|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Voluntary Medical Male Circumcision (VMMC) Continuous Quality Improvement (CQI)**    **Level 3 – Quality of Program**  **Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reviewer’s Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | |
| **Key Functions** | | | | | | | | | | | | | |
| This section assesses standards to ensure:   * Data are used for planning and improvement of service delivery * Moderate and severe adverse events or complications are reviewed * The facility has a functional supply and equipment ordering system   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”. | | | | | | | | | | | | | |
| *Verify the following:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.1. **Key Functions** – Functional quality improvement team (team structure). | | |  |  | |  |  | | | | | | |
| L3.2. **Key Functions** – Evidence that meetings are held at least monthly to review data. | | |  |  | |  |  | | | | | | |
| L3.3. **Key Functions** – Evidence that changes been made to services based on these data. | | |  |  | |  |  | | | | | | |
| L3.4. **Key Functions** – Client satisfaction survey or other form of client feedback process is planned / implemented at least twice a year. | | |  |  | |  |  | | | | | | |
| L3.5. **Key Functions** – Adverse events forms are available on site. | | |  |  | |  |  | | | | | | |
| L3.6. **Key Functions** – Adverse events forms are being filled in, filed and stored for management review. | | |  |  | |  |  | | | | | | |
| L3.7. **Key Functions** – There is a written procedure or algorithm available for classifying, documenting and managing adverse events (including emergency complications and life-support measures) in the areas where VMMC and clinical care are provided at the facility (SIMS 5.3, Q3). | | |  |  | |  |  | | | | | | |
|  | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.8. **Key Functions** – There are meeting minutes from a facility-level AE review committee with notes reflecting that all moderate/severe AEs are reviewed at least monthly and corrective actions have been taken (as necessary) (SIMS 5.3, Q4). | | |  |  | |  |  | | | | | | |
| L3.9. **Key Functions** – A systematic process exists for investigating moderate or severe adverse events to determine causes and outcomes | | |  |  | |  |  | | | | | | |
| L3.10. **Key Functions** – Actions have been taken to prevent a repeat of documented adverse events or determine if adverse events were handled properly | | |  |  | |  |  | | | | | | |
| *Verify the following:* | | |  |  | |  |  | | | | | | |
| L3.11. **Key Functions** – All VMMC instruments, medicines and supplies are integrated into routine forecasting, procurement and management systems | | |  |  | |  |  | | | | | | |
| L3.12. **Key Functions** – Requisition forms for VMMC commodities are available and used | | |  |  | |  |  | | | | | | |
| L3.13. **Key Functions** – Minimum stock levels are established for essential VMMC commodities (at the VMMC service or facility level) | | |  |  | |  |  | | | | | | |
| L3.14. **Key Functions** – Commodity stocks records are kept up-to-date | | |  |  | |  |  | | | | | | |
| L3.15. **Key Functions** – Facility stock-outs of key commodities are reported to management | | |  |  | |  |  | | | | | | |
| **Management Systems** | | | | | | | | | | | | | |
| This section assesses standards to ensure:   * Relevant VMMC Policies, Guidelines and Standards are available and staff are aware of them * The VMMC clinic is able to meet demand for services * The VMMC clinic or facility has clearly defined staff roles and responsibilities * Clear delineation of catchment population to be served * The VMMC clinic or facility has the human resources available to operate VMMC services   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”. | | | | | | | | | | | | | |
| *Verify the availability and knowledge of the following documents (latest):* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.16. **Management Systems** – Patient rights in local language(s) publicly visible | | |  |  | |  |  | | | | | | |
|  | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.17. **Management Systems** – Staff job descriptions | | |  |  | |  |  | | | | | | |
| L3.18. **Management Systems** – Written guidance on informed consent process (SIMS 5.4, Q3) | | |  |  | |  |  | | | | | | |
| L3.19. **Management Systems** – HIV/AIDS Risk reduction counseling guidelines | | |  |  | |  |  | | | | | | |
| L3.20. **Management Systems** – National HIV testing services guidelines (job aid or poster alone is not sufficient). | | |  |  | |  |  | | | | | | |
| L3.21. **Management Systems** – National STI diagnosis and treatment guidelines – Are national guidelines available on site? | | |  |  | |  |  | | | | | | |
