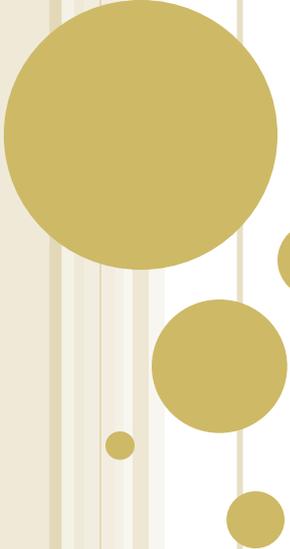


RECOGNIZING AND RECORDING STUDY OUTCOMES FROM OUTSIDE MEDICAL RECORDS



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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?

