HBV/HIV Follow-up (or Special Visit) Evaluation

General Instructions

Follow-up visits are completed at 24, 48, 72, 96, 120, 144, 168, and 192 weeks following the initial baseline visit. Special visits are completed as needed for any of the outcome events listed in the protocol (e.g. ALT flare, HBs/eAg loss, pregnancy).

The HBV/HIV Follow-up (or Special Visit) Evaluation form is completed at all the protocol follow-up visits and special visits.

There is a four (4) week window on either side of each follow-up evaluation date, beginning with the week 24 follow-up. However, information should be captured even when the evaluation is performed outside of this window.

This form captures information obtained from patient interview and medical record review. When information in the medical record conflicts with information provided by the patient, the medical record is normally considered to be the accurate source, although there may be instances when the information provided by the patient is more up to date or accurate. In this instance, the information from the patient may be used.

Information for the serology and laboratory sections of the form should be obtained from the patient's medical record.

The coordinator is responsible for obtaining the information recorded on this form. In non-English speaking patients, the interview may be performed through a certified interpreter. While a trained translator is preferred, a family member or friend of the patient (who speaks fluent English and the native language of the patient) may be acceptable for this role as determined on an individual basis.

Refer to the HBRN Cohort Codebook for items that require coded responses.

IMPORTANT: The patient must be fasting at the week 96 and 192 visits. A 12 hour fast is optimal but at least 8 hours is acceptable.

Refer to the HBRN Cohort Codebook for items that require coded responses.

Specific Instructions

Patient ID**:** Record the Patient ID number in the top right hand corner of each page.

Date of Evaluation: Record the date (month/day/year) that corresponds to the baseline visit.

Protocol timepoint: Record the protocol timepoint that corresponds to the visit.

Section I: Medical History

HIV Stage: Record the current stage of HIV according to the following criteria, or check "Unknown" if the stage cannot be determined.

Stage 1
- Asymptomatic
- Persistent generalized lymphadenopathy

Stage 2
- Moderate unexplained weight loss (<10% of presumed or measured body weight)
- Recurrent respiratory infections (sinusitis, tonsillitis, otitis media, and pharyngitis)
- Herpes zoster

- Angular cheilitis
- Recurrent oral ulceration
- Papular pruritic eruptions
- Seborrheic dermatitis
- Fungal nail infections

Stage 3

- Unexplained severe weight loss (>10% of presumed or measured body weight)
- Unexplained chronic diarrhea for >1 month
- Unexplained persistent fever for >1 month (>37.6ºC, intermittent or constant)
- Persistent oral candidiasis (thrush)
- Oral hairy leukoplakia
- Pulmonary tuberculosis (current)
- Severe presumed bacterial infections (e.g., pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia)
- Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis
- Unexplained anemia (hemoglobin <8 g/dL)
- Neutropenia (neutrophils <500 cells/µL)
- Chronic thrombocytopenia (platelets <50,000 cells/µL)

Stage 4

- HIV wasting syndrome, as defined by the CDC (see Table 1, above)
- *Pneumocystis* pneumonia
- Recurrent severe bacterial pneumonia
- Chronic herpes simplex infection (orolabial, genital, or anorectal site for >1 month or visceral herpes at any site)
- Esophageal candidiasis (or candidiasis of trachea, bronchi, or lungs)
- Extrapulmonary tuberculosis
- Kaposi sarcoma
- Cytomegalovirus infection (retinitis or infection of other organs)
- Central nervous system toxoplasmosis
- HIV encephalopathy
- Cryptococcosis, extrapulmonary (including meningitis)
- Disseminated nontuberculosis mycobacteria infection
- Progressive multifocal leukoencephalopathy
- Candida of the trachea, bronchi, or lungs
- Chronic cryptosporidiosis (with diarrhea)
- Chronic isosporiasis
- Disseminated mycosis (e.g., histoplasmosis, coccidioidomycosis, penicilliosis)
- Recurrent nontyphoidal *Salmonella* bacteremia
- Lymphoma (cerebral or B-cell non-Hodgkin)
- Invasive cervical carcinoma
- Atypical disseminated leishmaniasis
- Symptomatic HIV-associated nephropathy
- Symptomatic HIV-associated cardiomyopathy
- Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)

Opportunistic infection: Check “Yes” or “No” to indicated whether or not the patient has a history of opportunistic infection(s), and if yes, complete the Opportunistic Infection Log to record information related to the specific infections. Record “Unknown” if it is not known whether the patient has ever had an opportunistic infection.

