FINAL REPORT

WORKGROUP TO STUDY THE ISSUE OF HIV TESTING OF INDIVIDUALS WHO REFUSE TO CONSENT TO HIV TESTING IN THE EVENT OF AN OCCUPATIONAL EXPOSURE INVOLVING A HEALTH CARE WORKER OR FIRST RESPONDER HB 343, 2003

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EXECUTIVE SUMMARY & SIGNIFICANT FINDINGS

**Charge:**
In 2003, the Maryland General Assembly, through House Bill 343 – Hospitals – HIV Testing – Health Care Providers and First Responders, amended the law intended to protect health care providers who have occupational exposures to blood or body fluids of a patient. The new law, Health-General Article, §18-338.1 and §18-338.3, expanded coverage to include first responders; permitted the HIV testing of blood samples without informed consent in certain limited circumstances if a patient is unable or unavailable for consent; and added language regarding substitute consent (consistent with current Maryland law and regulation) to this Article.

In addition, House Bill 343 directed the AIDS Administration, in consultation with the Maryland Hospital Association (MHA) and AIDS advocacy organizations, to study the issue of HIV testing of competent individuals who refuse to consent to HIV testing when there has been an exposure involving a health care provider or a first responder. The AIDS Administration was required to submit a report on its findings and recommendations to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee by December 1, 2003.

**Workgroup Process:**
The Workgroup to Study the Issue of HIV Testing of Individuals Who Refuse to Consent to HIV Testing in the Event of an Occupational Exposure Involving a Health Care Worker or First Responder was convened by Liza Solomon, Dr. P.H., Director of the AIDS Administration and held scheduled monthly meetings from July through November, 2003.

The Workgroup considered and discussed a variety of issues. It looked at current instances of occupational exposure and refusal for HIV testing as indicated by the new “Survey of Occupational Exposures to Blood or Body Fluids”. It reviewed hospital policies regarding occupational exposure, reviewed and analyzed current state statutes, Centers for Disease Control and Prevention (CDC) guidelines for post-exposure prophylaxis (PEP), medical data on the tolerability and toxicity of PEP, and public testimony from the 2003 legislative session. The Workgroup discussed the history of informed consent in Maryland and considered the effectiveness of the 1991 law requiring informed consent and confidentiality of test results and the potential of the new law that includes first responders and allows for testing when either the source patient or substitute consenter is unable or unavailable to consent. The Workgroup considered questions of state and/or hospital liability in the case of HIV testing without consent and possible violations of HIPAA provisions if medical information about a source patient is released without consent or authorization.

**Workgroup Findings:**
- Exposed health care workers deserve fast, compassionate, and knowledgeable post-exposure care. The health care needs of the exposed health care worker are of critical importance. Appropriate management of any bloodborne pathogen exposure incident is important to prevent both infection and psychological harm to exposed health care workers (HCWs).
Maintaining a relationship of trust with physicians, hospitals, and our health care system is especially important for HIV/AIDS patients who need a lifetime of care with difficult treatment regimens. Testing for HIV without consent may be detrimental to maintaining trust in physicians, hospitals, and our health care system.

A new survey of acute care hospitals in Maryland commissioned by this Workgroup found that informed consent to HIV testing was obtained from 99% of the source patients asked. During the most recent year for which hospitals had data, of 2,320 exposure incidents, only 22 source patients refused HIV testing when asked. The absolute number of refusals appears to be very low in Maryland hospitals and the rate of refusals has declined from 6% in 1996 (when a previous study was performed by the AIDS Administration) to 1% in 2002.

Data from the new survey indicated that for the 104 patients for whom substitute consent was sought, consent was granted in 99% of the cases (103 of 104). Results were the same regardless of hospital size. The rate of refusal by surrogates is substantially reduced from the 1996 survey – from 13% to 1%.

Review of hospital policies regarding occupational exposure found that there is a wide range of practice among the hospitals and that size of the hospital is not a determinant of comprehensiveness of policy. Nor is there a correlation between comprehensiveness of policy and rate of agreement to informed consent for HIV testing by source patients.

Thirty-nine states (78%) have requirements for informed consent from either the patient or a substitute prior to HIV testing. Thirty-seven states (74%) have one or more exceptions that allow for testing over a patient’s refusal under certain circumstances. The laws vary with respect to their requirements prior to testing without consent.

**Recommendations:** After thorough discussion the Workgroup makes the following recommendations:

- Based on the evidence now available, maintain the current law as it stands;
- Conduct periodic evaluations to ensure that the needs of HCWs/first responders are met;
- AIDS Administration to survey first responders in one year to learn their experience in gaining consent for HIV testing in cases of occupational exposure;
- AIDS Administration, MHA and Maryland Institute for Emergency Medical Services Systems (MIEMSS) to develop guidelines to assist hospitals in implementing the requirements of HB 343. In addition to the specific requirements of the bill, the guidelines should include:
Information on “best practices” related to handling occupational exposures; and

A standardized process to document: the number of exposures between patients and health care workers/first responders; the number of requests for source patient testing and the responses; the number of requests for substitute consent and the responses; and the number of instances a patient was deemed unavailable or unable to consent and why;

- AIDS Administration, MHA, and MIEMSS to jointly plan and conduct an educational program to facilitate the uniform implementation of the guidelines; and

- Establish a task force to study the possible expansion of the current law to include health care workers in non-hospital settings (e.g. long-term care facilities, home care and clinic practices) and report to the General Assembly in one year.

