

HIV Testing: How Has Your Clinic Responded?

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Introductions

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Agenda Overview

- About the new CDC recommendations:
 - What are they?
 - What is the rationale for the change?
- What are the implementation issues?
 - Consent and California Law
 - Confidentiality and chart documentation
 - Ethics of Opt-Out vs. Opt-In protocol
 - Performing the test in a busy clinic
 - Disclosing results
- Resources for implementing routine screening in your clinic

Revised Recommendations for HIV Testing in Medical Settings

- What do they actually say?
- How is this a change from previous guidelines?
- What is the rationale for the change?

Old CDC Recommendations

- Every person in care should be screened for HIV transmission risk behavior.
- Those with a positive screen should be referred for testing for HIV.
- Those with identified risk should receive risk reduction counseling.

New/Revised CDC HIV Screening Recommendations

- **Routine HIV screening** test for all persons 13-64 in health care settings, not based on risk
- **Opt-out** design; include HIV test consent with general consent for care. (**Not legal in CA in 2007**. More on this later.)
- **Delinking** of traditional prevention counseling from testing

New/Revised CDC Recommendations:
Repeat Screening

“At least annually for all persons at high risk of HIV infection”

WHO WOULD YOU INCLUDE?

New/Revised CDC Recommendations:

Repeat Screening

- At least annually for all persons at high risk of HIV infection:
 - **Injection-drug users (IDUs)**
 - **Sex partners of IDUs**
 - **Persons who exchange sex for money or drugs**
 - **Sex partners of HIV infected**
 - **Men who have sex with men (MSM)**
 - **Heterosexuals who themselves or their sex partners have had >1 sex partner since last HIV test**
- Before new sexual relationship

Points for Clarification

- The new recommendations don't specify **RAPID TESTING**, they address **ROUTINIZING TESTING**, whether rapid or not.
- The new/revised recommendations apply to testing in medical settings, and **NOT** to testing that is paid for via the California State Office of AIDS Counseling and Testing program.

Rationale for the Change in Recommendations

- Increased case finding
- Earlier case finding, so better response to HIV treatment
- Prevention of spread

Rationale:
Increased Case Finding

- Many (especially young people and women) don't realize their risk, so don't know to ask for testing and are not being offered testing.
- More get tested with opt-out strategy.

Rationale:
Increased Case Finding

Awareness of HIV Status among Persons with HIV, U.S.

Number HIV infected 1,039,000 – 1,185,000

**Number unaware of
their HIV infection** **252,000 - 312,000 (24%-27%)**

Estimated new infections
annually 40,000

Rationale:

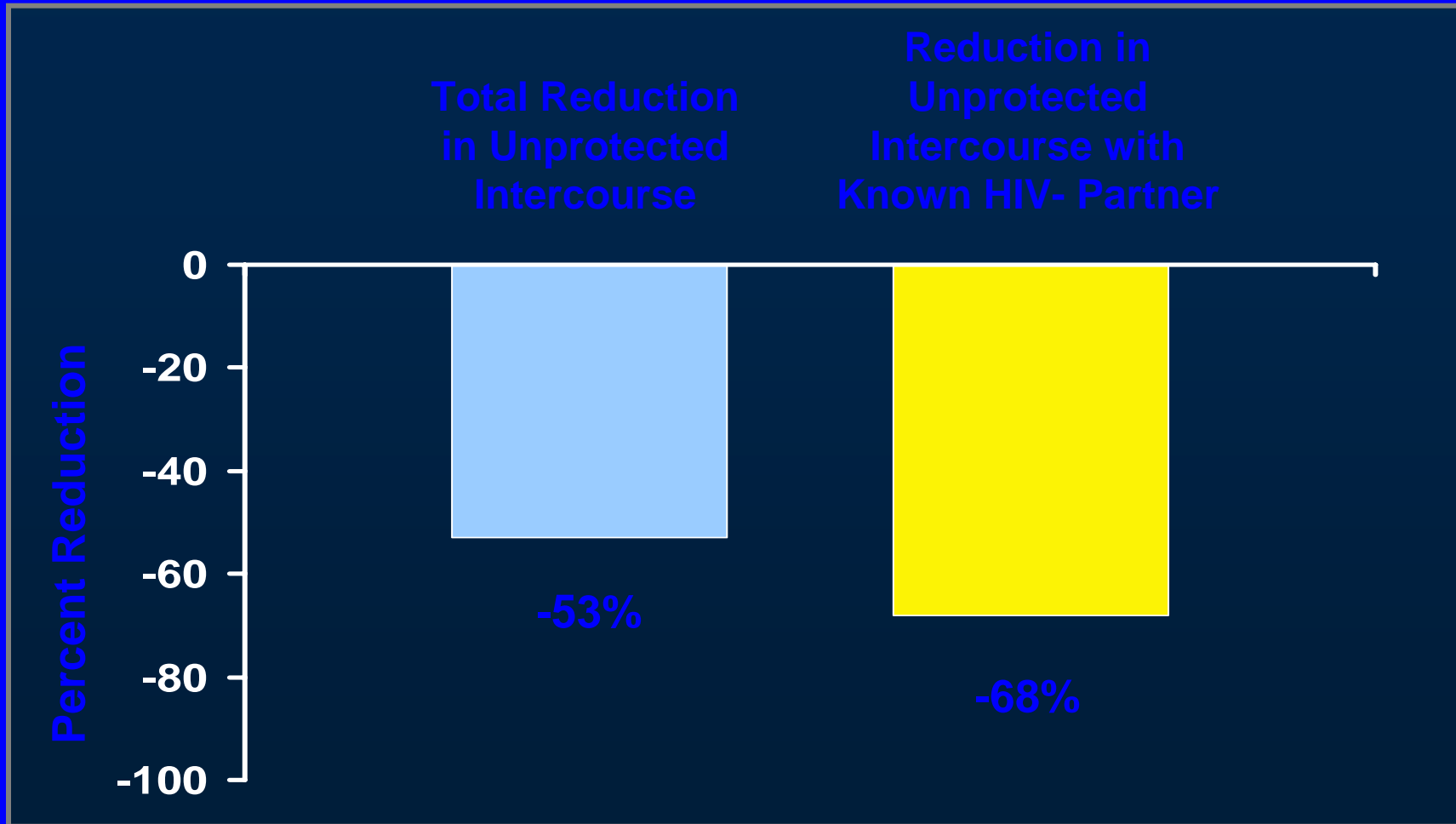
Earlier Case Finding

- Among 4,127 persons with AIDS*, 45% were first diagnosed HIV-positive within 12 months of AIDS diagnosis (“late testers”)
- Late testers, compared to those tested early (>5 yrs before AIDS diagnosis) were more likely to be:
 - Younger (18-29 yrs)
 - Heterosexual
 - African American or Latino

Rationale: Prevention

- Testing IS prevention.
- Current opt-in consent and counseling system is a barrier to testing:
 - For providers
 - For patients
- “HIV exceptionalism” perpetuates stigma of testing.

Rationale: Testing is Prevention



Rationale:

Counseling Requirement as a Barrier

- Providers perceive counseling as a barrier (survey of 54 providers/10 emergency departments)
 - 10% encouraged STD patients to get HIV test
 - 35% referred to outside testing
- Barriers cited: lack of follow-up (51%), believed they needed a counselor certification (45%), too time consuming (19%)

Rationale:

Opt-Out Screening and Stigma

Prenatal HIV testing for pregnant women:

- RCT of 4 counseling models with opt-in consent:
 - *35% accepted testing*
 - *Some women felt accepting an HIV test indicated high risk behavior*
- Testing offered as routine, opportunity to decline
 - *88% accepted testing*
 - *Significantly less anxious about testing*

Rationale:

Opt-out Reduces Barriers for Patients

Routine Opt-Out HIV Testing - Texas STD Clinics, 1996-97

	Opt-In	Opt-Out	
	N (%)	N (%)	% change
STD Visits	31,558	34,533	+9
Eligible Clients	19,184 (61)	23,686 (69)	+23
Pre-test counsel	15,038 (78)	11,466 (48)	-24
Tested	14,927 (78)	23,020 (97)	+54%
Post-test counsel	6,014 (40)	4,406 (19)	-27
HIV-positive	168 (1.1)	268 (1.2)	+59%

Questions So Far?

Implementation Issues

- **Consent Issues**
 - **Opt-in/Opt-out**
 - **Current California law and status update on changes**
 - **The consent debate**
- Confidentiality and chart documentation
- Performing the test in a busy clinic
- Communicating results and linking to care

Terminology

- *Informed consent*: a legal concept; defined as a communication between patient and provider resulting in an authorization to undergo HIV testing; capacity to understand testing should be assured.
- *Opt-out screening*: performing an HIV test after notifying the patient that the test will be done; consent is inferred unless the patient declines (i.e., opts out).
- *HIV prevention counseling*: interactive process to assess risk, recognize risky behaviors, and develop a plan to take steps that will reduce risks.

