

ANNEXURE 5: Medical Male Circumcision: Adverse Event Reporting Tool

Clinic Summary Form (Submission to DMT and Provincial MMC Co-ordinator)

SEVERE ADVERSE CLINIC REPORT	
Clinic:	<input style="width: 100%; height: 20px;" type="text"/>
Nearest Hospital:	<input style="width: 100%; height: 20px;" type="text"/>
Sub-district:	<input style="width: 60%; height: 20px;" type="text"/> Month: <input style="width: 15%; height: 20px;" type="text"/> / <input style="width: 15%; height: 20px;" type="text"/> / <input style="width: 15%; height: 20px;" type="text"/> / <input style="width: 15%; height: 20px;" type="text"/>
District:	<input style="width: 100%; height: 20px;" type="text"/>
Province:	<input style="width: 100%; height: 20px;" type="text"/>
Totals of Severe Adverse Events per type	
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Abscess formation	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Scarring / disfigurement
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Bleeding	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Sexual complications
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Damage to Penis	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Swelling / haematoma
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Excessive skin removal	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Torsion
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Insufficient skin	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Voiding problems
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Infection	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> wound dehiscence
<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> Pain	Total of All Severe Adverse Events: <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/>
Comments: <input style="width: 100%; height: 20px;" type="text"/>	
<input style="width: 100%; height: 20px;" type="text"/>	
<input style="width: 100%; height: 20px;" type="text"/>	
<input style="width: 100%; height: 20px;" type="text"/>	
Name of Facility Manager: <input style="width: 100%; height: 20px;" type="text"/>	
Signature of FM..... <input style="width: 40%; height: 20px;" type="text"/> Date: <input style="width: 15%; height: 20px;" type="text"/> / <input style="width: 15%; height: 20px;" type="text"/> / <input style="width: 15%; height: 20px;" type="text"/> / <input style="width: 15%; height: 20px;" type="text"/>	

ANNEXURE 5: Continued

SEVERE ADVERSE EVENT DISTRICT REPORT	
District: <input style="width: 100%;" type="text"/>	Month <input style="width: 100%;" type="text"/>
Province: <input style="width: 100%;" type="text"/>	
Totals of Severe Adverse Events per type	
<input style="width: 30px; height: 20px;" type="text"/> Abscess formation	<input style="width: 30px; height: 20px;" type="text"/> Scarring / disfigurement
<input style="width: 30px; height: 20px;" type="text"/> Bleeding	<input style="width: 30px; height: 20px;" type="text"/> Sexual complications
<input style="width: 30px; height: 20px;" type="text"/> Damage to Penis	<input style="width: 30px; height: 20px;" type="text"/> Swelling / haematoma
<input style="width: 30px; height: 20px;" type="text"/> Excessive skin removal	<input style="width: 30px; height: 20px;" type="text"/> Torsion
<input style="width: 30px; height: 20px;" type="text"/> Insufficient skin	<input style="width: 30px; height: 20px;" type="text"/> Voiding problems
<input style="width: 30px; height: 20px;" type="text"/> Infection	<input style="width: 30px; height: 20px;" type="text"/> wound dehiscence
<input style="width: 30px; height: 20px;" type="text"/> Pain	Total of All Severe Adverse Events: <input style="width: 40px; height: 20px;" type="text"/>
Comments: <input style="width: 100%; height: 20px;" type="text"/>	
<input style="width: 100%; height: 20px;" type="text"/>	
<input style="width: 100%; height: 20px;" type="text"/>	
<input style="width: 100%; height: 20px;" type="text"/>	
Name of District Manager: <input style="width: 100%;" type="text"/>	
Signature of DM:.....	Date: <input style="width: 30px; height: 20px;" type="text"/> / <input style="width: 30px; height: 20px;" type="text"/> / <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/>

ANNEXURE 6: Medical Male Circumcision: Adverse Event Form

To be completed for a patient presenting with an adverse event related to male circumcision

Clinic name: _____

Form completed by: _____ Date: __ __ / __ __ / 20__ (dd/mm/20yy)

