WOMEN'S INTERAGENCY HIV STUDY
ORAL PROTOCOL
FORM OP 4: ORAL MUCOSAL TISSUE EXAM

COMPLETING THE FORM

GENERAL INFORMATION

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.

Affix the Participant ID label in the space indicated.

Record the visit number.

Be sure the form version is the most current version date.

Record your initials.

Record the date.

SECTION A: LYMPH NODE EXAMINATION

A1. If the participant has no lymphadenopathy (palpable lymph nodes), the examiner will record "NO" for question A1 and will skip to Section B. If there are palpable lymph nodes, the examiner will record "YES" and will record information about each specific lymph node in questions A2 a–h.

A2a–A2h If the participant has lymphadenopathy, the examiner will record the status of each lymph node in question A2 as follows:

For each of the 16 nodes (right and left for each of eight listed regions), circle "yes" or "no" to indicate whether or not the node is present. If present, assess whether the node is larger than one centimeter, hard and/or tender, recording "1" for each specific criterion met, "0" for each criterion not met. If the node is not present, skip to assessment of the next listed node.

Missing values (-9) will only be recorded and entered if the examiner doesn't evaluate a specific node or if the node isn't present (e.g., due to surgical removal).

SECTION B: ORAL LESIONS

B1. Record the total number of oral lesions present. To promote standardized data collection, please refer to the Oral Mucosal Lesions Definition sheet at the end of these QxQs to guide you in your identification of lesions. If no lesions are present, record 00 (zero) in the space provided and skip to Section C.

B1a–B1f For each lesion sequence, under the heading of Lesion #, complete questions a–f. If more than four lesions are present, complete Form OP04a, ORAL LESION ADDENDUM.

a. Indicate the type of lesion by recording the letter code that corresponds to the lesion code key on page 2 of the form. If the lesion type is "other" (code S), be sure to specify the lesion type in the space provided.

b. Indicate the location of each lesion by recording the numeric location codes from the diagram on page 2 of the form. Space is provided for recording up to three separate locations, or use code #17 to indicate generalized lesions. Location codes are as follows:

01 – right lateral tongue
02 – left lateral tongue
03 – tip of tongue
04 – dorsal tongue
05 – oro-pharynx
06 – soft palate, uvula and fauces
07 – hard palate
08 – mucosa of upper lip and buccal mucosa superior to occlusal plane (including vestibule)
09 – mucosa of lower lip to buccal mucosa inferior to occlusal plane (including vestibule)
10 – right labial commissure
11 – left labial commissure
12 – floor of mouth
13 – vermilion of lower lip
14 – maxillary gingiva
15 – mandibular gingiva
16 – vermilion of upper lip
17 – generalized
18 – ventral tongue

c. Samples should be collected for lesion codes A, B, C, G, H and N and sent to the appropriate storage or testing sites. Indicate whether or not a sample was collected for these types of lesion by circling the appropriate response code. Samples should not be collected for lesion codes D, E, F, J, K, M, P, Q, R or S. For these lesion types, question B1c should be skipped, and "-1" entered into the database.

Oral lesion type and destination of samples:

(A) Angular Chelitis – samples sent to BBI.

(B) Pseudomebranous Candidiasis – samples sent to BBI.

(C) Erythematous Candidiasis – samples sent to BBI and the Oral Pathology Laboratory in Flushing, New York (see Procedures).

(G) Herpetic Ulcer Intraoral (HSV culture)

(H) Aphthous Ulcer Major (HSV culture)

(N) Other Ulcer (HSV culture)

The lesion number of any lesion from which a herpes smear was taken should be recorded on Form OP05.

d. Assess whether or not the patient is experiencing pain due to the lesion. Circle the appropriate response code.

e. Ask the participant to indicate how long she has had the lesion by reading the responses to her. Circle the appropriate response code as reported by the participant. If she has had the lesion for longer than three months, obtain the duration and specify in the space provided.

NOTE: At follow-up visits, you may notice lesions present that have persisted since the participant's last visit. Record all lesions found during the examination regardless of whether they are persistent or new. For persistent lesions, code sub-question B1e as "greater than 3 months" and specify in the space provided that the lesion was seen at the last visit. In addition, code sub-question B1f as "YES."

f. Inquire if the participant has a prior history of the lesion. Circle the appropriate response code. Proceed to Section C after all of the information about each lesion has been recorded on the form or on the Addendum.

