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Summer 1995

# Maine AIDS Care (Summer 1995)

Maine Medical Center's AIDS Consultation Service

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# Maine AIDS Care

*AIDS Consultation Service • Maine Medical Center • Summer 1995*

## Revised Maine HIV Testing Laws Go Into Effect

An "Act to Implement the Recommendations of the Maine HIV Advisory Committee Concerning HIV Testing" was heard before the Maine State Legislature this spring. After several changes and revisions, the bill, LD 321, was passed by the House & Senate and signed into law by Governor Angus King on July 3, 1995.

The new law amends and clarifies several major areas around which confusion had existed in the past, particularly regarding the definition of an HIV test, the meaning and handling of occupational exposure for both the exposed and the source, the handling of medical records and informed consent, the handling and content of pre and post-test counseling, and restrictions on requiring HIV tests or revealing HIV test results.

Key areas of the law are summarized below:

<u>HIV Test Definition</u>:

The new law makes clear that an "HIV Test" means not only a test of the presence of *antibodies* to HIV, but also any test that looks for the presence of an HIV *antigen* or *any other diagnostic determinants specific for HIV infection*. This would include P-24 antigens, as well as newer tests such as PCR for B-DNA or HIV RNA. Written informed consent must be obtained <u>prior</u> to doing any test included within this definition. Informed consent <u>is not</u> required for repeated HIV testing by health care providers to monitor the course of established infection. Anonymous test sites continue to be exempt from the requirement that the informed consent be in writing.

<u>HIV Pre & Post Test Counseling</u>: (see Insert)

<u>Medical Records</u>

This section of the law underwent only minor amendments. Key parts continue to be as follows:

- When any medical record entry is made concerning information of a person's HIV infection status, including the results of an HIV test, the person who is the subject of the HIV test must elect <u>in writing</u> whether to authorize the release of that portion of the medical record containing the HIV status information when that person's medical record has been requested. A new written election must be made when a change in the person's HIV infection status occurs or whenever the person chooses to make a new election. The written election should be obvious and clearly notable in the record.

*Continued on page 2*

## FDA Considers Home Testing Kits for HIV

Several kits for home use for HIV testing now await approval by the FDA.

Current tests rely on home collection with samples then sent to a lab for testing and interpretation. Examples include blood testing methods and a saliva sampling test (ie. Orasure).

Critics of these home tests are concerned that sample collection may not be correctly performed at home, leading to inaccurate results. Additionally, there are questions regarding the effectiveness of telephone post test counseling as opposed to a face to face encounter. However, surveys suggest that the availability of these tests could result in earlier detection of HIV for a substantial number of persons who currently do not seek testing at other sites. Initial studies of some of these test systems demonstrate high sensitivity and specificity, provided that the test is used correctly. A decision by the FDA is expected later this year.

**AIDS Consultation Service**
**Provider Information Hotline**
**1-800-871-2701**
***Mon-Fri 8:00-4:00pm***

*Continued from page 1*

The release form must clearly state whether or not the person has authorized the release of that information, and the person must be advised of the potential implications of authorizing the release of that information.

When release has been authorized in writing, the custodian of the medical record may release, upon request, the person's medical record, including any HIV infection status information. When release has not been authorized, only that portion of the medical record that does not contain HIV infection status information may be released upon request. By law, HIV infection status information may be released only if the person has specifically authorized a separate release of that information. A general release form is insufficient.

These confidentiality laws do not mean that medical records cannot be reviewed for utilization review, research, audits, peer review, or other such professional reasons. However, such reviews may not identify, directly or indirectly, any individual person, tested positive or negative, for HIV.

It is important, however, to be aware that Maine's HIV law does mandate that health care providers and others with access to medical records containing HIV infection status information must have a written policy providing for confidentiality of all patient information, and that the policy must require action consistent with disciplinary procedures for violations of the confidentiality policy.

