INTEGRATING HIV SCREENING INTO ROUTINE PRIMARY CARE:

A HEALTH CENTER MODEL

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The health center model has helped reduce health disparities among many poor and minority communities in such areas as diabetes, heart disease, and asthma. This approach has helped ensure that quality medical care is available not just to those who can pay for it, but also to those who need it most. We have an important opportunity to replicate our successes once again with HIV/AIDS.

PREVENTION holds the key to our success in reducing the burden of HIV/AIDS in our communities. Prevention is only possible when we assume the stance that all patients, really all of the population, have a right and need to know their HIV status. Screening for HIV should be as routine as testing for cholesterol and blood sugar, something we routinely offer our patients. It is only through knowing one’s HIV status that one can access effective new treatments against HIV and other services that prolong and enhance one’s quality of life. And for persons who are HIV positive, it provides them with knowledge that allows them to modify their behaviors so as to not place others at risk for infection.

“HIV screening” is used to describe assessment for HIV infection across a large population, in this case adolescent and adult health center patients. It typically employs simple test methods, such as finger stick tests or an oral swab, with results available in minutes – although any approved, conventional test can be used – and relies on counseling in the context of care rather than the historically cumbersome pre-test counseling process. “HIV testing” refers to confirmatory laboratory testing where samples, frequently obtained through venipuncture, are sent to an external laboratory for results and, if necessary, additional confirmatory tests. Conventional HIV testing typically utilizes a more comprehensive pre-test counseling process and a more extensive assessment of risks.
Adopting an HIV screening approach “normalizes” the process of HIV risk assessment and testing as patients come to expect these services within their routine primary care. This document provides a model for how your health center can design a process where everyone 13 to 64 years of age is screened for HIV as a routine part of medical care.

The model, as well as many of the tools and resources referenced in this document and accessible to you from the HIV Routine Screening Within Primary Care Virtual Office, were developed, tested, and successfully used by six community health centers participating in a Routine HIV Screening pilot supported by the Centers for Disease Control and Prevention (CDC)\(^1\). The National Association of Community Health Centers (NACHC) implemented this pilot from December 2006 through April 2008 in response to and in support of the CDC’s 2006 HIV Testing Recommendations. These Recommendations aim to make HIV testing a routine part of medical care and propose HIV screening for all patients ages 13-64 in all health care settings. For a summary of the Recommendations, read [CDC Releases Revised HIV Testing Recommendations in Healthcare Settings](http://www.cdc.gov/hiv/routine_screening). For the complete Recommendations, read [Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Healthcare Settings](http://www.cdc.gov/hiv/recommended/). Now, let’s get your health center started on a 90 day path to routine HIV screening.

- **Step 1:** Prework
- **Step 2:** Set up the Framework
- **Step 3:** Design the Patient Visit Process to Include Routine HIV Screening
- **Step 4:** Identify a Point Person to Track Reactives
- **Step 5:** Adopt HIV Screening Codes for Reimbursement
- **Step 6:** Commit
- **Step 7:** Launch
- **Step 8:** Realign

\(^1\) The following health centers participated in the Routine HIV Screening pilot: Aaron E. Henry Community Health Services Center, Clarksdale, MS; Mantachie Rural Health Care, Mantachie, MS; Northeast Mississippi Health Care, Byhalia, MS; Blue Ridge Community Health Services, Hendersonville, NC; Piedmont Health Services, Carrboro, NC; Margaret J. Weston Community Health Services, Clearwater, SC.
STEP 1: PREWORK

Days# 1 – 45

✓ Choose an HIV test
✓ Identify a point person for inventory/management of HIV tests and controls
✓ Solidify referral arrangements for HIV care
✓ Define working relationships with state/local departments of health
✓ Delineate local case management/supportive services
✓ Build state/local partnerships
✓ Schedule launch date
✓ Worksheet

Choose an HIV Test

HIV tests use blood, urine or saliva samples to detect the presence of HIV antibodies. These antibodies develop when HIV attacks a person’s CD4 or T-cells, the cells that fight infection. The choice of which HIV test to use will often be driven by cost and what may be available from state or local resources, including your state Health Department. Additionally, the 340B discount drug pricing program is a potential source of tests for participating health centers.

