Ministry of Health Safe Male Circumcision (SMC) Death Audit Report

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Forward

Uganda developed a policy on SMC, under which the scale-up of male circumcision is being conducted, but carefully observing clients’ safety. Non-surgical methods have previously been piloted for acceptability, and an evaluation of the first 1,000 circumcisions using Prepex under the “Adverse Events Surveillance Phase” following the WHO guidelines has recently been completed. Findings from this phase showed acceptable safety levels of the Prepex device, with an AE rate of 1.1% (11 AE cases). In the last four years, since 2010, just over two (2) million clients have been circumcised in Uganda, and four deaths after circumcision have recently been reported. The MOH has taken action in response to these four deaths and conducted death audits in order to better understand the underlying factors that may have led to these events among SMC clients.
Therefore, this report is a result of the audits and does provide some insights in the circumstance surrounding these four deaths. The report has been reviewed and the feedback discussed with a WHO team from Geneva, and OGAC during their November 2014 visit to Uganda. There has been a clear understanding that the available information only provides a glimpse of the issues of tetanus infection but with no conclusive evidence on the association with circumcision. An understanding has therefore been reached to conduct a more detailed assessment of the tetanus infection and its potential association with circumcision, because three out of the four reported deaths were diagnosed with tetanus infection.

Information accrued from the detailed assessment will help MoH develop guidelines and inform policy formulation for SMC implementation in the country.

Background

The Ministry of Health adopted SMC as one of the HIV prevention interventions after the 2007 WHO /UNAIDS recommendation. By the end of 2010, Uganda had only 9,137 SMC (~9% of the target), however within 4 years a total of 2 million circumcisions have been conducted as of October 2014.

By August 2014, only one death (1/1,823,479) related to circumcision had occurred and been reported suggesting acceptablesafety and quality of the SMC procedures in Uganda. The country has had two external quality assessments (EQAs) with one data quality assessment.
(DQA). These quality assessments were conducted by PEPFAR to ensure safety and quality of the SMC services offered. After the first EQA two IPs were funded to specifically monitor the quality and safety of SMC procedures of all the SMC IPs.

However, four (4) deaths related to SMC have been recently reported within 6 weeks (1\textsuperscript{st} September to 10\textsuperscript{th} October 2014). Two deaths occurred after conventional surgical method in two different facilities operated by the same IP and the other two after SMC with nonsurgical(Prepex) method. The cause of death was tetanus for three cases, while one was due to aspiration pneumonia secondary to anaphylactic shock. The safety monitoring team of the National Prepex Committee (NPC) has conducted the four deaths audits by visiting all the sites. It is hoped that these field visits will provide more insight and clearer background information of what happened so as to create more safety nets as the country continues to scale up this important intervention.

**Methodology**

When the MoH received death notification among the SMC clients, the safety monitoring team of the National Prepex Committee met to discuss the cases. An SMC-death audit form (see appendix) was developed to supplement the clinical notes from facilities that attended to the patients, as well as other information from the IPs who had conducted the circumcisions. The SMT visited the three IP sites (International Hospital-Kampala, Nyenga Hospital-Buikwe, and Villa Maria Hospital-Masaka) where a death had occurred among SMC-clients. At each of the three IP sites, the SMT-member held discussions about the deaths with the SMC-staff who included; surgeons, counselors, VHT, record’s officer and all other staff involved in the daily running of the SMC activities and those who participated in offering SMC service to the client who had dead. The SMC –death audit form provide clear guiding questions to elicit as much information as possible. The approach was a focus group discussion, which used both English and Luganda so as to ensure participation of all the group members. The SMT members also visited operation rooms were circumcisions are conducted for observational assessment of the environment where surgeries are done. With
varying circumstances, other data sources including listening to a recorded discussion between the IP and a grand-parent of clients, while a visit to the facility providing treatment and care of the tetanus patient was also done. It was not possible to visit the grieving relative where the patients resided because it was deemed unwise during the group discussions.