I. Client Information

Name: _____

ID No: _____

Client File No: _____

Date of visit: __ __ / __ __ / 20__ (dd/mm/20yy)

Date of Circumcision: __ __ / __ __ / 20__ (dd/mm/20yy)

Clinic where Surgery took place: _____

From existing clinical records, when patient presents at same facility where circumcision performed:

Doctor/Operator (who removed foreskin): _____

Nurse: _____

II. Adverse Event (first time patient presents with the condition)

Date of AE(s) Diagnosis: __ __ / __ __ / 20__ (dd/mm/20yy)

<input type="checkbox"/>	A	Intra-operative or prior to leaving clinic
<input type="checkbox"/>	B	Up to 30 days post-operative
<input type="checkbox"/>	C	More than 30 days post-operative

Clinician Name: _____

Signature: _____

III. Type and Severity of Adverse Event

Type of Adverse event (code)	Description of AE and/or Actions Taken (✓ as many as applicable)	Severity (✓1/ AE) Level	Treatment (write in)	Disposition or Outcome (✓1 & write in)
Bleeding (BL)	<ul style="list-style-type: none"> • More significant bleeding than usually experienced, but easily control (intra-operative) • Stained underwear/dressing with no active bleeding or Small amount of bleeding from minor clot disruption when changing dressing • Required 10 or less minutes of manual pressure to control 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to _____ <input type="checkbox"/> Repeat visit (date): ____/____/____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Bleeding difficult to control, requiring significant additional intra-operative time to control • Ongoing active bleeding and/or swelling that required a special return to the facility for medical attention • Required extra pressure dressing or extra couple of sutures to control • Observed patient for at least 1 hour and reviewed dressing before sending home or taking further action 	Moderate (2)		
	<ul style="list-style-type: none"> • Unable to control bleeding adequately during operation • Required post-operative blood transfusion (significant blood loss and/or signs of shock present) • Surgical re-exploration for ligation or cauterization of bleeding vessels • Required hospitalization • Transferred to another facility 	Severe (3)		
Swelling of penis/scrotum, including haematoma (SH)	<ul style="list-style-type: none"> • Significant circumferential swelling along incision line (without bleeding) that resolves with time 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____
	<ul style="list-style-type: none"> • Localized swelling associated with some bleeding that resolves spontaneously (with or without pressure dressing) 	Moderate (2)		
	<ul style="list-style-type: none"> • Generalized haematoma causing significant discomfort and distress, with ongoing oozing of blood from suture margins • Surgical re-exploration for drainage of haematoma • Required that residual bleeder be cauterized or transfixed 	Severe (3)		<input type="checkbox"/> Repeat visit (date): ____/____/____ <input type="checkbox"/> Other (list): _____

Type of Adverse event (code)	Description of AE and/or Actions Taken (✓ as many as applicable)	Severity (✓1/ AE)	Treatment (write in)	Disposition or Outcome (✓1 & write in)
Infection (IN)*	<ul style="list-style-type: none"> Required hospitalization Transferred to another facility Required transfusion 			
	<ul style="list-style-type: none"> Marked signs of erythema and minimal serous discharge or infective process noted at frenulum or suture margin Only topical antibiotics used Infected area less than 1 cm in length 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> Purulent discharge from wound Systemic (Oral or IV) antibiotics needed Infected area greater than one cm in length 	Moderate (2)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
Wound dehiscence &/or disruption (WD)	<ul style="list-style-type: none"> Abscess (also report AB) Severe cellulitis Wound necrosis (also refer to SD) Severe wound disruption (also report WD) Tissue loss Referral to specialist required for treatment or monitoring 	Severe (3)		
	<ul style="list-style-type: none"> Disruption involving only one suture or less than one cm 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> Disruption involving two or more sutures or 2 cm, but no surgical intervention Systemic antibiotics needed 	Moderate (2)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
Abscess formation (AB)	<ul style="list-style-type: none"> Wound disruption requiring additional surgery, e.g. re-suturing or debridement Transferred to another facility Required hospitalization 	Severe (3)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> Localized swollen, fluctuant area: hot to touch, offensive smell, and thick yellow pus discharge (patient may have fever) Opened, drained and irrigated on site Transferred to another facility 	Severe (3)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____

