

**WOMEN'S INTERAGENCY HIV STUDY  
QUESTION BY QUESTION SPECIFICATIONS  
GYNECOLOGICAL EXAM  
FORM 8**

Guidelines for completing Form 08, "Gynecological Exam." Note that not every question is detailed in these QxQs, but only those requiring further explanation than that listed on Form 8.

General Instructions:

1. Use the form version dated 10/01/04.
2. All dates should be recorded in the MM/DD/YY format.
3. Times should be recorded in HH:MM format. Remember to use leading zeros, e.g., 08:00.

Indicators for the beginning and end of all subforms have been added to the form. This has been done for data entry purposes only and will not affect how the form is completed.

**PARTICIPANT INFORMATION**

This section at the beginning of the form should be completed before beginning the gynecological exam. Record the actual time you began the gynecological exam in the space provided for "Time Module Began" and the actual time you ended the exam in the space denoted "Time Module Ended."

**SECTION A: GYNECOLOGICAL EXAM**

A number of vaginal and cervical specimens are collected during the GYN exam. Refer to the Gynecological Exam section of the WIHS Manual of Operations for the order and method of collection and tests to be performed.

A1a–e: Prior to inserting a clean vaginal speculum, examine the thighs, pubis, vulva, perineum, and perianal region and record your findings in each location. If any item "a–e" is abnormal, go to **PROMPT**.

**PROMPT: COMPLETE LESION CHART (LOCATED AT QUESTION A19) AFTER COMPLETING THE EXAM.**

A6. Assess vaginal discharge character and circle all appropriate response codes. **More than one code may be circled.**

**CERVICAL EXAMINATION**

A7. If the participant has no cervix, skip to question **A14**.

A8. If the cervical exam was done, circle "1" and proceed to question **A9**. If the cervical exam was not done, circle "2," specify the reason why in 25 characters or less and skip to question **A12**.

A9a. Assess the presence and severity of any cervical lesions. **COMPLETE THE LESION CHART (LOCATED AT QUESTION A19) FOR ANY LESIONS PRESENT AFTER COMPLETING THE EXAM.**

A10. Assess the presence of cervical exudate. If there is no cervical exudate, circle "2" and skip to question **A12**.

## UTERINE EXAMINATION

A13. If the participant has no uterus, skip to question A14.

## ADNEXAL EXAMINATION

A14. If the participant has no adnexae, skip to question A15.

## RECTAL EXAMINATION

A17. Beginning with visit 21, the rectal examination will be performed once per year only, at even-numbered visits. In question A17a, indicate whether the visit attended is even-numbered or not. If even, proceed to question A17b. If odd, skip to question A18.

If rectal exam is performed, indicate in question A17c whether the results were normal or abnormal. If abnormal, the participant should be referred as appropriate to her medical provider.

## GYNECOLOGICAL EXAM & ABNORMALITY/LESION CHART

The following are definitions of the numbered regions on the abnormal lesion chart at question A19:

The *labia majora* (locations 1 and 2) extend from the area of the *clitoris* (13) posteriorly to the *perineum* (7 and 8). The lateral aspects are covered with pubic hair. The inner aspects of the labia majora are not hair bearing, but may have prominent sebaceous glands. The labia majora are separated from the *labia minora* (3 and 4) by the interlabial sulcus. The labia minora are covered by keratinized squamous mucosa and extend from the region of the clitoris to the *introitus* (5 and 6).

Anteriorly, covering the pubic synthesis, is the *mons pubis* (15). Lateral to the pubis are the *inguinal regions* (9 and 10). The inner *thighs* (11 and 12) are lateral to the hair-bearing regions of the labia majora.

The *urethra* (14) and periurethral region is located between the clitoris and vagina introitus and is demarcated laterally by the inner aspects of the labia minora.

The *perineum* (7 and 8) is the region located between the vaginal introitus and anus.

The perianal region is the area immediately surrounding the external anal sphincter and is arbitrarily divided into four quadrants: upper left, lower left, lower right and upper right (27, 28, 29 and 30). The internal anal canal (31) is examined via anoscopy (anal colposcopy). The region beyond the perianus blends with the inner thighs (11 and 12).

A19. Indicate whether or not any abnormalities or lesions were found during the GYN exam. Code "1" indicating "YES," if abnormalities were noted in response to questions A1 or A9. Indicate the locations of those abnormalities on the diagram by circling the numbers. If no abnormalities or lesions were present, code "2" indicating "NO," and skip to question A44.

A19a. Record the total number of locations where external genitalia, vaginal or cervical lesions are present. This number must be consistent with the number of locations circled at question A19 and reported in questions A20–A43.

