



## Pregnancy Questionnaire (Adult)

### **General Instructions**

The Pregnancy Questionnaire is completed at the Baseline Visit on all female patients that have ever been pregnant, regardless of the outcome of the pregnancy. The questionnaire captures information regarding the patient's pregnancy history, hepatitis B treatment during each pregnancy of a live birth, and the hepatitis B status and HBIG/vaccination at each live birth.

This information is 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 provided by the patient may be used.

The coordinator is responsible for obtaining the information captured 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.

### **Specific Instructions**

Patient ID: Record the Patient ID in the top right hand corner.

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

### **Section I: Pregnancy History**

Number of pregnancies: Record the number of pregnancies the patient has had in her lifetime, including a current pregnancy if the patient is pregnant at the time. If this number is not known, check "Unknown".

- a. Record the number of nonviable pregnancies for each category. If this is the patient's first pregnancy, record 0 for each category.
  - i. Miscarriage: loss of an embryo or fetus prior to 20<sup>th</sup> week of pregnancy.
  - ii. Stillborn: fetus dies during birth or  $\geq$  20 weeks of pregnancy.
  - iii. Terminated: medically induced termination of pregnancy.
- b. Record the number of live births (children). If this is the patient's first pregnancy, record 0.

For each child, complete the following information:

- i. Year of Birth: record the year the child was born. If year is unknown, record UNK [-3].
- ii. Tested for hepatitis B: check "Yes", "No" or "Unknown" to indicate if the child was tested for hepatitis B.
- iii. Diagnosed with hepatitis B: check "Yes", "No" or "Unknown" to indicate if the child was diagnosed with hepatitis B. Diagnosed is defined as a positive hepatitis surface antigen (HBsAg) test result.



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- iv. HBIG: check "Yes", "No" or "Unknown" to indicate if the child received Hepatitis B Immune Globulin (HBIG) within 12 hours of birth.
- v. HBV vaccine: check "Yes", "No" or "Unknown" to indicate if the child received the hepatitis B vaccine within 12 hours of birth.
- vi. Hepatitis B treatment: check "Yes, throughout", "Yes, 3<sup>rd</sup> trimester only", "No" or "Unknown" to indicate if the patient (mother) received interferon or oral agents to treat hepatitis B during the pregnancy.
  - 3<sup>rd</sup> trimester is defined as  $\geq 26$  weeks.
  - Treatments include but are not limited to interferon, peg-interferon, entecavir, telbivudine, lamivudine, adefovir, tenofovir, emtricitabine, and truvada.  
*Note:* Tenofovir (TDF) = Tenofovir disoproxil fumarate  
Tenofovir (TAF) = tenofovir alafenamide fumarate

If "yes, throughout" or "yes, 3<sup>rd</sup> trimester only", check each treatment that was received. If the patient received interferon or oral agents for hepatitis B during the pregnancy but cannot recall the specific agent, check "Unknown".

*This section captures data for up to four children. If the patient has more than four children and the information is being recorded on paper forms, print another form, collect the information for the additional children and enter it into the system. If the information is entered directly into the HBRN data management system, the system will allow for more than four children.*