**Conclusion:**

Based on the evidence now available this Workgroup recommends that no changes be made to the law at this time. Periodic review and evaluation of the ability of health care workers/first responders to obtain informed consent of patients in the event of an occupational exposure should be performed. The current law requiring informed consent for HIV testing of a source patient in instances of occupational exposure is successful in obtaining consent in 99% of the cases when it is requested. The new law allows physicians to order testing when the source patient is unavailable or unable to consent. This recent expansion of the law will provide health care workers/first responders with a legal mechanism to obtain HIV test results in these instances. In the cases when informed consent is not obtained from a competent person, that refusal must be respected. CDC and OSHA guidelines for exposure evaluation and use of PEP should be followed in all cases. The AIDS Administration will join the MHA and MIEMSS to develop guidelines to assist hospitals in implementing the requirements of HB 343, provide information on “best practices” related to handling occupational exposures, and suggest a process for hospitals to document occupational exposures and informed consent. A new task force should be established to study the possible expansion of the law to include health care workers in non-hospital settings.
INTRODUCTION

In 2003, the Maryland General Assembly, through House Bill 343 – Hospitals – HIV Testing – Health Care Providers and First Responders, amended the law intended to protect health care providers who have occupational exposures to blood or body fluids of a patient. The new law, Health-General Article, §18-338.1 and §18-338.3:

- expanded coverage to include first responders (previous legislation included only health care providers);
- permitted the HIV testing of blood samples without informed consent in certain limited circumstances when a patient is unable or unavailable for consent; and
- added language regarding substitute consent (consistent with current Maryland law and regulation) to this Article.

In addition, House Bill 343 directed the AIDS Administration, in consultation with the Maryland Hospital Association (MHA) and AIDS advocacy organizations, to study the issues of HIV testing of competent individuals who refuse to consent to HIV testing when there has been an exposure involving a health care provider or a first responder. The AIDS Administration was required to submit a report on its findings and recommendations to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee by December 1, 2003. A copy of HB 343 may be found in Attachment 1.

The Workgroup to Study the Issue of HIV Testing of Individuals Who Refuse to Consent to HIV Testing in the Event of an Occupational Exposure Involving a Health Care Worker or First Responder was convened by Liza Solomon, Dr. P.H., Director of the AIDS Administration, in accordance with House Bill 343 – Hospitals – HIV Testing – Health Care Providers and First Responders (2003). To ensure the appropriate expertise regarding the issue and to meet the requirements of the legislation, representatives from twelve agencies and organizations were included in the Workgroup (a full list of the members may be found in Attachment 2).

The Workgroup held scheduled monthly meetings from July through November 2003 at the offices of the AIDS Administration, Maryland Department of Health and Mental Hygiene. To obtain the most recent information available, the Workgroup commissioned a “Survey of Occupational Exposures to Blood or Body Fluids”, and conducted an updated review of legislation in other states related to occupational exposure and HIV testing. Survey results and other reports and documents were assessed and discussed in detail. The recommendations of the Workgroup were reached by consensus.

BACKGROUND

Occupational Exposures and the Risk of Occupational Transmission

Since the first report of occupationally transmitted HIV in 1984, health care facilities have instituted a variety of risk management strategies to reduce the risk of exposure and subsequent infection. Regulatory changes (e.g. OSHA’s Bloodborne Pathogen Standard), administrative changes (e.g. pre-exposure training and development of comprehensive post-exposure protocols), and engineering changes (e.g. the development of safer sharps) have led to documented reductions in exposures in hospitals.1

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Research has shown that needlestick injuries can be reduced by as much as 86% by using needles with safety features or by eliminating the use of needles altogether. The American Nurses Association considers 90% of needlestick injuries to be preventable with safer medical devices. While attempts have been made to eliminate needlesticks, not all needlestick injuries can be prevented and exposure to bloodborne pathogens continues to be a major concern for health care workers.

While there are more than 20 diseases that can be transmitted by blood products as a result of occupational exposure, the diseases that pose the most serious threat are Hepatitis B, Hepatitis C and HIV. Among these, the chance of infection from blood containing HIV is considered to be very low – 0.3% or 1 in 333. The risk of infection from blood containing Hepatitis B is estimated to be between 6% and 30% (between 1 in 16 and 1 in 3), and the risk of infection from blood containing Hepatitis C is estimated to be 5% (1 in 20). A 1997 OSHA report indicates that 2% of the total annual needlestick injuries occur with needles contaminated with HIV.

Occupational transmission of HIV is rare. In the twenty years from 1981 through December 2001 for which the CDC has data on HIV/AIDS (the most recent information available), the Centers for Disease Control had documented a total of fifty-seven (57) health care workers who had contracted HIV after occupational exposures. Twenty-six of these individuals have developed AIDS. An additional 138 individuals (including first responders) contracted HIV but the source of their infection was uncertain and cannot be positively attributed to the occupational exposure.