Routine HIV screening generally involves the use of a rapid HIV test. Rapid HIV tests use blood or oral fluid and produce a result in 10—20 minutes. While negative results are considered accurate, reactive results are viewed as “preliminary” and require further confirmatory testing before a person is considered infected with the HIV virus. There is a small window of error in all screening tests so it is possible a reactive result does not mean a person is infected with HIV.

There are three Food and Drug Administration (FDA)-approved rapid tests that have received a Clinical Laboratory Improvements Amendments (CLIA) waiver, which means they are less complex and can readily be applied in a health center setting as well as alternate settings such as homeless shelters, substance abuse
treatment programs, mobile vans and health fairs. For waived tests, there are no federal requirements for personnel, quality assessment, or proficiency testing. To perform waived tests, an organization must obtain a certificate of waiver from the CLIA program (or, if authorized by the Centers for Medicare & Medicaid Services (CMS), be included with the CLIA-certified laboratory under a multiple-site exception) and follow the manufacturer’s instructions for the test procedure. The FDA also requires that persons tested with rapid HIV tests receive the “Subject Information” pamphlet provided with the test.

The three FDA-approved waived tests are:

1. Uni-Gold Recombigen HIV
2. OraQuick ADVANCE Rapid HIV 1/2 Antibody Test
3. Clearview HIV 1/2 STAT-PAK

1. Uni-Gold Recombigen HIV

The Uni-Gold Recombigen HIV test is a waived test when used as a single-use rapid test for the detection of HIV-1 antibodies in whole blood obtained by fingerstick or venipuncture. It is intended for use as a point-of-care test. The test involves gathering a drop of blood (via fingerstick or from blood obtained through venipuncture) and dropping it over a sample port on the device. Wash solution is added to the sample port and test results are read 10 to 12 minutes after the specimen is added.

The Uni-Gold Recombigen HIV test includes an internal control that indicates whether the test is functioning correctly (assuming blood sample has been added). Positive and negative external controls should be run by each new operator before performing testing on patient specimens, whenever a new lot of test kits is used, if the conditions of testing or storage (e.g., temperature) fall outside the range recommended by the manufacturer, and at periodic intervals specified in the laboratory’s quality assurance program. External controls are not included in the test kits and must be ordered separately from the manufacturer. The controls require refrigeration and can be stored for 21 days after they are opened. The shelf life of the kits is 1 year from the date of manufacture if stored at room temperature.
2. OraQuick ADVANCE Rapid HIV-1/2 Antibody Test

The OraQuick ADVANCE Rapid HIV 1/2 Antibody Test is approved as a waived test for use with oral fluid specimens or whole blood specimens obtained by fingerstick or venipuncture. It is intended for use as a point-of-care test. Oral fluid samples are obtained by using an absorbent pad on the end of a test device to swab the outer surface of the upper and lower gums. This test device is then inserted into a vial containing developing solution. If whole blood is used, a sample is collected on a specimen loop then added to the developer solution and mixed. Whether whole blood or oral fluid is used, test results are read no sooner than 20 minutes but no later than 40 minutes after the OraQuick device is added to the developer solution.

The OraQuick ADVANCE test includes an internal control that verifies that specimen has been added and that the test has been run correctly. Positive and negative external controls should be run by each new operator before performing testing on patient specimens, whenever a new lot of test kits is used, if the conditions of testing or storage (e.g., temperature) fall outside the range recommended by the manufacturer, and at periodic intervals specified in the laboratory’s quality assurance program. External controls are not included in the test kits and must be ordered separately from the manufacturer. Controls have a shelf life of 1 year if unopened or 8 weeks after opening, if refrigerated. The shelf life of the kits is 6 months from date of manufacture if stored at room temperature.

3. Clearview HIV 1/2 STAT-PAK

The Clearview HIV 1/2 STAT-PAK is a single-use, waived rapid test that detects antibodies to HIV-1 and HIV-2 when used with whole blood obtained via fingerstick or venipuncture. The Clearview HIV test is intended as a point-of-care test.

The test involves gathering a drop of blood (via fingerstick or from blood obtained through venipuncture) and adding it to a sample port on the device. Buffer solution is then added slowly to the sample port and test results are read 15 to 20 minutes after the specimen is added. Reactive results may be observed and read earlier than 15 minutes. To verify a
nonreactive test result, the entire 15 minutes is needed. Results cannot be read after 20 minutes.