**Restrictions on Requiring Tests or Disclosure of Test Results**:

Maine HIV law states that an employee or applicant for employment may not be required to submit to an HIV test or to reveal whether they have obtained an HIV test or its results, except when based on a bona fide occupational qualification. Likewise, the employment status of an employee may not be affected or changed because of the result of any HIV test. (*The Maine Human Rights Commission is mandated to enforce this regulation.)*

**Bona Fide Occupational Exposure**:

The new Maine HIV law was specifically amended to define this term. It means "...skin, eye, mucus membrane or parenteral contact of a person with the potentially infected blood or other body fluids of another person that results from the performance of duties by the exposed person in the course of employment." Consent need not be obtained when the bona fide occupational exposure creates a significant risk of infection, provided that a court order has been obtained according to the procedure outlined in the law. A pertinent amendment in this section specifically states that the fact that an HIV test was given as a result of an occupational exposure, and the results of that test, may not appear in any records of the source person. Pretest and post-test counseling must be offered, and the subject of the test may choose not to be informed about the result of the test. The specific procedures for obtaining a court order are outlined in the law and will not be covered here.

**For more information on how to obtain a copy of the new Maine law regarding HIV Testing please call:
The State of Maine Revisions Office at (207)287-1650.**

## CDC Guidelines for HIV Counseling and Voluntary Testing for Pregnant Women

The Centers for Disease Control and Prevention have released guidelines that call upon medical professionals to provide HIV counseling and voluntary testing for all pregnant women.

In 1993 (the most recent year for which complete data are available), an estimated 7,000 HIV-infected women gave birth in the United States. The prevalence of HIV infection in women giving birth was about 1.6 per 1,000, or about 1 in every 625. Assuming an HIV transmission rate from mother to infant is about 15-30%, about 1,000-2,000 HIV-infected infants were born in the U.S. in 1993.

The prevalence of HIV infection in women giving birth in Maine in 1993 was 0.1 per 1,000 births of HIV-infected infants in Maine per year.

The finding of a 67.5% reduction in HIV transmission in the NIH Clinical Trial 076 for pregnant women taking AZT has been a major motivation of the current CDC Guidelines. However, in low prevalence areas of the U.S., the benefit of routine testing of pregnant women is still controversial. Also, specific issues around treatment and strategies for insuring drug availability and compliance have not been resolved.

Printed copies of the guidelines and recommendation of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus (MMWR 1994:43 [RR-11]) which has more information about AZT treatment during pregnancy are available from the CDC National AIDS Clearinghouse Hotline at 1-800-3452-AIDS.

# Summary of Requirements for
# HIV Pre & Post Test Counseling in Maine

The new law continues the former regulation that persons who are the subjects of HIV tests must be offered pretest and post-test counseling. However, the new law additionally clarifies that persons offered counseling under this section may decline the offer by signing a waiver stating that counseling has been offered and is being declined.

**Pre-Test Counseling** must include the following:

1. Personal "face to face" counseling that includes, at a minimum, a discussion of:
   - the nature and reliability of the test being proposed
   - the person to whom the results of the test may be disclosed
   - the purpose for which the test results may be used
   - any reasonably foreseeable risks and benefits resulting from the test
   - information on good HIV prevention practices and HIV risk reduction plans
2. A written memorandum summarizing the contents of the discussion that includes a written informed consent form which may be used to satisfy the requirement for a written memorandum if it contains all the required information.
   *A written consent form does not satisfy the requirement for personal counseling.*
   *The provider of an HIV test may offer group pretest counseling, but individual counseling must be provided if the subject of the test requests it.*

**Post-Test Counseling** must include the following:

1. Personal counseling that includes, at a minimum, a discussion of:
   - the test results and the reliability and significance of the test results
   - information on good preventive practices and risk reduction plans
   - referrals for medical care and referrals for support services, including social, emotional support, and legal services as needed
2. A written memorandum summarizing the contents of the discussion given to the person being counseled
3. The offer of face-to-face counseling. If the subject of the test declines, the provider of the test may provide an alternative means of providing the information required above. *This is an important addition to the old law, because it allows telephone or written (in a letter) follow-up if the subject of the test refuses or does not show up for post test counseling.*

Sharing or disclosing of HIV test results was also clarified. The subject of an HIV test must designate in writing the authorized disclosure of HIV test results to a person or organization providing health care. The health care provider may make these results available only to other health care providers working directly with the patient, and only for the purpose of providing direct medical or dental care. Any health care provider who discloses HIV test results in good faith pursuant to this subjection is immune from any criminal or civil liability for the act of disclosing HIV test results to other health care providers.