| L3.22. **Management Systems** – Waste management SOP (includes disposal of biohazardous and non-biohazardous waste and disposable instruments) | | |  |  | |  |  | | | | | | |
| L3.23. **Management Systems** – Blank (unused) client record forms | | |  |  | |  |  | | | | | | |
| L3.24. **Management Systems** – Infection prevention and control protocols | | |  |  | |  |  | | | | | | |
| L3.25. **Management Systems** – Blood-borne Pathogen Exposure SOP, including PEP | | |  |  | |  |  | | | | | | |
| L3.26. **Management Systems** – VMMC Surgical Manual (WHO or national adaptation) | | |  |  | |  |  | | | | | | |
| L3.27. **Management Systems** – Immediate post-operative care guidelines (These may be within the surgical manual). | | |  |  | |  |  | | | | | | |
| L3.28. **Management Systems** – Post-operative (return visit) follow-up protocol (These may be within the surgical manual). | | |  |  | |  |  | | | | | | |
| L3.29. **Management Systems** – Post-operative written instructions for clients | | |  |  | |  |  | | | | | | |
| L3.30. **Management Systems** – Guidelines or Protocols for Medical Emergencies (anaphylaxis, etc.) | | |  |  | |  |  | | | | | | |
| L3.31. **Management Systems** – Minutes from quality improvement team meetings | | |  |  | |  |  | | | | | | |
| L3.32. **Management Systems** – Guidelines/SOPs on monitoring, reporting and management of device-related AEs available on site (may be included in the PrePex/ShangRing guidelines), as applicable. | | |  |  | |  |  | | | | | | |
| L3.33. **Management Systems** – Care instructions for clients while wearing a device (PrePex or ShangRing, as applicable) are available on site for the client to take home. | | |  |  | |  |  | | | | | | |
| L3.34. **Management Systems** – Care instructions for clients after removal of a device (PrePex or ShangRing) are available on site for the client to take home. | | |  |  | |  |  | | | | | | |
| *Verify the following:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.35. **Management Systems** – Documentation of the circumcisions performed in the last quarter | | |  |  | |  |  | | | | | | |
| L3.36. **Management Systems** – It is clear to clients when site is open for circumcision (daily or designated schedule | | |  |  | |  |  | | | | | | |
| L3.37. **Management Systems** – Written roles and responsibilities (job descriptions are sufficient) for all staff involved in male circumcision services | | |  |  | |  |  | | | | | | |
| L3.38. **Management Systems** – Catchment area map available and well displayed | | |  |  | |  |  | | | | | | |
| *Indicate if there are full-time staff working in the roles listed below (some staff may be filing multiple roles but only count each staff member one time):* | | | **Y** | **N** | | **Category** | | | **Number** | | | **Trained** | |
| **Y** | **N** |
| L3.39. **Management Systems** – Site managers | | |  |  | |  | | |  | | |  |  |
| L3.40. **Management Systems** – VMMC providers | | |  |  | |  | | |  | | |  |  |
| L3.41. **Management Systems** – VMMC assistants | | |  |  | |  | | |  | | |  |  |
| L3.42. **Management Systems** – Pre- and post-operative care clinicians | | |  |  | |  | | |  | | |  |  |
| L3.43. **Management Systems** – Hygienists/cleaners/infection prevention officers | | |  |  | |  | | |  | | |  |  |
| L3.44. **Management Systems** – Counselors | | |  |  | |  | | |  | | |  |  |
| L3.45. **Management Systems** – Community health workers | | |  |  | |  | | |  | | |  |  |
| L3.46. **Management Systems** – Runners | | |  |  | |  | | |  | | |  |  |
| L3.47. **Management Systems** – Data clerks | | |  |  | |  | | |  | | |  |  |
| L3.48. **Management Systems** – Receptionists | | |  |  | |  | | |  | | |  |  |
| *Verify the following:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.49. **Management Systems** – Client flow was free of bottlenecks that would be caused by insufficient staffing in one area. | | |  |  | |  |  | | | | | | |
| **Monitoring & Evaluation** | | | | | | | | | | | | | |
| This section assesses standards to ensure:   * Availability of relevant tools for VMMC data management * Client records are complete with all relevant VMMC tools for data management * Client records correspond with all relevant VMMC tools for data management   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”. | | | | | | | | | | | | | |
| *Verify the availability of the following documents with an entry in the last month:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.50. **Monitoring & Evaluation** – VMMC register | | |  |  | |  |  | | | | | | |
| L3.51. **Monitoring & Evaluation** – HTS Register | | |  |  | |  |  | | | | | | |
| L3.52. **Monitoring & Evaluation** – Adverse Event Register | | |  |  | |  |  | | | | | | |