Information obtained from the group discussions, the observations conducted and the clinical notes was then triangulated and synthesized to inform this report, as shown in the findings below;
Findings of the SMC-death audits

Table showing a summary of the four SMC death audits as of November 15 2014

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Case # 1</th>
<th>Case # 2</th>
<th>Case # 3</th>
<th>Case # 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of circumcision</td>
<td>Prepex</td>
<td>Dorsal slit</td>
<td>Dorsal slit</td>
<td>Prepex</td>
</tr>
<tr>
<td>Date SMC conducted</td>
<td>Placement: 19th August 2014</td>
<td>16th September 2014, After mother’s consent and HIV-testing (Negative)</td>
<td>28th September 2014, Reviewed at 48 hours and at day 7</td>
<td>Placement: 27th September 2014, Early request October 2nd 2014</td>
</tr>
<tr>
<td>IP responsible for conducting the SMC</td>
<td>STAR-EC</td>
<td>Uganda Catholic Medical Bureau</td>
<td>Uganda Catholic Medical Bureau</td>
<td>IHK</td>
</tr>
<tr>
<td>Date of death</td>
<td>1st September 2014</td>
<td>16th September 2014</td>
<td>10th October 2014</td>
<td>10th October 2014</td>
</tr>
<tr>
<td>Place of death</td>
<td>Masafu Hospital</td>
<td>Nyenga Hospital</td>
<td>Villa Maria Hospital</td>
<td>Mulago Hospital</td>
</tr>
<tr>
<td>Notification of the SMC national coordinator</td>
<td>2nd September, 2014</td>
<td>October 31st 2014</td>
<td>October 17th 2014</td>
<td>28th October 2014</td>
</tr>
<tr>
<td>Name of person/client</td>
<td>R. M</td>
<td>Baby D.B</td>
<td>J B K</td>
<td>OR</td>
</tr>
<tr>
<td>Age</td>
<td>19 years</td>
<td>Infant, 8 weeks &amp; 4 days DoB 18th July 2014</td>
<td>11 Years</td>
<td>32 Years</td>
</tr>
<tr>
<td>Occupation</td>
<td>Brick Layer/subsistence Farmer</td>
<td>Infant</td>
<td>Pupil/Caretaker of aging Grandparents</td>
<td>Bodaboda Rider</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Tetanus</td>
<td>Aspiration pneumonia secondary to anaphylactic shock following SMC</td>
<td>Tetanus</td>
<td>Tetanus</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Medical history</td>
<td>Not known/ nothing was mentioned. The wound was clean after removal of the ring</td>
<td>During the MoH audit, information came up that infant had just been discharged from hospital due to complicated malaria 4 days prior to SMC. Immunization history is not known.</td>
<td>During the MoH audit, information came up that child’s grandfather revealed possible chronically ‘convulsions’ (ekimbekimukuba). Grandmother had died of tetanus around 1986 (28 years ago) (Need to contact mother’s for immunization card, but says he was fully immunized)</td>
<td>Patient was first diagnosed with HIV in 2008 with CD4 cell count of 30 cells/mm. He was enrolled on ART (Combivir and Nevarapine) in 2009. At his death he was on Combivir+Efavirenz with a CD4 cell count of 600. He was enrolled at AlIVE Medical Centre (within 200m from IHK) were he first reported with Tetanus. Immunization history is not known.</td>
</tr>
<tr>
<td>Social History</td>
<td>Hewasco-resident with his mother in Bugiri the district where SMC was conducted. Four days before he died he went to visit his paternal uncle (policeman), in a neighboring district. His father died earlier. His mother was very poor and the hygiene of their home was not good, living in a semipermanent structure with non-</td>
<td>Parents were adolescents from different ethnic backgrounds. The father wasn't circumcised and the grandmother blamed the mother for taking the infant for SMC. The mother is a stay home mom while the father works in Metha sugar plantations (as a porter).</td>
<td>Parents separated, but stay in Kampala working as casual laborers. Child has been staying with grandparents (both around 80 years) for the past 1 year. He was a pupil in P5, and he was the primary caretaker of his grandparents, who does almost all the household chores; grandmother is bedridden. The child was asked to wear a skirt for the first 3 days after SMC, yet he did not have an underwear/briefs. A non-constructed toilet was used as latrine (a hole with wooden logs)</td>
<td>He was not married though he had a non-co-resident girlfriend. His next of kin was his brother who was staying nearby. He was a Bodaboda rider renting a one room in Kisugu slum, a peri urban area. A close relative working with CDC-Uganda provided information about his death.</td>
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</tr>
<tr>
<td></td>
<td>cemented floor. Ronald’s mother was blamed for ‘causing’ his death.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Observations