## Diagnostic Tests for HIV

| Test | Sensitivity/Specificity | Indications | Cost |
|---|---|---|---|
| Antibody Test: Elisa and Western Blot | 99% | Routine HIV test | $20.00 (approx) |
| P24 Antigen | Low sensitivity | Neonatal HIV, Primary HIV syndrome | $95.00 |
| PCR or bDNA for HIV RNA | 99% sensitivity<br>100% specificity | Neonatal HIV, Primary HIV syndrome & confirmation of diagnosis in unusual case | $200.00 |
| Viral Culture | high sensitivity<br>100% specificity | Confirmation of diagnosis in an unusual case | $200.00 - $500.00 |

# ANONYMOUS HIV ANTIBODY TESTING LOCATIONS (MAINE)

Augusta

**Augusta Family Planning**
122 State Street
(207)626-3426
*Appointments booked on Monday early AM for various days. $20.00 cash - flat rate*

Bangor

**Bangor STD Clinic**
103 Texas Avenue
(207)947-0700
*Hours: Monday - Friday 8:00am - 4:30 pm, Wednesday evenings until 6:30 pm. $15.00 - flat rate*

Biddeford

**York County STD Clinic**
Univ. of New England
11 Hills Beach Road
(207)282-1516
*Hours: Tuesday 5:30 - 7:00 pm. $20.00 sliding scale.*

Ellsworth

**Downeast Family Planning**
PO Box 1087
(207)667-5304
(800)492-5550
*Hours: Thursday 8:00 am - 4:30 pm. Fee $20.00 - Flat ($15.00 retest)*

Farmington

**TriCounty Health Services**
15 Front Street
(207)778-4553
*Hours: Thursday 8:00am -4:30 pm*

Lewiston

**The STD Clinic**
PO Box 70
1 Auburn Center
(207)795-4019
*Hours: Monday, Tuesday, and Thursday 9:00am - 3:00pm. Fee $20.00 sliding scale*

Portland

**The AIDS Project**
142 High Street, 6th Floor
(207)775-1267
(800)851-2437
*Hours: Monday and Wednesday 5:30 - 7:15 pm. (Appointments can be scheduled Mon-Fri 9:00-5:00)*

**Portland STD Clinic**
389 Congress St, 3rd Flr
(City Hall)
(207)874-8300ext.8784
*Hours: Mon-Fri 8:00-5:00 by appointment and based on an emergency basis as well.*

Presque Isle

**ACAP Family Planning**
184C Academy Street
PO Box 1116
(207)768-3062
*Hours: Monday - Friday 8:00am - 5:00pm. $20.00 cash, flat rate.*

Rockland

**Mid Coast Family Planning**
22 White Street
(207)594-2551
*Hours: 9:00am - 4:00pm $20.00 flat rate*

It is important to note the difference between "anonymous" and "confidential" testing.

- Anonymous

  There is no name or social security number connected to the test, and there is no medical record. The person to be tested is assigned a number and this number is the only information that links the result to the person being tested. If the counselor knows the person to be tested, someone else does the counseling to further protect the anonymity of that person.

- Confidential

  A name is connected to the test and there is a medical record, but there is a confidentiality agreement that allows the person being tested to decide who has access to the results.

## The Patient's Perspective

*This issue's "Patient's Perspective" is written by Myles Rightmyre, who is not infected by HIV, but is affected by HIV on a daily basis. Myles' job is to provide the pre and post test counseling at the City of Portland STD Clinic, and he offers these suggestions for providing pre & post test counseling.*

The effectiveness of the post test positive counseling is largely determined by the work that has been done in the pretest session. A thorough risk evaluation with the patient helps prepare the patient and the provide for the result. A sexual/drug use history helps the patient confront risk factors that may have long been denied. The combination of distinguishing HIV infection and AIDS and explaining the implications of a possible positive result allows for teaching at a time when a patient is more likely to be able to grasp the information.

Learning how a patient thinks he/she might respond to a positive result can prepare the provider for the work ahead. Accessing the patients support system and evaluating for suicidality together create an opening for planning appropriate intervention should a result be positive. Knowing that the provider has a plan for the patient's health care should the result be positive will increase his/her sense of safety while awaiting a result.

