RECOGNIZING AND RECORDING STUDY OUTCOMES FROM OUTSIDE MEDICAL RECORDS

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October 29, 2013
OUTLINE

- Recognizing study outcomes from outside medical records.
- Recording study outcomes from outside medical records.
ReCAP: MTN-016 Study Outcomes

- Study outcomes that may be captured from outside Medical Records
  - Pregnancy loss
  - Adverse Pregnancy Outcomes
  - Infant Malformations
RECOGNIZING STUDY OUTCOMES FROM OUTSIDE MEDICAL RECORDS

- Participant report.
  - Participants are counseled to inform study staff of any medical issues that happen at home.

- Health Visitor/Outreach worker report
  - Usually through information gathered by home visit or call

- Clinician Suspicion
  - History taking.
  - Request for any outside medical records
  - Missed study visits.
  - In discrepant Clinical findings from previous visits e.g., Change from positive to negative hcg urine tests.
RECOGNIZING STUDY OUTCOMES FROM OUTSIDE MEDICAL RECORDS

- In case of any medical occurrence between study visit, study staff requests a participant to present medical form.
- If absent, participant requested to request it from Health provider.
- In case of Mulago Hospital, a copy is obtained after verbal permission from participant.
- Copy of the Medical Record filled.
Recording study outcomes from outside medical records

- Information verified with clinical assessment with the mother/infant.
- Clinically verifiable information is transcribed on relevant CRFs forms.
- In case, site clinician does not believe the outside information. Reason for doubt is documented in the study document and information not transcribed.
QUESTIONS?