

Guidance for Collecting HIV Testing and Antiretroviral Treatment History

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Introduction

The purpose of this guidance is to describe how to collect HIV testing and antiretroviral treatment history (TTH) information from patients diagnosed with HIV or AIDS. These questions are part of the HIV/AIDS case report form (CRF) and are required data elements for all HIV/AIDS diagnosis made in San Francisco. The HIV testing and antiretroviral treatment history (TTH) questions obtain important information to identify new or long-term HIV infections reported from public and private health care providers in San Francisco.

There were two main revisions made to the HIV TTH that will be implemented at the beginning of 2012. The revisions were made so it would be possible to data enter HIV TTH information into eHARS, a new document-based data system developed by the Centers for Disease Control (CDC). The first change is the addition of a new question, *Ever had a previous positive HIV test?* The second change is how the source of the HIV TTH is documented; different HIV TTH forms will need to be collected when new or additional information is collected from different sources.

Procedures for Collecting HIV Testing and Antiretroviral Treatment History

The general principle for collection HIV testing and treatment history is to obtain the most accurate and complete information possible to characterize a person's HIV testing and antiretroviral treatment use. When completing the HIV TTH data collectors (medical providers, HIV counseling and testing staff or HIV epidemiology field staff) may have access to multiple sources of information, including the patient, the medical records, laboratory reports, and other databases. It is important to examine all the information available to ensure the most accurate information of the patient's actual HIV testing history and antiretroviral use are documented.

Ideally, all HIV TTH information should be based on patient's self-report as close as possible to the date of their original HIV or AIDS diagnosis. This takes advantage of the patient's ability to recall information that's closer to the date of their original diagnosis; also longer intervals may increase the risk of recall bias. Yet, this consideration should not prevent efforts to obtain testing and treatment information whenever possible after the original HIV/AIDS diagnosis.

The purpose of the HIV TTH is to determine testing frequency to estimate the probability of being tested during the STARHS (serologic testing algorithm for recent HIV sero-conversion) BED recency period and whether HIV antiretroviral (ARV) use might have affected the STARHS-BED results. Patients who are on ARV's for HIV may look like a recently infected person due to viral suppression when they have actually been infected for a longer time.

To be consistent with the principles of document-based data collection for eHARS, multiple HIV TTH forms should be filled out if collected from different sources, or to update information. Data collectors should record data collected during separate investigations on separate HIV TTH forms. A case report form sent in by a provider versus one completed by surveillance staff during a medical chart review will have different HIV TTH forms completed and the *Main Source of TTH Information* will be different.

A data collector conducting a medical chart review should abstract the best information obtained from all sources reviewed, whether from patient self-report found in physician notes or laboratory results noted in the chart. Similarly, for a provider report the information will reflect all the information available, including the providers knowledge of a previous positive or negative HIV test that was not reported by the patient. However, when the interviewer collects most of the HIV TTH during the patient interview and obtains the rest of the information from a medical chart or other database, two forms should be completed because these represent two different data collection sources. For example, during an interview a patient reports never having a negative HIV test, but the interviewer also finds in a database the date of a previous negative HIV test for which the patient never returned for the results. The interviewer should enter the information from the database on a separate HIV TTH form. An HIV TTH form completed during one investigation at the same site should summarize all the information obtained during that particular investigation. A separate HIV TTH form should be completed for different sites the patient was seen at.

The HIV TTH collection form is used by: HIV health care providers, HIV counseling and testing staff, and HIV epidemiology field staff to obtain information on newly reported HIV/AIDS case on the HIV/AIDS case report form (CRF). The HIV TTH information should be collected for 'OOJ' (out of San Francisco's jurisdiction) and 'OOS' (Out of the State of California) cases residing in other incidences jurisdictions. The list of incidence jurisdictions participating are: Alabama, Arizona, California, Chicago, Colorado, Connecticut, District of Columbia, Florida, Houston, Indiana, Los Angeles, Louisiana, Massachusetts, Michigan, Mississippi, New Jersey, New York, New York City, North Carolina, Philadelphia, South Carolina, Texas, Virginia, and Washington.

How to introduce the HIV testing history questions to the patient?

As a HIV health care provider you are in the unique position of being able to collect confidential information essential to continually improving our understanding of new HIV infections occurring every year. Whenever we ask questions about HIV testing or medication it's important to remain non-judgmental and culturally sensitive.

Here are some suggestions to introduce these questions to patients at your clinic:

"I would like to ask you some questions about HIV tests you've had in the past and if you used any HIV antiretroviral medications before testing today. Please take your time in answering these questions."

