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**Guidelines for Collecting**

**HIV Testing and Antiretroviral History**

**From Patients at HIV Testing Sites**

**Introduction**

These instructions are a guide to assist HIV healthcare providers to administer the “***HIV Testing History***” questions located on page 2 of the confidential HIV/AIDS case report form (CRF). The CRF is to be administered by public and private HIV health care providers to all patients who are diagnosed with HIV in San Francisco. The HIV testing history questions (THQ) on the second page of the CRF collect information about patient’s HIV testing history and HIV antiretroviral therapy (ART) use. The answers to these questions are confidential and help increase our understanding of how often and why people get tested for HIV.

While healthcare providers may choose to read the questions as written to patients, you are also encouraged to develop your own professional and culturally sensitive style in asking these questions. The information collected on the HIV testing history section of the CRF may be obtained from many sources (directly from the patient, medical records, provider reports, and lab results) if available and the questionnaire may be shortened accordingly.

The primary purpose of these questions is to gather HIV testing history information from patients recently diagnosed with HIV in San Francisco.

**How to introduce the HIV testing history questions (THQ)**

**to the patient?**

As an HIV health care provider you are in the unique position of collecting confidential health information essential to improving our understanding of *new* HIV infections occurring in San Francisco. Whenever we ask questions about HIV testing or medication use it’s important to remain non-judgmental and culturally sensitive.

Here are some suggestions on how to introduce the HIV THQ to patients at your health care site:

*“I would like to ask you some questions about HIV tests you’ve had in the past and if you used any HIV medications before testing today.”*

*“I’d like to ask you about previous HIV tests you’ve had, to help our understanding of why people like yourself seek HIV testing.”*

*“I’m going to ask you a few questions about your HIV testing history and medications you may have previously used.”*

There will be times when the patient is unable to remember the exact date of their HIV test, in these cases the patient should be asked to estimate the date to the best of their recollection.

Probes that might assist the client in remembering dates for the following questions include;

*“Think about the time of year that you had the HIV negative/positive test.”*

*“Did you have the HIV test close to a significant event/date in your life, like a birthday, holiday or the beginning of a new relationship?”*

**General Guidance**

The following are descriptions of the common response options:

* **“Yes”** indicates that there was sufficient documented evidence that the event occurred. Evidence can be from patient self-report, health care provider note, or laboratory documentation.
* **“No”** indicates that there was sufficient documented evidence that the event did not occur. Evidence can be from patient self-report or health care provider documentation of no previous negative test.
* **“Refused”** means patient refused, health care provider recorded “refused”, or facility refused to permit the medical record review.
* **“Don’t know/Unknown”** indicates that the patient reported “don’t know”, the health care provider documented “unknown”, or there was insufficient documented evidence for or against (supporting or denying) the occurrence of the event.
* **Blank** indicates that the usual data sources were not investigated and/or the health care provider/staff were not asked.

**Note for Dates:**

* For questions regarding dates for month and year, use two numeric digits for month and four digits for year. Example: April 2007 = “04/2007”. You may also use the codes “99” for unknown month, “9999” for unknown year and “77” for when the patient refused to provide a specific month and “7777” for refused to provide year.
* *For example*, if the year for the first positive HIV test is unknown, document with “9999” or if the month is unknown but the year is documented, you may use “99/2007”.

**For indeterminate HIV test results,** collectors should ignore indeterminate test results in recording responses to previous testing history questions including previous positive tests, negative tests, and number of negative tests. An indeterminate test is neither positive nor negative for HIV. The guidance for indeterminate tests differs from the guidance for unknown test results, e.g. where patient never received test results because it may be possible to determine from another source that the unknown test result was either positive or negative.

