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APPENDIX 2: CEM QUESTIONNAIRES

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Safety Platform for Emergency vACcines

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CEM Questionnaire	17-Sept-2024	V1.0	SPEAC Executive Board	Creation of the document

CEM AESI Questionnaire

Demographics

1. What is your age? _____ years/months
2. Sex: [ ] M [ ] F [ ] TGM [ ] TGF
    a. If F = YES, and Age > 10 years:
    Pregnancy status: [ ] Unknown [ ] Not pregnant [ ] Pregnant
    LMP: ___/___/___ (dd/mo/yr)
3. HIV status: [ ] Unknown [ ] Negative [ ] Positive
    a. If HIV positive:
    Last CD4: _____ Date: ___/___ (mo/yr)
    Last VL: _____ Date: ___/___ (mo/yr)
    Currently taking antiretroviral therapy: [ ] Yes [ ] No
4. Do you have any other condition that could affect your immune system?
    [ ] Yes [ ] No
    a. If Yes: What is the condition? _____
    When were you diagnosed with this? ___/___/___ (dd/mo/yr)
    Are you currently taking medication to treat this? [ ] Yes [ ] No
    If yes, list your medications: _____
5. Do you take any medications that could affect your immune system? [ ] Yes [ ] No
    If yes, list your medications and when you started taking them:
    _____ Date: ___/___ (mo/yr)
    _____ Date: ___/___ (mo/yr)

CEM Reactogenicity Screening Questions (daily x 7 days after vaccination, then monthly x 3 months)

1. Systemic Reactogenicity: In the first week after vaccination have felt unwell? Did it affect your usual activities? Did you seek medical care?

2. Local Reactogenicity: Have you noticed any skin reaction at the site of vaccination? [ ] Yes [ ] No
    a. If Yes: complete the Dermatologic AESI form

CEM SAE Screening Questions (daily x 7 days after vaccination, then monthly x 3 months)

3. SAEs: Have you been hospitalized?
    a. Note: If lost to followup, seek family member to administer questions below [or verbal autopsy form]

CEM AESI Screening Questions by System (daily x 7 days after vaccination, then monthly x 3 months)

4. Anaphylaxis
    a. Have you had difficulty breathing, rash or hives, swelling of the skin, sick to your stomach, and feeling weak and faint starting within several hours after vaccination?

5. Cardiac
    a. Have you had chest pain, fluttering heart, or a fast heart rate during the six weeks after vaccination?
6. Dermatologic
    a. Have you had a rash around the vaccine site or elsewhere on your body that occurred within two weeks after vaccination ?
7. Ophthalmologic
    a. Have you had any change in your vision (blurry vision, painful eyes, double vision) in the 30 days after vaccination?
8. Neurologic
    a. Have you had severe headache, confusion, or limb movements you couldn't control in the three weeks after vaccination?

If “Yes” to any of the screening questions, trigger the relevant AESI questionnaire by body system

CEM AESI-specific Questionnaires (and associated Data Collection Forms)

1. General (Anaphylaxis)
2. Cardiac (Myocarditis/Pericarditis)
3. Dermatologic (Rash, robust take, generalized vaccinia, eczema vaccinatum, inadvertent autoinoculation)
4. Ophthalmologic (E.g. keratitis, blepharoconjunctivitis, EOM paresis)
5. Neurologic (Encephalitis, seizure)

For any possible in-person followup by study staff/focal point, review available records or registers at health post/center/hospital or arrange for evaluation by study staff to complete the Simplified Data Collection Forms (DCFs) as possible.

CEM AESI Questionnaire - Anaphylaxis

Anaphylaxis screening question: Have you had difficulty breathing, rash or hives, swelling of the skin, sick to your stomach, and feeling weak and faint starting within several hours after vaccination?

1. If yes, please specify which you had:

    a. Difficulty breathing? Y/N (if yes, answer below)
        i. When did it start? (date, approximate time)
        ii. When did it stop, or is it ongoing? (date/ongoing)

    b. Rash or hives, at a location other than where you got the vaccine? Y/N (if yes, answer below)
        i. When did it start? (date, approximate time)
        ii. When did it stop, or is it ongoing? (date/ongoing)

    c. Swelling of the skin at a location other than where you got the vaccine? Y/N (if yes, answer below)
        ii. Where did you have swelling of the skin?
        iii. When did it start? (date, approximate time)
        iii. When did it stop, or is it ongoing? (date/ongoing)

    d. Sick to your stomach, with new vomiting or diarrhea? Y/N (if yes, answer below)
        i. When did it start? (date, approximate time)
        ii. When did it stop, or is it ongoing? (date/ongoing)

    e. Feeling faint? Y/N (if yes, answer below)
        iv. When did it start? (date, approximate time)
        iv. When did it stop, or is it ongoing? (date/ongoing)