Case # 1: 19 Year Old at Masafu Hospital, Tetanus after Prepex

- Patient used different names during SMC and during illness
- Patient was circumcised from Bugiri but died from a neighboring district, Busia
- He was bricklayer and a subsistence farmer
- Resident in a semi-permanent house with a mud floor, and co-resident with his mother
- VHT also indicated that the hygiene and sanitation at his mother’s home was poor
- On day 9 (2 days after device removal) he notified the VHT about a mild fever
- No information on history of immunization, or infestation history with jiggers
- At time of death, hospital indicates that wound was septic, although while at circumcising district during device removal the wound was clean, and mentioned no use of any traditional herbs, and no known wound
- He resumed work (brick Laying) and washed his body in swampy dirty water
- Died on 13th day after SMC with diagnosis as tetanus, in a neighboring district
- He was the 8th Patient to die of tetanus in Masafu Hospital in 2014. However, the previous 7 cases were not related to SMC
- Prior to his death he is reported to have joined a culture dance (Imbalu) for with his cousins. However they deny having applied any substances (such as local/traditional herbs or animal dung) on the wound
- It was noted that poor hygiene and sanitation, mud floor at his residence, and being a bricklayer may have increased this person’s exposure to the risk of tetanus

Case #2: Infant at Nyenga Hospital, Aspirational Pneumonia secondary to Anaphylactic shock
• An infant was circumcised in a camp setting
• Initially the patient chart didn't have weight and the staff agreed to having no weighing scale
• Possible anesthesia over dose since child’s weight seems to have been known but patient presented with anaphylactic shock signs and symptoms
• The Infant had been hospitalized with complicated malaria and discharged 4 days prior to the SMC
• SMC Protocol deviation was very clear in this case; circumcising of an infant during the campaign for SMC for HIV prevention, and lack of post-operative care during the first 30 minutes of the procedure
• Emergency kit at the camp-site lacked some vital equipment, and the whole emergency strategy for such cases is not well organized or coordinated
• Although the VHT advised the mother not to proceed with SMC because of the infant’s recent illness, this information was not picked up by the SMC-team prior to conducting the procedure; thus a complete medical history beyond what the SMC-form has was missed.
• Social background indicated that both parents are adolescents and of low social economic status; father 17 years and works in sugar plantation (as a porter), while mother is 16 years and is a home-maker
• None of the SMC hospital staff were SMC-trained, apart from the counselor; however, this counselor did not have a medical background
• Given the targets, other SMC circumcisers are usually hired from out (i.e. non hospital staff)
• So far the couple has experienced marital disruptions; the mother had been asked to vacate her home. However, the VHT has been able to counsel the family to stay together.
• Due diligence for a detailed medical review, and protocol deviation may have led to this unfortunate event

Case #3-11 y old Villa Maria Tetanus after Surgery

• The assent and consent on the SMC client’s form seem to be inconsistent with the client and guardian’s characteristics, suggesting absence of actual consent/assent
• Client was the care-taker of his aging (80+ years) sick grand parents
• The SMC coordinator at the hospital indicated that tetanus is quite common at the hospital, and that ~ 40% of the patients have jiggers
• Patient also had jiggers
• Patient put on a skirt for the first three days post operatively and patient had no underwear
• He first reported 9th day post operational day with neck pains, seen at OPD by non SMC staff
• Client came back the following day with worsened symptoms, and he was admitted
• This clear, appears to have had potential exposure including issues with personal hygiene and sanitation, and wounds (due to jiggers). This may have been worsened by his use of a skirt without underwear, and the non-clear follow-up guidelines for the SMC-clients within the first 6 weeks appear to have led to this unfortunate event.