SECTION C. SALIVARY GLAND EXAMINATION

C1. Parotid – Begin with the parotid gland examination. First assess the left gland for enlargement, tenderness and saliva expression. Then assess the right gland.

C2. Submandibular /Sublingual – Continue with the submandibular/sublingual examination. First assess the left gland for enlargement, tenderness and saliva expression. Then assess the right gland.

EQUIPMENT

- 2 mouth mirrors
- 2 x 2 gauze squares

PROCEDURES

SECTION A: LYMPH NODE EXAMINATION

1. Stand in front of the patient.
2. Examine the nodes bilaterally using the flat aspects of finger pads and tips of the first, second and third fingers. Palpate each of the sites in the order outlined below for the superficial lymph nodes.
3. Touch each area lightly, then increase pressure. Vary the touch pressure among the fingers. This will allow the node to demonstrate movability.
4. Maintain skin contact while moving in small circles along each lymph node chain.
5. Look for any tenderness, enlargement > 1cm, and consistency (hard or soft).
6. Examine the nodes in the following order:
   A. Postauricular nodes over the mastoid process.
   B. Preauricular nodes in front of the ear.
   C. Start at the angle of the mandible and move forward under the jaw until the hands meet, thus palpating the submandibular (posteriorly) and the submental (anterior aspect) nodes.
   D. Begin at the base of the skull to palpate the occipital nodes, moving from there into the posterior cervical triangle, palpating the entire contents of the triangle down to the clavicle

(use the borders of the sternomastoid and the trapezius muscles as the boundaries). Move into the supraclavicular fossae to palpate those nodes.

E. Return to the angles of the mandible and palpate down the anterior edges of the sternomastoid muscles until the clavicle is reached for the anterior cervical nodes.

See picture of lymph node location and direction.

Referral reminder: Consider referral for any lymph node that is hard, fixed or > 1cm in diameter. Note this action on OP16.

SECTION B: ORAL LESIONS

The examination procedure follows a systematic assessment of the lips; labial mucosa and sulcus; commissures, buccal mucosa and sulcus; gingiva and alveolar ridge, tongue; floor of the mouth; hard and soft palate; salivary glands, and lymph nodes.

1. Begin examination by observing the lips with the mouth both closed and open. Note the color, texture and any surface abnormalities of the upper and lower vermilion borders.

2. With the mouth partially open, visually examine the labial mucosa and sulcus of:

   a. the maxillary vestibule and frenulum, and

   b. the mandibular vestibule.

   Observe the color and any swelling or other abnormalities of the vestibular mucosa and gingiva.

3. Using the two mouth mirrors as retractors and with the mouth open wide, examine first the right, then the left buccal mucosa extending from the labial commissures and back to the anterior tonsillar pillar. Note any change in pigmentation, color, texture, mobility and other abnormalities of the mucosa, make sure that the commissures are examined carefully and are not covered by the mouth mirrors during retraction of the cheek.

4. Next, examine the gingiva and alveolar ridges (processes).

   a. Buccal and Labial Aspects – Start with the right maxillary posterior gingiva and alveolar ridge and move around the arch to the left posterior gingiva. Continue with the left mandibular and move around the arch to the right posterior gingiva.

   b. Palatal and Lingual Aspects – Same as above except on the palatal for the maxillary (right to left) examination and on the lingual for the mandibular (left to right) examination.

5. With the tongue at rest, and mouth partially open, inspect the dorsum of the tongue for any swelling, ulceration, coating or variation in size, color or texture. Also note any change in the pattern of the papillae covering the surface of the tongue and examine the top and the tip of the tongue. The subject should then protrude the tongue, and the examiner should note any abnormality of mobility. With the aid of mouth mirrors, inspect the margins of the tongue. Grasping the tip of the tongue with a piece of gauze will assist full protrusion and will aid examination of the margins. Then observe the ventral surface.