The Clearview HIV 1/2 STAT-PAK includes an internal control that verifies sample was added and the test is performing correctly. External controls are not included in the test kits and must be ordered separately from the manufacturer. The controls require refrigeration and can be stored for two years after they are opened. The shelf life of the kits is 24 months from the date of manufacture if stored at room temperature.

For additional information about HIV tests visit the CDC’s website at: http://www.cdc.gov/hiv/topics/testing/index.htm
At a Glance……FDA-Approved and CLIA-Waived HIV Rapid Tests

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Method</th>
<th>Time Needed to Develop</th>
<th>List Price Per Device(^)</th>
<th>Internal Control</th>
<th>External Controls</th>
<th>Shelf life of test (from date of manufacture)</th>
<th>Shelf life of controls</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uni-Gold Recombigen HIV</td>
<td>Fingerstick Venipuncture</td>
<td>10-12 mins</td>
<td>$15.75 ($9.95 340B Price)</td>
<td>Included**</td>
<td>Ordered and priced separately $26.25 each</td>
<td>1 year</td>
<td>21 days after opening; require refrigeration</td>
<td>Trinity Biotech <a href="http://www.unigoldhiv.com">www.unigoldhiv.com</a></td>
</tr>
<tr>
<td>OraQuick ADVANCE Rapid HIV-1/2 Antibody Test</td>
<td>Fingerstick Venipuncture Oral Swab</td>
<td>20-40 mins</td>
<td>$17.50</td>
<td>Included</td>
<td>Ordered and priced separately $25.00 each</td>
<td>6 months</td>
<td>1 year if unopened; 8 weeks after opening, if refrigerated</td>
<td>OraSure Technologies, Inc. <a href="http://www.orasure.com/">http://www.orasure.com/</a></td>
</tr>
<tr>
<td>Clearview HIV 1/2 STAT-PAK</td>
<td>Fingerstick Venipuncture</td>
<td>15*-20 mins</td>
<td>$17.50 ($8.75 340B Price)</td>
<td>Included</td>
<td>Ordered and priced separately $50.00/set</td>
<td>2 years</td>
<td>2 years, even if opened; require refrigeration</td>
<td>Inverness Medical Professional Diagnostics <a href="http://www.invernessmedicalpd.com/poc/products/clr_hiv_statpak.html">http://www.invernessmedicalpd.com/poc/products/clr_hiv_statpak.html</a></td>
</tr>
</tbody>
</table>

\* Reactive results can be read before 15 minutes.

\(^\) Actual price may vary by purchasing agreements with manufacturers. Check with 340B Prime Vendor Program for pricing.

\**Assumes blood sample was added.
Identify a Point Person for Inventory/Management of HIV Tests and Controls

Regardless of the source for HIV rapid tests or the particular test used, it is critical that a staff person be identified who has responsibility for receiving, logging, and monitoring the use of HIV tests and controls. This person will need to ensure an adequate supply of tests is always on hand, that tests and controls are current (with those closest to their expiration date used before those with later expiration dates), and that orders are placed prior to supplies being exhausted. Typically the staff person who is responsible for the ordering and inventory of other laboratory tests can be given the responsibility for management of the HIV tests and controls.

Solidify Referral Arrangements for HIV Care

Prior to the start of routine HIV screening, it is necessary to determine if your health center will provide HIV related care for persons identified as HIV positive or whether you will refer out for HIV care. If you intend to refer patients off-site for HIV related services, it is critical that you establish referral arrangements prior to the start of routine HIV screening.

For instance, if you intend to refer a person newly diagnosed with HIV infection to a local Ryan White Program, meet with contacts from this program first to discuss the best process for referring patients to their program. In some states, arrangements can be made with the Health Department Disease Intervention Specialists (DIS workers) working in your area so that they are available to provide counseling and follow-up with the patient at the same visit when you confirm their HIV infection. This latter arrangement can be particularly helpful if your health center does not employ a social worker or staff person dedicated to post-test counseling. DIS workers are also responsible for gathering the CDC data requirements on all HIV positive individuals, if not already gathered, and for tracking contacts of persons with HIV.
Define Working Relationships with State/Local Departments of Health

In addition to the services of the DIS workers, your health center may benefit from other training or resources offered by your state or local Health Department. Communicate your plans for routine HIV screening with the state/local Health Department and meet with them to determine what resources/support they can provide. Possible resources include: HIV rapid tests, training, and patient follow-up and tracking.