Informed Consent and Patient Autonomy

The concept of informed consent has long been a primary concern of medical practice and ethics because it allows individuals to make their own assessment of the risk and benefits of a particular medical decision. The primary justification of informed consent stems from the concept of respect for individual autonomy and is rooted in the U.S. legal and medical traditions of the importance of individual freedom and choice. In the medical field, legal doctrine related to informed consent and patient autonomy has focused on particular aspects of this general right. One important aspect is protection from physical intrusions by others. Thus, failure to obtain informed consent may lead to charges of negligence and/or battery against health care professionals and institutions. In addition to the concern with nonconsensual physical intrusions, U.S. law recognizes an individual’s privacy interest in sensitive medical information contained in his or her blood and other bodily substances, and an individual’s interest in being in control of decisions about medical procedures. The precedent in law and practice is to respect a competent adult’s decision to refuse medical procedures, including medical tests.

Voluntary Testing and Patient Trust in the Health Care System

One of the benefits of the practice of voluntary testing for medical procedures and tests is to allay fears and thus help maintain trust in the health care system. An individual who knows they may tested for HIV against their will may avoid seeking health care. Maintaining a relationship of trust with health care providers is especially important for HIV/AIDS patients who need a lifetime of care with complicated and difficult treatment regimens.

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1991 Maryland Legislation Regarding HIV Testing and Occupational Exposure

In 1991 a number of bills regarding HIV testing and reporting were proposed in the Maryland General Assembly. In the House of Delegates, two competing bills related to testing of the source patient in cases of occupational exposure of a health care provider were presented.

HB 241 – HIV - Health Care Providers – Exposure, allowed testing of a patient without consent when a health care worker may have been exposed to HIV. Testimony on this bill noted that it had an overly broad definition of exposure, that it did not require informed consent, and it did not protect the privacy or confidentiality of the patient.

House Bill 194 - Health Care Providers – Exposure, provided a mechanism for HIV testing of a patient who was the source of a verified exposure of a health care provider. This bill included:

1. a requirement to obtain the written informed consent of the patient prior to HIV testing;
2. the CDC definition of exposure;
3. requirements for reporting and documenting the exposure; and
4. protection of the confidentiality of the test results.

HB 194 was based on the concept that patients should be encouraged but not coerced to have an HIV test. In testimony supporting this bill the problems associated with discrimination and stigma were raised. HB 194 was supported by the Maryland Public Health Association, the Department of Health and Mental Hygiene, Maryland Disability Law Center, Inc., AIDS Legislative Committee, Maryland Bar Association, Maryland Hospital Association, Governor’s Advisory Council on AIDS, and Johns Hopkins Health Systems among others. The patient’s right to privacy and confidentiality were clearly important to the legislature as evidenced by the passing of HB 194 requiring informed consent and the confidentiality of test results and the defeat of HB 241.

1996 Survey of Occupational Exposures and Requests for Informed Consent

To determine how effective the 1991 law was in giving exposed health care workers access to the HIV serostatus of the source patient, the AIDS Administration conducted a survey of acute care hospitals in Maryland in 1996. The survey asked how often occupational exposure occurred and how often informed consent to HIV testing was requested and obtained. Information was requested for the one-year period from July 1995 to June 1996. Completed surveys were received from 38 of 48 hospitals (79%). During the designated period these 38 hospitals reported 2,050 significant exposures. In 1,732 (84%) of these significant exposures the health care worker requested information regarding the source patient’s HIV status. Of these 1,732 requests, information on the HIV status was found in the source patient’s medical records in 116 (7%) of the cases. Of the remaining 1,616 requests, 266 (16%) source patients were not asked for consent to test for HIV. Of the 1,350 requests of source patients made:

- 1,237 (92%) source patients consented to HIV testing
- 77 (6%) source patients refused testing
- 36 (2%) source patients knew their HIV status

Substitute consent for HIV testing was requested for 100 of these exposures and granted in 87 (87%) cases.6

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1999 Maryland Safe Needle Legislation

In 1999 the Maryland General Assembly passed House Bill 287 – Health Care Workers’ Safety Act – Bloodborne Pathogen Standard, which required the Department of Health and Mental Hygiene (DHMH) to conduct a study on the exposures of health care workers to bloodborne pathogens including an evaluation of needleless systems and sharps with engineered sharps injury protection. This study led to a number of recommendations regarding implementation of safer sharps systems in Maryland hospitals and adoption of the 2001 OSHA Bloodborne Pathogens Standard 1910.1030.

Current Environment

Post-exposure management

In the twelve years since the passage of HB 194 much has been learned about occupational transmission of HIV/AIDS, and the importance of a variety of risk management strategies to reduce the risk of exposure and subsequent infection. Regulatory changes (e.g. OSHA’s Bloodborne Pathogen Standard), administrative changes (e.g. pre-exposure training and development of comprehensive post-exposure protocols), and engineering changes (e.g. the development of safer sharps) have led to documented reductions in exposures in hospitals.

