

## Adverse Event Classification Form (Adapted for Swaziland from WHO AE Guidelines)

NAME \_\_\_\_\_ MC Unique ID Number \_\_\_\_\_

Date of MC \_\_\_\_\_ Date of Initial AE Diagnosis \_\_\_\_\_ Date of symptom onset: \_\_\_\_\_

CODE(s) FOR INITIAL AE(s) \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_

Treatment for Initial AE(s): \_\_\_\_\_

Diagnosing Clinician Name/Number: \_\_\_\_\_

Classification for AEs involves a three part code which incorporates timing (A=intraoperative or prior to leaving clinic, B=up to 30 days post-operative, and C=more than 30 days post operative), AE type (two letter code is listed below each AE type in chart below), and severity (1=mild, 2=moderate, and 3=severe). For example, a patient with a bleeding complication that required re-exploration at clinic on post-operative day #1 would be classified B-BL-3.

Keep in mind that additional AEs can develop over time or that an existing AE can be upgraded in severity over time. The same criteria for classification apply, however, changes in severity or additional AEs must be documented separately along with the date of new diagnosis. Space for additional AE codes and clinical notes can be found at the end of the document. Any severe AE should be reported to the MC Help Line at \*\*\*\*\*.

Adverse Event Type (abbreviation code noted below each type)	Timing of initial diagnosis (tick only one box)	Severity of Initial Diagnosis		
		Mild (1)	Moderate (2)	Severe (3) ***
<b>Excessive Bleeding (BL)</b>	Bleeding was diagnosed: <input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) =Code A <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> bleeding that requires minimal intra-operative attention? <input type="checkbox"/> bleeding that required less than 10 minutes of direct pressure to control?	<input type="checkbox"/> bleeding requiring significant intraoperative effort to control? <input type="checkbox"/> bleeding that required extra pressure dressing to control? <input type="checkbox"/> unscheduled return to the clinic for medical attention? (not just for reassurance)	<input type="checkbox"/> Surgical re-exploration for ligation or cauterization of bleeding vessels? <input type="checkbox"/> Hospitalization? <input type="checkbox"/> Transfer to another facility? <input type="checkbox"/> Transfusion? <input type="checkbox"/> Any hemodynamic instability
<b>Infection (IN)</b>	Infection was diagnosed: <input type="checkbox"/> Within the 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Mild erythema and minimal serous discharge from wound <input type="checkbox"/> Only topical antibiotics used <input type="checkbox"/> Infected area less than 1 cm in length	<input type="checkbox"/> Purulent discharge from wound <input type="checkbox"/> Oral or IV antibiotics needed <input type="checkbox"/> Infected area greater than one cm in length	<input type="checkbox"/> Abscess <input type="checkbox"/> Severe cellulitis <input type="checkbox"/> Wound necrosis <input type="checkbox"/> Severe wound disruption <input type="checkbox"/> Tissue loss
<b>Pain (PA)</b>	Pain was noted: <input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) =Code A <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B	<input type="checkbox"/> Mild discomfort	<input type="checkbox"/> Moderate discomfort <input type="checkbox"/> Pain requiring interruption of operation for additional local anesthetic <input type="checkbox"/> Pain resulting in inability to work or cancellation of normal activities lasting for 4-7 days after surgery.	<input type="checkbox"/> Pain resulting in early termination of MC or administration of general anesthesia <input type="checkbox"/> Pain severe enough to result in inability to work or cancellation of normal activities lasting for at least 8 days after surgery.
<b>Swelling of penis/scrotum, including hematoma (SH)</b>	Swelling noted: <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Significant circumferential swelling along incision line (without bleeding) that resolves with time	<input type="checkbox"/> Localized swelling associated with some bleeding, resolves spontaneously (with or without pressure dressing)	<input type="checkbox"/> Surgical re-exploration for drainage of hematoma? <input type="checkbox"/> Hospitalization? <input type="checkbox"/> Transfer to another facility?