Type of Adverse event (code)	Description of AE and/or Actions Taken (✓ as many as applicable)	Severity (✓1/ AE)	Treatment (write in)	Disposition or Outcome (✓1 & write in)
Scarring &/or disfigurement (SD)	<ul style="list-style-type: none"> • Patient complains of disfigurement but physical exam normal • Visible ridging which the client complains about or provider notices, but no distortion of the penile organ • The affected portion of the suture line is more than a third of the circumference 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Disfigurement noted on physical exam but no re-operation necessary • Ridging is gross and either involving more than a third of the suture line or the suture line describes more than one circumferential line • Penis looks like it will be able to remould during healing (sufficient penile skin left to permit moulding) 	Moderate (2)		
	<ul style="list-style-type: none"> • Discernible scarring/disfigurement • Such distortion that the client cannot tolerate the appearance • Surgical intervention required • Transferred to another facility 	Severe (3)		
Pain (PA)	<ul style="list-style-type: none"> • Mild discomfort (3-4 on pain scale) with client able to remain still and cooperate for duration of procedure • No additional local anaesthetic required 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____ / _____ / _____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Moderate discomfort (5 or 6 on pain scale), with client expressing pain clearly • Required interruption of operation for additional local anesthetic • Patient unable to work or cancelled normal activities lasting for 4-7 days after surgery 	Moderate (2)		
	<ul style="list-style-type: none"> • Severe discomfort (7 on pain scale), with client expressing pain and the addition of local anaesthesia having no effect • Required early termination of MC or administration of general anaesthesia • Patient unable to work or cancelled normal activities lasting for 7 or more days after surgery 	Severe (3)		

Type of Adverse event	Description of AE and/or Actions Taken (✓ as many as applicable)	Severity (✓1/ AE)	Treatment (write in)	Disposition or Outcome (✓1 & write in)
Damage to Penis (DP)	<ul style="list-style-type: none"> • Bruising or abrasion • Superficial burn or laceration to glans or shaft • Required extra dressings 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Significant laceration or burn to glans or shaft • Required prolonged intra-operative attention to treat • Required extra pressure dressing • Requires additional clinic follow up care 	Moderate (2)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Severe injury including severed portion of glans, shaft laceration with ongoing bleeding or significant burn injury leading to tissue necrosis/death/loss or strangulation from too tight a dressing or device application. • Required additional surgery • Transferred to another facility • Required hospitalization 	Severe (3)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
Insufficient skin removed (IS)	<ul style="list-style-type: none"> • Prepuce extends over the coronal margin but less than one third of the glans is covered at rest in flaccid state 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Between one and two thirds of glans is covered by residual prepuce at rest in flaccid state 	Moderate (2)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Greater than two thirds of glans is covered by residual prepuce at rest in flaccid state 	Severe (3)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
Excessive skin removed (ES)	<ul style="list-style-type: none"> • Intra-operative excess removal noted requiring either: <ul style="list-style-type: none"> ◦ mobilization of skin near wound margin ◦ placement of extra sutures for reinforcement • Post-operative tightening of the skin is discernible, but re-operation not required 	Moderate (2)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> • Provider was unable to adequately close the wound margins • Mobilization of skin to close the wound margin required • Discernible tightening requiring reoperation • Transferred to another facility • Required hospitalization 	Severe (3)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): _____/_____/_____ <input type="checkbox"/> Other (list): _____