In addition to these changes in medical practices, there have been major changes in testing (particularly the recent introduction of rapid tests), drug treatments, and guidelines for post-exposure prophylaxis (PEP). A rapid test for detecting antibody to HIV is a screening test that produces rapid results, in 30 minutes or less. In comparison, results from the commonly used HIV antibody screening test are not available for 1-2 weeks. New rapid testing technologies can provide almost immediate information on the HIV status of the source patient after an occupational exposure. In addition, since publication of the 1998 HIV post-exposure guidelines, several new antiretroviral agents have been approved by the Food and Drug Administration (FDA), and more information is available about the use and safety of HIV PEP. Some animal studies indicate that PEP using a combination of these drugs might modify or prevent viral infection if initiated within two to twenty-four hours of exposure. In spite of the benefit of newer treatments failure of PEP to prevent HIV infection in health care workers has been reported in at least 21 instances.

The U.S. Public Health Service periodically issues updated guidelines for PEP to reduce the risk of transmission of bloodborne pathogens. Factors used to determine the risk associated with exposure are the type of fluid (e.g. blood, visibly bloody fluid, or other fluid or tissue), and the type of exposure (percutaneous injury, mucous membrane or non-intact skin exposure). Evaluation of the exposed worker and the source patient are recommended. The serostatus of the source patient is one of several factors used to evaluate the exposure and determine the course of PEP. If the serostatus is unknown, the clinical or epidemiological likelihood of infection in the source patient is considered. Finally, the risks and benefits of PEP to the exposed HCW must be considered. Reports indicate that about 74% of health care workers who receive PEP experience some side effects, the most common of which are nausea, fatigue, headache, vomiting and diarrhea. About 53% choose to discontinue treatment before completing the four-week course due to multiple factors. One of the factors cited is the side effect(s) experienced.

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New provisions in the law

In testimony presented to the 2003 Maryland General Assembly, concerns regarding the ability to obtain the serostatus of the source patient were presented, particularly when neither the patient nor an appropriate substitute were available for consent. The interests of other related health care workers, namely first responders, in obtaining the HIV serostatus of the source patient when an occupational exposure had occurred were also presented. To address these concerns House Bill 343 – Hospitals – HIV Testing – Health Care Providers and First Responders, amended the law intended to protect health care providers who have occupational exposures to blood or body fluids of a patient. The new law, Health-General Article, §18-338.1 and §18-338.3, which took effect October 1, 2003:

- expands coverage to include first responders;
- permits the HIV testing of blood samples without informed consent in certain limited circumstances if a patient is unable or unavailable for consent; and
- adds language regarding substitute consent (already part of Maryland law and regulation) to this Article.

In addition, House Bill 343 directed the AIDS Administration, in consultation with the Maryland Hospital Association (MHA) and AIDS advocacy organizations, to study the issues of HIV testing of individuals who refuse to consent to HIV testing when there has been an exposure involving a health care provider or a first responder. The AIDS Administration is required to submit a report on its findings and recommendations to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee by December 1, 2003.

WORKGROUP PROCESS

The Workgroup to Study the Issue of HIV Testing of Individuals Who Refuse to Consent to HIV Testing in the Event of an Occupational Exposure Involving a Health Care Worker or First Responder was convened by Liza Solomon, Dr. P.H., Director of the AIDS Administration, in accordance with House Bill 343 – Hospitals – HIV Testing – Health Care Providers and First Responders (2003). To ensure the appropriate expertise regarding the issue and to meet the requirements of the legislation, representatives from the following twelve agencies and organizations were included in the Workgroup:

1. ACLU of Maryland
2. AIDS Action Baltimore
3. AIDS Administration, Maryland DHMH
4. Association of Professionals in Infection Control & Epidemiology (APIC)
5. Chase Brexton Health Services
6. HERO
7. Johns Hopkins Bloomberg School of Public Health
8. Johns Hopkins Hospital Legal Department
9. Maryland Hospital Association
10. Sisters Together and Reaching (STAR)
11. University of Maryland School of Law AIDS Law Clinic
12. Whitman Walker Clinic

A full list of the members’ names and affiliations may be found in Attachment 2. Although HB343 required participation by the AIDS Administration, the Maryland Hospital Association and AIDS advocacy groups, the Workgroup recognized that other parties might have an interest in the proceedings. Accordingly, an invitation to present to the Workgroup was offered to the Maryland Nurses Association (MNA) and MIEMSS and both groups were present at two of the four Workgroup meetings.
Representatives of the MNA and MIEMSS received copies of the draft report and provided comments to the Workgroup during its third and fourth meetings.

To obtain the most recent information on occupational exposures, the Workgroup commissioned a “Survey of Occupational Exposures to Blood or Body Fluids”. The questionnaire requested information on the number of exposures of health care workers (including first responders), the number of requests for patient or substitute consent to HIV testing and the number of refusals for HIV testing. Hospitals were also asked to submit a copy of their policies regarding occupational exposure, and testing and follow-up for the health care worker and patient. Results of this survey were compared to the results of the “Occupational Exposure Survey” conducted by the AIDS Administration in 1996. Best practices and areas of concern in current hospital policies regarding occupational exposure, as well as testing and follow-up for the health care worker and patient were reviewed. In addition, a review and analysis of current state statutes relating to requirements and exceptions for informed consent to HIV testing in the case of occupational exposure was conducted. The Workgroup also considered medical data on the tolerability and toxicity of post-exposure prophylaxis (PEP), and public testimony from the 2003 legislative session.