2. Did you see a medical person for help? Y/N
    a. If yes, which type and when did you see them?

Type	**Location**	**Date(s)**
Health post [ ]		
Health center [ ]		
Hospital [ ]		
Traditional healer [ ]		
Pharmacy [ ]		

    b. If yes, CEM nurse should complete the following from available records (ask patient for their take-home chart, check register for signs and symptoms, review hospital records)

3. If 1a. Difficulty breathing = yes, did you have or were you told by family or friends that you had:
    a. Faster breathing than your usual breathing rate?
    b. Skin turning blue or gray (e.g., your lips, fingertips)?
    c. Increased effort required to take a breath (e.g., big movements in the muscles of your chest in order to take a breath in)
    d. A rattling or high-pitched squeaking or whistling sound when you breathed in or out?
    e. Swelling of your tongue or inside your mouth or throat?
    f. Low oxygen level (e.g., on a health clinic's fingertip oxygen monitor)

CEM AESI Questionnaire - Cardiac

Myocarditis screening question: Have you had chest pain, shortness of breath, irregular or fast heartbeat, fatigue, sweating or fever since having vaccination?

2. If yes, please specify which you had:

b. Chest Pain? Y/N (if yes, answer below)
   ii. When did it start? (date, approximate time)
   iii. How long did it last?
   iii. When did it stop, or is it ongoing? (date/ongoing)
   iv. Was it sharp, throbbing, dull or pounding?

c. Shortness of Breath? Y/N (if yes, answer below)
   v. When did it start? (date, approximate time)
   v. When did it stop, or is it ongoing? (date/ongoing)
   vi. Was it made worse with exertion? (walking or climbing stairs)

f. Irregular or fast heartbeat? Y/N (if yes, answer below)
   i. When did it start? (date, approximate time)
   vi. How long did it last?
   vii. When did it stop, or is it ongoing? (date/ongoing)
   viii. Have you had multiple episodes?

g. Fatigue? Y/N (if yes, answer below)
   ii. When did it start? (date, approximate time)
   iii. When did it stop, or is it ongoing? (date/ongoing)

h. Sweating? Y/N (if yes, answer below)
   i. When did it start? (date, approximate time)
   ii. When did it stop, or is it ongoing? (date/ongoing)

f. Fever? Y/N (if yes, answer below)
   i. When did it start? (date, approximate time)
   ii. How long did it last?
   iii. How high was it?

3. Did you see a medical person for help? Y/N
    b. If yes, which type and when did you see them?

Type	Location	Date(s)
Health post [ ]		
Health center [ ]		
Hospital [ ]		
Traditional healer [ ]		
Pharmacy [ ]		

    b. If yes, CEM nurse should complete the following from available records (ask patient for their take-home chart, check register for signs and symptoms, review hospital records)

4. If 1a. Chest Pain = yes, did you do any of the following?
    a. Have your blood pressure checked?
    b. Have an electrocardiogram?
    c. Have an echocardiogram?
    d. Take any medicines (e.g. aspirin, ibuprofen, paracetamol)

5. If 1a. Shortness of Breath = yes, did you have or were you told by family or friends that you had:
    g. Faster breathing than your usual breathing rate?
    h. Skin turning blue or gray (e.g., your lips, fingertips)?
    i. Increased effort required to take a breath (e.g., big movements in the muscles of your chest in order to take a breath in)
    j. A rattling or high-pitched squeaking or whistling sound when you breathed in or out?
    k. Swelling of your tongue or inside your mouth or throat?
    l. Low oxygen level (e.g., on a health clinic's fingertip oxygen monitor)

6. If 1f. Fever = yes, did you do any of the following?
    a. Take any medicines (aspirin, paracetamol, ibuprofen)?

7. Have you had any other recent illness in the last 4 weeks? Y/N
(if yes, answer below)

    What illness were you diagnosed with? List: _____

8. Were you taking any medicines, herbal medicines, or vaccines in the 4 weeks before this happened? Y/N (if yes, answer below)

    Which medicines, herbal medicines or vaccines? List: _____

CEM AESI Questionnaire - Dermatologic

Dermatologic screening question: Have you had a rash around the vaccine site or elsewhere on your body that occurred within two weeks after vaccination?