<b>Anesthesia reaction or complication (AN)</b>	Reaction was diagnosed: <input type="checkbox"/> Intraoperatively or immediately post-operative (prior to discharge from clinic) =Code A	<input type="checkbox"/> Palpitations, vaso-vagal reaction, or emesis managed with observation at MC clinic?	<input type="checkbox"/> Symptoms requiring medical intervention at clinic?	<input type="checkbox"/> Transfusion? <input type="checkbox"/> patient transferred or referred to another facility for anaphylaxis or other anesthetic reaction? <input type="checkbox"/> Patient hospitalized for anaphylaxis or other anesthetic reaction?
<b>Wound disruption/dehiscence (WD)</b>	Disruption was noted: <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Disruption involving less than one cm	<input type="checkbox"/> Disruption involving up to 2 cm but no surgical intervention.	<input type="checkbox"/> Wound disruption requiring additional surgery? <input type="checkbox"/> Transfer to another facility? <input type="checkbox"/> Hospitalization?
<b>Damage to Penis (DP)</b>	Injury was noted: <input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) =Code A <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B	<input type="checkbox"/> Superficial burn or laceration	Significant laceration or burn requiring: <input type="checkbox"/> Prolonged intraoperative attention to treat <input type="checkbox"/> Extra pressure dressing <input type="checkbox"/> Additional clinic follow up care	Severe injury (amputation, laceration, urethral injury, significant tissue loss or severe burn) requiring: <input type="checkbox"/> Additional surgery needed? <input type="checkbox"/> Transfer to another facility? <input type="checkbox"/> Hospitalization? <input type="checkbox"/> Transfusion
<b>Sexual or erectile dysfunction/undesirable sensory changes (ED)</b>	Sexual problems noted: <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Dysfunction transient, resolves within 3 months	<input type="checkbox"/> Dysfunction transient, resolves between 3-6 months	<input type="checkbox"/> Dysfunction lasting longer than 6 months
<b>Scarring/disfigurement (SD)</b>	Poor cosmetic result noted: <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Client complains of disfigurement but physical exam normal	<input type="checkbox"/> Disfigurement noted on physical exam but no re-operation necessary	<input type="checkbox"/> Surgical intervention required
<b>Torsion of Penis—new onset (TO)</b>	Torsion noted: <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Torsion visible but does not cause discomfort	<input type="checkbox"/> Torsion causes mild discomfort with erection but no surgery needed	<input type="checkbox"/> Severe symptomatic torsion requiring re-operation
<b>Excessive skin removed (ES)</b>	Excessive skin removal noted: <input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) =Code A <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Intra-operative recognition of excess removal noted but not enough to warrant additional surgical steps <input type="checkbox"/> Post-operatively patient complains of tightening but physical exam is normal	<input type="checkbox"/> Intra-operative recognition of excess removal noted requiring either: <input type="checkbox"/> mobilization of skin near wound margin <input type="checkbox"/> placement of extra sutures for reinforcement  <input type="checkbox"/> Post-operatively, tightening of the skin is discernible but re-operation not required	<input type="checkbox"/> Additional surgery required? <input type="checkbox"/> Transfer to another facility? <input type="checkbox"/> Hospitalization?
<b>Insufficient skin removed (IS)</b>	<input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) =Code A <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Prepuce extends over the coronal margin but less than one third of the glans is covered at rest in flaccid state.	<input type="checkbox"/> Between one and two thirds of glans is covered by residual prepuce at rest in flaccid state.	<input type="checkbox"/> Greater than two thirds of glans is covered by residual prepuce at rest in flaccid state.
<b>Voiding problems (difficulty urinating) (VO)</b>	Voiding problems noted: <input type="checkbox"/> After discharge from clinic and up to 30 days post operative=Code B <input type="checkbox"/> Greater than 30 days post operative=Code C	<input type="checkbox"/> Resolves spontaneously or with loosening of dressing	<input type="checkbox"/> Requires treatment in clinic - such as transient catheterization	<input type="checkbox"/> Requires surgical re-exploration for urethral injury or blockage <input type="checkbox"/> Requires placement of suprapubic tube
<b>Device Application Difficulty (DA)</b>	<input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) =Code A	<input type="checkbox"/> Could not apply device, changed to surgical method of MC	<input type="checkbox"/> Device caused mild bleeding or other mild AE requiring change to surgical method of MC	<input type="checkbox"/> Device caused significant bleeding or other significant AE requiring change to surgical method of MC