Survey results and the other reports and documents were reviewed and discussed in detail at the Workgroup’s scheduled meetings on July 16, August 14, September 18, and November 3, 2003 at the offices of the AIDS Administration, Maryland Department of Health and Mental Hygiene. All the Recommendations for the Workgroup were reached by consensus.

**WORKGROUP FINDINGS**

**2003 Survey of Occupational Exposures, Requests for HIV, and Frequency of Refusal To Be Tested**

The Workgroup requested information on the current number of occupational exposures in Maryland hospitals. A new “Survey of Occupational Exposures to Blood or Body Fluids” was composed and sent to 45 acute care hospitals in Maryland with 30 or more beds. (A copy of the survey form may be found in Attachment 3 and a copy of survey results may be found in Attachment 5). The two smallest acute care hospitals with 9 and 12 beds each were not included in the study. Thirty-five sites representing 36 hospitals (80%) returned completed survey forms. Hospitals provided data from the most recent one-year period for which they had the information requested (most commonly January 1, 2002 to December 31, 2002). Questions were asked to determine the following:

- How common are occupational exposures?
- How often do hospitals request patient consent for HIV testing?
- How often do patients refuse HIV testing?
- How often is substitute consent requested?
- How often is substitute consent refused?

**The Ability to Gain Informed Consent from the Source Patient**

The results of this latest survey showed that there were 2,320 incidents of significant exposure and that health care workers requested information of HIV status in 2,142 cases (92%). Of those, 1,935 source patients could be identified whose HIV status was unknown and who were competent to provide consent. Informed consent to HIV testing was obtained from 99% (1,913) of the source patients asked. Only 22 source patients refused HIV testing when asked. The absolute number of refusals appears to be
very low in Maryland hospitals in a given year and the rate of refusals has declined from 6% in 1996 to 1% in 2002.

The Ability to Obtain Substitute Consent when Needed

Twenty-eight (28) of the thirty-five (35) reporting hospitals record instances in which source patients were not competent to give consent. These 28 facilities found 112 patients not competent. In four (4) cases the hospitals were unable to obtain substitute consent because the patient had died, they could not reach family members, or for unknown reasons; and in four (4) cases substitute consent was not sought. For the remaining 104 patients for whom substitute consent was sought, consent was granted in 99% of the cases (103 of 104). Results were the same regardless of hospital size. Here again, the rate of refusal is substantially reduced from the 1996 survey – from 13% to 1%.

“Best Practices” of Hospitals in Handling Occupational Exposures

The Workgroup sought to determine if different policies or procedures related to requests for HIV testing in cases of occupational exposure influenced the rate of obtaining informed consent. The survey asked if the hospital had such a policy or protocol and, if so, for a copy of this policy. The CDC has long emphasized the importance of infection control and safety practices related to bloodborne pathogens. Guidelines for the management of occupational exposure to HIV and other bloodborne pathogens and for the use of post-exposure prophylaxis are readily available in print, on the CDC and OSHA websites, and from the CDC hotline (PEPline) offering health care providers around-the-clock advice in managing occupational exposures. Based on these guidelines and a review of the submitted policies, the Workgroup identified “best practices” and areas of concern.

Of the 35 respondents to the survey, 34 submitted their policies and/or protocols for managing exposure to bloodborne pathogens and obtaining informed consent for HIV testing of the source patient. Review of these policies found a wide range of practice among the hospitals and that size of the hospital is not a determinant of comprehensiveness of policy. Nor is there a correlation between comprehensiveness of policy and rate of agreement to informed consent for HIV testing by source patients.

Characteristics of “Best Practices”

A review of the policies revealed that best practices include an emphasis and training on safety practices in general and for bloodborne pathogens in particular. Such activities can decrease the number and the seriousness of exposures. Hospital policies for managing exposures that do occur should include the following practices/points:

- Well-defined and detailed instructions should be available regarding immediate treatment, reporting, evaluation, testing, post-exposure prophylaxis, and follow-up.

- The designated point of contact for the health care worker should be known and available for all shifts. During day shifts this is often the Employee Health Services (EHS) office. Off-shift coverage, for example, may be an EHS staff on-call or a designated person in the Emergency Department (ED).

- Responsibilities for each party involved (HCW, EHS, ED, lab, pharmacy, any other parties involved) should be clear and well defined. Some hospitals use flow charts, others use checklists.
“Exposure Packets” that include all necessary forms and step-by-step instructions should be readily available to the exposed worker and the person responsible for managing the response to that exposure.

Clear instructions and guidelines should be present to assess the exposure and its risk to the HCW, to determine what tests should be ordered, and to determine if PEP should be offered.

Clear instructions and guidelines should be present on how best to gain informed consent.

There should be defined responsibility for follow-up of the exposed worker so that reactions to PEP and appropriate follow-up testing for infection are accomplished.

Areas of concern

Items of concern were also found in the submitted policies, these included vague language and contradictory instructions. In some instances off-shift assistance to the HCW was unclear, and there was a lack of information on defining significant exposure, location of necessary forms, defining responsibility or procedures for evaluation, reporting, follow-up and/or use of PEP. The most serious areas of concern were poorly defined or incorrect procedures related to confidentiality and required testing of the exposed worker.