If yes:

1. Where on your body did the rash occur? _____
2. When did it start? (date)
3. When did it stop, or is it ongoing? (date/ongoing)
4. What does it look like? _____
5. Could you send a photo?
    i. If yes, refer to expected vaccine takes and complications to classify OR apply a program such as VisualDx to classify and complete Derm AESI-specific questions below, and associated DCFs
    ii. If no, ask participant to come for an in-person visit to assess them or have a CHW visit them to assess the rash, and complete Derm AESI-specific questions below, and associated DCFs]
6. Did you see a medical person for help? Y/N
7. If yes, which type and when did you see them?

Type	**Location**	**Date(s)**
Health post [ ]		
Health center [ ]		
Hospital [ ]		
Traditional healer [ ]		
Pharmacy [ ]		

Derm AESI-specific questions:

Re Robust Take

Re Generalized vaccinia, Inadvertent inoculation and eczema vaccinatum – general question for all 3

- Did any lesions, similar to the one at the vaccination site, develop in other skin areas beyond the vaccination site?
    - If Yes, what body areas were involved. (face, trunk, R/L arm, R/L leg, buttocks
- In the week before or since vaccination, were you in contact with anyone with an infectious rash (such as chickenpox, scabies…..list the commonly known vesicular-pustular diseases in the area)?

Follow up question relevant for inadvertent inoculation

- Did any lesions occur inside your mouth, in your nose, in your eyes or private parts (vagina, glans penis, anus)?
- Did you scratch any of the skin areas or rub your eyes, nose or inside your mouth prior to the lesions appearing?

Follow up question relevant to eczema vaccinatum

- At the time of vaccination did you have any skin rash due to eczema or other skin problem?
- If yes did the skin lesions following vaccination occur in the involved areas of skin?

Re Progressive vaccinia [ONLY if immunocompromised host = yes]

- Briefly describe the expected evolution of vaccination site – e.g.: About a week after vaccination a small red bump (papule) or 'blister' (vesicle) appears at the site; over the next several days blister may look like a p ustule, and then a scab forms which should drop off leaving a small depressed area in the skin (scar) by the end of the 3rd week.,
    - Does this match what you experienced? If not how was it different?
    - How big did the reaction at the vaccine site get? – could compare to known things (common fruit, coins, width of local currency notes etc). – would focus on lesions that persist beyond two weeks
    - Did the centre of the lesion look black (necrosis).
    - [1 month and after] Did the scab fall off, leaving a sore area underneath?

For study staff: Consider obtaining photo by text or in person, or refer to poster guide of usual vaccine take progression to complete the simplified DCFs

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CEM AESI Questionnaire - Neurologic

Neurologic screening question: Have you had severe headache, confusion, or limb movements you couldn't control in the three weeks after vaccination?

1. If yes, please specify which you had:
    1. Fever? Y/N (if yes, answer below)
        i. When did it start? (date)
        ii. When did it stop, or is it ongoing? (date/ongoing)

    2. Headache? Y/N (if yes, answer below)
        i. When did it start? (date)
        ii. When did it stop, or is it ongoing? (date/ongoing)

    3. Confusion? Y/N (if yes, answer below)
        i. When did it start? (date)
        ii. When did it stop, or is it ongoing? (date/ongoing)

    4. Limb movements you couldn't control Y/N (if yes, answer below)
        i. When did it start? (date)
        ii. When did it stop, or is it ongoing? (date/ongoing)

2. Did you see a medical person for help? Y/N
    1. If yes, which type and when did you see them?

Type	**Location**	**Date(s)**
Health post [ ]		
Health center [ ]		
Hospital [ ]		
Traditional healer [ ]		
Pharmacy [ ]		

3. If 1b. Confusion = yes, did you have or were you told by family or friends that you had:
    1. Lethargy for more than 1 day?
    2. Change in your personality for more than one day?

4. Were you taking any medicines, herbal medicines, or vaccines in the 3 weeks before this happened? Y/N (if yes, answer below)
    1. Which medicines, herbal medicines, or vaccines? List: _____

5. If 2. Sought medical care = yes, CEM nurse should complete the Neuro Data Collection Form (or adapted version) from available records (ask participant for their take-home chart, check register for signs and symptoms, review hospital records), and/or evaluate participant in person