| L3.53. **Monitoring & Evaluation** – AE register indicating which clients were referred for AEs, documenting outcomes (Reviewer should verify the documentation of the resolution of an AE) | | |  |  | |  |  | | | | | | |
| *Select a random sample of 5 client records and verify: All 5 VMMC Clients Records are completely and correctly filled, using the following checklist. Mark “Yes” if the field is filled on the client form, “No” if not completed, and “N/A” if not applicable (selected questions only):* | | | | | | | | | | | | | |
| **Client records** | | **1** | | | **2** | | | **3** | | **4** | **5** | | |
| L3.54. **Monitoring & Evaluation** – Age (in years) | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.55. **Monitoring & Evaluation** – Result of documented HIV test or refusal | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.56. **Monitoring & Evaluation** – Signed consent form by client (if adult) or parent/guardian (if minor) (*Note: May include thumbprints for those unable to write)* | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.57. **Monitoring & Evaluation** – Medical history | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.58. **Monitoring & Evaluation** – Blood pressure | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.59. **Monitoring & Evaluation** – Weight | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.60. **Monitoring & Evaluation** – Temperature | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.61. **Monitoring & Evaluation** – VMMC method | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.62. **Monitoring & Evaluation** – Date of procedure documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.63. **Monitoring & Evaluation** – Name of the provider | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| **Client records** | | **1** | | | **2** | | | **3** | | **4** | **5** | | |
| L3.64. **Monitoring & Evaluation** – Anesthetic type (e.g., lidocaine, or lidocaine and bupivacaine) (*If topical/device was used, skip to L3.68*) | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.65. **Monitoring & Evaluation** – Anesthetic strength | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.66. **Monitoring & Evaluation** – Anesthetic volume | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.67. **Monitoring & Evaluation** – Documentation of presence or absence of intra-operative adverse events | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.68. **Monitoring & Evaluation** – Documentation of presence or absence of post-operative adverse events | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.69. **Monitoring & Evaluation** – Device size used (*if no device, skip to question L3.75*) | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.70. **Monitoring & Evaluation** – Device batch documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.71. **Monitoring & Evaluation** – Date of placement documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.72. **Monitoring & Evaluation** – Date of removal documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.73. **Monitoring & Evaluation** – Presence or absence of adverse events at placement documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| **Client records** | | **1** | | | **2** | | | **3** | | **4** | **5** | | |
| L3.74. **Monitoring & Evaluation** – Presence or absence of adverse events at removal documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.75. **Monitoring & Evaluation** – Presence or absence of adverse events at follow up visit documented (if follow up visit occurred) | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| N/A |  | | |  | | |  | |  |  | | |
| L3.76. **Monitoring & Evaluation** – At least one follow-up visit by the client is documented | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| *Select a random sample of 5 client records and verify whether relevant data elements are consistent across the following documents:* | | | | | | | | | | | | | |
| **Clients** | | **1** | | | **2** | | | **3** | | **4** | **5** | | |
| L3.77. **Monitoring & Evaluation** – VMMC Client Form/File | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.78. **Monitoring & Evaluation** – VMMC Register | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.79. **Monitoring & Evaluation** – HTS Register | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.80. **Monitoring & Evaluation** – Adverse Events Register | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| L3.81. **Monitoring & Evaluation** – VMMC Follow Up Registers | Yes |  | | |  | | |  | |  |  | | |
| No |  | | |  | | |  | |  |  | | |
| *Verify the evidence of the following:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.82. **Monitoring & Evaluation** – Facility provides M&E training or refresher training for VMMC Program/M&E staff | | |  |  | |  |  | | | | | | |