6. With the tongue still elevated, inspect the floor of the mouth for swellings or other abnormalities.

7. With the mouth open and the subject's head tilted backward, gently depress the base of the tongue with a mouth mirror. First inspect the hard, and then the soft palate.

8. Next, evidence of major gland swelling and/or tenderness upon palpation and failure of saliva to be elicited from either Wharton's or Stensen's ducts are evaluated. Scores are recorded as 0 (absence of sign or symptom) or 1 (presence of sign or symptom).

   a. Inspect patient's face and score presence or absence of parotid gland enlargement.

      0 = no enlargement

      1 = enlargement

      Palpate left and right parotid glands. Ask patient to open the mouth. Retract left cheek with the ball of thumb. Pick up a piece of 2x2 gauze with your hand and gently dry the area around the orifice of the parotid duct. Now use the other hand to gently massage the side of the face from the ear lobe forward. Continue to retract the left cheek with your hand and repeat the procedure one more time. *Look for the presence or absence of clear flow of saliva*. If flow is limited to 1–2 drops or if it is viscous or contaminated with puss or blood, score "absent" (i.e., score = 1). To examine right parotid, repeat the same procedure, switching hands if necessary.

   b. Palpate left and right submandibular/sublingual glands. Ask patient to open. Dry the floor of the mouth with 2x2 gauze. Place your index finger under the left side of the jaw and press up against skin covering the inner side of the mandible. Place your index finger between the lower left molar teeth and bring your finger forward, massaging the duct of submandibular gland. Repeat one more time. *Look for clear flow of saliva and score its presence or absence.*

      To examine right submandibular gland, while patient's mouth remains open, dry the floor of the mouth again and repeat the examination on the other side.

Procedures for Mucosal Smear of Erythematous Candidiasis (lesion code C only)

- The smear kit provided contains a wooden spatula, a cotton swab, two glass slides and a packet of fixative. The directions in the kit are for taking vaginal samples and should therefore be ignored.
- Open the packet and remove the packet of fixative, the wooden spatula and cotton swab.
- Tear the covering of the packet along the perforation so that the slide part of the packet can be handled separately. Do not remove slides from the packet.
- Label both slides on the frosted end with WIHSID in pencil.
- Using the wooden spatula, scrape over the surface of the erythematous area(s) and spread the sample over the two slides.
- Immediately, open the packet of fixative and wet the smeared area of both sides with fixative. Let slides dry.
- Close the packet and place a pre-printed label (with participant's ID) on the outside of the packet. Record the collection date and the visit number on the label.
- Place pre-printed label with WIHSID and date of smear on the laboratory slip. If there is no pre-printed label available, write the WIHISID and date of smear on the laboratory slip.
- Place the packet with the slides enclosed in the special self-addressed mailing envelope provided.

The address of the Oral Pathology Laboratory is:

Oral Pathology Laboratory
56 – 26 Main St.
Flushing NY 11355

- When additional smear kits are needed, please contact Dr. Joan Phelan at:

Phone: (516) 261-4400 ext. 7415
FAX: (516) 266-6020
Email: phelan.joan@northport.va.gov

SECTION C: SALIVARY GLAND EXAMINATION

Finally, evidence of major gland swelling and/or tenderness upon palpation and failure of saliva to be elicited from either Wharton's or Stensen's ducts are evaluated. Scores are recorded as 0 (absence of sign or symptom) or 1 (presence of sign or symptom).

1. Inspect patient's face and score presence or absence of parotid gland enlargement.

   0 = no enlargement

   1 = enlargement

   Palpate left and right parotid glands. Ask the participant to open her mouth. Retract the left cheek with the ball of thumb. Pick up a piece of 2x2 gauze with your hand and gently dry the area around the orifice of the parotid duct. Now use the other hand to gently massage the side of the face from the ear lobe forward. Continue to retract the left cheek with your hand and repeat the procedure one more time. *Look for the presence or absence of clear flow of saliva*. If flow is limited to 1–2 drops or if it is viscous or contaminated with puss or blood, score "absent" (i.e., score = 1). To examine right parotid, repeat the same procedure, switching hands if necessary.

