

Efficacy of knowledge and competence-based training of non-physicians in the provision of early infant male circumcision using the Mogen clamp in Rakai, Uganda

Edward Nelson Kankaka*, Godfrey Kigozi*, Daniel Kayiwa*, Nehemiah Kighoma*, Frederick Makumbi*[†], Teddy Murungi*, Dorean Nabukalu*, Resty Nampijja*, Stephen Watya*, Daniel Namuguzi*[‡], Fred Nalugoda*, Gertrude Nakigozi*, David Serwadda*[†], Maria Wawer*[§] and Ronald H. Gray*[§]

*Rakai Health Sciences Program, Kalisizo, [†]School of Public Health, Makerere University College of Health Sciences, Kampala, [‡]Department of Surgery, Makerere University College of Health Sciences, Kampala, Uganda, and [§]Johns Hopkins University, Bloomberg School of Public Health, Baltimore, MD, USA

Objective

To assess acquisition of knowledge and competence in performing Early Infant Male Circumcision (EIMC) by non-physicians trained using a structured curriculum.

Subjects and Methods

Training in provision of EIMC using the Mogen clamp was conducted for 10 Clinical Officers (COs) and 10 Registered Nurse Midwives (RNMWs), in Rakai, Uganda. Healthy infants whose mothers consented to study participation were assigned to the trainees, each of whom performed at least 10 EIMCs. Ongoing assessment and feedback for competency were done, and safety assessed by adverse events.

Results

Despite similar baseline knowledge, COs acquired more didactic knowledge than RNMWs ($P = 0.043$). In all, 100 EIMCs were assessed for gain in competency. The greatest improvement in competency was between the first and third

procedures, and all trainees achieved 80% competency and retention of skills by the seventh procedure. The median (interquartile range) time to complete a procedure was 14.5 (10–47) min for the COs, and 15 (10–50) min for the RNMWs ($P = 0.180$). The procedure times declined by 2.2 min for each subsequent EIMC ($P = 0.005$), and rates of improvement were similar for COs and RNMWs. Adverse events were comparable between providers (3.5%), of which 1% were of moderate severity.

Conclusion

Competence-based training of non-physicians improved knowledge and competency in EIMC performed by COs and RNMWs in Uganda.

Keywords

EIMC, infant circumcision, Mogen clamp, Rakia, training non-physicians

Introduction

Early infant male circumcision (EIMC) is the most common neonatal surgical procedure in males [1]. It has also been incorporated as a component in combination HIV prevention in 14 Sub-Saharan African countries with high HIV prevalence and low circumcision coverage [2,3]. EIMC has advantages over adult circumcision due to lower adverse events (AEs), no risk of early resumption of sex, and potentially lower cost [4–6]. Sub-Saharan African countries have low physician coverage, but comparatively higher coverage of non-physicians who could facilitate roll out of circumcision

for HIV prevention. The major concern has been safety of the procedure and complications can be mitigated by adequate training using a structured curriculum [7–11] with a didactic and supervised practicum, step-by-step checklists, and immediate feedback from mentors. Anatomical models have also been shown to enhance trainee learning [12–15].

Providers' knowledge of both didactic material and practical skills is highly variable [16,17]. A South African study found that most providers knew that circumcision significantly reduced the risk of HIV acquisition in men, but most did not have the knowledge to communicate this to clients [18].

Common provider training deficiencies included screening for contraindications, provision of effective analgesia, and managing AEs [1,19–21].

A study in Zambia showed that nurse midwives and clinical officers (COs) could be trained to safely provide EIMC using the Mogen clamp [22]. However, there is a paucity of data on training of non-physicians in neonatal circumcision in sub-Saharan Africa.

Most safety studies have been conducted during routine service provision, and not during training. Complications included missed contraindications [21], inadequate pain control, loss of anatomical landmarks with use of anaesthetic cream [23], cosmetic problems [7,8,10,24–28], and bleeding [29,30]. A systematic review noted a higher likelihood of such complications with increasing infant age [7].

As preparation for a trial to assess the safety and acceptability of EIMC, we trained non-physicians to provide EIMC. The main objective was to impart knowledge and competency to perform EIMC. Here, we present results of training of the Registered Nurse-Midwives (RNMWs) and COs in provision of EIMC using the Mogen clamp.

Subjects and Methods

In all, 10 COs and 10 RNMWs with no prior training in EIMC were recruited from four government health centres in Rakai and Lyantonde Districts in Southwestern Uganda and trained in EIMC. COs are equivalent to a physician's assistant who receive 3 years of formal training, including surgery, and are licensed to perform minor surgery including circumcision. RNMWs have 3 years training in general nursing and obstetrics and are licensed to do episiotomies and repair first

and second degree tears during delivery, but are not trained or licensed to perform circumcision.

Qualified EIMC trainers, supervised by two experienced urologists, conducted the training using the WHO/JHPIEGO manual for EIMC [31].

Didactic training was conducted over 5 working days and training included: good clinical practice, informed consent, screening and enrolment, surgical anatomy of the infant penis and relevant applied anatomy with a focus on penile abnormalities (Figs 1 and 2), basic surgical skills including haemostasis and suturing, postoperative instructions and care, infection control, AE management, and emergency resuscitation. Interactive sessions, role plays, and case scenarios were used. Trainees were examined to assess their knowledge, before and after the didactic training. Passing the post-didactic test with a score of $\geq 80\%$ was required before proceeding to practical surgical training. For those who scored below the pass mark, the problematic areas were addressed to the satisfaction of the trainers, before they were allowed to progress to the practicum.

The hands-on surgical training was conducted at Kibuli Hospital and at the four study sites. Surgical skills were imparted by direct 'over-the-shoulder' observation and mentoring. Each trainee had to observe and assist in five EIMCs, and then perform a total of 10 supervised EIMCs. To evaluate competency, procedures 1, 3, 5, 7 and 9 performed by each trainee were assessed using a checklist for acquisition of skills including: education and screening, client preparation, surgical technique using the Mogen clamp, and postoperative care. Skill scores were graded as: 0 = poor, 1 = below average, 2 = average, 3 = above average or satisfactory. Remedial retraining was provided for deficient skills through coaching and immediate feedback. A trainee who was not competent by

Fig. 1 Sample pictures of contraindications for EIMC seen.

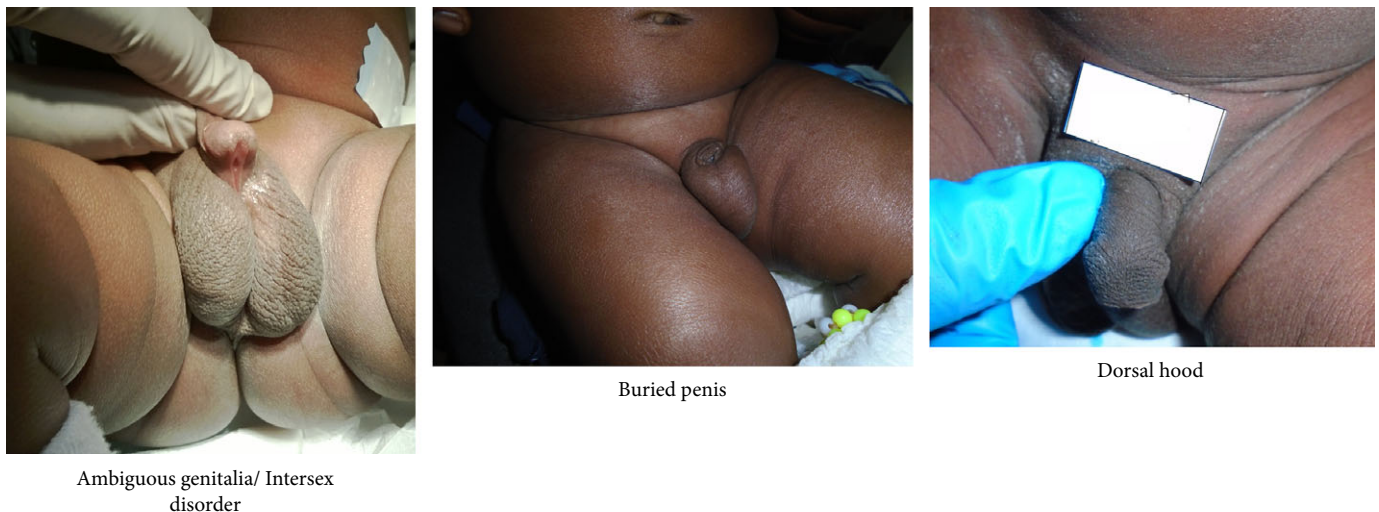


Fig. 2 Normal appearance of penis before, soon after circumcision, and a healed circumcised penis.



Neonatal Penis Before circumcision

Neonatal penis soon after circumcision

Healed penis by week 4 post circumcision

the ninth circumcision as assessed by a score of <80% was required to perform additional supervised procedures until they gained satisfactory skills. The Neonatal Infant Pain Scale (NIPS) was used for pain assessment [32]. Trainees who did not complete the training (three COs) were replaced with new trainees.

A study regulatory binder including a log of certified personnel, their valid registration licenses, and training assessments was maintained at the four study sites.

Mothers were approached in the antenatal, maternity, and postnatal units and provided with information on EIMC based on the WHO/JHPIEGO manual. Boys aged 1–28 days whose mothers were interested in EIMC were registered, the babies screened for eligibility and mother's written consent was obtained for circumcision. Mothers were encouraged to inform their spouses, but paternal consent was not required.

Infants were excluded if the mother was aged <18 years or was not competent to provide consent, the infant was aged >28 days, had a congenital anomaly, low birth weight (<2.5 kg), abnormal vitals, or current medical or surgical contraindications to EIMC.

Infants were assigned to a trainee who had performed the least number of procedures. For example, all trainees had to complete their third EIMC before any could proceed to their fourth procedure. Those waiting on others would participate in screening and assisting during the procedure in turns, so as to have similar number of assists and procedures among the COs and RNMWs.

Infants were given vitamin K (1 mg, i.m. injection) to minimise bleeding. An anaesthetic cream containing 2.5% lidocaine and 2.5% prilocaine was applied to the penis and an occlusive dressing applied for 60 min before circumcision. A 40 mg rectal paracetamol suppository was administered to minimise pain. Crying infants were de-stressed with up to 1 mL of 24% sucrose solution on a pacifier as needed. The infant was swaddled and placed on a strap board. All instruments were sterilised using standard hospital procedures. The penis, scrotum, adjacent areas were prepped with povidone iodine, and sterile drapes placed to allow the penis to protrude through a small fenestration. Haemostats were placed at the 3 and 9 o'clock positions and adhesions released with a blunt probe or small haemostats. With the prepuce in its natural position, a mark was made with a surgical pen or gentian violet along the coronal sulcus. With gentle traction on the haemostats, the glans was pushed below the mark by lightly pinching the prepuce, the Mogen clamp was placed from the 12 to the 6 o'clock position, with the curved/grooved surface facing the glans. The glans was palpated to ensure it was not trapped in the clamp and foreskin was aligned with the marked line. The clamp was closed for 5 min before excising the prepuce with a scalpel using the flat surface of the clamp as a guide. The clamp was then opened, and the glans delivered with gentle pressure at the penile base. Pure petroleum jelly was applied and the mother was instructed on how to apply the petroleum jelly, retract the penile skin to prevent adhesions, and was given sterile gauze dressings for replacement with every diaper change for the first 24 h. A hotline telephone contact was provided in case of any problems.

Mothers were called 24 h after the procedure to check on the infant and a review scheduled for any reported problems.

The study was reviewed and approved by Institutional Review Boards (IRBs) in Uganda and the USA (the Scientific and Ethics Committee, now renamed the Research Ethics Committee, of the Uganda Virus Research Institute; the Uganda National Council of Science and Technology; and the Johns Hopkins University, Bloomberg School of Public Health IRB). Maternal written informed consent was obtained and verbal consent obtained from the father if deemed necessary by the mother. Mothers received compensation of 10 000 Uganda shillings (~3 American dollars) for time, and a transportation refund.