"I'd like to ask you about HIV tests you've had, to help our understanding of why people seek HIV testing."

"I'm going to ask you a few questions about your HIV testing history and use of antiretroviral meds; which some people take to prevent infection."

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

"Think about the time of year that you had the HIV test."

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

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

Note for Dates

Dates are very important elements for the HIV TTH. ***The most important dates to collect are: The date of first positive HIV and last negative HIV test***, which help classify persons as new or long-term infections. In the hierarchy of incidence estimation algorithms, dates supersede ‘yes’ and ‘no’ answers. In many cases the day or even the month will be unknown. It is acceptable to leave the day or month blank, ***but it is important to try to obtain at least the year***, which can be used in calculations. An approximate date reported by a patient is better than no date at all.

All dates on the form use; mo/day/year, please use two numeric digits indicating the month and day. Use four numeric digits for the year.

- Example: February 14, 2012 = 02/14/2012. Some values such as, ‘99/99/9999’ for a missing date will *not* be accepted by eHARS and should not be documented on the HIV TTH form.

To indicate an unknown or missing date document using dashes ‘ - - ’, for example; if the patient recalls just the year off their last HIV negative test was done in 2010, document ‘ - - / - - / 2010’. Or if the patient recalls having a previous HIV positive test around Christmas 2009, document, ‘ 12/- - /2009’. Please document at least the year for all dates when you can.

Indeterminate Test Results

HIV TTH data collectors should ignore indeterminate antibody test results in recording responses to all HIV testing history questions, including previous positive tests, previous negative tests and number of negative tests. An indeterminate test is neither positive nor negative for HIV.

Guidance for ‘Yes, No, Refused or Unknown’ Responses

- **“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. Don’t know’ and ‘can’t find evidence’ are treated similarly.
- **Blank** indicates that the usual data sources were not investigated and/or the health care provider/staff were not asked.

HIV Testing and Treatment History Questions

Testing and Treatment History Information	
1. Main Source of TTH information	[1] Provider [2] Patient [3] Medical Record [4] Other
2. Date patient reported information	<input style="width: 20px; height: 20px;" type="text"/> (mm/dd/yyyy)
3. Ever had a previous positive H test?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
4. Date of first positive H test	<input style="width: 20px; height: 20px;" type="text"/> (mm/dd/yyyy)
5. Ever had a negative H test?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
6. Date of last negative H test	<input style="width: 20px; height: 20px;" type="text"/> (mm/dd/yyyy)
7. Number of negative H tests in the 2 years <u>before</u> 1 st positive test	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>(Include previous negative H test from question#6 if within time frame)</small>
8. Ever taken any antiretroviral medications (ARVs)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
9. If yes, list ARV used (Please don't use codes)	<input style="width: 100%; height: 20px;" type="text"/> <input style="width: 100%; height: 20px;" type="text"/> <input style="width: 100%; height: 20px;" type="text"/>
10. First date any ARV used:	<input style="width: 20px; height: 20px;" type="text"/> (mm/dd/yyyy)
11. Last date any ARV used:	<input style="width: 20px; height: 20px;" type="text"/> (mm/dd/yyyy)
18. Reason(s) why tested when received 1 st positive H result:	
a. Concerned about exposure to H in the 6 months before 1 st positive result	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
b. Were getting tested for H routinely (for example every 6 months)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
c. Were just checking to make sure are H negative	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
d. Were required to test (court order, insurance, military, etc)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
e. Had some other reasons	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
f. If other reasons, specify:	<input style="width: 100%; height: 20px;" type="text"/>
Local Fields	
Was last H negative conducted in SF?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
If yes, list the name of site:	
<input style="width: 100%; height: 20px;" type="text"/>	

If the date is missing, enter the date the HIV TTH form was completed or received at the health department.

In general, the data collector should select the latest date (most recent date) of interview, patient visit or provider report that contributed to the testing and treatment information. It represents the point in time when HIV TTH information was obtained from a patient. It does not necessarily mean the last patient visit.

3. Ever had a previous positive HIV test? (No, Yes, Refused, Don't Know)

The data element *Ever Had a Previous Positive HIV Test* question provides information about the patient ever having a positive HIV test before the current test.

The purpose of this question is to ascertain whether the patient had an earlier positive HIV test other than the current positive HIV test, for example a patient could have been tested in another state, country or anonymously and not be reported to the surveillance system. Having an earlier test accompanied by an approximate date, might indicate a long-term HIV infection.