| L3.83. **Monitoring & Evaluation** – Client data confidentiality policy and procedures | | |  |  | |  |  | | | | | | |
| L3.84. **Monitoring & Evaluation** – There is a computerized system that assists staff in capturing, managing and analyzing data | | |  |  | |  |  | | | | | | |
| L3.85. **Monitoring & Evaluation** – There is a systematic process of ensuring data quality control at all levels of implementation, including spot checks or validation rules | | |  |  | |  |  | | | | | | |
| L3.86. **Monitoring & Evaluation** – A data clerk or M&E officer reviews records for completeness on a daily basis | | |  |  | |  |  | | | | | | |
|  | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.87. **Monitoring & Evaluation** – There is a documented data management process that helps reporting requirements to be met (for example establishing responsibilities and timelines for data capture) | | |  |  | |  |  | | | | | | |
| L3.88. **Monitoring & Evaluation** – The facility regularly (minimum monthly) analyzes reports and data received in order to assess achievements and challenges | | |  |  | |  |  | | | | | | |
| L3.89. **Monitoring & Evaluation** – Age-disaggregated data are included in this analysis | | |  |  | |  |  | | | | | | |
| L3.90. **Monitoring & Evaluation** – Information monitoring system assists the facility in decision-making and planning | | |  |  | |  |  | | | | | | |
| **Waste Management** | | | | | | | | | | | | | |
| This section assesses standards to ensure:   * Waste is disposed of / handled appropriately * The system for interim waste storage is appropriate * The facility ultimately disposes of waste properly (may not be observed at the same time as other standards given disposal may be off site)   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”. | | | | | | | | | | | | | |
| *Observe whether medical waste is transported to the interim storage area or for disposal in adequate closed containers:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.91. **Waste Management** – Sharps in puncture-resistant containers (heavy card box, hard plastic or can containers) | | |  |  | |  |  | | | | | | |
| L3.92. **Waste Management** – Sharps containers are not emptied and reused | | |  |  | |  |  | | | | | | |
| L3.93. **Waste Management** – Other medical waste (e.g., used cotton rolls, gauze, dressing, etc.) kept in leak-proof containers | | |  |  | |  |  | | | | | | |
| L3.94. **Waste Management** – General waste is collected from all areas in adequate closed containers and transported to the interim storage area or for disposal | | |  |  | |  |  | | | | | | |
| *Observe whether housekeeping personnel do the following:* | | |  |  | |  |  | | | | | | |
| L3.95. **Waste Management** – Wash hands with running water and soap for 40-60 seconds and dry with an individual clean towel, paper towel or allows hands to air-dry, OR rub hands with 3–5 ml of an alcohol-based solution 15-30 seconds | | |  |  | |  |  | | | | | | |
| *Verify whether:* | | | **Y** | **N** | | **N/A** | **Notes** | | | | | | |
| L3.96. **Waste Management** – Contaminated waste doesn't cross path with clients and providers | | |  |  | |  |  | | | | | | |
| L3.97. **Waste Management** – The interim storage area is locked or contains a clear sign indicating entry is prohibited for general staff, patients/clients and visitors | | |  |  | |  |  | | | | | | |
| L3.98. **Waste Management** – Containers are leak-proof and closed with tight lids | | |  |  | |  |  | | | | | | |
| L3.99. **Waste Management** – There is no waste sticking out of the containers | | |  |  | |  |  | | | | | | |
| L3.100. **Waste Management** – The disposal sites are well-secured (fenced, locked) and away from traffic | | |  |  | |  |  | | | | | | |
| L3.101. **Waste Management** – Disposal sites are well-situated (avoid residential areas) | | |  |  | |  |  | | | | | | |
| L3.102. **Waste Management** – There are appropriate personnel to manage the disposal sites | | |  |  | |  |  | | | | | | |
| L3.103. **Waste Management** – Disposal sites are properly managed (i.e., incinerator is run for right time at right temperature, buried wastes are not left in an open pit uncovered, etc.) | | |  |  | |  |  | | | | | | |
| L3.104. **Waste Management** – Used disposable MC kits are decontaminated in 0.5% chlorine solution for 10 minutes before disposal, or disposed of in leak-proof container before being incinerated | | |  |  | |  |  | | | | | | |
| L3.105. **Waste Management** – Are one of the below options available to dispose of used instruments?   * Burial of instruments in a secure instruments/sharps pits/concrete vaults * Transporting the instruments to a recycling / smelting facility * Specialized encapsulation | | |  |  | |  |  | | | | | | |
| **Additional Comments/Notes:** | | | | | | | | | | | | | |