**PROMPT: IF THE TOTAL NUMBER OF LOCATIONS WITH LESIONS IS GREATER THAN FOUR, PLEASE USE A COPY OF PAGE 4 OR 5 OF THE FORM AND INSERT IT AFTER PAGE 5.**

- A20. **LOCATION #1.** Using the two-digit location codes provided at question A19, enter the appropriate location code for location #1. If the location code recorded is “31” (three or more locations), specify all affected locations in the space provided.
- A21–A25: Indicate whether the lesion type present at location #1 is a wart, ulcer, rash, mass or other lesion type.
- Indicate how many lesions are in that location.
  - Enter the size of the lesion in mm (width x length). If more than one lesion is present, measure the largest one.
- A22c. If the lesion reported at this location is an ulcer, it should also be assessed for depth. Ulcers are the only lesion type that will require a depth assessment. If more than one ulcer is present, measure the size and depth of the largest one.
- A25. If there is lesion present at location #1 that is not a wart, ulcer, rash or mass, specify what it is on the line provided in question **A25**.

**PROMPT: ENTER “99” IN COLUMN “a” IF THERE ARE TOO MANY LESIONS TO COUNT.**

- A26–A31: **LOCATION #2.** Using the two-digit location codes provided at question A19, enter the appropriate code for location #2. If the location code recorded is “31,” specify all affected locations. Complete questions A27–A31, following the above instructions for questions A21–A25.
- A32–A37: **LOCATION #3.** Using the two-digit location codes provided at question A19, enter the appropriate code for location #3. If the location code recorded is “31,” specify all affected locations. Complete questions A33–A37, following the above instructions for questions A21–A25.
- A38–A43: **LOCATION #4.** Using the two-digit location codes provided at question A19, enter the appropriate code for location #4. If the location code recorded is “31,” specify all affected locations. Complete questions A39–A43, following the above instructions for questions A21–A25.
- A44a. Perform the Wet Prep/Saline Mount according to the Lab Procedures Manual.
- Assess the presence or absence of Trichomonas.
  - Assess the presence or absence of clue cells.
  - Assess whether there are increased wbcs (i.e., whether wbc:epithelial cells is greater than 1:1).
- A44b. Perform the KOH Mount according to the Lab Procedures Manual.
- Assess the presence or absence of yeast.
  - Assess the presence or absence of amine odor.

### **SECTION B: CLINICAL IMPRESSION**

- B1. Record your clinical impression (“1” = “YES” or “2” = “NO”) as to whether or not the participant is pregnant.

- B2. Record your clinical impression as to whether or not the participant is menopausal. Menopause is defined as prior hysterectomy and/or surgical removal of both ovaries and/or on HRT and/or amenorrhea for greater than one year.
- B3. If overall clinical impression of this participant/exam is normal, circle "1" = "YES" and **END**.
- B4–B18: **Record the presence or absence of these clinical diagnoses by circling the appropriate response codes and following the indicated skip patterns.**
- B4. If vaginitis is present, indicate whether or not B4a, b or c is the cause of the vaginitis. If no vaginitis is noted or the cause is unknown, skip to question **B5**.
- B6. Diagnoses of PID (pelvic inflammatory disease) may include tubo-ovarian abscess (TOA), endometritis and/or salpingitis.
- B7. If proctitis is present, indicate whether or not B7a or b is the cause of the proctitis. If no proctitis is noted or the cause is unknown, skip to question **B8**.
- B8. If herpes is present, indicate whether or not B8a, b or c best describes this herpes episode. If no herpes is noted, skip to question **B9**.
- B10. If syphilis is present, indicate whether or not B10a or b best describes the characteristics of the current disease stage. If no syphilis is noted, skip to question **B11**.
- B11. If warts are present, indicate whether or not the warts are located at B11a, b, c, d and/or e. If no warts are noted, skip to question **B12**.
- B12. If any other cervical abnormality is present, specify what that abnormality is on the line provided.
- B13. If any other vaginal abnormality is present, specify what that abnormality is on the line provided.
- B15. If any other anal abnormality is present, specify what that abnormality is on the line provided.
- B16. If any other vulvar abnormality is present, specify what that abnormality is on the line provided.
- B17. If an adnexal mass (not PID) is present, indicate whether it is on the right (B17a) or left (B17b) side. If no adnexal mass is present, skip to question **B18**.
- B18. If adnexal tenderness (not PID or mass) is present, indicate whether it is on the right (B18a) or left (B18b) side. If no adnexal tenderness is present, skip to question **B19** the form.
- B19. Indicate whether colposcopy is indicated for the participant based on exam findings.

**PROMPT: ANY FINDINGS SUGGESTIVE OF SEXUAL OR PHYSICAL ABUSE ARE TO BE FOLLOWED UP BY THE CLINICIAN AND REFERRED TO THE APPROPRIATE REFERRAL SOURCES (i.e., LOCAL SOCIAL SERVICE AND/OR LAW ENFORCEMENT AGENCY).**

**PROMPT: COMPLETE "TIME MODULE ENDED" ON PAGE 1 OF THE FORM.**

**PLEASE NOTE: ANY NECESSARY ADDITIONAL COMMENTS SHOULD BE WRITTEN IN THE SPACE PROVIDED ON THE LAST PAGE.**