This information may come from the patient, evidence of an anonymous test, record of a test performed in another country, a doctor's note, discussion with another provider, or other source that is probably not a laboratory report. A confirmed positive from an HIV home test kit should be considered the same as a self-reported anonymous test. It is not reported to the health department.

Data collection may differ by source of information. In a patient interview, a person will likely state that he or she has or has not had a previous positive test. Persons with a previous positive test often were tested anonymously and are now converting to confidential testing. Also, the person may have been tested in another state or was tested previously and is now seeking care. If so, record 'yes' and make an effort to obtain the date of first positive for *Date of First Positive HIV Test* (variable #4).

Ignore indeterminate and false positive HIV tests. If the only previous HIV test was indeterminate, do not consider that test as a positive test; in that case, enter 'no'. If there is no evidence of a previous positive test enter 'Don't know' on the data collection form. This is useful information for interpreting a date for the *Date of First Positive HIV Test* (variable #4).

Examples Previous Positive HIV test by Source of Information:

Patient Interview:

- Patient self-reported a previous test—interviewer should record 'yes'.
- Patient reported a positive HIV test from a home test kit that was sent into a laboratory—interviewer should record 'yes'.
- Only previous test was 'indeterminate'—interviewer should record 'no'.
- Patient reported a positive oral screening test followed by a negative Western Blot—interviewer should record 'no'. This test is considered a negative HIV test.

- Patient had a false positive HIV test when she was pregnant 3 years ago and was confirmed to be HIV negative 6 months later—record 'no'.
- Patient says this is the first test ever taken – interviewer should record 'no'.
- Patient did not know—interviewer should record 'don't know'.
- Patient reported 'no' or 'don't know' but the interviewer later found evidence of an earlier positive test– interviewer should leave the patient's answer as 'no'. The date of the earlier positive test should

be entered on a separate TTH document. If it is a documented positive confirmatory test, it also should be entered on an ACR or Laboratory document.

Medical Record Review:

- Chart abstractor found evidence/report of a previous positive test in the medical record; for example, a doctor’s note that said ‘patient tested HIV positive in New York in 2006’—abstractor should record ‘yes’.
- Chart abstractor found information about a previous positive HIV test in a clinic database, regardless of whether patient knew about it—abstractor should record ‘yes’.
- Medical record indicated that the patient never had a previous positive test; for example, a note saying ‘this is the patient’s first positive HIV test’—abstractor should record ‘no’.
- The patient reported that the only previous HIV test patient had was ‘indeterminate’ —abstractor should record ‘no’.
- Patient reported she never got her results—abstractor should record ‘don’t know’.
- There was no definitive evidence either way; for example, the provider did not ask the question or made no note in the chart—abstractor should record ‘don’t know’. This indicates that effort was made to find the answer but it was unavailable. Do not assume that no evidence is the same as no previous positive test.

Provider Report:

- Health care providers should be encouraged to ask patients about previous HIV testing and record notes in the medical record.
- Provider knows from patient report that this was the first positive HIV test that the patient ever received—provider should record ‘no’.
- Provider knows there was an earlier positive HIV test before the one being reported, but has no date—provider should record ‘yes’.
- Provider does not know about any previous positive HIV test—provider should record ‘don’t know’.

4. Date of first positive HIV test? (mm/dd/year)

**Very important data element for incidence estimation.*

The *Date of First Positive HIV Test* variable is the date of the earliest known positive HIV test for the patient. It represents the date that the specimen was collected for the very first positive HIV test. This date could represent an anonymous test that will never be reported to the HIV surveillance system. Most of the time, this date is self-reported.

Note: Any documented positive HIV laboratory test result should also be entered in eHARS on a case report form.

During interviews, chart abstraction, or completion of the case report form some data collectors will enter the date of the current HIV positive test for the purposes of calculating subsequent answers. When it is known that the current test date is the date of first positive HIV test, it is important to answer ‘no’ for the *Ever had a Previous Positive HIV Test* data element (#3 above). Do not record any dates for ‘indeterminate’ HIV tests, false positive tests or for tests with unknown results.

5. Ever had a Negative HIV Test? (No, Yes, Refused, Don’t Know)

This variable, *Ever Had a Negative HIV Test*, captures whether or not the person ever had a negative HIV test result at any time in the past. Persons with a ‘yes’ answer—indicating a previous negative HIV test—are classified as repeat testers, and those with a ‘no’ answer are classified as new testers.

