

MTN-008 Data Communiqué #7

16 May 2013

This is official study documentation for MTN-008. Please circulate it among relevant staff for their review, print it, and place it in your MTN-008 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-008 SSP manual.

UPDATES

None.

CLARIFICATIONS

1. AE Log form (AE-1), item 1

In order to help with the reporting of **future** AEs in MTN-008 we would like to clarify some aspects related to AE Log form completion and the potential effects on MedDRA coding. Information recorded in the comments section of the AE Log form may be considered during the coding process. To reduce AE coding queries, please include relevant descriptors to the reported adverse event in item 1 of the AE Log form. It is very important that any information recorded in the comments field is consistent with the text recorded in item 1. For example, if the site records “anemia” for item 1 on the AE Log form, and in the comments records “due to pregnancy” this will receive a clinical QC because there is a specific MedDRA code for “anemia of pregnancy” (see table below). For AEs which are “not related” to study product, sites can record “due to alternate etiology” in the comments section of the AE Log form.

With specific regard to the newborn participants, please note that “neonate” refers the first 28 days of life; whereas, “infant” refers to older than 29 days. Please do not use the terms interchangeably on the AE Log form, as this will generate an AE coding query. MedDRA has over 600 terms for neonatal status (Examples: Neonatal jaundice, neonatal hypothermia, neonatal anemia). Please specify “neonatal” on item 1 of the AE CRF when reporting neonate adverse events.

****NOTE:** Please do not edit previously reported AEs based on these guidelines, but follow them for reporting any future AEs for this study.

The table below provides a list of several AEs we have seen in MTN-008 which have caused a higher number of QCs. We hope to minimize confusion and site burden by providing some standardized guidance on AE terminology. The “AE Text (item 1)” column is the most applicable to site operations.

Category	AE Text (item 1)	MedDRA preferred term	System Organ Class
PAIN	Incisional site pain related to cesarean section	Incisional site pain	Injury, poisoning and procedural complications
	Pain related to cesarean section	Post procedural pain	Injury, poisoning and procedural complications
	Post-partum uterine pain	Afterbirth pain	Pregnancy, puerperium and perinatal conditions

Category	AE Text (item 1)	MedDRA preferred term	System Organ Class
	Post-partum perineal pain	Afterbirth pain	Pregnancy, puerperium and perinatal conditions
	Post-partum vaginal pain	Afterbirth pain	Pregnancy, puerperium and perinatal conditions
PRURITIS	Pruritis due to anesthetic	Anesthetic complication	Injury, poisoning and procedural complications
	Pruritis due to pain medications	Adverse drug reaction	General disorders and administration site conditions
NON DELIVERY RELATED PAIN	Pelvic pain	Pelvic pain	Reproductive system and breast disorders
	Premenstrual cramping	Premenstrual cramps	Reproductive system and breast disorders
	Menstrual cramping/Dysmenorrhea	Dysmenorrhoea	Reproductive system and breast disorders
	Lower abdominal cramping (only to be reported when it is gastrointestinal in nature)	Abdominal pain lower	Gastrointestinal disorders
	Abdominal cramping (only to be reported when it is gastrointestinal in nature)	Abdominal pain	Gastrointestinal disorders
	Vulvovaginal burning	Vulvovaginal burning sensation	Reproductive system and breast disorders
HEMORRHAGE	Post vaginal hemorrhage	Post-partum hemorrhage	Pregnancy, puerperium and perinatal conditions
	Post cesarean hemorrhage	Post procedural haemorrhage	Injury, poisoning and procedural complications
	Incisional site bleeding	Incision site haemorrhage	Injury, poisoning and procedural complications
ANEMIA* *if ppt is on PNV, record anemia, not decreased hemoglobin	Anemia related to pregnancy	Anemia of pregnancy	Blood and lymphatic system disorders

Category	AE Text (item 1)	MedDRA preferred term	System Organ Class
HYPERTENSION	Gestational hypertension*	Gestational hypertension	Pregnancy, puerperium and perinatal conditions
	Hypertension <i>(in non-pregnant participant)</i>	Hypertension	Vascular disorder
	Elevated Blood Pressure (if one isolated elevation)	Blood Pressure Increased	Investigations

*NOTE: Gestational hypertension is defined as having at least two consecutive elevated blood pressure readings.

REMINDERS

1. All CRFs

When recording text responses (letters and/or numbers) please remember to write legibly. QCs will be applied if the responses cannot be easily read.