Case #4- IHK 32 year Old, Tetanus after Prepex

• Patient’s age and name was different at IHK and Mulago where he died
• Delayed death notification, which occurred 18 days after his death
• Patient was HIV positive, on HAART with CD4 cell count of 600
• Although patient had a girlfriend they were not staying together and she was not mentioned as the next of kin

• No mention/documentation of SMC was made at the 2 clinics that first got in contact with the patients, until he got to Mulago national referral hospital.

• Patient’s tribe and religion were not documented; these may be important to track behavioral post –op

This case appears to have protocol deviation because an HIV+ person was not eligible for circumcision with prepex at this stage. No documentation on wound was available. However, he was residing in a slum and riding a boda-boda, which may have been a risk factor for injuries that could expose him to the tetanus. However, this is merely speculative.

Discussion

All the four deaths were in different regions of the country, Kampala (Central), Masaka (southern central), Buikwe (Eastern) and Busia (Mid Eastern). Two of the cases were after surgical and two were after Prepex, but Tetanus diagnosis was common in 3 of the 4 cases while the third was due to aspirational Pneumonia.

The three tetanus cases do not appear to have clear portal of entry for tetanus, poor hygiene and sanitation, jigger infestation, occupational hazard (including brick laying and motor cycle taxi-Bodaboda) may have increased their risk of tetanus infection. None of these cases had documented immunization history, which could further have made them more susceptible to tetanus infection. Given their social history the three tetanus cases come from low socio-economic environment.

Evidence of care and management of these patients appears to suggest that the care provided was not timely, and recommended tetanus treatment guidelines may not have been fully adhered to thus increasing the risk of deaths. It is important to note that the SMC facilities
were not the tetanus care providers because the patients did not make contact with the providers.

The background tetanus rates in the facilities were the patients died were reported to be high. This may suggests unknown risk exposures even in the absence of safe male circumcision.

The fourth case was an infant who was diagnosed with inspirational pneumenonia after being circumcised in an environment not recommended for clients of his age. The provider did not fully elicit the important medical history, which would have made this infant ineligible for male circumcision. The 8 weeks old baby had just been discharged from a health facility 4 days prior to the circumcision.

One of the key challenges among the SMC providers who had these cases was lack of SMC focused training. It is hoped that such trainings could reduce the potential and may be averted these cases.

In Uganda, a study on tetanus was conducted in St Francis Hospital Buluba (SFHB), a rural hospital in Southeastern Uganda, which reviewed in-patient registers for all patients admitted to the pediatrics and general medicine wards between January 2005 and December 2008. A total of 163 cases of tetanus representing a prevalence of 0.65% were reported. Mean of was 13.5 years and case-fatality of 47%. Three-quarters (76.1%) had wound as the portal of entry, Jiggers (12.6%) and these wounds were in the lower extremities in two thirds (66.2%) of the cases.

Studies conducted elsewhere that investigated the risk of circumcision and tetanus, tend to suggest that circumcision and occupational hazards including motorcycle taxis (boda-boda) are potential risk factors for the portal of entry for the tetanus infection (Sow et al (Dakar Med. 1993; 38(1): 55-9; Soumaré M et al (Bull SocPatholExot. 2008 Feb; 101(1): 54-7;

However, in all these studies nearly all patients were either unimmunized or had no evidence of ever receipt of immunization. Also the method of circumcision is likely to have been the traditional methods and mainly among young children whose exposure to poor sanitation and hygiene is usually high. In the Uganda study, circumcision was not mentioned, but two thirds (66%) of the wounds were in the lower extremities. Therefore lack of important confounders in these studies may weaken the observed evidence for the relationship between tetanus and circumcision, and has potential to misinterpret, and lead to inappropriate policy/program guidelines.

**Conclusion**

There is no sufficient evidence to suggest an association between circumcision (Prepex and Surgical) and tetanus infection in these settings. All facilities reported high background tetanus cases prior to SMC rollout in these environments. There was no documentation on portal of entry and their causes among these patients.