For the purposes of incidence estimation, when *Ever Had a Negative HIV Test* is unknown or missing, *Date of Last Negative Test* is blank, and *Number of Negative HIV Tests Within 24 Months before First Positive HIV Test* is unknown, missing, or '0' (zero), persons will be classified as a new or repeat tester using multiple imputation. Multiple imputation is a statistical process that will assign cases to either the 'new' or 'repeat' tester groups.

Since this data element is used to classify cases as new testers or repeat testers for incidence estimation, it is important to have accurate information because misclassification can strongly impact the accuracy of the incidence estimate. The data collector should not make the assumption that there was never a negative test when he or she could not find any information about a negative test. Because people are tested for HIV in many different venues or with different providers, the absence of information about previous testing does not mean that previous tests did not occur.

If an interviewer has knowledge of a previous negative HIV test, he or she should prompt the patient to recall it. If the interviewer finds evidence of a previous negative test after the interview, even though the patient answered 'no', the interviewer should record the *Date of the Last Negative HIV Test* (#6) but he or she does not need to change the patient's response. The algorithm for classifying new testers and repeat testers gives priority to the *Date of Last Negative HIV Test* and will assign the person to the repeat tester category.

It is best practice for the data collector to enter the date of the negative test on a separate TTH form when those data were found separately from other information.

If the patient reports that he or she doesn't know, if the health care provider does not know whether the patient had any negative HIV tests, or there was insufficient documented evidence in the medical record supporting or denying the occurrence of a negative test, the data collector should select 'don't know'. 'Don't know' and 'can't find evidence' are treated similarly. The field should be left blank if the usual data sources have not been investigated and/or the health care provider did not ask the patient.

If the patient's only previous HIV test was positive, select 'no'. Ignore indeterminate tests. If the only previous test was indeterminate, select 'no', because there is no evidence of a previous negative. Similarly, an undetectable viral load is not evidence of a negative HIV test.

If 'Ever tested HIV negative?' is 'No', skip local field questions at bottom of form.

6. *Date of Last Negative HIV Test?* (mm/dd/yyyy)

****Very important data element for incidence estimation.***

This variable, *Date of Last Negative HIV Test*, is the date of the last known negative HIV test and represents a point in time when the person was known not to be infected with HIV.

Because this is one of the most important data elements for incidence surveillance, extra effort should be made in collecting this date. Any available information about testing history is useful including an approximate date or only the year tested.

It is important to train interviewers, providers, and chart abstractors to record the last known date of a negative HIV test, even if the data collector does not know if negative results for the patient have occurred for later HIV tests performed at other facilities. If there are two dates for negative HIV

tests, the most recent one should be entered. If the provider or chart abstractor is using the standard case report form and has evidence of a documented negative HIV test with a test type, the date should be entered in the Laboratory Data section of the case report form in the *Date of Last Documented Negative HIV Test* field. Otherwise, he or she should enter the date in the HIV Testing and Treatment History Information section of the case report form. Do not include dates of tests with unknown or indeterminate results.

7. Number of Negative HIV Tests within 24 months before First Positive HIV Test?

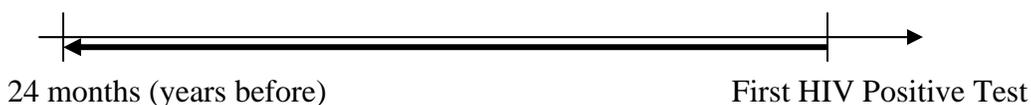
This variable, *Number of Negative HIV Tests within 24 Months before First Positive HIV Test*, is used to quantify the number of negative HIV tests within the 24 months(2 years) preceding the first positive HIV test.

If the interviewer, abstractor or provider knows of at least one previous negative HIV test in the 24 months before first positive test, he or she should enter '1' even if there could be more unknown tests in this period.

If it is known that the patient did not have any HIV tests in the previous 24 months, then '0' should be recorded.

If the patient doesn't remember whether they had a negative test, or the provider or abstractor has no evidence about whether or not there was a previous test, enter 'D' for 'don't know' or 'R' for 'refused'. Do not record zero ('0'). Do not count an indeterminate test as a negative test. Ignore indeterminate tests.

If the patient/provider/chart reviewer does not know whether the patient ever had a previous positive HIV test, but he has information on the number of tests in the past two years, then this information should be captured. For example, the patient remembers one negative HIV test in the past 24 months but doesn't know if he had a previous positive. Entry of '1' allows us to categorize the patient as a repeat tester and estimate frequency of testing.