Statistical analyses

The primary endpoint was achievement of competence to provide safe EIMC assessed by scored knowledge acquisition and from practical hands-on training. Analysis was performed for every other EIMC completed by a trainee for a total of five EIMCs per trainee, starting with the first EIMC. Scores were stratified by cadre, and the pass mark for competency set at 80%. Learning curves for each health worker were plotted. Multivariable analysis used a mixed effects model (xtmixed in Stata 13.1) to generate random effects at provider level with 95% CIs, accounting for variation within and between the providers. We measured the adjusted changes in scores.

Infant characteristics assessed before EIMC were compared between providers using the Wilcoxon rank-sum test. The NIPS total scores were classified as: 0 = no pain, 1–2 = mild, 3–4 = moderate, and 5–6 = severe. This was further categorised into two groups of no/mild pain (score 0–2) and pain (score 3–6). Bivariate analyses of the pain scores

stratified by cadre were assessed using chi-square tests before and during surgery. AEs were categorised according to WHO/JHPIEGO guidelines. Analyses were performed using Stata 13.1 (Stata Corp LP, College Station, TX, USA).

Results

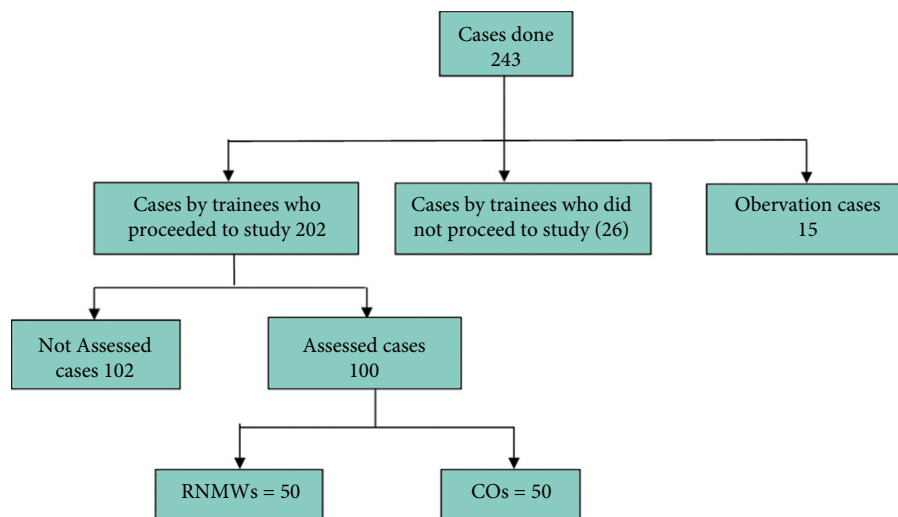
The baseline knowledge of the COs and RNMWs of EIMC was similar, but COs' knowledge scores were significantly higher than the RNMWs after didactic training ($P = 0.043$). Only 20% of the COs and 10% of the RNMWs scored $\geq 80\%$ before didactic training compared with 100% and 60%, respectively after didactic training ($P = 0.043$, Table 1). The four RNMWs, who scored $<80\%$ in the post-didactic test had scores of 76%, 76%, 76% and 78% and were mentored until the senior trainers allowed them to proceed to the practicum. No additional tests were administered as individual scores were close to the required pass mark.

Figure 3 shows the EIMC and assessment flow by cadre. In all, 243 infants were screened and their caretakers consented to study participation. Most of the infants (202/243) were circumcised by trainee COs (100) and RNMWs (102) who

Table 1 Knowledge assessment before and after the didactic sessions.

Competency	Study arm, <i>n</i>			<i>P</i>
	CO (<i>N</i> = 10), <i>n</i>	RNMW (<i>N</i> = 10), <i>n</i>	Total (<i>N</i> = 20), <i>n</i> (%)	
Before training				
<80%	8	9	17 (85)	0.500
$\geq 80\%$	2	1	3 (15)	
After training				
<80%	0	4	4 (20)	0.043
$\geq 80\%$	10	6	16 (80)	

Fig. 3 Flow of infants participating in the EIMC training.



had completed training. In all, 15 infants were circumcised by trainers as observational cases, and 26 were circumcised by three CO trainees who did not complete the training due to change in job assignments. Two RNMWs performed an extra procedure each; one had not satisfied the trainer on the

Table 2 The infants' preoperative characteristics by arm.

Characteristics	RNMW	CO	P (rank sum)
Total number	50	50	
Median (IQR [Q1, Q3])			
Temperature, °C	36.6 (0.6 [36.4, 37.0])	36.6 (0.5 [36.8, 36.3])	0.909
Respiratory rate, breaths/min	52.0 (14.0 [46.0, 60.0])	56.0 (12.0 [47.0, 59.0])	0.498
Weight, kg	3.8 (1.1 [3.1, 4.3])	3.7 (0.8 [3.4, 4.2])	0.817

Table 3 Pain scores during surgery.

Pain during surgery	RNMW, n (%)	CO, n (%)	Total, n (%)	P (chi-squared)
No pain	8 (21.1)	9 (22.5)	17 (21.8)	0.887
Pain	30 (78.9)	31 (77.5)	61 (78.2)	
Total	38 (100.0)	40 (100.0)	78 (100.0)	

Table 4 Reported AEs during training.*

Cadre	Description	Severity
CO	Insufficient skin removal	Mild
RNMW	Insufficient skin removal	Moderate
CO	Foreskin swelling [†]	Mild
CO	Foreskin swelling [†]	Mild
RNMW	Foreskin swelling [†]	Mild
RNMW	Foreskin swelling [†]	Mild
CO	Penile skin swelling [‡]	Moderate

*Two infants whose mothers reported 'unsatisfactory skin removal' were not verifiable because physical review, with repeated attempt, was futile for these infants. [†]Foreskin swelling was noted to be a result of topical cream applied to the inner foreskin, especially early in the training (Fig. 4). This was stopped, and no further similar events were noted.

Fig. 4 Swelling of penis (first image) and swelling of foreskin (second image) after lignocaine/prilocaine topical cream.



particular step of glans delivery, while the other performed the extra procedure only because a mother's request to have her eligible infant circumcised was granted. There were no differences in preoperative temperature, respiratory rate, and weight among infants assigned to each cadre (Table 2)

During the first three EIMC procedures improvement in competency scores was rapid and similar among COs (+5.87 points, 95% CI 3.14–8.60) and RNMWs (+7.9 points, 95% CI 5.89–9.86). The rate of improvement during the subsequent procedures was modest for COs (+2.12, 95% CI 0.48–3.77) and RNMWs (+1.24, 95% CI 0.04–2.45). There were no differences in NIPS scores between COs and RNMWs (Table 3).

The median [interquartile range (IQR)] time required for circumcision was 14.5 (10, 47) min for COs compared and 15 (10, 50) min for the RNMWs.

One screening error occurred where an infant with a congenital buried penis was circumcised. The anomaly was later corrected by a urologist.

Overall, the AE rate was 3.5% and of these two (1.0%) were moderate (Table 4) (Fig. 4). The number of insufficient skin removals was the same for COs (one) and RNMWs (one). Two infants whose mothers reported 'unsatisfactory skin removal' were not verified by a physical examination. If these were included, the overall AE rate would be 4.5%.

Discussion

Didactic training of COs and RNMWs showed improved knowledge scores, which were more pronounced among COs than RNMWs. There was also rapid improvement in competency of EIMC; by the fifth procedure >90% were judged to be competent and by the tenth procedure, all were classified as competent. There were no differences between COs and RNMWs for the time required for surgery, NIP scores or AEs. Foreskin swelling was due to topical anaesthetic cream, which has been reported with lignocaine/

prilocaine topical cream [23,33–35]. Application of the cream to the inner mucosa at the foreskin tip was stopped, and no further similar events were noted.

The combined analgesia using lignocaine/prilocaine cream, rectal paracetamol and 24% sucrose ameliorated but did not eliminate pain.

There are limitations to the present study. This was not a randomised trial, but infant characteristics were comparable between the two cadres suggesting no bias in the allocation of cases. Scoring of only half (five out of 10) of the procedures may incompletely capture trainee performance, but this was comparable between cadres. Follow-up at the 24-h maternal call was passive, and some AEs might have been missed, but this would affect both cadres equally. The NIPS parameters are subjective and may not reflect changes in pain during specific components of the procedure.