Review of Current Practices in Other States

To inform discussion and to find possible models for Maryland use, the Workgroup requested the most recent information available on practices in other states related to requirements for informed consent for HIV testing in cases of occupational exposure. The AIDS Administration conducted a review of laws relating to HIV exposure by health care workers for all 50 states. A wide range of practices among the states was found. Eleven (11) states have no statutes applicable to HIV testing in cases of health care provider exposure. Three states (California, Connecticut and Rhode Island) required that the serostatus of the exposed worker be determined and that ‘reasonable’ or ‘good faith’ efforts be made to obtain voluntary informed consent prior to testing of the source patient without consent. If the health care worker were HIV positive, no test would be required of the source patient. An additional six states (including Maryland) require a test of the health care provider as well as the source patient.

Thirty-nine states (78%) have requirements for informed consent from either the patient or a substitute prior to HIV testing. Thirty-seven states (74%) have one or more exceptions that allow for testing over a patient’s refusal under certain circumstances. The laws vary with respect to their requirements prior to testing without consent. In those states with exemption statutes, nineteen (19) require a court order for testing if the patient or substitute refuses testing; one state assigns the authority to override refusal to an Exposure Evaluation Group established for each hospital. Ten (10) states, including Maryland have provisions for obtaining substitute consent. Ten states (10) allow testing of an existing blood sample in the event of a significant exposure in spite of refusal for testing by the source patient. Nine (9) states allow the testing of source patients against their will but do not prescribe in statute how to carry out such testing. Notably, one state, Indiana, prohibits a medical facility from restraining a patient in order to test for the presence of a dangerous communicable disease. In states that allow testing without consent of the source patient, strong confidentiality protections concerning the release of client information are mandated by statute. A chart listing the 50 states with references to their applicable statutes may be found in Attachment 4.
Questions of Liability

The question of state and/or hospital liability in the case of compelling HIV testing without a patient’s consent was raised. One particular area of concern arises from testing for HIV against a patient’s will and providing information regarding these tests to another party. Questions were raised regarding whether this could constitute a HIPAA violation. This question arises as a result of HIPAA privacy rules. Under HIPAA privacy rules the results of medical tests are protected health information and prohibited from disclosure without the authorization of the patient. Thus, it may be a violation of HIPAA to test a source patient and notify the exposed health care worker of the results of the patient’s HIV test since such notification would provide confidential health information about the source patient without their consent. However, HIPAA regulations do allow disclosure of protected health information without consent of the patient to a person who may have been exposed to a communicable disease if the covered entity making such a disclosure is authorized by law to notify such a person as necessary in the conduct of a public health intervention. Since no known legal challenges have been made regarding this question in any state, the question remains unanswered.

A second area of concern arises from the legal doctrine related to informed consent and patient autonomy, particularly protection from physical intrusions by others. Thus, failure to obtain informed consent may lead to charges of negligence and/or battery against health care professionals and institutions. In addition to the concern with nonconsensual physical intrusions, U.S. law recognizes an individual’s privacy interest in sensitive medical information contained in his or her blood and other bodily substances, and an individual’s interest in being in control of decisions about medical procedures. These latter two interests are implicated when a patient’s blood or other sample is tested for highly sensitive information such as the presence of the HIV virus, even if the patient already consented to the withdrawal of the blood sample for another purpose.

RECOMMENDATIONS OF THE WORKGROUP

Exposed health care workers deserve fast, compassionate, and knowledgeable post-exposure care. It is important to recognize that an exposure incident is an extremely stressful event for the exposed health care worker. Appropriate management of any bloodborne pathogen exposure incident is important to prevent both infection and psychological harm to exposed HCWs. To allay the fear after an exposure, the HCW needs accurate, fact-based information relayed by knowledgeable and trained personnel.

The Workgroup considered and discussed a variety of issues. It looked at current instances of occupational exposure and rates of refusal for HIV testing determined by the new “Survey of Occupational Exposures to Blood or Body Fluids”. It reviewed hospital policies regarding occupational exposure, reviewed and analyzed current state statutes, CDC guidelines for post-exposure prophylaxis (PEP), medical data on the tolerability and toxicity of PEP, and public testimony from the 2003 legislative session. It deliberated on the history of informed consent in Maryland, and it considered the effectiveness of the 1991 law requiring informed consent and confidentiality of test results and the potential of the new law that includes first responders and allows for testing when the source patient or substitute consenter is unable or unavailable. The Workgroup raised questions of liability in the case of testing for HIV without consent and possible violations of HIPAA provisions if medical information

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8 45 CFR 164-512(b)(1)(iv)
about a source patient is released without consent or authorization. After thorough discussion the Workgroup makes the following recommendations:

- Based on the evidence now available, maintain the current law as it stands;
- Conduct periodic evaluations to ensure that the needs of HCWs/first responders are met;
- AIDS Administration to survey first responders in one year to learn their experience in gaining consent for HIV testing in cases of occupational exposure;
- AIDS Administration, MHA and Maryland Institute for Emergency Medical Services System (MIEMSS) to develop guidelines to assist hospitals in implementing the requirements of HB 343. In addition to the specific requirements of the bill, the guidelines should include:
  - Information on “best practices” related to handling occupational exposures; and
  - A standardized process to document: the number of exposures between patients and health care workers/first responders; the number of requests for source patient testing and the responses; the number of requests for substitute consent and the responses; and the number of instances a patient was deemed unavailable or unable to consent and why;
- AIDS Administration, MHA, and MIEMSS to jointly plan and conduct an educational program to facilitate the uniform implementation of the guidelines; and
- Establish a task force to study the possible expansion of the current law to include health care workers in non-hospital settings (e.g. long-term care facilities, home care and clinic practices) and report to the General Assembly in one year.

