
MTN-008 Data Communiqué #1

5 April 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

1. Home Breast Milk Specimens

Visit Codes. Each participant in the Lactation Cohort is asked to collect breast milk specimens on two different days while at home. These collections do not correspond to any protocol required visits, but we will need to document a visit code for each specimen. For the two specimens collected by the participant at home please use the following visit codes on the *specimen labels* and for *entry into LDMS*:

- Specimen #1 = 02.1
- Specimen #2 = 02.2

Do NOT complete an Interim Visit form for these cases.

CLARIFICATIONS

2. Mother Targeted Physical Exam form

Item 4. Breast Exam. This item is only required for participants in the Lactation Cohort (see protocol Appendix III). For participants in the Pregnancy Cohort, mark the “not evaluated” box.

3. Pregnancy Outcome form

Item 11a. For this item, item 11a6, “none of the above” should never be marked. If item 11 is marked “yes” one or more of the response boxes for items 11a1-11a5.

4. Product Hold/Discontinuation Log form

Item 2c. The response option for “mother has gone into labor” is defined as when the maternal participant is admitted to the Labor and Delivery department.

REMINDERS

None.