MTN-016: Abdominal examination in pregnancy

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MTN Regional Meeting
Capetown, South Africa
DATE
Objectives

- Review MTN-016 protocol and CRF requirements related to abdominal examination in pregnancy
- Review steps
- Discuss do’s and don’ts
- Optional clinical skills practice: measuring fundal height
Individuals who meet the following criteria are eligible…:

2. During participation in a parent protocol, has/had a known confirmed pregnancy, meeting at least one of the following sets of criteria in A or B:

- **A**: Two consecutive monthly visits with + pregnancy tests
- **B**: One or more of the following assessments:
  - Auscultation of fetal heart tones
  - Positive pregnancy test confirmed by clinic staff in the presence of clinically confirmed enlarged uterus
  - Positive pregnancy test confirmed by clinic staff in the presence of missed menses by participant report
  - Clinical assessment of fetal movement
  - Demonstration of pregnancy by ultrasound
Woman Enrollment (WEN-1)

Criteria B. *Mark all that apply.*

- 3b1. auscultation of fetal heart tones
- 3b2. positive pregnancy test confirmed by clinic staff in the presence of clinically confirmed enlarged uterus
- 3b3. positive pregnancy test confirmed by clinic staff in the presence of missed menses by participant report
- 3b4. clinical assessment of fetal movement
- 3b5. demonstration of pregnancy by ultrasound

• **Items 3a–3b5:** These items document which criteria within A or B were met to determine the confirmed pregnancy. If item 3a1 is marked, record the dates of the two positive pregnancy tests, and go to item 4. If the confirmed pregnancy was made using criteria B, skip 3a1 and mark all that apply for items 3b1–3b5.
# Pregnancy Report and History (PR-1)

<table>
<thead>
<tr>
<th>PREGNANCY REPORT</th>
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<tbody>
<tr>
<td>1. First day of last menstrual period: ..................................................</td>
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<td>2. Estimated date of delivery: .......................................................................</td>
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<tr>
<td>3. What information was used to estimate the date of delivery?</td>
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<tr>
<td>3a. last menstrual period .............................................................................</td>
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<td>3b. initial ultrasound &lt; 20 weeks ..................................................................</td>
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<td>3c. initial ultrasound ≥ 20 weeks ..................................................................</td>
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<td>3d. physical examination ...............................................................................</td>
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<td>3e. conception date by assisted reproduction ...............................................</td>
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<td>3f. other, specify: ......................................................................................</td>
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- **Item 3d**: Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.

*If either are yes, complete Ultrasound Results form.*
Rationale

- Gestational age data in MTN-016
- Study product adherence measures (e.g., PK data) in parent study

= Estimate timing & duration of study product exposure in pregnancy
Why not just use LMP?

- If everyone had normal, regular menstrual periods every 28 days AND
- If all could remember LMP date, AND
- If ovulation ALWAYS occurred on cycle day 14, THEN
- Gestation age calculation could be easy! BUT that’s not real life…
  - Bleeding can be irregular, esp. with use of hormonal contraception or anovulatory cycles, and we are only forgetful humans!
Ranking strategies for estimating gestational age

1\textsuperscript{st} trimester ultrasound

2\textsuperscript{nd} trimester ultrasound

3\textsuperscript{rd} trimester ultrasound
Steps (the obvious stuff!)

- Introduce yourself
- Confirm the participant’s identity
- Confirm the participant has emptied her bladder!
- Wash your hands
- Explain the exam
Steps (cont.)

- Participant flat as possible on the exam table, without making her too uncomfortable
- Keep draped, but able to be exposed from the pubic bone to below breasts
- Note
  - Obesity or other nutritional status problems
  - Previous operative scars, e.g., previous caesarean delivery
  - Uterine size/shape
Uterine size <20 weeks gestation

- Anatomical landmarks are used, i.e., the symphysis pubis and the umbilicus
  - Gently palpate abdomen with left hand
  - If fundus palpable just above symphysis pubis, gestational age approximately 12 weeks
  - If fundus reaches half way between symphysis and umbilicus, gestational age ~16 weeks
  - If fundus at same height as umbilicus, gestational age ~20 weeks (one finger under umbilicus = 18 weeks and one finger above umbilicus = 22 weeks)
  - Standards/guidance may vary by country!
Palpation

1. Anatomical landmarks are used, i.e., the symphyses pubi and the umbilicus.
2. Gently palpate the abdomen with the left hand to determine the height of the fundus of the uterus:
   (i) If the fundus is palpable just above the symphysis pubis, the gestational age is probably 12 weeks.
   (ii) If the fundus reaches half way between the symphysis and the umbilicus, the gestational age is probably 16 weeks.
   (iii) If the fundus is at the same height as the umbilicus, the gestational age is probably 22 weeks.
Measurement by tape

- Feel for uterine fundus
  - Gently palpate from lower end of the sternum
  - Continue to palpate down abdomen
  - If uterus is rotated away from midline, highest point will not be in midline but will be to left or right!
  - Palpate away from midline to make sure you mark highest point at which fundus can be palpated

- Hold end of tape at top of symphysis pubis
- Lay tape over curve of uterus to point marking top
- Measure distance in cm from symphysis pubis to top of the fundus (symphysis-fundus height)
Tricky measurements

Correct

Incorrect measurement of uterus rotated away from midline
Do’s and Don’ts

- **Do**
  - Distinguish your exam from antenatal care! Some of these assessments are components of antenatal visits, but study visits CANNOT substitute for antenatal care.

- **Don’t**
  - Don’t move fundus into midline before marking highest point
  - Don’t stretch the tape measure
Estimating gestational age

- McDonald’s rule
  - Fundal Height (>22 cm) = Gestational age in weeks

- Remember: this is a rough estimation and is subject to inter-rater variability!
  - Measurements can vary from provider to provider
  - Aim for careful consistency
Fetal heart rate
Fetal vs. Maternal

- Fetal heart rate (FHR) : 110-180
  - 180 is on the high side, but may be seen briefly during normal FHR acceleration
- Maternal heart rate: 60-90
- When in doubt, palpate maternal HR while listening to fetal HR
FHR auscultation

- If 016 eligibility assessment occurs initially in late pregnancy...
Help!

- **In general**
  - mtn016mgmt@mtnstopshiv.org
  - Includes several clinicians, including Chair and Co-chair

- **Medical Officer**
  - Jeanna Piper: piperj@niaid.gov

- **Protocol Chair & Co-chair**
  - Richard Beigi: rbeigi@mail.magee.edu
  - Samuel Kabwigu: skabwigu@mujhu.org
Acknowledgements

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