**CONCLUSION**

Based on the evidence now available this Workgroup recommends that no changes be made to the law at this time. Periodic review and evaluation of the ability of health care workers/first responders to obtain informed consent of patients in the event of an occupational exposure should be performed. The current law requiring informed consent for HIV testing of a source patient in instances of occupational exposure is successful in obtaining consent in 99% of the cases when it is requested. The new law allows physicians to order testing when the source patient is unavailable or unable to consent. This recent expansion of the law will provide health care workers/first responders with a legal mechanism to obtain HIV test results in these instances. In the cases when informed consent is not obtained from a competent person, that refusal must be respected. CDC and OSHA guidelines for exposure evaluation and use of PEP should be followed in all cases. The AIDS Administration will join the MHA and MIEMSS to develop guidelines to assist hospitals in implementing the requirements of HB 343, provide information on “best practices” related to handling occupational exposures, and suggest a process for hospitals to document occupational exposures and informed consent. A new task force should be established to study the possible expansion of the law to include health care workers in non-hospital settings.
ATTACHMENTS

1. House Bill 343
2. List of members of the Workgroup
3. Copy of survey sent to Maryland acute care hospitals
4. Chart of 50 states with reference to statutes regarding informed consent and exceptions to informed consent
5. Slide presentation to Workgroup on survey results
HOUSE BILL 343

Unofficial Copy
J1
HB 254/97 - ENV


Introduced and read first time: February 3, 2003
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 21, 2003

CHAPTER_______

1 AN ACT concerning

2 Hospitals - HIV Testing - Health Care Providers and First Responders

3 FOR the purpose of requiring certain individuals in a hospital to order tests to be
4 conducted in a certain manner and in accordance with certain recommendations
5 on blood samples or other body fluids of certain individuals for the presence of
6 antibodies to the human immunodeficiency virus (HIV) under certain
7 circumstances; requiring a first responder to give certain notice to a certain
8 medical director under a certain circumstance; requiring the medical director to
9 act as a certain intermediary between the first responder and a certain officer;
10 requiring the medical director and a certain officer to ensure that certain
11 information is confidential; establishing a certain exception for HIV tests
12 conducted under this Act to the requirement that informed consent be obtained
13 before conducting an HIV test; requiring certain individuals to disclose the
14 results of HIV tests conducted under this Act in a certain manner to certain
15 individuals and provide counseling to certain individuals under certain
16 circumstances; specifying the confidentiality of certain medical records and
17 other information; requiring hospitals to adopt certain procedures; specifying
18 the payment of costs for HIV tests conducted under this Act; providing for a
19 certain limitation of liability for certain individuals under this Act; requiring the
20 AIDS Administration in the Department of Health and Mental Hygiene, in
21 consultation with certain groups, to conduct a certain study and make certain
22 recommendations to certain committees of the General Assembly on or before a
23 certain date; defining certain terms; and generally relating to conducting tests
24 on blood samples or other body fluids of individuals in a hospital for the
25 presence of antibodies to the human immunodeficiency virus (HIV) under
certain circumstances.

BY repealing and reenacting, with amendments,
Article - Health - General
Section 18-336(b) and 18-338.1(b)
Annotated Code of Maryland
(2000 Replacement Volume and 2002 Supplement)

BY repealing and reenacting, without amendments,
Article - Health - General
Section 18-338.1(c)
Annotated Code of Maryland
(2000 Replacement Volume and 2002 Supplement)

BY adding to
Article - Health - General
Section 18-338.3
Annotated Code of Maryland
(2000 Replacement Volume and 2002 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

18-336.

(b) Except as provided in Title 11, Subtitle 1, Part II of the Criminal Procedure
Article OR § 18-338.3 OF THIS SUBTITLE, before obtaining a fluid or tissue sample from
the body of an individual for the purpose of testing the fluid or tissue for the presence
of HIV infection, a health care provider shall:

(1) Obtain written informed consent from the individual on a uniform
HIV informed consent form that the Department shall develop consistent with the
requirements of the Department as established by regulations adopted by the
Department; and

(2) Provide the individual with pretest counseling, including:

(i) Education about HIV infection and methods for preventing
transmission;

(ii) Information about a physician's duty to warn; and

(iii) Assistance in accessing health care available to an individual
who tests positive for the HIV infection.
1 18-338.1.