<b>Device Displacement or detachment (DD)</b>	<input type="checkbox"/> After discharge from clinic and up to 30 days post operative= <b>Code B</b>	<input type="checkbox"/> Post operative device displacement and bleeding, 3 or fewer sutures required.	<input type="checkbox"/> Displacement or detachment and bleeding, more than 3 sutures required.	<input type="checkbox"/> Device displacement or detachment penile damage present.
<b>Occupational Exposure of Healthcare Provider (OT)</b> Note that Occupational Exposure Form must be completed by employee. Call MC Help Line*****	<input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) = <b>Code A</b> <input type="checkbox"/> After discharge from clinic and up to 30 days post operative= <b>Code B</b>	<input type="checkbox"/> Blood splashes on intact skin	<input type="checkbox"/> Needlestick <input type="checkbox"/> Blood splatters in eye  No illness as a result	<input type="checkbox"/> Any seroconversion or illness attributed to exposure
<b>Other AE (describe) (OA)</b> _____ _____ _____ _____	<input type="checkbox"/> Intraoperative or immediately post-operative (prior to discharge from clinic) = <b>Code A</b> <input type="checkbox"/> After discharge from clinic and up to 30 days post operative= <b>Code B</b> <input type="checkbox"/> Greater than 30 days post operative= <b>Code C</b>		<input type="checkbox"/> AE resulting in inability to work or cancellation of normal activities lasting for 4-7 days after surgery.	<input type="checkbox"/> AE severe enough to result in inability to work or cancellation of normal activities lasting for at least 8 days after surgery. <input type="checkbox"/> Transfer to another facility? <input type="checkbox"/> Hospitalization?

Date of Re-examination \_\_\_\_\_, Clinician Name/Number: \_\_\_\_\_

If new/upgraded AE , enter CODE \_\_\_\_\_ and \_\_\_\_\_

Resolution of the following AE(s) \_\_\_\_\_ and \_\_\_\_\_

Clinically improving but not yet resolved No change in clinical status Referred to: \_\_\_\_\_

Consultation by \_\_\_\_\_ in person over phone

Clinical Follow up Notes:

Date of Re-examination \_\_\_\_\_, Clinician Name/Number: \_\_\_\_\_

If new/upgraded AE , enter CODE \_\_\_\_\_ and \_\_\_\_\_

Resolution of the following AE(s) \_\_\_\_\_ and \_\_\_\_\_

Clinically improving but not yet resolved No change in clinical status Transferred to: \_\_\_\_\_

Consultation by \_\_\_\_\_ in person over phone

Clinical Follow up Notes:

Date of Re-examination \_\_\_\_\_, Clinician Name/Number: \_\_\_\_\_

If new/upgraded AE , enter CODE \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_

Resolution of the following AE(s) \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_

Clinically improving but not yet resolved  No change in clinical status  Referred to: \_\_\_\_\_

Consultation by \_\_\_\_\_  in person  over phone

Clinical Follow up Notes:

Date of Re-examination \_\_\_\_\_, Clinician Name/Number: \_\_\_\_\_

If new/upgraded AE , enter CODE \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_

Resolution of the following AE(s) \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_

Clinically improving but not yet resolved  No change in clinical status  Transferred to: \_\_\_\_\_

Consultation by \_\_\_\_\_  in person  over phone

Clinical Follow up Notes:

DATE OF CLOSING CASE: \_\_\_\_\_

FINAL AE CODE(S) \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_

\_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_ and \_\_\_\_\_ -- \_\_\_\_\_ -- \_\_\_\_\_