Section II: Physical Exam

Lipodystrophy/ Lipoatrophy: Record the current grade for the patient's lipodystrophy or lipoatrophy, defined as diffuse fat accumulation, in the face, neck, dorso-cervical spine, arms, breasts, abdomen, buttocks, or legs, as well as the presence, site, and number of any lipomata (focal accumulations of fat), or check "Not Done" if the assessment is not performed.

The degree of lipoatropy, diffuse fat accumulation, or lipomatosis at every site on the body should be graded as

Grade 0 (none): absent
Grade 1 (mild): noticeable on close inspection
Grade 2 (moderate): readily noticeable by patient or physician
Grade 3 (severe): readily noticeable to a casual observer

Section III: HBV/HIV Treatment

Change in HBV or HIV Treatment: Check "Yes" or "No" to indicate if there has been a change in the HBV or HIV antiviral therapy since the previous evaluation. .

If Yes, update the treatment specific information on the HBV/HIV Antiviral Therapy Log.

Missed Doses: Check "Yes" or "No" to indicate whether the patient has missed any doses of their prescribed HIV therapy since the previous evaluation.

If Yes, record the number of days of HIV antiviral therapy that were missed. If the exact number of days is not documented, it may be necessary to accept patient report.

Section IV: Risk Assessment

Injection drugs: Check "Yes" or "No" to indicate whether the patient has recently used or is currently using injection (or intravenous) drugs not prescribed by a physician (e.g. heroin, cocaine, PCP, barbiturates, morphine, amphetamines, and methamphetamine), or check "Unknown" if this cannot be reliably determined.

Intra-nasal drugs: Check "Yes" or "No" to indicate whether the patient has recently used or is currently using intra-nasal illicit drugs (drug by inhalation through the nose, which include but is not limited to cocaine, heroin, and amphetamines), or check "Unknown" if this cannot be reliably determined.

Section V: Serologies

HIV-1 RNA quant: Record the result from a sample obtained at the time of the follow-up evaluation or the most recent result obtained since the previous protocol evaluation and the date of sample (month/day/year) for the HIV-1 RNA quantitative test. If the test was never performed or a result is not available, check "Not done".

HCV RNA quant:
(1) Record the result from a sample obtained at the time of the follow-up evaluation or the most recent result obtained since the previous protocol evaluation and record the date of the sample (month/day/year) for the HCV RNA quantitative test. If the test was never performed or a result is not available, check "Not done".
(2) Check "IU/mL" or "copies/mL" to indicate the unit of measure.
(3) Record the lower limit of detection for the test. If the lower limit of detection is not available or unknown, record "Unk".

Section VI: Labs

Record the most recent result for each lab test. Tests are to be performed at the time of the baseline evaluation or within one month prior to the baseline evaluation. Check "Not Done" if a test was not performed and a recent result is not available.

Date of sample: Record the date of sample (month/day/year) for the lab tests listed in this section.

Lab results:
(1) Record the result of the lab test.
(2) If a date of sample for a specific lab is not the same as the date of sample recorded at the top of the section, record the date (month/ day/year) the sample was obtained. If any part of the date is unknown, record "Unk".
(3) If the lab test was not completed or the result is not available, check "Not Done".

Section VII: Biospecimens

In addition to samples obtained for the HBRN Cohort Study, serum from a 9mL Bumble Bee Top (BBT) tube must be obtained at the baseline visit and at weeks 96 and 192 for this ancillary study. Process whole blood per the Sample Collection procedures and aliquot into three vials, 1.5mL serum per vial, store locally, and then batch ship to the NIDDK Repository along with other frozen samples.

BBT obtained: Check "Yes" or "No" to indicate whether a sample was obtained in a BBT tube at the baseline visit.

Section VIII: FRAX (WHO Fracture Risk Assessment Tool) Scores

The FRAX Scores should be calculated at the baseline evaluation and the 96 week (2 year) and 192 week (4 year) visits.

Use the FRAX Worksheet to collect the information needed to calculate the 10-year fracture risk scores. Once the information is recorded on the worksheet, go to the FRAX website to enter the information and obtain the scores. Record the Major Osteoporotic and Hip Fracture risk scores obtained from the website on both the FRAX Worksheet and the HBV/HIV Follow-up (or Special Visit) Evaluation form. Retain the completed FRAX Worksheet as a source document.

Scores must be calculated without Bone Mineral Density (BMD). If a BMD measurement is available then the scores should be calculated with the BMD too.

FRAX Website: http://www.shef.ac.uk/FRAX/tool.jsp
Select "Calculation Tool", "North America" and then the appropriate category (Canada or US).