A positive result should be given face to face in a private meeting with the provider. It is important to allow the patient ample time to process and ask questions. Most people report that beyond hearing that the result was positive, they have no recollection of what may have been discussed in the session. Having pamphlets and printed materials on hand (there is excellent material currently available) can provide the client with information that he/she can grasp when ready to take it in. Referrals to case management and support groups are very important as they will allow the client to begin to establish a support system or expand an existing one.

Another concern that both the provider and the patient face centers around those sex or needle sharing partners who may have been exposed to HIV. The Maine Bureau of Health offers assistance with **partner notification**, if desired. In these cases, counselors visit those named as partners in a face to face, quiet, and nonintrusive manner and explain the risk of exposure without disclosing any information about the source patient, including gender, age, race, or times of exposure. Partners who receive these visits are offered the chance to test at the time of the visit or they are offered referrals to local anonymous test sites if they so prefer. In any case pretest counseling is offered, which includes the nature of the test and its reliability, confidentiality, and reporting concerns, information on transmission and the importance of risk reduction, and referrals to local community based support organizations.

*Providers who have not had an HIV positive patient or would like assistance or guidance in preparing for a post-test positive session can receive information and support through the Maine Bureaus of Health by calling the* ***HIV Prevention Program*** *in Augusta at* ***(207)287-2899*** *or by calling local Bureau of Health reps in Portland at 874-8446, in Lewiston at 795-4019, and in Bangor at (207)947-0700.*

## Update on Diagnostic Confirmation of HIV

The combination of a positive ELISA screening test for antibodies to HIV coupled with a positive Western Blot remains the cornerstone of HIV testing. Over the years, most of these tests have been modified to detect both HIV-1 and HIV-2, and provide high sensitivity and specificity (98-100%) for HIV infection. Antibody tests are not sensitive during the first 1-2 months after exposure, but are nearly always positive by the third month.

On occasion, an individual will have an indeterminate antibody test for HIV characterized by a positive ELISA and an indeterminate Western Blot. In situations of high likelihood for infection, this pattern represents an early antibody response that will become truly positive on repeat testing in 1-2 months. In low likelihood situation, indeterminate tests usually result from a false positive ELISA test. Sequential antibody testing with ELISA and Western Blot has been shown to have a false positive rate of less than 1 per 1000.

In special circumstances, tests for the P-24 antigen of HIV may be useful. For example, P-24 antigen testing may be useful in confirmation of neonatal infection, or during the primary HIV syndrome before antibody has developed.

Polymerase chain reaction (PCR) testing for HIV RNA is highly sensitive and specific, and can be useful when antibody tests are not interpretable. Roche labs now offer HIV PCR testing commercially at a cost of approximately $200.00.

Finally, viral culture techniques are highly sensitive, but often require 2-3 weeks for incubation, and are very expensive.

| | |
|---|---|
| World AIDS Cases | 4,500,000 (estimated) |
| US AIDS Cases | 461,234 (04/25/95) |
| US AIDS Deaths | 282,200 (04/25/95) |
| Maine AIDS Cases | 651 (06/30/95) |
| Maine AIDS Deaths | 316 (06/30/95) |

## Upcoming HIV/AIDS Education

October 04, 1995 AIDS Update - *Emergency PA Conference, Ramada Inn, Portland ME*
*Robert P. Smith, M.D.*

New Fall Semester Course at U.S.M.

AIDS: Scientific, Social, & Political Foundations

Course Summary

*This course will approach HIV/AIDS from a multidisciplinary perspective. It is intended to provide a solid introduction to HIV/AIDS for persons who are likely to be confronting AIDS issues in their professional work. Scientific topics to be considered include HIV virology, immunology, transmission, and community epidemiology. Guest lecturers will also address psychosocial and social aspects of the epidemic, as well as issues in law, ethics, and HIV prevention strategies. The course is open to advanced undergraduate and graduate students.*

Faculty

***Geoff Beckett, PA-C, MPH*** (Principle Instructor), is Assistant State Epidemiologist for Maine, and has worked with HIV and related infectious disease issues for more than seven years.

**Steve Fleming** (Associate Instructor), has been an HIV Public Health Educator in Maine since 1989 and has specialized in community-level HIV prevention efforts.

**Stephen D. Sears, MD, MPH** (Associate Instructor) is an infectious disease specialist and HIV/AIDS clinicians.

*For further information contact Geoff Beckett at (207)287-5551.*

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