – Aspirate syringe with each movement of the needle. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-25. **Male Circumcision Procedure** – If further anesthetic is needed, use a new needle and syringe (avoid double-dipping). | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-26. **Male Circumcision Procedure** – Wait for 3-5 min for the anesthetic to work. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-27. **Male Circumcision Procedure** – Test for pain sensation using toothed dissecting forceps. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-28. **Male Circumcision Procedure** – Manage pain by administering additional anesthetic if necessary throughout the procedure, up to safe limit. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-29. **Male Circumcision Procedure** – Place the inner ring below or proximal to the level of the coronal sulcus. Using clamps at the 3, 6, 9, and 12 o’clock positions, evert the foreskin (turn it inside out) over the inner ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-30. **Male Circumcision Procedure** – If necessary due to tight foreskin or frank phimosis, make a dorsal incision of about 1 cm to permit eversion of the foreskin over the inner ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-31. **Male Circumcision Procedure** – Secure the outer ring over the inner ring, placing the foreskin between the two rings. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-32. **Male Circumcision Procedure** – After engaging the first ratchet of the outer ring, adjust foreskin if needed to ensure the proper placement of the device. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-33. **Male Circumcision Procedure** – Ensure there are no extra folds of skin caught between the two rings and check that rings are in proper location before engaging second ratchet of the outer ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-34. **Male Circumcision Procedure** – Excise the foreskin distal to the device using curved iris scissors, with care taken to protect the glans. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-35. **Male Circumcision Procedure –** Clean the wound with antiseptic. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-36. **Male Circumcision Procedure –** Check to ensure there is hemostasis. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| *Observe whether the provider does the following:* |  | | | | | | |
| L1-SR-IJ-FL-37. **Male Circumcision Procedure –** Explains the need to avoid intercourse and masturbation while wearing the device. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-38. **Male Circumcision Procedure –** Discusses risk reduction methods if abstinence is absolutely not possible: masturbation poses less risk than sexual intercourse; use a condom if intercourse is not avoidable, but note any type of sexual activity may result in complications or prolong wound healing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-39. **Male Circumcision Procedure –** Instructs client to wear clean underwear that fits comfortably and allows penis to stay in position while healing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-40. **Male Circumcision Procedure –** Instructs client that one day after circumcision they may shower while the device is in place as long as they carefully dry the penis and ShangRing afterwards, but they should not go swimming or wash in a bathtub. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-41. **Male Circumcision Procedure –** Reminds client to return for device removal after 7-10 days. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-42. **Male Circumcision Procedure –** Instructs client not to let anyone but a qualified provider remove the device, as this could result in complications requiring surgery. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-43. **Male Circumcision Procedure –** Instructs client not to apply any home remedies or traditional medicines, such as herbal remedies, ash, or animal dung, as these can increase chances of tetanus, which can be fatal. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-44. **Male Circumcision Procedure –** Explains normal symptoms while wearing device are swelling, and pain that is manageable with analgesic tablets. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-45. **Male Circumcision Procedure –** Explains how to recognize and return in case of any danger signs or signs of complications. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-46. **Male Circumcision Procedure –** Gives information on how to manage penile erections while wearing the device: spontaneous erections may feel uncomfortable, but ordinarily are not a cause for concern and urinating at the first urge may reduce their duration/severity; contact VMMC site if device appears to have moved as a result of erection. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-47. **Male Circumcision Procedure –** Makes sure the client knows where to go if complication arise and have a contact phone number. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-48. **Male Circumcision Procedure –** Gives next appointment date. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-49. **Male Circumcision Procedure –** If age appropriate and/or sexually active client, provides condoms. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-50. **Male Circumcision Procedure –** Reinforces HIV prevention messages. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| *Observe whether a staff member or healthcare provider:* |  | | | | | | |
| L1-SR-IJ-FL-51. **Male Circumcision Procedure –** Fills in the follow-up visit date on the client appointment card. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-52. **Male Circumcision Procedure –** Fills in emergency contact number on the client appointment card. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-53. **Male Circumcision Procedure –** Completes VMMC Client Record. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-54. **Male Circumcision Procedure –** Records any intra-procedural complications or adverse events on the VMMC Client Record and Adverse Event Form. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| **Removal** | | | | | | | |
| *Observe whether the providers do the following:* |  | | | | | | |
| L1-SR-IJ-FL-55. **Male Circumcision Procedure –** Assess and document any AEs that have occurred while device has been in situ | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-56. **Male Circumcision Procedure –** Spray 1%-2% lidocaine to the area around the wound and leave for approximately 1-2 minutes to take effect. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-57. **Male Circumcision Procedure –** Insert the tip of the removal key opener into the ‘key hole’ located on the hinge of the outer ring and twist or bend the removal key opener to break the ratchet, allowing for easy removal of the outer ring. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-58. **Male Circumcision Procedure –** Gently pull the inner ring back from the edge of the wound using a clamp. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-59. **Male Circumcision Procedure –** Cut the inner ring at two points opposite each other, e.g., the 6 and 12 o’clock positions, using the removal cutter. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-60. **Male Circumcision Procedure –** Apply bandage to wound. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-61. **Male Circumcision Procedure –** Explain the need to avoid intercourse and masturbation for 6 weeks after device removal. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
|  |  | **Client 1** | | | **Client 2** | | **Notes** |
| L1-SR-IJ-FL-62. **Male Circumcision Procedure –** Discuss risk reduction methods if abstinence is absolutely not possible: masturbation poses less risk than sexual intercourse; use a condom if intercourse is not avoidable, but note any type of sexual activity may result in complications or prolong wound healing. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-63. **Male Circumcision Procedure –** Instruct client to keep the dressing dry. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-64. **Male Circumcision Procedure –** Remind client to return for follow-up after 2 days or any time he has a concern. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-65. **Male Circumcision Procedure –** Instruct client to wash normally using soap and clean water from the third day onward. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-66. **Male Circumcision Procedure –** Instruct client not to apply any home remedies or traditional medicines, such as herbal remedies, ash, or animal dung, as these can increase chances of tetanus, which can be fatal. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-67. **Male Circumcision Procedure –** Complete the follow-up notes section of the VMMC Client Record. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-68. **Male Circumcision Procedure –** Record any complications or adverse events on the MC Client Record and Adverse Event Recording Form. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-69. **Male Circumcision Procedure –** If age appropriate and/or sexually active client, provide condoms. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| L1-SR-IJ-FL-70. **Male Circumcision Procedure –** Review and reinforce HIV prevention messages. | **Y** |  | | |  | |  |
| **N** |  | | |  | |
| **N/A** |  | | |  | |
| **Additional Comments/Notes:** | | | | | | | |