Consent and Pretest Information

“Screening should be voluntary and undertaken only with patient’s knowledge and understanding that HIV testing is planned.”

“Ins and Outs” of HIV Testing

- Opt-In...*linked* to counseling
 - Assessment for HIV risk done verbally
 - Patient requests or is offered the test
 - Explicit consent obtained, usually written
 - Requires pre- and post- test counseling (variably performed in actuality)
- Opt-Out...*de-linked* from counseling
 - Patient informed he or she may be tested for HIV as part of routine blood work, unless patient requests *not* to be
 - Counseling not integrated
 - No separate consent for HIV testing; general medical consent covers

General Legal Considerations

- These CDC recommendations do not supersede state and local laws that govern HIV testing.
- Legal requirements related to informed consent and pretest counseling differ among states.
- Certain states, jurisdictions, or agencies (such as CA) do not now allow opt-out screening or may impose specific requirements for counseling, consent, confirmatory testing, or communicating HIV test results.
- Proof of consent may be important to preserve in settings where capacity to consent is questionable or population is vulnerable.

Existing California Law

- Specific written consent for HIV testing is required
EXCEPT: “physicians and surgeons” may obtain verbal consent
- Opt-out *not* legal in California *currently*
- Prevention counseling not required except in prenatal care

Existing California Law: *HIV Testing in Pregnancy*

- Testing is voluntary but HIV information and testing must be offered to all pregnant women.
 - This includes women in Labor & Delivery who may not have been offered testing in care
- Documentation of HIV test should be performed using the CDHS/OA form or equivalent.
- Pregnant women must receive information or counseling, as appropriate, explaining implications of test for mother's and infant's health.
- Women testing HIV-positive, whenever possible, should be referred to group specializing in such care.

Opt-Out Not Legal in CA (...yet)

Opt-out testing bill (AB 682). Would allow opt-out testing without counseling. The new law would require medical care providers, prior to ordering an HIV test, to inform patient that:

- HIV testing is planned
- information about the test will be provided
- information about treatment options and further testing needed will be given
- the patient has the right to decline the test

Should a patient decline the test, the medical provider must note that fact in the patient's medical file.

Last amended July 18, 2007; referred to Senate Appropriations

Consent Issues: The Debate

Exceptionalism

vs.

Routinization

Arguments for Treating HIV Testing Differently

Public Health Arguments

- Low HIV prevalence in many medical care settings renders this approach cost *ineffective*
- More people tested doesn't mean more people in medical care
- Will people avoid medical care (ER, pre-natal) because they don't want to be tested?

Arguments for Treating HIV Testing Differently

Social and Ethical Arguments

- Opt-out consent design does not guarantee truly *informed* consent
- HIV diagnosis is a significant life event
- **Ignoring** stigma is not the same as **addressing** stigma – *which continues to exist*

Arguments for Treating HIV Testing Differently

Testing without counseling ignores reducible risk

- Behavioral prevention interventions *done correctly* can be effective
- New guidelines will move emphasis from prevention to medical intervention
- Current guidelines have not been fairly tested; insufficient resources invested to support real counseling in medical settings

Arguments for Routine Screening

Public Health Arguments

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Arguments for Routine Screening

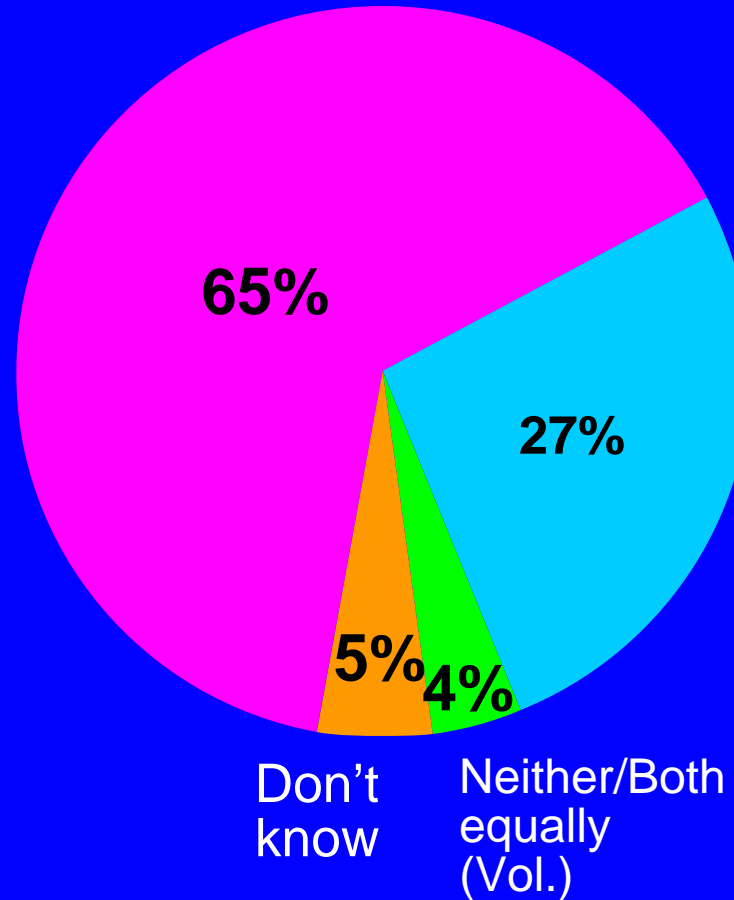
Social and Ethical Arguments

- “Normalization” of HIV testing reduces stigma.
- Many do not realize HIV testing is handled differently.

“I’m sure I was tested for HIV – they tested me for everything.”

Public View of Routine HIV Testing

HIV testing should be treated just like routine screening for any other disease, and should be included as part of regular check-ups and exams



HIV testing is different from screening for other diseases, and should require special procedures, such as written permission from the patient in order to perform the test

Reconciling Difficult Trade-offs between Personal Freedom and Common Good

“For vulnerable communities, it may not be enough to focus absolutely on rights, but also on health and collective well-being.”

...that may be the message of the evolution toward a public health model for combating HIV/AIDS”

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- Communicating results and linking to care

Documenting HIV Test Results

- Positive or negative HIV test results should be documented in the patient's confidential medical record and should be available to all of her health-care providers
- The HIV test result of a pregnant woman also should be documented in her infant's medical record

HIV Status in the Chart: CA

California Health and Safety Code Section 120975-121020: The results of an HIV test.....may be recorded by the physician who ordered the test in the test subject's medical record or otherwise disclosed without written authorization of the subject of the test, or the subject's representative as set forth in Section 121020, to the test subject's providers of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code, for purposes of diagnosis, care, or treatment of the patient, except that for purposes of this section "providers of health care" does not include a health care service plan.

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Performing the Test in a Busy Care Setting: Two Case Studies

- Amanda Newstetter: Incorporating Rapid Testing in a Family Planning setting
- Chris Hall: Experience at San Francisco General Hospital and DPH Care System

Association Between HIV Testing Rates and Elimination of Written Consent in San Francisco

- Consent mechanism altered and streamlined at San Francisco DPH Care System
- In May 2006:
 - Conventional consent forms removed from medical settings
 - HIV antibody test added to routine lab requisition
 - Clinicians required to document in chart that patient consent was obtained
 - Patient signature was not required

Association Between HIV Testing Rates and Elimination of Written Consent in San Francisco

- Results of this structural intervention:
 - Monthly rate of HIV testing increased after this policy change, from 13.5 tests /1000 visits in June 2006 to 17.9 in December 2006
 - Mean number of positive HIV tests per month increased from 20.6 to 30.6
- Conclusion:
 - Administrative policy change simplifying consent was followed by an increase in HIV testing and increased positivity rate

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New CDC Recommendations: Communicating HIV Test Results

- Negative HIV test results can be conveyed without direct personal contact
- Positive HIV test results should be communicated confidentially, through personal contact
 - Friends or family members should not be used as interpreters
 - Patients should be linked to clinical care, counseling, support, prevention services

Linking to Care

- Local care networks
- Many communities have Ryan White Program funded care for uninsured/Medicaid.
- “Warm handoff” is standard of care

Training and Other Resources

*SEE
RESOURCES
DOCUMENT*

Questions?

Opportunities and Challenges

- Which test to use
- Clinic flow
- Client counseling
- Personnel
- Giving Results
- Documentation
- Costs
- State laws & funding requirements

Which Test to Use

Routine doesn't mean rapid

- Standard or Rapid test?
 - ◆ Blood, oral, urine
- Confidential and/or Anonymous
- Cost

Clinic Flow

Questions to ask:

- Are we offering testing only?
- Does testing require 1 or 2 visits?
 - ◆ Will standard HIV results be given in person or on the phone?
 - ◆ Testing everyone or those at risk?

Clinic Flow- Counseling

- Are we offering counseling with testing?
 - ◆ Paradigm shift for many of us
 - ◆ Counseling has been a barrier
 - ◆ May be a requirement of funding
- Some clients may still want/need counseling
- When do we do the counseling?

Clinic Flow cont

- What happens after we run the test?
- Are the same staff counseling, administering the test and giving results?
- Where are rapid tests run?
- Can the rapid test be moved once initiated?
- How long does it take to get the rapid results?

Personnel

- Who will conduct all the additional tests?
- How do staff get training?
- How do you address staff resistance to changes?
- Do the same staff do the counseling, test and results?
- Do we cross train staff or have separate HIV staff?
- RT: who will follow the positive results through confirmatory process?

Giving Results

- Who is trained to give positive results?
 - RT: are all staff prepared to give positive results on the spot?
- How do you prepare staff for false test results on RT?
- How do you keep staff motivated after first false or inconclusive results?
- Should we change system to “No news is good news?”
- Should we consider giving results over the phone?

Documentation

- **How are HIV results documented?**
- **How are results shared among staff?**
- **Do you know the laws related to sharing of HIV results?**

Costs

- More tests doesn't always mean more money
- RT: only one visit
- No lab revenues with RT
- Different test, different cost
- More tests lowers the cost
- New system may require less staff training

Transitioning to CDC Recommendations

- How far along are your staff and clinics now?
- What does your staff and clinic need to make this transition?

Implementation: Getting Started

- Getting buy-in from administration
- Educating staff about CDC recommendations
- Staff meetings to discuss where we are & where we want to go
- Pilot testing before roll out
- Additional training as needed

How RTCs can help

- Facilitate staff discussions/meetings
- Staff training
 - ◆ Overview of CDC recommendations
 - ◆ Rapid Testing
 - ★ Overview
 - ★ How to conduct the test
 - ★ Giving results – what do they mean?
 - ◆ Staff values regarding a new approach
 - ◆ Counseling options
- Other Technical assistance
 - ◆ Analysis of current clinic systems
 - ◆ Recommendations for systems change

Giving Preliminary Positive Rapid HIV Test Results

1. Disclose rapid positive test result

- State in a direct and neutral tone: “your rapid HIV test result is preliminary positive.”

2. Remind client/patient of what the rapid HIV test result means

- This is a screening test, we need to do another blood test and send it off to a lab
- This second test is called a confirmatory test
- This result means it is likely you have HIV but we won't know with absolute certainty until the confirmatory test result is known
- If the confirmatory result is also positive, it means you have HIV infection
- Review the possibility that the preliminary positive result is a false positive. Know the likelihood of a false positive result with the particular test you are using. All rapid HIV tests generate a small percentage of false positives and false negatives.
- If relevant, let the client know causes of false positive results, e.g., multiple consecutive pregnancies, auto-immune disorders, and prior or current syphilis infections
- Discuss how long it takes in your setting to obtain results of confirmatory tests. Make an appointment for your client to come in and obtain his or her confirmatory test result

3. Talk in more detail about the client's recent risk behaviors

- Assess the time frame for risk behaviors to determine whether they occurred in the antibody window period (generally, less than 3-6 months since risk behavior, though newer-generation HIV antibody tests detect antibody as early as 3-6 weeks)
- Explain the need to repeat HIV testing if most recent risk was less than 3-6 months ago

4. Discuss strategies to reduce or eliminate HIV risk behavior

- Ask whether the client has questions about how to reduce his or her HIV risk related to sex and drug or alcohol use
- Even while the confirmatory HIV test result is pending, encourage clients to assume the preliminary positive HIV test result is accurate (i.e., do not have unprotected sex, do not share hypodermic needles, etc.)
- Advise that once HIV infection is confirmed, additional resources and referrals will be offered to the client to assist him or her with disclosing HIV status to recent sex partners.

5. Assess the client's emotional state and feelings

- Does the client seem anxious, relaxed, or indifferent about this test result?
- Check in: “*How are you doing with all of this?*”
- “*What would be most helpful to you right now?*”
- Explore plans for and consequences of disclosure to others
- Ask if the client has anyone he or she can share this information with. Provide HIV hotline or crisis hotline numbers and general counseling referrals?

6. Explore information and thoughts

- Assess the client's understanding of the test result again and clarify misconceptions
- You may need to repeat the information more than once
- Explain that you will be collecting a blood sample today for the confirmatory HIV test, and tell the client when the result will be available

7. Be prepared to respond: “What if I am really positive, then what?”

Messages to give to the client:

- HIV has become a manageable chronic disease, for those able to participate in medical care and/or take recommended medications as directed
- People with HIV can live healthy, rewarding lives and continue to have intimate relationships
- Follow-up with medical providers knowledgeable about HIV is critical
- We will help you get connected to the best HIV providers, clinics, and support systems in the area
- Be prepared for additional testing at the first HIV clinic appointment, to determine the stage of HIV infection and assess how the immune system is functioning
- Certain medications may be necessary to prevent secondary infections; medications for HIV may or may not be started immediately based on a variety of factors.
- Many people with HIV are living happy, healthy lives. You are not alone!

8. Provide referrals and closure

- Emphasize how important it is to come back for the confirmatory HIV test result
- Make an appointment to receive the result (if possible, with the same provider)
- Provide reassurance and grounding to the client before they leave the session (i.e., “*I can refer you to organizations that provide support to people with HIV.*”) Ensure your referral lists are updated and available to provide clients at initial visits.

9. Collect blood sample for confirmatory HIV testing and other tests

- If drawing blood for syphilis screening, hepatitis C screening, or other tests at the start of the visit, you may wish to collect an additional tube for confirmatory HIV testing, should it be required later.

RESOURCES RELATED TO REVISED RECOMMENDATIONS FOR HIV TESTING

<i>Organization</i>	<i>Description</i>	<i>Internet Address</i>
CALIFORNIA:		
CA AIDS Clearinghouse	Information on available services and local PCRS contacts	http://www.hivinfo.org/links/lhj.htm
California AIDS Hotline	Search more than 1,200 organizations providing HIV/AIDS & STD services in California	http://www.aidshotline.org/crm/asp/refer/ (800) 367-AIDS (English/Español) (888) 225-AIDS (TDD)
CDPH - Office of AIDS	Information on HIV laws in California	http://www.dhs.ca.gov/aids/Reports/aidslaws/pdf/28492006AIDSLAWS061407.pdf
STD Checkup.org	PCRS contacts, reporting requirements, and other resources for STDs in CA	Resources for Clinicians Tab at: www.stdcheckup.org
NATIONAL:		
AIDS Education and Training Centers (AETCs)	Resources and scheduled training events across the US, featuring the revised CDC recommendations	http://www.aids-ed.org/aidsetc?page=et-aetc-testing
Albert Einstein College of Medicine, and partners	Monograph: Opportunities for Improving HIV Diagnosis, Prevention, and Access to Care in the US	http://www.stophiv.us/cme/monograph.pdf
American Academy of HIV Medicine (AAHIVM)	Resources to help clinicians implement new HIV testing guidelines into their practices	http://www.aahivm.org/index.php?option=com_content&task=category&sectionid=4&id=194&Itemid=253
Health Research and Education Trust (HRET)	US States' HIV Testing Laws	www.hret.org/hret/about/hivmap.html
HIV Medicine Association (HIVMA)	Support for clinicians providing health care to PLWHA	www.hivma.org
Kaiser Family Foundation (KFF)	a) Review of state laws regarding written consent for HIV testing and b) Pre-test counseling c) Fact Sheet: HIV Testing in the United States d) Ask the Experts: HIV Testing (6/26/2007)—Podcast, video, and transcripts	a) http://www.statehealthfacts.org/comparemactable.jsp?ind=587&cat=11&yr=18&typ=5&o=a&sort=980 b) http://www.statehealthfacts.org/comparemactable.jsp?ind=588&cat=11&yr=18&typ=5&sort=a c) http://www.kff.org/hivaids/upload/6094-06.pdf d) http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=2183
National Alliance of State and Territorial AIDS Directors (NASTAD)	Report on Findings from an Assessment of Health Department Efforts to Implement HIV Screening in Health Care Settings, June 26, 2007	http://www.nastad.org/Docs/highlight/2007626_NASTAD_Screening_Assessment_Report_062607.pdf
National Network of STD/HIV Prevention Training Centers (NNPTC)	CDC-funded group of regional centers that provides health professionals with state-of-the-art educational opportunities including experiential learning with an emphasis on prevention.	www.stdhivpreventiontraining.org
UCSF HIV Insite	Comprehensive info on HIV/AIDS treatment, prevention, and policy	www.hivinsite.org
US Centers for Disease Control and Prevention	Revised Recommendations for HIV Testing MMWR: a) PDF, and b) related resources	a) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr514a1.htm b) http://www.cdc.gov/hiv/topics/testing/healthcare/