In conclusion, our present findings show that COs and RNMWs can acquire knowledge and gain competency in provision of EIMC using a structured curriculum with ‘over-the-shoulder’ mentoring and timely feedback.

Acknowledgements

This training was funded by the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID) grant 5U01A1100031-02. We wish to thank the health units and patients who participated, the Uganda Nurses and Midwives Council and the Ugandan Ministry of Health for their support.

Conflicts of Interest

Ronald H. Gray received a grant from the NIH/NIAID for this study. However, the sponsors had no input in preparation of manuscript or decision to publish. Other authors have nothing to disclose.

References

- Demaria J, Abdulla A, Pemberton J, Raeas A, Braga LH. Are physicians performing neonatal circumcisions well-trained? *Can Urol Assoc J* 2013; 7: 260–4
- World Health Organization (WHO)/UNAIDS. New Data on Male Circumcision and HIV Prevention: Policy and Programme Implications. Montreux, 6–8 March 2007. Available at: http://apps.who.int/iris/bitstream/10665/43751/1/9789241595988_eng.pdf. Accessed October 2016
- UNAIDS. Getting to Zero: HIV in Eastern & Southern Africa. Regional Report 2013. Available at: <http://www.unicef.org/esaro/Getting-to-Zero-2013.pdf>. Accessed October 2016
- Binagwaho A, Pegurri E, Muita J, Bertozzi S. Male circumcision at different ages in Rwanda: a cost-effectiveness study. *PLoS Med* 2010; 7: e1000211
- Kalichman SC. Neonatal circumcision for HIV prevention: cost, culture, and behavioral considerations. *PLoS Med* 2010; 7: e1000219
- Schoen EJ, Colby CJ, To TT. Cost analysis of neonatal circumcision in a large health maintenance organization. *J Urol* 2006; 175: 1111–15
- Weiss HA, Larke N, Halperin D, Schenker I. Complications of circumcision in male neonates, infants and children: a systematic review. *BMC Urol* 2010; 10: 2
- Ekenze SO, Ezomike UO. Complications of neonatal circumcision requiring surgical intervention in a developing country. *J Trop Pediatr* 2013; 59: 292–7
- Chandran L, Latorre P. Neonatal circumcisions performed by pediatric residents: implementation of a training program. *Ambul Pediatr* 2015; 2: 470–4
- Pieretti RV, Goldstein AM, Pieretti-Vanmarcke R. Late complications of newborn circumcision: a common and avoidable problem. *Pediatr Surg Int* 2010; 26: 515–18
- Ekenze SO, Ugwu JO, Onumaegbu OO. Evaluation of neonatal circumcision training for resident doctors in a developing country. *J Pediatr Urol* 2015; 11: 263.e1–6.
- Erickson SS. A model for teaching newborn circumcision. *Obstet Gynecol* 1999; 93: 783–4
- Brill JR, Wallace B. Neonatal circumcision model and competency evaluation for family medicine residents. *Fam Med* 2007; 39: 241–3
- Roca P, Alvarado C, Stausmire JM, Farooq S, Hill-Engstler EA. Effectiveness of a simulated training model for procedural skill demonstration in neonatal circumcision. *Simul Healthc* 2012; 7: 362–73
- Smith A, Maizels M, Korets R, et al. A novel method of teaching surgical techniques to residents—computerized enhanced visual learning (CEVL) with simulation to certify mastery of training: a model using newborn clamp circumcision. *J Pediatr Urol* 2013; 9: 1210–13
- Starzyk EJ, Kelley MA, Caskey RN, Schwartz A, Kennelly JF, Bailey RC. Infant male circumcision: healthcare provider knowledge and associated factors. *PLoS ONE* 2015; 10: e0115891
- Howard CR, Howard FM, Garfunkel LC, de Blicke EA, Weitzman M. Neonatal circumcision and pain relief: current training practices. *Pediatrics* 1998; 101: 423–8
- Milford C, Rambally L, Mantell JE, Kelvin EA, Mosery NF, Smit JA. Healthcare providers’ knowledges, attitudes and practices towards medical male circumcision and their understandings of its partial efficacy in HIV prevention: Qualitative research in KwaZulu-Natal, South Africa. *Int J Nurs Stud* 2016; 53: 182–9
- Le B, Sharma V, Kim D, Dupree J, Maizels M. Routine neonatal circumcision: opportunities for improving residency training. *J Pediatr Urol* 2013; 9: 605–8
- Yawman D, Howard CR, Auinger P, Garfunkel LC, Allan M, Weitzman M. Pain relief for neonatal circumcision: a follow-up of residency training practices. *Ambul Pediatr* 2006; 6: 210–14
- Langer JC, Coplen DE. Circumcision and pediatric disorders of the penis. *Pediatr Clin North Am* 1998; 45: 801–12
- Bowa K, Li MS, Mugisa B, et al. A controlled trial of three methods for neonatal circumcision in Lusaka, Zambia. *J Acquir Immune Defic Syndr* 2013; 62: e1–6
- Plank RM, Kubiak DW, Abdullahi RB, et al. Loss of anatomical landmarks with eutectic mixture of local anesthetic cream for neonatal male circumcision. *J Pediatr Urol* 2013; 9: e86–90
- Ponsky LE, Ross JH, Knipper N, Kay R. Penile adhesions after neonatal circumcision. *J Urol* 2000; 164: 495–6
- Hadidi AT. Buried penis: classification surgical approach. *J Pediatr Surg* 2014; 49: 374–9