**Recommendations**

1. SMC stakeholders need to be addressed, may be funders and implementers separately
2. The quality of SMC services need to be monitored rigorously especially the moderate and severe AEs
3. A national AEs surveillance committee needs to be nominated to ensure regular monitoring and evaluations of these AEs
4. Prepex rollout should be closely monitored with proper documentation of all moderate and severe AEs
5. Ministry should ensure proper and close supervision of all SMC IPs with regular spot checks for safety and quality
6. Ministry should mobilize resources for SMC AEs surveillance, which should be independent from the IPs

7. Harmonize training, develop National training curriculum for all SMC training schools in the country to use and follow

8. National SMC website should be developed and linked to the Ministry of Health website

9. MoH should plan for studies to provide evidence for Tetanus immunization policy

10. SMC stakeholders should meet regularly to communicate/ update any relevant information about the SMC programme

Appendix

The four case summaries

**Tetanus Case 1:** This patient had Prepex placed in Bugiri yet he reported to facilities in another though nearby district, Busia. He was had the ring removed on the seventh day and he was again followed on the 9th day on which he complained of mild fever to which he was given paracetamol. It was further reported that this patient went back to brick laying after ring placement which could have been the time he contaminated the wound with soil which could have had tetanus spores. This patient used to stay with his mother since his father had died when she was an infant. At the time of his illness he has visited his paternal relatives who were very happy to see him, he was involved in a cultural dance with his cousins but the family members denied any use of herbs or other concoctions on the circumcision wound. The immunization history for this patient wasn’t known yet Busia district is known to have many tetanus cases though the patients are usually scrap mental dealers. He was the 8th patient to die of tetanus since the beginning of the year. This patient had no obvious portal of entry for tetanus though he had many factors that could have increased his risk to tetanus. These included dirty home environment, having returned to his brick-laying job, having been
involved in a cultural dance and having been circumcised with prepex thirteen days before his death.

**Tetanus Case 2:** The 32 year old ‘motorcycle taxis” Bodaboda rider who died from tetanus after Prepex placement. He was HIV positive though his CD4 cell count was 600 and was on HAART (Combivir and Nevarapine). This patient never went back to his hospital where he had received the SMC services but instead he went to his ART clinic that was about 200 metres. He was referred to three was hospitals before he finally ended in the National Referral hospital where he died 2 days after admission. During all this it was in the last facility that circumcision history was elicited which may mean that the health care workers don’t understand the linkage how circumcision can predispose a client to tetanus. While the patient was admitted in Mulago his care was not the best, he spent more than 38 hours on other wards where they don’t even provide a dark room although the diagnosis of tetanus was made. He was administered with medications that further suppressed his respiratory function, which is the usual cause of death to these patients. His social history was very had to elicit since he was staying alone and wasn’t married. During his illness he went to his ART clinic by himself that further limited what was documented since he started convulsing from the initial point of contact. This patient unlike the first case didn’t have any other obvious portal of entry for tetanus other than the circumcision wound, which was documented to be clean at the time of admission. Even though Prepex wasn’t supposed to be placed on HIV positive clients, this patient still had Prepex placed.

**Tetanus Case 3:** Though this patient had tetanus, it was after surgical circumcision and he died on the 12th day post-operative. This patient’ possible portal of entry for tetanus included multiple jigger wounds, circumcision wound since he put on a skirt without under wear during the first three days after surgery. Even though he was 11 years old, his immunization history wasn’t clear though his mother said that he was immunized there was no immunization card to confirm is immunization status. His grandmother died of tetanus 28 years ago. The home environment was very dirty which all may have predisposed this patient
to tetanus. The health care workers from the facility where this patient died from agree that tetanus cases are very common in this area but they said he was the first tetanus patient after being circumcised. This young boy had spent one year with his grandparents and he was their primary care taker, grandmother was bed ridden and both are above 80 years old.

