



MTN-008 Data Communiqué #5

20 October 2011

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. Pregnancy Outcome form (PO-3), item 11

Per the protocol (page xv), “preterm premature rupture of membranes (prior to onset of labor) and term premature rupture of membranes (prior to onset of labor)” are considered specific pregnancy complications. If there are cases which constitute premature ROM (i.e. prior to the onset of labor) then item 11 must be marked “yes.” If the only pregnancy complication is the premature ROM, then you will mark item 11a6 “none of the above” and complete item 11b, accordingly.

This clarification contradicts Communiqué #1, 5 April 2011, Clarification #3. Please disregard that item and in cases where premature ROM is the only pregnancy or postpartum complication, you will mark item 11a6 “none of the above,” and continue to item 11b.

REMINDERS

1. Pregnancy Outcome form (PO-1), item 5

Please review the form instructions for item 5 on page 1 of the Pregnancy Outcome form. “Record whether labor was “spontaneous” or “induced.” If labor was induced, record the indication. Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.”