Here’s the HIV Testing History Section of the case report form:

|  |
| --- |
| **HIV TESTING HISTORY** |
| Source of HIV testing history is: **🞏** Patient Interview **🞏** Medical Record **🞏** Provider Report **🞏** Other:\_\_\_\_\_\_\_\_\_Date Patient Reported Information: (month/day/year) **\_\_\_ \_\_\_ /\_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_**  |
| 1. Have you ever received an HIV negative test result? *(Check answer in box below)* **🞏**Yes, had previous HIV negative test **🞏**Never had an HIV negative test *(skip to question #4)*  **🞏**Refused **🞏**Don’t Know/Unknown |
| 2.What month and year did you receive your last (most recent) HIV negative test? (mo/year) **\_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_** |
| 3. Was your last HIV negative test conducted in San Francisco?  |
|  **🞏**Yes, it was in SF. List the name of site \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **🞏**No, it was outside of San Francisco **🞏**Don’t Know/Unknown |
| 4. Date of very first **HIV confirmed positive** test: (mo/year) **\_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_** *(Record date of test, not of results)* |
| 5. How many HIV negative tests did you get in the 2 years before first HIV confirmed positive?  | \_\_\_\_\_\_\_\_\_\_\_\_ |
| 6. Reason you got tested for your first HIV positive test? Did you get tested because you . . . . . . | *Mark Yes or No for each* |
| * were concerned about possible exposure to HIV in past 6 months. .. . . . . .
 |  🞏 Yes 🞏 No |
| * time for regular test (for example, every 6 months) . . . . . . . . . . . . . . . . . .
 |  🞏 Yes 🞏 No |
| * just checking to make sure negative . . . . . . . . . . . . . . . . . . . . . . . . . . . . .
 |  🞏 Yes 🞏 No  |
| * required to take test by court order, military or insurance . . . . . . . . . . . . . .
 |  🞏 Yes 🞏 No |
| * other reason, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |  🞏 Yes 🞏 No  |
| ***Antiretroviral Therapy(ART) also known as Post-Exposure Prophylaxis or PEP is used to treat or prevent HIV or Hepatitis***7. Have you ever taken any antiretroviral medications to treat or prevent HIV or Hepatitis?  **🞏** Yes **🞏** No(*End of Form*) **🞏** Refused **🞏** Don’t Know/Unknown |
| 7a. If Yes, list ART used: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ /\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 7b. First date any ART used:(mo/day/year) | **\_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_** |
| 7c. Last date any ART used: (mo/day/yr) | **\_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_** |

***Source of HIV Testing History is:***

**Description of Sources:** How were the answers to the questions in the HIV testing history section collected? Check the appropriate box indicating how the questions in this section were administered or collected, if from multiple sources check the source where the majority of information was collected. If the source of information was the patient, check ‘patient interview’ box.

*Patient Interview:* Was the patient asked *any* of these questions by a health care provider or through a self-administered manner? If yes, check this box. IF the patient answered all or most of the questions from the HIV testing history section check the ‘patient interview’ box.

*Medical Record:* The HIV health care provider obtained most of the information through a review of the patient’s medical chart, electronic medical records or other databases. A few elements may come from the provider or other source. When health department staff visits a health care provider’s site and extracts data from medical records, the source is ‘medical record’.

*Provider Report:* Information was obtained from a health care provider-submitted case report form or from a phone call with a provider. The health care provider does not indicate having directly asked patients for most of this information from the THQ. Information was found by the provider from chart notes, laboratory reports, or recollection from discussion with the patient or another health care provider. If the health care provider administered a series of questions from a case report form (CRF) or another facility form, then ‘patient interview’ should be selected.

*Other:* Information was obtained from another source not listed above. If the only source is a database for example the ADAP database select ‘other’.

***Date Patient Reported Information:(mo/day/year)*\_ \_/\_ \_/\_ \_ \_ \_**

**Description of Patient Reported Information:** This variable represents the date of the patient interview if information was obtained face-to-face, or the date of the provider note for the last (most recent) patient encounter at which THQ information was ascertained from a medical record. The variable ‘*Date Patient Reported Information’* represents different dates, depending on the circumstances in which the information was primarily obtained. *If there is no patient contact date, then the date of provider report or chart review can be used.*

**HIV Testing History Questions:**

1. ***Have you ever received an HIV negative test result?***

 ***Yes, had previous HIV negative test (continue)***

***Never had HIV negative test (skip to question #4)***

 ***Refused (skip to question #4)***

 ***Unknown (skip to question #4)***

It’s important to know if the patient had a previous HIV negative test, because this will play an important role with understanding how recently they may have been exposed to HIV. Check the appropriate box indicating whether or not the patient ***ever*** received an HIV negative test result previously in their life.