Aspirational Pneumonia Death: Case 4
The infant died of aspirational pneumonia secondary to anaphylactic shock given the fact that he presented with difficulty in breathing yet if it was anaesthesia overdose he would have presented with heart failure signs and symptoms. The child’s actual age wasn’t captured and weight was not documented. This infant had been admitted and put on drip four days prior to being circumcised. SMC is for HIV prevention and the recommended age is 10 years and above. The policy says all but not for SMC and it’s safe for children to be circumcised in a camp with local anesthesia. Both parents were adolescents with uncircumcised father, but they hadn’t agreed on the infant getting circumcised. The mother took the child immediately after the procedure and only came back 15 minutes when the baby developed complications with breathing. The emergency team wasn’t coordinated which probably would have saved this baby’s life.
**SMC-Death Audit Form**

**Purpose:** SMC is a Public Health intervention for HIV prevention. If we are to provide safe and high quality SMC services, AE monitoring must be done regularly. This death audit tool seeks to explore the factors associated with the AEs with special emphasis on the following:

1. Are the service providers giving the needed care to the clients?
2. Are their client’s characteristics that may hinder wound healing?
3. Is the clients’ environment conducive for wound healing?
4. Are there cultural practices, norms and beliefs that may jeopardize personal hygiene and wound care?

<table>
<thead>
<tr>
<th>ID ____________________________</th>
</tr>
</thead>
</table>

**I Demographics**

Name
Age
Sex
Occupation
Address (Village, Parish, District)
Marital Status
No. of Spouses/partners
Tribe
Religion

**II Client’s Home Environment**

<table>
<thead>
<tr>
<th><strong>Housing condition/structure</strong></th>
<th>Comments/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the home permanent or temporary?</td>
<td></td>
</tr>
<tr>
<td>What is the floor made of? mud or cement</td>
<td></td>
</tr>
<tr>
<td>Does house have adequate ventilation</td>
<td></td>
</tr>
<tr>
<td>Any animals at home? Is living space shared with animals</td>
<td></td>
</tr>
<tr>
<td>Does home have a pit latrine, and hand washing facilities?</td>
<td></td>
</tr>
</tbody>
</table>
### III Health status of the dead person prior to death

<table>
<thead>
<tr>
<th>Questions</th>
<th>Response</th>
<th>Comments/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the deceased suffer from any health conditions within 3 months prior to death?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the deceased receiving any treatment/health care for this ailment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What were the source(s) of health care/treatment, including local/tradition treatment?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### IV Health of the other Family Members

At the time of death, was there anybody sick person in the family? If yes what is was the illness.

Have they ever lost any relative?

If yes, take the particulars of the dead and what did the person die of.

Do the family members regularly seek medical care?

### V SMC-Service Provider Characteristics

Name of circumciser:

Cadre

Roles of circumciser on the SMC team:

Is the provider trained to conduct SMC?

Where was the SMC provider trained?

How long has the SMC provider been offering SMC services?

### VI SMC- counsellor

Name of the counselor

Cadre

Roles of counselor on the SMC team:

Is counselor trained to conduct SMC counseling?

Where was the SMC counselor trained?

How long has the SMC provider been offering SMC counseling?

Does the counselor give post-operative care instructions?
How much is personal hygiene and wound care emphasized?
Does the counselor have/use IEC/BCC materials?

Vital Signs
NB: Get copy of the client form

VIII Observe and document the practices both at the client's home and the health facility
Acknowledgment
The SMT members acknowledge the following who provided them with technical guidance, and support before, during and after data collection of the SMC-death audit. We acknowledge IP who provided the financial support to enable this activity to bear fruit. Lastly we would like to thank all the IPs who continue to work hard towards maintaining the safety of all clients as the country scales up this important intervention. The following fulfill the acknowledgement criteria as indicated above; Dr. Aceng Jane Ruth the Director General of Health Services, Dr Alex Opio Commissioner of NCD, Dr Joshua Musinguzi, the ACP Manager PEPFAR- Uganda, Rakai Health Sciences program (for the funding the audits), all IPs, health facilities, districts and VHTs who participated in this important exercise, thank you.

References:

