



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

CLINICAL ADVISORY UPDATE: ROUTINE HIV SCREENING OF ALL PREGNANT WOMEN IN MASSACHUSETTS

TO: Massachusetts Prenatal, Maternal & Newborn Care Providers
FROM: John Auerbach, Commissioner
Lauren A. Smith, MD, MPH, Medical Director
Date: February 2012
Re: Routine HIV Screening of Pregnant Women

This Massachusetts Department of Public Health (MDPH) Clinical Advisory Update provides clarification on national guidelines and outlines MDPH recommendations for routine HIV screening of all women in prenatal care. Routine HIV screening identifies undiagnosed HIV infection, facilitates the provision of effective and early clinical care to mothers for their own health and to prevent perinatal infection of their newborns. In 2006, the American Congress of Obstetricians and Gynecologists (ACOG) (www.acog.org) and the Centers for Disease Control and Prevention (CDC) (www.cdc.gov) both recommended that **HIV counseling and testing be performed routinely for ALL pregnant women, without reference to their risk profile**. MDPH has consistently strongly recommended routine screening in all past advisories, and continues to do so. The ACOG and CDC recommendations further support the elimination of written consent for HIV counseling and testing of pregnant women, which is *not* consistent with current Massachusetts law. In the Commonwealth, M.G.L. c. 111, § 70F, requires written informed consent for HIV testing. However, there are simple steps that hospitals and health providers can take to ensure routine HIV testing that are completely consistent with current Massachusetts law.

Massachusetts Routine HIV Counseling and Testing Recommendations:

- **Routine counseling and testing should be provided to ALL pregnant women (regardless of the provider's or woman's perception of their risk)**. All pregnant women should be offered HIV testing and should be tested, with their consent, as part of the routine battery of prenatal laboratory tests during each pregnancy. Determining the HIV status of pregnant women is implicit in 105 C.M.R.

130.601 (105 CMR 130.601: HOSPITAL LICENSURE SUBPART D – SUPPLEMENTARY STANDARDS: PARTICULAR SERVICE Department Designation of Level of Maternal and Newborn Care in a Hospital) which requires a maternal risk assessment to identify special risks to the health of both the woman and fetus, and to determine if any specialized services are necessary.

- **Provide all women in prenatal care with printed materials about HIV testing and treatment options.** The MDPH has developed two documents which are available free of charge for your use. These may be obtained by contacting the MA Health Promotion Clearinghouse at www.maclearinghouse.com:
 - **Counseling and Testing:** HIV Questions and Answers, which provides information on counseling and testing including different types of tests.
 - **Women and HIV:** HIV Questions and Answers for women, with a specific section dealing with pregnancy.

Review of these MDPH-issued patient information materials regarding HIV testing is adequate prevention counseling and is recommended to accompany any HIV screening.

- **Obtain written informed consent for testing in accordance with 105 C.M.R. 130.616(C)(2), and M.G.L. c. 111, § 70F AND obtain consent for documentation of maternal HIV status in the newborn record in accordance with 105 C.M.R. 130.627 (A), (B) and M.G.L. c. 111, § 70F.** (See samples of model language at the end of this document.)

105 C.M.R. 130.616 (C) (2) requires all maternal and newborn services to have documentation of informed consent for both maternal and newborn care and M.G.L. c. 111, § 70F requires written informed consent for HIV testing. MDPH strongly recommends the inclusion of distinct HIV testing language in the general consent for maternal and newborn care. This is sufficient to meet the requirements of M.G.L. c. 111, § 70F. Consent may also be obtained on a separate form.

105 C.M.R. 130.627 (A), (B) indicates antenatal blood serology shall be included in the maternal record and significant maternal diseases shall be documented in the newborn record. MDPH considers an HIV test to be part of antenatal blood serology and a positive HIV test result in a pregnant woman to be a significant maternal disease. MDPH strongly recommends the inclusion of distinct separate language in the general consent for release of HIV test results to the newborn record. This is sufficient to meet the requirements of M.G.L. c. 111, § 70F. Consent may also be obtained on a separate form.

MDPH has developed model informed consent language for testing and separate language for release of results which facilities/practices may choose to adapt for local use. These both can be included in the general consent to streamline the consent process.

Frequently Asked Questions (FAQs) on M.G.L. c. 111, § 70F are attached.

- **Provide repeat voluntary HIV testing during pregnancy to those women at continued risk, or who previously declined testing during the current pregnancy.**
- **Provide voluntary rapid HIV testing in labor and delivery for women with undocumented HIV status** (if test is reactive, initiate prophylactic treatment of mother and then newborn after consultation with the patient, while awaiting confirmation from a serum test, and obtain Infectious Disease consultation).

MDPH is committed to providing assistance to prenatal care providers as they work to respond to the Department's recommendations. Given the enormous advances in HIV prophylaxis for pregnant women and newborns, it is clear that early identification and individualized treatment of all pregnant women with HIV infection is the best way to prevent pediatric HIV disease and promote maternal health.