Delineate Local Case Management/Supportive Services

Patients infected with HIV will require a full range of health and social services, including transportation, housing, and mental health support. Identify persons or organizations that can assist your health center in meeting these needs for your HIV infected patients (See also Step 4).

Build State/Local Partnerships

Integrating HIV screening into routine primary care puts your health center at the forefront of our nation’s fight against HIV/AIDS. This important activity provides your health center the opportunity to gather critical data that can inform local, state and national policies around the care and follow-up of persons with HIV/AIDS. As a result of your HIV screening efforts, new and unique opportunities for partnerships and/or research will likely emerge that can benefit both your patients and your health center.

Schedule Launch Date

Giving consideration to what is involved in Prework and other events and circumstances that may be occurring at your health center, schedule a date to begin routine HIV screening. If you have multiple sites, identify in advance whether you will launch routine screening simultaneously at all sites on the first day or whether you will stagger the start to routine HIV screening. The launch date should closely follow the staff-wide forum discussed in Step 6 and any necessary training your center will convene. This helps sustain the momentum for the start-up process and reinforces the importance of the initiative. Identify in advance the
person, or persons, responsible for trouble shooting any problems during start-up.

**Worksheet**

Use the *Step 1: Prework Worksheet* on the next page to track key activities through to completion.
Integrating HIV Screening into Routine Primary Care:  
* A Health Center Model 

Worksheet 
Step 1: Prework 

<table>
<thead>
<tr>
<th>Key Activities</th>
<th>HIV Test</th>
<th>HIV Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV Test</strong></td>
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<tr>
<td>Determine the test your center will use</td>
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<tr>
<td>Estimate quantity of tests for first six months of testing (# of unduplicated visits for patients 13-64 yrs of age)</td>
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<tr>
<td>Identify source(s) for tests</td>
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<tr>
<td>Appoint a staff person to receive, manage, and coordinate test supplies</td>
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<tr>
<td><strong>HIV Care</strong></td>
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</tr>
<tr>
<td>Determine whether HIV follow-up care will be provided in-house or through referral</td>
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<tr>
<td>If HIV care is through referral, specify referral agency and the name, phone and email for your leadership contact and staff contact (the person your staff calls when they want to make a referral)</td>
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<tr>
<td>Identify the role of Disease Intervention Specialists (DIS), if any, in counseling or referral support</td>
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<tr>
<td><strong>State/Local Health Department</strong></td>
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<tr>
<td>List how the state/local health departments will support your HIV screening efforts</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Local Case Management/Supportive Services</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Identify persons or organizations that can assist your health center in meeting the health and social service needs of your HIV infected patients</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>State/Local Partners</strong></th>
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</thead>
<tbody>
<tr>
<td>Identify state/local organizations that your health center can partner with for routine HIV screening efforts. List agency, contact person, and what the partnership provides.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Launch Date</strong></th>
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</thead>
<tbody>
<tr>
<td>Determine whether you will launch routine screening simultaneously at all sites on the first day or whether you will stagger the start to routine HIV screening</td>
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</tr>
<tr>
<td>Schedule official date(s)</td>
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</tr>
<tr>
<td>Identify staff member(s) to trouble shoot any problems during launch</td>
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</tbody>
</table>
STEP 2: Set Up the Framework

Days #2 – 30

- **Finalize tool for data collection and medical record documentation**
- **Prepare test logs**
- **Develop a written informed consent, if required by law**
- **Prepare patient educational materials**
- **Draft staff tools**
- **Worksheet**

**Finalize Tool for Data Collection and Medical Record Documentation**

While the CDC and others have recommended HIV screening as a routine part of primary care, our national health care system has quite a way to go to achieve this goal. Your health center can be at the cutting edge of this frontier. As such, you have the opportunity, and responsibility, to gather critical data on HIV prevalence, the acceptability of testing among various populations, and information on why people refuse HIV testing. Thus, data collection is a critical part of routine HIV screening, and your health center may find itself as part of a local, regional, state, or national initiative that requires participation in a data collection effort. Furthermore, your health center has the opportunity to report HIV testing data as part of its 330 grant funding and can use the data to apply for new grants and resources.