- 26 Plank RM, Ndubuka NO, Wirth KE, et al. A randomized trial of Mogen clamp versus Plastibell for neonatal male circumcision in Botswana. *J Acquir Immune Defic Syndr* 2013; 62: e131–7
- 27 Bergeson PS, Hopkin RJ, Bailey RB, McGill LC, Piatt JP. The inconspicuous penis. *Pediatrics* 1993; 92: 794–9
- 28 Eroğlu E, Bastian OW, Ozkan HC, Yorukalp OE, Goksel AK. Buried penis after newborn circumcision. *J Urol* 2009; 181: 1841–3
- 29 Plank RM, Steinmetz T, Sokal DC, Shearer MJ, Data S. Vitamin K deficiency bleeding and early infant male circumcision in Africa. *Obstet Gynecol* 2013; 122: 503–5
- 30 Puckett RM, Offringa M. Prophylactic vitamin K for vitamin K deficiency bleeding in neonates. *Cochrane Database Syst Rev* 2000;4:CD002776.
- 31 World Health Organization (WHO) and Jhpiego. Manual for early infant male circumcision under local anaesthesia, 2010. Available at: http://apps.who.int/iris/bitstream/10665/44478/1/9789241500753_eng.pdf. Accessed October 2016
- 32 University of California Los Angeles (UCLA). Pain Assessment Tools: Neonatal/Infant Pain Scale (NIPS). Available at: http://www.anes.ucla.edu/pdf/assessment_tool-nips.pdf. Accessed August 2016.
- 33 Buckley MM, Benfield P. Eutectic lidocaine/prilocaine cream. A review of the topical anaesthetic/analgesic efficacy of a eutectic mixture of local anaesthetics (EMLA). *Drugs* 1993; 46: 126–51
- 34 Villada G, Zetlaoui J, Revuz J. Local blanching after epicutaneous application of EMLA cream. A double-blind randomized study among 50 healthy volunteers. *Dermatologica* 1990; 181: 38–40
- 35 Russell CT, Chaseling J. Topical anaesthesia in neonatal circumcision: a study of 208 consecutive cases. *Aust Fam Physician* 1996; Suppl. 1: S30–4

Correspondence: Edward Nelson Kankaka, Rakai Health Sciences Program, P.O. Box 279, Kalisizo, Uganda.

e-mails: ekankaka@rhsp.org; ken1edd@gmail.com

Abbreviations: AE, adverse event; CO, Clinical Officer; IQR, interquartile range; RNMW, Registered Nurse-Midwife.