8. Ever Taken Any Antiretroviral (ARV) Medications? (No, Yes, Refused, Don't Know)

The variable, *Ever Taken Any Antiretroviral Medications*, is used to determine whether the patient took any antiretroviral (ARV) medication to prevent or treat HIV or hepatitis at any time before the collection of the specimen used for the STARHS-BED test.

This data element is important because ARV use may cause the STARHS-BED result to appear 'recent' when the infection is not recent.

It is critical to provide dates to know whether ARVs might have had any effect on the STARHS-BED results. If ARVs were started after the collection of the specimen used for the STARHS or ended more than 6 months before that date, the STARHS results will be used as reported.

A list of current medications used to treat HIV is available at:
http://www.crine.org/templates/cr/pdfs/cr_pillchart_jan09_ver3.pdf

A database to search medications by name is available at:
<http://aidsinfo.nih.gov/DrugsNew/Default.aspx>

9. If yes, list ARV used: _____ / _____ / _____

This variable, *If yes, list ARV used*, list at least one but no more than three of the ARVs or hepatitis medications that the patient has taken but may not include all medications used.

The purpose of this data element is to verify that at least one medication taken was actually an antiretroviral used to prevent or treat HIV or hepatitis. This is mostly used for verification during a patient interview.

It is not necessary to list every HIV drug combination used; record at least one ART medication. It is important to record dates of first and last use (#10 and #11)

10. First Date ARV Used: (mm/dd/yyyy)

This date, *First Date ARVs used*, represents the earliest date of any ARV use.

The purpose of this data element is to determine whether the patient took any antiretroviral medication to prevent or treat HIV or hepatitis before the date that the specimen used for the BED test was collected. This variable is important because ARV use may cause the BED results to appear ‘recent’ when the infection is not recent.

This data element is important for determining the period when any ARV 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 month and year of ARV use.

Note: This date is not necessarily related to the time medication named in #9 was taken.

11. Last Date ARV Used: (mm/dd/yyyy)

This variable, *Last Date ARV Used*, represents the date when ARVs were last taken by the patient.

The *Date Patient Reported Information* should be recorded as the *Date of Last ARV Use* if the patient was still on ARVs as of that date.

The purpose of this data element is to determine whether the patient took any antiretroviral medication to prevent or treat HIV or hepatitis in the 6 months before the date that the specimen used for the STARHS-BED test was collected. This variable is important because ARV use may cause the STARHS-BED result to appear ‘recent’ when the infection is not recent.

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. For health department field staff who conduct medical chart abstractions, this should also be the date of ‘Last vital status’ on the local variable form; when the patient’s last contact with the health care site.

In summary, if a patient is currently on ARV's record the most recent date of the when the patient had contact with the site on, Last Date ARV used, Date Patient Reported Information (#2), and on the local variable form for HSU(health status update).

12. Reason for First Positive HIV Test: (No, Yes, Refused, Don't Know)

- a. Concerned about exposure to HIV in the 6 months before 1st positive result?
- b. Were getting tested for HIV routinely? (for example every 6 months)
- c. Were just checking to make sure you were HIV negative?
- d. Were required to test? (court order, insurance, military, etc.)
- e. Had some other reasons?
- f. If other reason, specify: _____

The purpose of these variables, collectively named *Reason for First Positive HIV Test*, was to ascertain whether the patient was motivated to get tested by an exposure or had other reasons for testing that would affect the probability of being tested in the BED window period. The above named variables were collected for reason for testing at the time of the self-reported first positive test. This variable is also helpful for identifying risk for certain cases.

**13. Was the last HIV negative test conducted in San Francisco?
(No, Yes, Refused, Don't Know)**

The purpose of this variable is to document whether the last HIV negative test was conducted in San Francisco. and the name of the testing site where the client had their last HIV negative test conducted (Examples of sites, 'City Clinic' or 'AIDS health project').

If 'Ever tested HIV negative?' is 'No', skip this question.

14. If yes, list the name of site: _____

The purpose of this variable is to document the name of the HIV test site where the patient had their last HIV negative test done. If the client cannot remember the exact name of the site and it is part of a larger institution please write down the name of the larger institution (Example, 'San Francisco General Hospital' or 'Health Care Center in SF'). Please print clearly.

If 'Ever tested HIV negative?' is 'No', skip this question.

Thanks for taking the time to answer these questions!

Send questions or comments to: Anthony.buckman@sfdph.org or call 554-9074