2. Palpate left and right submandibular/sublingual glands. Ask the participant to open. Dry the floor of the mouth with 2x2 gauze. Place your index finger under the left side of the jaw and press up against skin covering the inner side of the mandible. Place your index finger between the lower left molar teeth and bring your finger forward, massaging the duct of submandibular gland. Repeat one more time. *Look for clear flow of saliva and score its presence or absence.*

   To examine the right submandibular gland, while the participant's mouth remains open, dry the floor of the mouth again and repeat the examination on the other side.

DEFINITION OF ORAL MUCOSAL LESIONS

A. Angular Chelitis (BBI sample)

- Found only in the corners (angles) of the mouth – location codes 10 and 11.
- Erythema, fissures, or linear ulcers.
- If lesion can be attributed to recent injury, do not code as angular chelitis.

B. Pseudeomembranous Candidiasis (BBI sample)

- Yellow-white, loosely adherent plaque(s) located anywhere in the mouth.
- Plaques must wipe off.
- Plaques must be adherent to the mucosa. If not certain that plaques are adherent, have the patient rinse. If plaques remain and can be wiped off, code as pseudomembranous candidiasis.
- Underlying mucosa is usually erythematous, but erythema is not essential to coding the lesion as pseudomembranous candidiasis.

C. Erythematous Candidiasis (OPL Mucosal Smear and BBI)

- Diffuse or irregular, erythematous, macular patches on mucosal surfaces.
- Dorsum of tongue – irregular, depapillated area or areas which may or may not be erythematous.
- In any location, areas are not sharply defined.

D. Leukoplakia

- A white patch or plaque.
- Lesion does not wipe off and cannot be characterized as any other disease.

E. Hairy Leukoplakia

- Vertically corrugated, slightly elevated, white surface alteration of the lateral or ventral tongue margin. VERTICAL CORRUGATIONS are essential to the coding of hairy leukoplakia.
- When extending to ventral tongue, white lesion may be flat and not corrugated, BUT vertical corrugations must be noted in the associated lesion on the lateral tongue.
- Lesion does not wipe off.

F. Herpes Labialis (NO HSV culture)

- Single or multiple vesicles or ulcers with crusting.
- Located on vermilion portion of lips and adjacent facial skin.
- Lesion does not extend past the dry/wet line.
- Whether on or around the lips, is marked as location 13 or 16.

G. Herpetic Ulcer Intraoral (HSV culture)

- Solitary, multiple or confluent ulcers.
- Shallow ulcer(s).
- No yellowish-white ulcer surfaces.
- Minimal to no erythematous peripheral halo.
- Ulcer begins with tiny vesicle formation which may not remain at time of examination.

H. Apthous Ulcer Major (HSV culture)

- Size – greater than 1 cm.
- Solitary or multiple.
- Painful ulcer.
- Well circumscribed ulcer.
- Ulcer surrounded by distinct erythematous peripheral halo.
- Yellowish-white ulcer surface.

J. Apthous Ulcer Minor

- Size – less than 1 cm.
- Solitary or multiple.
- Painful ulcer.
- Well circumscribed ulcer.
- Located on non-keratinized mucosa.
- Ulcer surrounded by distinct erythematous peripheral halo.
- Yellowish-white ulcer surface.

K. Denture Stomatitis

- MUST be located and limited to the mucosa under a full or partial denture.
- Erythematous mucosa.
- Flat to granular to papillary/nodule texture.

M. Denture Ulcer

- Mucosal ulcer determined to be directly caused by full or partial denture.

N. Ulcer – Unknown Etiology (HSV Culture)

- Any other ulcer than those coded above.
- Cause of ulcer is unknown.
- Code clearly identified traumatic ulcers under "(S) Other."

P. Oral Papilloma / Wart

- Papillary outgrowth(s) of the oral mucosa (may be "cauliflower-like" or flat).
- Solitary or multiple.
- Small to extensive.

Q. Kaposi's Sarcoma

- Brown, red, blue or purple macule, papule or nodule.
- If not certain the lesion is KS, code it as "S" and indicate "Vascular lesion R/O KS."
- Previously confirmed by biopsy or KS diagnosed elsewhere.

R. Abscess

- Raised erythematous nodule on the attached gingiva associated with a tooth which is likely to be causative.
- Must identify pus draining from the lesion.

S. Other

- Any lesion other than those listed above.