In addition to collecting data for a larger initiative or purpose, your health center will also want to document in the patient’s health record that an HIV test has been offered and performed and results obtained.

A template for data collection and medical record documentation was created specifically for the health centers participating in the Routine HIV Screening pilot. The centers piloted a simple tool that captures key information for each patient that is offered HIV screening. The **Routine Testing Flow Sheet** can be used as is or modified to meet your center’s needs.
Prepare Test Logs

Similar to any lab test provided to patients, your health center should maintain a log of your routine HIV screening activity. Each time a test is performed, it should be recorded in a log with details about the test lot number, the date and time the test was performed, test results, results of quality controls, and the name of the person who performed the test. A log should also be maintained to document the specific details of all internal and external test controls that are performed.

A sample HIV Test Results Log and Control Results Log have been developed and used by the Routine HIV Screening pilot health centers. These logs can readily be used for the Uni-Gold, OraQuick or Clearview HIV rapid tests.

Informed Consent

When adopting routine HIV screening in states that allow opt out testing, health center staff need to communicate the type and purpose of testing, allowing patients the opportunity to “opt out” of HIV testing, if desired. Scripted language can be provided to staff that assists them in offering an HIV test:

It is now recommended that all persons 13-64 years of age be tested for HIV.

Health Center is now offering this service to all patients in this age group as part of routine medical care.

If you would like to receive a free screening for HIV today we will do a simple fingerstick [oral swab].

The fingerstick [oral swab] is testing for HIV antibodies, which are what your body produces if you are infected with the HIV virus.

The test shows results in ten minutes [10-20 minutes depending upon test used] and is done while you are here for your visit. The results are accurate 99% of the time.
Would you like to have an HIV fingerstick [oral swab] test today?

In states where written consent is still required, consent can generally be incorporated into the health center’s general consent for care. To learn what laws apply in your state, look at the Compendium of State HIV Testing Laws compiled by the National HIV/AIDS Clinicians’ Consultation Center at the University of California at San Francisco.

http://www.nccc.ucsf.edu/StateLaws/Index.html

A sample General Consent for Care form that incorporates consent for HIV testing is available for your use. Additionally, health literacy experts have modified this general consent for care form in both English and Spanish.

Prepare Patient Educational Materials

It is helpful to provide patients with simple, clear information on HIV/AIDS and HIV testing. The health centers participating in the Routine HIV Screening pilot used a brochure that provides information on HIV testing in a clean, simple format and at a reading level that is accessible to most health center patients. There is a section at the end of the Patient Brochure where you can enter your health center-specific information. This brochure is also available in Spanish.

Draft Staff Tools

In providing HIV screening as a routine part of primary care, it is important to recognize that nurses and providers may need guidance in ways to discuss and offer testing. They likely will need guidance on how to inform patients of test results, particularly reactive rapid HIV test results.

A sampling of tools has been developed to assist nurses and providers within the context of routine HIV screening. These tools provide suggested language for 1) discussing routine HIV screening and offering an HIV test; 2) language for delivering negative HIV rapid test results; and 3) language for delivering reactive HIV rapid test results (which should be done by the provider). These tools can readily be adapted for use with any type of HIV rapid test.
Additionally, the two tools for delivering test results can also be used as handouts to give to patients. If you choose to use them as handouts, be sure to enter your health-center specific information as well as specify which HIV rapid tests you offer.

**How to Offer Routine HIV Screening**
- **Negative Rapid HIV Test Result Handout -- English**
- **Negative Rapid HIV Test Result Handout -- Spanish**
- **Reactive Rapid HIV Test Result Handout -- English**
- **Reactive Rapid HIV Test Result Handout -- Spanish**

**Worksheet**

Use the *Step 2: Set Up the Framework Worksheet* on the next page to track key activities through to completion.
## Integrating HIV Screening into Routine Primary Care: A Health Center Model