The pregnancy of an HIV infected woman should be considered a high-risk pregnancy. HIV infected women in prenatal care should also be in the care of a clinician knowledgeable and experienced in the provision of HIV-related care. If the pregnant woman does not already have such a clinician, appropriate referrals should be made. The cost of HIV medications for some women may be covered through the state HIV Drug Assistance Program (HDAP) ([HDAP website](#)). In addition, this website: www.aidsinfo.nih.gov has the most current recommendations for treatment of perinatal HIV.

Model Informed Consent for HIV Testing

MDPH recommended standard language to be used to document informed written consent for HIV testing. **NOTE: To simplify the consent process and to improve compliance with the recommendation for routine HIV testing during pregnancy, this language may be included in the general consent for medical and newborn care.**

My signature below indicates that:

1. I agree to be tested for HIV.
2. I have been given information about the test.
3. All of my questions about the test have been answered.
4. I understand that this consent will expire one year from the date it is signed.
I understand that I may withdraw my consent at any time.
5. My decision to be tested is completely voluntary.

Name (please print)

Signature

Date

Model Informed Consent for Documentation of Maternal HIV Status in the Newborn Record

MDPH recommended standard language to document informed written consent for release of HIV test results to the newborn record. **NOTE: To simplify the consent process and to improve compliance with the recommendation that maternal HIV test results be documented in the newborn's chart, this language may be included in the general consent for medical and newborn care.**

My signature below indicates that:

1. I agree to have my HIV test results documented in the record of my newborn.

Name (please print)

Signature

Date

Chapter 111, Section 70F, of the Massachusetts General Laws

Frequently Asked Questions

In September 2006, the Centers for Disease Control and Prevention (CDC) issued recommendations regarding routine testing for HIV in health care settings. The Massachusetts Department of Public Health (MDPH) endorses these recommendations. The rationale for routine testing for HIV in health care settings is that often people infected with HIV visit health care settings long before they are diagnosed with HIV infection, but are never tested for HIV. According to the CDC, if health care facilities routinely offer voluntary HIV screening as a regular part of medical practice, more people will know their HIV status sooner, and will receive effective care earlier.

M.G.L. chapter 111, section 70F is sometimes viewed as a barrier to instituting routine testing, but this should not be the case. Section 70F requires that the individual is adequately informed of the test and agrees in writing to be tested, and it should not interfere with the implementation of a routine testing program.

Without obtaining an individual's written informed consent, Section 70F prohibits health care providers and facilities from:

- Testing a person for HIV;
- Disclosing the results of the person's HIV test; and
- Identifying the person as the subject of an HIV test.

However, promoting routine HIV testing while complying with M.G.L. c. 111, §70F (70F) and maintaining existing protections related to testing can be accomplished without additional burden. The following are frequently asked questions about the applicability of 70F:

Q. Does the consent signed by the patient have to be lengthy in order to meet the "written informed consent" requirement?

A. No. The law is silent on the issue of what the consent must look like. A simple statement indicating that the patient understands what s/he is being tested for and agrees to be tested is sufficient. (See attached model consent form.)

Q. Does 70F require a pre-test counseling session before an HIV test is administered?

A. No. Section 70F does not mention counseling.

Q. Does the law specify that the signed consent must "follow" the patient through the health care facility (e.g., from the ordering physician to the laboratory to follow-up care)?

A. No. As long as the patient has been informed about the test and has signed a consent, the consent form itself does NOT need to be held or viewed by other staff involved in the testing or follow-up process. The signature of the ordering physician on the test request form will serve as notice that the patient has provided written informed consent.

Q. Does the law specify who may obtain consent from a patient or who may conduct specimen procurement, interpretation of results, or delivery of results to patients?

A. No. The law is silent on this point. Anyone who is authorized by the state to conduct HIV testing, including rapid testing and collection of oral mucosal samples, may obtain consent and participate in all other ways in the testing and follow-up procedures. Authorized individuals may include HIV testing counselors, physicians, nurses, nurse practitioners, physician assistants, and other health care professionals.

Q. May an HIV test consent be included among other consents and legal documents at intake? For instance, may the consent for HIV testing be part of a general consent to care developed by individual sites?

A. Yes. The consent may be part of a general consent to care form, as long as the language pertaining to the HIV test is distinct from the rest of the consent. Provided that the person consenting to the HIV test is informed about the test and understands what it is, 70F allows health care providers to include the consent with other materials and to obtain the consent at intake. If the consent to HIV testing is temporally separate from the test itself, the provider should let the individual know when the test is actually performed, but does not need to have patient sign an additional consent form.

Q. Does the law specify how the signed consent needs to be stored?

A. No. Section 70F does not mention storage of consent forms. Existing rules and regulations regarding confidential storage of medical records apply to consent forms for HIV testing.

Q. Does the law require a time-limit on the consent?

A. No, the law does not. The MDPH recommends that consent expire after no more than one year.