Type of Adverse event (code)	Description of AE and/or Actions Taken (✓ as many as applicable)	Severity (✓1/ AE)	Treatment (write in)	Disposition or Outcome (✓1 & write in)
Torsion of Penis—new onset (TO)	<ul style="list-style-type: none"> Torsion is visible as misalignment of the two lines, causing a twisted/rotated appearance, but does not cause discomfort in all states of turgidity 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): ____/____/____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> Flaccid penis appears rotated and is increasingly apparent at erection Torsion causes mild pain or discomfort with erection but no surgery needed Torsion less than 90 degrees 	Moderate (2)		
	<ul style="list-style-type: none"> Distortion is apparent in the flaccid state Erections are painful and the client cannot tolerate the appearance, discomfort, or pain Severe symptomatic torsion requiring re-operation Torsion greater than 90 degrees 	Severe (3)		
Voiding problems, difficulty urinating (VO)	<ul style="list-style-type: none"> Partial obstruction that is transient Resolved spontaneously or with loosening of dressing 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): ____/____/____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> Partial obstruction requiring special return to clinic outside of routine follow-up Required treatment in clinic - such as transient catheterization 	Moderate (2)		
	<ul style="list-style-type: none"> Complete urinary retention/obstruction Required surgical re-exploration for urethral injury or blockage Required placement of supra-pubic tube Transferred to another facility 	Severe (3)		
Anaesthesia reaction or complication (AN)	<ul style="list-style-type: none"> Mild palpitations, vaso-vagal reaction (fright-headedness/dizziness) or nausea requiring monitoring at clinic 	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): ____/____/____ <input type="checkbox"/> Other (list): _____
	<ul style="list-style-type: none"> Resolved spontaneously without medical treatment 			
	<ul style="list-style-type: none"> Significant palpitations, vasovagal reaction or emesis (vomiting) Required medical intervention at clinic 	Moderate (2)		

Type of Adverse event (code)	Description of AE and/or Actions Taken (✓ as many as applicable)	Severity (✓1/ AE)	Treatment (write in)	Disposition or Outcome (✓1 & write in)
	<ul style="list-style-type: none"> Severe allergic reaction or other reaction to anaesthetic Transferred/referred to another facility Hospitalised for anaphylaxis or other anaesthetic reaction 	Severe (3)		
Occupational Exposure (OE)	•	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____
	•	Moderate (2)		<input type="checkbox"/> Repeat visit (date): _____ _____ / _____ / _____
	•	Severe (3)		<input type="checkbox"/> Other (list): _____ <input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____
Sexual Complications (SC)	• Transient occurrence impairing sexual function, lasting less than 3 months	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____
	• Transient occurrence impairing sexual function, lasting between 3-5 months	Moderate (2)		<input type="checkbox"/> Repeat visit (date): _____ _____ / _____ / _____
	• Permanent sexual dysfunction lasting more than 6 months	Severe (3)		<input type="checkbox"/> Other (list): _____ <input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____
Other:	•	Mild (1)		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____
	•	Moderate (2)		<input type="checkbox"/> Repeat visit (date): _____ _____ / _____ / _____
	•	Severe (3)		<input type="checkbox"/> Other (list): _____ <input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____

ANNEXURE 6: continued

Additional Notes:

IV. Continuing Adverse Event (to be completed when patient returns for follow up of AE)

Note: Adverse events can progress over time; the outcome of an adverse event may become more or less severe over time.

Changes in severity or additional AEs must be documented separately along with the date of new diagnosis.

Date of Re-examination: __ __ / __ __ / 20__ (dd/mm/20yy)

Timing (check one):

<input type="checkbox"/>	A	Intra-operative or prior to leaving clinic
<input type="checkbox"/>	B	Up to 30 days post-operative
<input type="checkbox"/>	C	More than 30 days post-operative

Clinician Name: _____ Signature: _____

ANNEXURE 6: continued

AE Treatment and disposition

a. Updated Diagnosis from previous AE:

Type & severity (write in)	Treatment (write in)	Disposition/Outcome (✓one & write in)
		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): __ __ / __ __ / __ __ <input type="checkbox"/> Other (list):
		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): __ __ / __ __ / __ __ <input type="checkbox"/> Other (list):

b. New AE Treatment and Disposition

Type & severity (write in)	Treatment (write in)	Disposition/Outcome (✓one & write in)
		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): __ __ / __ __ / __ __ <input type="checkbox"/> Other (list):
		<input type="checkbox"/> Resolved (no further action) <input type="checkbox"/> Referred to: _____ <input type="checkbox"/> Repeat visit (date): __ __ / __ __ / __ __ <input type="checkbox"/> Other (list):

Additional Notes:
