

MTN-016

Newborn Initial Visit Procedures



Objectives

- Understand infant eligibility criteria for inclusion.
- Understand infant visit scheduling.
- Understand procedures to be performed at each infant visit and who is responsible for conduct of the visits.

MTN-016: Inclusion/Exclusion

Main Infant Inclusion Criterion

- Born to EMBRACE participant mother from pregnancy concurrent with participation in parent study.

Main Infant Exclusion Criteria

- Has reached 1 year birth date.

Remember:

- Every VOICE Study Visit is a potential MTN-016 Study Visit!
 - Newborn/Initial Visit
 - Months 1, 6 or 12
 - Infant Interim Visit



Newborn/Initial Visit

- Anytime an MTN-016 participant returns to VOICE with a newborn:
 - Has infant already had Newborn/Initial Visit?
 - If not, do not miss this opportunity to capture the infant as an MTN-016 participant.



Newborn/Initial Visit

- Completed within 10 days of birth.
- Ideally to occur at same time as L&D.
- Remember to confirm infant consent has been given prior to conducting any study assessments.



Visit Procedures

- Informed Consent
- Collect Locator Information
- Collect Medical History
- Collect Medication History
- Clinical Procedures:
 - Physical Exam
- As Indicated:
 - Major Malformation Assessment Worksheet
 - Photographic Documentation
 - Social Harms Assessment
 - Infant HIV testing



Physical Exam

- Abnormalities
 - MTN-016 Primary Endpoint
 - Major Malformation Assessment
- Growth Parameters
 - MTN-016 Secondary Objective
 - Weight
 - Length
 - Head Circumference



Wild Card Question

Melody is a pregnant VOICE participant referred for enrollment to MTN-016 and she signs the Screening and Enrollment Informed Consent Form.

- Her son is born with the help of a midwife. The child has polydactyly, which the midwife treats with ligation. Mother and child go home.
- Your staff learns that Melody's baby died on day 4 after birth, 2 days before his first Newborn/Initial Visit.
- Is the mother still enrolled in the study?
- Is the infant enrolled in the study?

Wild Card Question

- Melody is enrolled through pregnancy outcome, regardless of the status of her infant.
- Melody's son was enrolled when conditions of consent were met:
 - Melody signed the IC, which covers both herself and her baby.
 - Melody's son was born alive, which fits eligibility criteria.

For the WOMAN:

- Pregnancy Outcome form (for MTN-016 AND 003,
- PO form, pg 2, items 8, 8a, and 8b to document the polydactyly. Mark "yes" for item 8, mark "other" for item 8a16, and then explain the anomaly and the procedure treatment completed by the midwife in item 8b. Be sure to also complete as much as possible on page 3 of this form.
- Woman Termination form
- Woman End of Study form
- Update the Woman Con Meds form(s) and refax

For the INFANT:

- Infant Enrollment form (from the Infant Newborn/Initial Visit form packet)
- Infant Concomitant Medications Log form
- Infant Missed Visit form (use visit code 1.0)
- Infant Termination form (in the "as needed" form supply or the Month 12 Visit form packet)
- Infant End of Study form (in the "as needed" form supply or the Month 12 Visit form packet)

Newborn Procedures Scenario

Judith's ultrasound for MTN-016 revealed the presence of a multiple gestation:



Newborn Procedures Scenario

Four months later, she appears at the local hospital in labor.

Although earlier than expected, delivery is without complications and mother and babies are well.

How will you assign infant PTIDs?

How will you file CRFs for each infant?

Newborn Procedures Scenario

Answer Slide...

you tell *me*!

Infant Exam and Ballard

- <http://www.med.umich.edu/medstudents/courses/M3/peds/index.html>
- All staff responsible for conducting infant exams on the Delegation of Authority log must view and file documentation of viewing these two videos.



MTN-016

Infant Months 1, 6, & 12 Visit Procedures



Objectives

- Learn the MTN-016 infant visit procedures.
- Consider how to coordinate MTN-016 infant visits with VOICE visits.
- Identify MTN-016 primary and secondary endpoints.
- Demonstrate use of the Gestational Age Worksheet.

Infant Visits Scenario

- Sandi and her infant have just completed the MTN-016 newborn initial visit; her infant is happy and healthy.
- Sandi's next scheduled VOICE visit is on 18 June 2010; her infant participant calendar is as follows:

Visit	Target Window Opens	Target Date	Target Window Closes
Month 1	17-May-10	31-May-10	14-Jun-10

Remember:

- Every VOICE Study Visit is a potential MTN-016 Study Visit:
 - Newborn/Initial Visit
 - Month 1, 6 or 12
 - Infant Interim Visit



Infant: Month 1, 6 and 12

- Anytime an MTN-016 participant returns to VOICE with a baby:
 - Is the baby within the window for a scheduled MTN-016 follow-up visit?
 - If so, do not miss this opportunity to complete the follow-up visit procedures.
 - If not, but the infant has current clinical issues, consider MTN-016 interim visit.

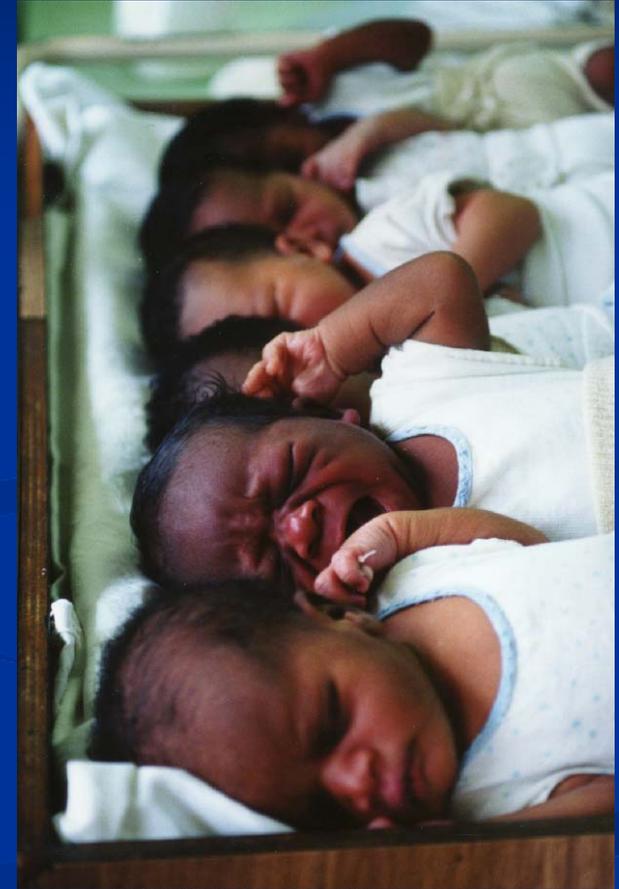
Visit Procedures: Months 1, 6, & 12

- Update Locator
- Update Medical History
- Update Medication History
- Clinical Procedures:
 - Physical Exam
 - Denver Developmental: Months 6 & 12
- As Indicated:
 - Major Malformation Assessment
 - Photographic Documentation
 - Social Harms Assessment
 - Infant HIV testing



Physical Exam

- Abnormalities
 - MTN-016 Primary Endpoint
 - Major Malformation Assessment
- Growth Parameters
 - MTN-016 Secondary Objective
 - Weight
 - Length
 - Head Circumference



Infant: Months 1, 6 and 12

- Month 1

- Visit window is +/- 2 weeks
- Developmental assessment: NO

- Months 6 and 12

- Visit windows are +/- 1 month
- Developmental assessment: YES



Denver II Developmental Assessment

- MTN-016 Exploratory Objective
 - Site personnel to be trained
 - Kits and videos available for each CTU



Adjusted vs. Chronological Age

■ Infant Developmental Screening CRF

1. Adjusted age or chronological age at testing months days

- Born <36 Weeks = Adjusted Age
- Born ≥36 Weeks = Chronological Age

■ Utilize Gestational Age Worksheet

Back to Sandi...

- Next scheduled VOICE visit is on 18 June 2010

Visit	Target Window Opens	Target Date	Target Window Closes
Month 1	17-May-10	31-May-10	14-Jun-10

- Do you reschedule the VOICE visit?

Infant Interim Visit Scenario

- Do you reschedule the VOICE visit?
 - Consider VOICE visit target date and window
 - Consider VOICE visit type
 - Consider availability of clinician designated for MTN-016 infant exams
 - Priority: VOICE target or MTN-016 target?

Infant Interim Visit Scenario

- Sandi and her infant have an uneventful MTN-016 Month 1 visit, the baby is happy and well.



- At a subsequent VOICE visit, Sandi's now 4 month old infant has a fever.

Interim Infant Visits

- Reasons for an unplanned interim visit:
 - Missed visit(s)
 - Acute clinical issues (sick visit)
- Reasons for a planned interim visit:
 - Follow-up on previous abnormal finding
 - Follow-up testing on HIV-exposed or HIV-infected infant
 - Follow-up on a reported social harm

Interim Visit Procedures

- Update Locator
- Update Medical History
- Update Medication History
- As Indicated:
 - Photographic Documentation
 - Physical Exam
 - Social Harms Assessment
 - Infant HIV testing



Infant Interim Visit Scenario

- At a subsequent VOICE visit, Sandi's now 4 month old infant has a fever.
- Should this be an MTN-016 visit?

Infant Interim Visit Scenario

- Should this be an MTN-016 visit?
 - Too early for the 6 month visit window.
 - Consider MTN-016 interim visit.
 - Consider availability of clinician designated for MTN-016 infant exams.
 - Update medical and medication history as needed, infant physical exam form.

Infant Interim Visit Scenario 2

Clara is enrolled in both VOICE and EMBRACE.

- She missed several VOICE visits and didn't appear as scheduled for the first MTN-016 quarterly visit.
- A visit to the woman's home reveals that she's returned to her home village.
- Six months later, Clara reappears at the MTN-016 clinic with her 3 month old baby girl.

Which infant procedures should you consider now?

Which visit should you schedule next?

Infant Interim Visit Scenario 2

- Obtain Infant Informed Consent
- Obtain permission for access to infant delivery records
- Forms to complete:
 - Infant enrollment
 - Infant visit
 - Infant physical exam
 - Infant medical history/ con med logs
 - Infant missed visit form