If the patient previously tested HIV confirmed positive, then they should provide the date of the HIV negative test before the earlier positive test. Also, if the patient’s first and only HIV test result was confirmed positive, they could never have had a previous HIV negative test.

For this question HIV negative screening test results are acceptable.

***If the client’s response is: no, refused or don’t know, skip to question #4.***

***If yes, check the appropriate box and ask the next question.***

1. ***What month and year did you receive your last (most recent) HIV negative test? \_\_\_ \_\_\_ /\_\_\_ \_\_\_ \_\_\_ \_\_\_***

Document the month and year when the patient had their most recent HIV negative test prior to the first confirmed HIV positive test. It is crucial to know the month and year when the **blood was drawn/specimen collected** for the patient’s last negative test result. Simply asking when they received a negative test result is not appropriate, because they may not have returned for the result in a timely manner, and the date they learned of the negative result may not be indicative of when they were actually tested. Please use two numeric digits indicating the month and four numeric digits for the year in the space provided, for example, May 2007 is 05/2007.

1. ***Was your last HIV negative test conducted in San Francisco?***

 ***Yes, it was in S.F., list the name of the site? \_\_\_\_\_\_\_***

 ***No, it was outside of SF (Out of Jurisdiction; OOJ)***

 ***Unknown***

Please check the appropriate box for whether the last HIV negative test was done at a testing facility in or outside of San Francisco. If yes, document the name of the HIV testing site where the most recent HIV negative test was conducted. For example this could be the name of a health clinic, blood bank, doctor’s office, or STD clinic. If it is part of a larger facility please document where the test was collected within that facility. If the client went to an HIV counseling and testing site, please write the exact name of that site (e.g. AIDS Health Project, or Magnet). Please use acronyms only if the site is readily identifiable by them, otherwise try to avoid using them. Print as clearly as possible.

If, the site where the last HIV negative test was conducted is outside of San Francisco please check the ‘No’ box and do not document the name of the site. Only HIV negative test sites conducted within San Francisco should be noted for this question.

If the patient can’t remember either the exact name of the site, please check the ‘ Unknown’ box.

1. ***Date of very first HIV confirmed positive test:***

***(month/year)***

Only document HIV confirmed positive tests (by Western Blot or IFA) for this question. If a patient received a reactive/positive result from a screening test such as Elisa, viral load or a Rapid Test, that didn’t have a confirmatory component or algorithm; *it shouldn’t be considered a true HIV positive test result*. These types of tests are more likely to be false positive and do not reflect an accurate HIV diagnosis. All screening tests should be followed up with a confirmatory test. If a screening test was followed-up with a confirmation, than the date of the screening test collection should be used as the first time the patient tested HIV confirmed positive.

Please document the month and year when the specimen for the very first HIV confirmed positive test was collected from the patient. Please use two numeric digits for the month and four numeric digits signifying the year in the space provided, for example, May 2007 is 05/2007. Simply asking when the person received a positive result is not appropriate, because the patient may not have returned for his or her results in a timely manner, and the date he/she learned of the positive result may not be indicative of when he/she tested. If the patient received more than one HIV positive test, focus on the **first** time they tested HIV confirmed positive.

You may document a date that is earlier than the current HIV test date, if the patient reports testing HIV antibody positive with a confirmatory test previously. If the patient reports an HIv confirmed positive test conducted earlier, make sure to use this earlier test date (month/year) for other questions in this section of the case report form. For example, a patient tests HIV antibody positive on June 15, 2009, but during the post-test visit they report having an earlier HIV antibody test 3 months ago, so you need to use the HIV positive test from March 15, 2009 to answer other questions in this section.