### Worksheet
### Step 2: Set up the Framework

<table>
<thead>
<tr>
<th>Key Activities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Collection and Documentation Tool</strong></td>
<td></td>
</tr>
<tr>
<td>Finalize and print data collection and medical record documentation tool</td>
<td></td>
</tr>
<tr>
<td><strong>Test Logs</strong></td>
<td></td>
</tr>
<tr>
<td>Prepare an HIV Rapid Test Log for each testing site</td>
<td></td>
</tr>
<tr>
<td>Prepare an HIV Rapid Test Control Log for each testing site</td>
<td></td>
</tr>
<tr>
<td><strong>Informed Consent</strong></td>
<td></td>
</tr>
<tr>
<td>Build informed consent into the health center’s general consent for care, if desired</td>
<td></td>
</tr>
<tr>
<td>Prepare a separate written consent only if required by local/state law</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Educational Materials</strong></td>
<td></td>
</tr>
<tr>
<td>Adapt and print copies of patient educational brochure, or other simple educational information; place in waiting areas and have available where staff will offer testing</td>
<td></td>
</tr>
<tr>
<td><strong>Staff Tools</strong></td>
<td></td>
</tr>
<tr>
<td>Prepare tool for staff that will be discussing and offering HIV testing to patients</td>
<td></td>
</tr>
<tr>
<td>Prepare a handout that can be provided to patients, if desired, when test results are negative</td>
<td></td>
</tr>
<tr>
<td>Prepare a handout that can be provided to patients when their test results are “reactive” or “preliminarily positive”</td>
<td></td>
</tr>
</tbody>
</table>
STEP 3: Design The Patient Visit Process To Include Routine HIV Screening

Days# 2 – 30

✓ **Develop a patient visit flowchart that includes routine HIV screening**
✓ **Define a process to respond to negative and reactive test results and Western Blot confirmatory test results**
✓ **Worksheet**

**Develop a Patient Visit Flowchart that Includes Routine HIV Screening**

While the circumstances of your clinic will determine where in the patient visit process routine HIV screening will occur, the most natural place is usually at the time of nursing intake/vitals. At the same time that nursing staff inquires as to the purpose of the visit and obtains key vitals, the patient can be informed that the health center offers **ALL** patients 13 – 64 years of age the opportunity to be screened for HIV and asked if they would like to be tested now. When offered in this manner, the requirements of either verbal consent or opt-out testing are generally satisfied. If written consent is required by your state, the health center can generally build consent for HIV testing into the organization’s overall consent for care while also discussing and offering HIV testing during the intake/vitals process. (See Step 2, Informed Consent and visit the Compendium of State HIV Testing Laws compiled by the National HIV/AIDS Clinicians’ Consultation Center at the University of California at San Francisco.

[http://www.nccc.ucsf.edu/StateLaws/Index.html](http://www.nccc.ucsf.edu/StateLaws/Index.html)

Health Centers engaged in the Routine HIV Screening pilot used a model for the patient visit that added HIV screening into the vitals/intake portion of the visit. This particular flow process is graphically depicted in the **Patient Visit Flow Process with Opt Out Routine HIV Screening** and is suitable for use in states with opt-out testing. A slightly different **Patient Visit Flow Process with Opt In Routine HIV Screening** has been used by community...
health centers in Ohio where written informed consent is required. Your center can use either of these flow processes as is or adapt one of them to fit the design of your existing patient visit.

**Define a Process to Respond to Negative And Reactive Rapid HIV Test Results and Western Blot Confirmatory Test Results**

It is also necessary to define the process for responding to negative and reactive HIV screening results within the patient visit, and to communicate this plan to all staff. In general, those patients who test “negative” to a rapid HIV test require no additional follow-up. Staff should, however, inform patients that rapid HIV tests might not be able to detect antibodies to HIV in persons recently infected (the time during which the rapid tests may not detect infection is called the “window period”). Therefore, staff members who offer the test, as well as those who provide the result, should inform all patients that if they believe they may have been infected recently (within the last three months), they should be tested again in three months.

All “reactive” rapid HIV tests require follow-up. At the time a provider informs a patient of his or her “reactive” test result, the provider should reinforce that the result is preliminary and that additional blood work is needed to determine HIV status. A Western Blot is required for confirmation of HIV infection. After drawing the Western Blot, the patient should be given a follow-up visit appointment in 5 clinic days to receive the results of the Western Blot test. Additionally and based on prior arrangements, the local Disease Intervention Specialist (DIS) from the Health Department should be informed of all reactive rapid HIV test results (See Step 1, Solidify Referral Arrangements for HIV Care) so that he or she can be prepared to provide the patient with appropriate counseling and referral services when the results of the Western Blot are given to the patient at the five-day follow-up appointment.

If the Western Blot result comes back negative, the patient should be instructed to return in three months for another test, as it may be that the Western Blot cannot detect recent infection due to the window period. If the result of the Western Blot is indeterminate, blood should be drawn for a second test.
However, if the initial Western Blot comes back positive, the person is confirmed to have HIV infection.

The HIV Screening Algorithm graphically depicts a process for responding to reactive and negative rapid HIV test results as well the process for responding to negative, indeterminate and positive Western Blot confirmatory test results. The Post Test Counseling & Referral Algorithm graphically depicts the involvement of the local Disease Intervention Specialist in these processes.

The Step-by-Step Response to Reactive Rapid HIV Test Results was developed for a group of Ohio health centers participating in a rapid HIV testing and data collection initiative in collaboration with the Ohio Department of Health.

Worksheet

Use the Step 3: Design the Patient Visit to Include Routine HIV Screening Worksheet on the next page to track key activities through to completion.
Integrating HIV Screening into Routine Primary Care:  
*A Health Center Model*  

**Worksheet**  
**Step 3: Design The Patient Visit**  
To Include Routine HIV Screening

<table>
<thead>
<tr>
<th><strong>Key Activities</strong></th>
<th><strong>Patient Visit Flow</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Determine where in the patient visit process routine screening will occur</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Create a flow chart of the redesigned patient visit</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Responding to HIV Rapid Test Results**  
- Determine a process to respond within the visit to negative test results  
- Determine a process to respond within the visit to reactive test results  
- Create an algorithm to depict the process for responding within the visit to negative and reactive HIV rapid test results

**Responding to Western Blot Confirmatory Test Results**  
- Determine a process to respond to negative test results  
- Determine a process to respond to indeterminate test results  
- Determine a process to respond to positive test results  
- Create an algorithm to depict the process for responding to Western Blot confirmatory test results
Step 4: Identify a Point Person to Track Reactives

Days# 10-30

✓ Worksheet

Prior to initiating routine HIV screening, it is vital that your organization identify a point person who will be responsible for tracking patients who have a “reactive” screening test. While the number of reactives will be small for most health centers, it is imperative that someone within the organization have responsibility for ensuring that confirmatory testing is performed, that the results of the confirmatory tests are reviewed and, if the person is infected with HIV, that the patient gets follow-up HIV related care and services.

It is simply not enough to screen patients for HIV. With screening comes the responsibility to ensure that those patients identified as HIV-infected through this process are connected to a full complement of health and social support services. One key way to ensure these connections are made, and secure, is to identify a single point of contact to assume responsibility for these tasks. This point person can establish a Reactive Tracking Tool for each patient with a reactive test result.

Worksheet

Use the Step 4: Identify A Point Person to Track Reactives Worksheet on the next page to track key activities through to completion.
Worksheet
Step 4: Identify a Point Person to Track Reactives

<table>
<thead>
<tr>
<th>Key Activities</th>
<th>Tracking Reactives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify a staff member within your organization who is responsible for ensuring that patients with reactive test results receive confirmatory testing and, if HIV infection is confirmed, follow-up HIV related care and services</td>
<td></td>
</tr>
<tr>
<td>Prepare a Reactives Tracking Sheet</td>
<td></td>
</tr>
</tbody>
</table>
Step 5: Adopt HIV Screening Codes for Reimbursement

Days# 30-45

As of Jan 1, 2008, providers can bill for performing an HIV test with a rapid test kit. Providers can add Modifier “92” for “Alternative Laboratory Platform Testing” to the usual laboratory procedure code for HIV testing within the CPT® system. The following is the CPT language for this service:

“When laboratory testing is being performed using a kit or transportable instrument that wholly or in part consists of a single use, disposable analytical chamber, the service may be identified by adding modifier 92 to the usual laboratory procedure code (HIV testing 86701-86703). The test does not require permanent dedicated space; hence by its design it may be hand carried or transported to the vicinity of the patient for immediate testing at that site, although location of testing is not in itself determinative of the use of this modifier.”

In May 2008, the American Academy of HIV Medicine (AAHIVM), in partnership with the American Medical Association (AMA), released Coding Guidelines for Routine HIV Testing in Health Care Settings. This is an easy to use resource to help health care providers, billing personnel, and others become familiar with the proper coding requirements for HIV testing as a routine part of patient care.
Step 6: Commit

Days# 60-90

✓ Convene a staff-wide forum
✓ Convene profession-specific training
✓ Worksheet

Convene a Staff-wide Forum

Just prior to launching routine HIV screening, health center leadership should gather all staff together for the purposes of: 1) stating their commitment to routine HIV screening; 2) sharing data that illustrates the importance of this screening effort; and 3) providing basic information to all staff about HIV/AIDS and its impact on the health center and the patients and community it serves.

While health center leadership should spearhead this forum, other partners can be included such as state/local Health Department representatives, and staff from organizations where you will refer patients. This demonstration of leadership support, presentation of the need and importance of routine HIV screening, and partnership visibility, can be accomplished in a one-hour session with staff.

Convene Profession-specific Training

Following the all-staff forum, staff can be broken up into profession-specific work groups. In a 45-60 minute session, providers can receive guidance in discussing HIV test results with patients, particularly “reactive” results; nurses can receive training in offering the test as well as training in administration of the test itself; and front desk and related staff can participate in a session on cultural sensitivity for persons with HIV and issues of confidentiality (also to be covered in the nurse and provider breakouts). Additional and ongoing profession-specific trainings can be added, as needed, during the start-up of routine HIV screening.

Worksheet

Use the Step 6: Commit Worksheet on the next page to track key activities through to completion.
### Integrating HIV Screening into Routine Primary Care: A Health Center Model

**Worksheet**

**Step 6: Commit**

<table>
<thead>
<tr>
<th>Key Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff Wide Forum</strong></td>
</tr>
<tr>
<td>Schedule date for all-staff forum</td>
</tr>
</tbody>
</table>

| **Profession-specific Training**   |
| Provide profession-specific training on topics critical to implementation of routine HIV screening |

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January 14, 2009
Step 7: Launch

Days# 60-90

On the day (or days if launch will be staggered across multiple sites) pre-specified by leadership, begin offering HIV screening to all patients 13-64 years of age who come to your health center for primary care – regardless of the reason for their visit. The staff person or persons appointed to trouble shoot should be prepared to respond to problems as necessary.
Step 8: Realign

✓ Worksheet

As your health center gains experience with HIV rapid testing, you will develop and incorporate new ideas, tools and methods for screening, training, or service delivery. Additionally, you will want to identify someone to regularly visit the HIV Routine Screening Within Primary Care Virtual Office to look for new resources to apply to your HIV screening process.

Instructions for joining the NACHC HIV Routine Screening Within Primary Care Virtual Office housed on the HRSA Knowledge Gateway web site are as follows:

If you do not already have an account at the HRSA Knowledge Gateway web site:

1. Go to http://www.healthdisparities.net and follow the link in the Welcome Box at the top right hand side for “new user signup.”
2. Complete “General Information” form and then hit “Continue” at the bottom of the form.
3. On the “Group Memberships” page, check the box next to “HIV Routine Screening Within Primary Care” in the “Operational” category.
4. Click “Save Changes” at the bottom of the page. You will receive an Account Confirmation. This also will generate a request for membership in the HIV Routine Screening Within Primary Care Virtual Office. You will receive a reply shortly from the Administrator letting you know that your membership has been granted.

If you already have an account at the HRSA Knowledge Gateway web site:

1. Go to http://www.healthdisparities.net and log in to the web site with your user name and password.
2. Highlight “Office” in the main navigation bar and select “My Account.”
3. Click on the “Group Memberships” tab.
4. Check the box next to “HIV Routine Screening Within Primary Care” in the “Operational” category.
5. Click “Save Changes” at the bottom of the page. This will generate a request for membership in the HIV Routine Screening Within
Primary Care Virtual Office. You will receive a reply shortly from the Administrator letting you know that your membership has been granted.

Once a member of the NACHC HIV Routine Screening Within Primary Care Virtual Office, simply log in at http://www.healthdisparities.net/hdc/html/virtualOffice.aspx

Worksheet

Use the Step 8: Realign Worksheet to track key activities through to completion.
Integrating HIV Screening into Routine Primary Care:  
*A Health Center Model*

**Worksheet**  
Step 8: Realign

<table>
<thead>
<tr>
<th>Key Activities</th>
<th>Virtual Office Check-in</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Identify the person responsible for periodic check-in with the HIV Routine Screening Within Primary Care Virtual Office</td>
</tr>
</tbody>
</table>