



GENITAL BLEEDING

Regional Meeting 2013

COMMON QUESTIONS

- What is a bleeding AE?
- What if the participant establishes a regular monthly menses in follow-up? Is this an AE? How is this documented?
- Do I have to do an exam with every report of bleeding that is different from baseline?
- How do I fill out the FP CRF regarding LMP?
- How do I handle blood on the vaginal swab?



WHAT IS A BLEEDING AE

- New instances of heavy or prolonged menstrual bleeding or intermittent bleeding
 - compared to the participant's baseline bleeding pattern
 - regardless of whether it is attributed to contraception
- Post-coital bleeding if not present at baseline



THE EXCEPTION: RETURN OF NORMAL MENSES

- SSP Section 10.6.
- If an irregular baseline bleeding pattern recorded on the PRE resolves and a more normal monthly menses resumes, this does not need to be captured as an AE.
- Instead, simply record a resolution date for this condition on the Pre-existing Conditions Resolution Tracker



THE DILEMMA

- When do you decide that bleeding in follow up is “normal menses?”
- How do you document this transition in thinking?



NORMAL MENSES

- “Normal menses” is per clinician discretion
 - Normal refers to population definition of normal- not the participant’s definition
 - 3-5 days of bleeding every 28-30 days
 - YES
 - 2-4 days of bleeding every 27-31 days
 - YES
 - 4-6 days of bleeding every 84-90 days
 - NO
 - 1-2 days of bleeding every 15-30 days
 - NO
 - Regularly timed bleeding approximately 4 weeks apart



RESOLVING THE AE

- Once bleeding in follow up is determined to be “normal menses,” delete previous AEs for what is now deemed to be normal
- Is this ok? Delete an AE?
- YES! An AE is an untoward medical condition. “Normal menses” is not an untoward medical condition



SCENARIO # 1

- At baseline, a participant reports 1-2 days of bleeding every 2-3 months. She is on DMPA.
- In follow up she changes her contraception to IUCD.
- At the month 7 visit she reports 4 days of bleeding one month after her last episode of bleeding



SCENARIO #1 CONT'D

- Do you need to do a pelvic exam?
 - Yes, it is bleeding different from baseline. This is a new AE until proven otherwise
- Do you file an AE?
 - Yes, bleeding different from baseline....and not yet clear that it is a new monthly bleeding pattern
- What do you call it?
 - Metrorrhagia
- Do you close it or leave it open?
 - Close



SCENARIO #1 CONT'D

- The participant returns over the next two months and reports 2 more episodes of bleeding lasting 4 days and occurring 4 weeks apart.
- What is your clinical assessment?
 - She is having regularly timed menses now.
 - Three months of regularly monthly bleeding
- Is this an AE?
 - No
- How do you document?
 - Document your reasoning in a chart note
 - Delete the AE (s) for metrorraghia which you filed since Month 7



IS A PELVIC EXAM REALLY NECESSARY FOR BLEEDING AEs?

- **New** adverse events for bleeding should prompt a pelvic exam even if the bleeding has subsided by the time of the report (SSP 10.4.2)
 - i.e., when you fill out an AE CRF for a bleeding AE, fill out a pelvic exam CRF
- If a participant has an open adverse event for a bleeding adverse event, a pelvic exam is not required each time the participant reports bleeding (SSP 10.6.1)
 - provided the clinician assesses the bleeding to be consistent with the bleeding captured by the open adverse event



SCENARIO #1 CONT'D

- What about the FP-1?
- At Month 7 when she first reported 4 days of bleeding
 - Did she have her menses since last visit?
 - Some might answer yes, others might answer no
 - Record reported bleeding pattern somewhere to reference later
 - Bleeding log
 - Chart notes
- At Month 8, she has 4 days of bleeding since her last visit 4 weeks after her prior bleed
 - Did she have her menses since last visit
 - Yes (clinically appears to be menses, even though AE can't be deleted quite yet)
- At Month 10, when you decide these are normal menses
 - Did she have her menses since her last visit?
 - Yes



FP-1 CRF

- “Has the participant had or started her menstrual period since her last visit?”
- What constitutes a menstrual period?
 - Clinician discretion
 - Menstrual like bleeding
 - Menstrual like according to the patient’s baseline
 - Menstrual like according to population standards
 - Both irregular and regular menstrual bleeding (early menses, menorrhagia, late menses)
 - OK to have an open AE for metrorrhagia and record an LMP if your clinical assessment if that the participant had menstrual like bleeding
 - Factors to consider?



RESEARCH NEEDS VS CLINICAL SENSE

- Bleeding that is different from baseline has to be captured as an AE initially
 - This ensures participant safety
 - Most of these bleeding events will fall under “metrorrhagia” because we MAKE you call it that
 - This is a construct of the coding system
 - “irregular menses” “vaginal spotting” “early menses” would all get MedDRA tracked differently.
 - The bleeding terms are for ease of classification
 - Many of these events aren’t true “metrorrhagia”
 - Determining whether an AE has occurred and what to call it are dictated by research needs
- The LMP question is a clinical question
 - Answer it independently of what you are “calling” the bleeding event for research purposes



SCENARIO #2

- A participant is enrolled and describes her bleeding pattern at baseline as follows
 - 3-4 days
 - Every 28-34 days
- At month 6 she reports that her last cycle occurred 27 days after her prior bleeding event. When you review her chart from last month, you realize that her cycle was only 27 days in length then too
 - Has an AE occurred?
 - What do you call it?
 - When is the start date?
 - Do you leave it open or close it out? When do you decide this?



SCENARIO # 2 (CONT'D)

- How do you fill out the FP-1 CRF this month
 - Did she have a menstrual period?



MOVING FORWARD

- SSP will be updated
 - ~~If an irregular baseline bleeding pattern recorded on the PRE resolves and a more a normal monthly menses is noted in follow-up resumes~~, this does not need to be captured as an AE
- Guidance for LMP on FP-1 should be followed moving forward
- If a metrorrhagia AE was deleted when normal menses was noted, sites will be asked to go back and update FP-1 LMP date
 - SCHARP will send a list of ptids with deleted metrorrhagia AEs



BLEEDING ON SWAB- QUESTIONS TO CONSIDER

- You note blood on the self collected vaginal swab
- Has a new AE occurred?
 - Depends
 - When was her last menses?
 - Does this bleeding event fit into a previously opened AE for metrorrhagia?
 - IoR discretion
- Is a pelvic exam indicated?
 - If you are filling out an AE form, yes



- Questions?