1. ***How many HIV negative tests did you get in the 2 years***

 ***before first HIV confirmed positive?***

Using the date from the first HIV confirmed positive test (from question #4) document the total number of other HIV tests the patient had two years before this date; do not include the first HIV confirmed positive test in the total number. If the patient’s first HIV positive test was in February 2006 (02/2006) then you want to find out how many other HIV tests they had during the two years prior; from February 2004 to February 2006. Include all types of HIV tests the patient had in the previous two years, such as rapid, antibody or others.

***6. Reason you got tested for your first HIV positive test.***

 ***Did you get tested because you…***

***▪ Were concerned you might have been exposed to HIV in the past 6***

 ***months?***

***▪ Were getting tested for HIV routinely and it was time for you to***

 ***get tested again?***

***▪ Were just checking to make sure you were negative?***

***▪ Were required to take test by court order, military or insurance?***

***▪ Had some other reason, specify: \_\_\_\_\_\_\_.***

Document the reason(s) why the client was seeking HIV testing for their first HIV positive test by checking the “Yes” or “No” boxes for each reason. **Check all that apply to the patient**

Be sure to mark “No” for any reason that is not applicable to the client.

**Antiretroviral Therapy (ART) also known as Post-Exposure Prophylaxis (PEP) is used to treat or prevent HIV or Hepatitis**

***7. Have you ever taken any antiretroviral medications to***

 ***prevent or treat HIV or Hepatitis?***

 ***Yes No (END OF FORM) Refused Don’t Know/Unknown***

Check whether the patient has ever taken any HIV antiretroviral therapy (ART) medications. Sometimes one or more of these HIV medications are used to prevent HIV infection, this is called Post Exposure Prophylaxis (PEP). Some of antiretroviral medications are also used to treat Hepatitis B. These medications are also used for HIV treatments and are called, HAART.

Each patient must be asked whether they are using or have used ART for any reason. For any reported use of ARTs, even if ART use began after the date of HIV diagnosis, record ‘yes’ but be sure to include *Date ART Medications Began* and *Date of Last ART Use*. Even if start/end dates are unknown, record ‘yes.’ When it is unknown whether the patient ever used ART’s, record ‘don’t know.’ Do not assume that the absence of ART use information is the same as never used ART’s. Note that when there is no patient interview, it is difficult to know about previous ART use.

If the patient reports sporadic ART use before HIV diagnosis, enter ‘yes’ and make an effort to obtain dates when first used and last used.

If no ART was ever used by the patient, please check ‘no’ and stop administering this form.

***7a. If yes, list ART used: \_\_\_\_\_\_\_\_\_\_ /\_\_\_\_\_\_\_\_\_\_ /\_\_\_\_\_\_\_\_\_\_***

If the patient reports using ART document the first three medication(s) taken. It is not necessary to list every drug combination that may have been used; record at least one ARV medication. It is important to record dates of first and last use.

***7b. First date any ART used: (mo/day/year) \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_***

Document the first day (month, day and year) the patient began using *any* ART. If the patient has trouble remembering the exact date, ask for their *best estimate*. If multiple medications were used at different times, document the medication taken first.

This data element is important for determining the time period when earliest ART use started. Medical record abstractors should pay attention to start dates of ARV use, even those after initial HIV diagnosis. Providers should be informed that the start date is the critical piece of information. Record the earliest date of use. Do not be concerned if ARV use has been sporadic. Note that this date is not necessarily related to the time that the specific medication named in #9 was taken.

***7c. Last date any ART used: (mo/day/year) \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_***

Document the last day (month, day and year) the patient stopped using *any* ART. If multiple medications were used, document the date of the medication used last. If the patient is currently on the medication, document the date they plan to stop using the medication. If the date they plan to stop using ART is after the first time they tested HIV confirmed positive, document the date of the HIV confirmed positive test here. No information after the first HIV confirmed positive test date will be collected.

Record the last date when the patient was known to be taking ARV medications, prescribed or not. If ARVs are currently being taken, record the date when the patient was last known to be taking ARVs. That is likely to be the same as *Date Patient Reported Information (#2),* the date of the interview, chart note or provider encounter.

***Thanks for taking the time to answer these questions!***

***If you have any questions about these guidelines or the HIV testing and antiretroviral history questions please contact:***

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