2 (b) [A] EXCEPT AS PROVIDED IN § 18-338.3 OF THIS SUBTITLE, A physician,
3 nurse, or designee of a health care facility shall, at the request of an exposed health
4 care provider, seek the informed consent of a patient to test a blood sample of the
5 patient for the presence of HIV when:

6 (1) There has been an exposure between the patient and the health care
7 provider;

8 (2) The health care provider involved in the exposure has given prompt
9 written notice of the exposure, in accordance with the standards of the health care
10 facility, to the chief executive officer or the chief executive officer's designee of the
11 health care facility where the exposure occurred;

12 (3) The exposure occurred based on the judgment of a physician who is
13 not the health care provider involved in the exposure; and

14 (4) The health care provider involved in the exposure has given informed
15 consent and has submitted a blood sample to be tested for the presence of HIV in
16 accordance with the provisions of subsection (d) of this section.

17 (c) If, by virtue of the physical or mental condition of a patient, a physician,
18 nurse, or designee of a health care facility is unable to obtain the informed consent of
19 the patient to test a blood sample of the patient for the presence of HIV in accordance
20 with subsection (b) of this section, the physician, nurse, or designee of the health care
21 facility shall seek the consent of any person who has authority to consent to medical
22 care for the patient as provided under § 5-605 of this article or as otherwise
23 authorized by law.

24 18-338.3.

25 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
26 INDICATED.

27 (2) (I) "BODY FLUIDS" MEANS:

28 1. ANY FLUID CONTAINING VISIBLE BLOOD, SEMEN, OR
29 VAGINAL SECRETIONS; OR

30 2. CEREBROSPINAL FLUID, SYNOVIAL FLUID, OR AMNIOTIC
31 FLUID.

32 (II) "BODY FLUIDS" DOES NOT INCLUDE SALIVA, STOOL, NASAL
33 SECRETIONS, SPUTUM, TEARS, URINE, OR VOMITUS.

34 (3) "EXPOSURE" MEANS AS BETWEEN A PATIENT AND A HEALTH CARE
35 PROVIDER:

36 (I) PERCUTANEOUS CONTACT WITH BLOOD OR BODY FLUIDS;
HOUSE BILL 343

(II) MUCOCUTANEOUS CONTACT WITH BLOOD OR BODY FLUIDS;

(III) OPEN WOUND, INCLUDING DERMATITIS, EXUDATIVE LESIONS, OR CHAPPED SKIN, CONTACT WITH BLOOD OR BODY FLUIDS FOR A PROLONGED PERIOD; OR

(IV) INTACT SKIN CONTACT WITH LARGE AMOUNTS OF BLOOD OR BODY FLUIDS FOR A PROLONGED PERIOD.

(4) "FIRST RESPONDER" MEANS AN INDIVIDUAL WHO:

(I) IS LICENSED OR CERTIFIED UNDER § 13-516 OF THE EDUCATION ARTICLE; AND

(II) PROVIDES SERVICES TO AN INDIVIDUAL BEFORE THE INDIVIDUAL IS ADMITTED TO A HOSPITAL.

(4) (5) (I) "HEALTH CARE PROVIDER" MEANS AN INDIVIDUAL WHO IS LICENSED, CERTIFIED, OR OTHERWISE AUTHORIZED UNDER THE HEALTH OCCUPATIONS ARTICLE OR THIS ARTICLE TO PROVIDE HEALTH OR MEDICAL CARE IN:

1. THE ORDINARY COURSE OF BUSINESS OR PRACTICE OF A PROFESSION; OR

2. AN APPROVED EDUCATION OR TRAINING PROGRAM.

(II) "HEALTH CARE PROVIDER" INCLUDES ANY AGENT OR EMPLOYEE OF A HOSPITAL.

(III) "HEALTH CARE PROVIDER" DOES NOT INCLUDE AN INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE NOTIFICATION UNDER THE PROVISIONS OF § 18-213 OF THIS TITLE, INCLUDING ANY LAW ENFORCEMENT OFFICER OR ANY MEMBER OF ANY FIRE DEPARTMENT, AMBULANCE COMPANY, OR RESCUE SQUAD.

(5) (6) "HIV" MEANS THE HUMAN IMMUNODEFICIENCY VIRUS THAT CAUSES ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(6) (7) "HOSPITAL" HAS THE MEANING STATED IN § 19-301 OF THIS ARTICLE.

(3) NOTWITHSTANDING THE PROVISIONS OF § 18-338.1 OF THIS SUBTITLE, THE DESIGNATED INFECTIOUS DISEASE/COMMUNICABLE DISEASE OFFICER OF A HOSPITAL SHALL ORDER A TEST FOR THE PRESENCE OF ANTIBODIES TO THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) UNDER SUBSECTION (C) (D) OF THIS SECTION WHEN:

(1) THERE HAS BEEN AN EXPOSURE IN A HOSPITAL BETWEEN A PATIENT AND A HEALTH CARE PROVIDER, OR AN EXPOSURE BETWEEN THE PATIENT AND A FIRST RESPONDER BEFORE ADMISSION OF THE PATIENT TO A HOSPITAL.
THAT, IN ACCORDANCE WITH THE CENTERS FOR DISEASE CONTROL AND
PREVENTION RECOMMENDATIONS, WOULD WARRANT RECOMMENDING OR
OFFERING CHEMOPROPHYLAXIS TREATMENT FOR THE HEALTH CARE PROVIDER OR
FIRST RESPONDER;

(2) INFORMED CONSENT, OR SUBSTITUTE CONSENT AS REQUIRED
UNDER § 18-338.1(C) OF THIS TITLE, OF THE PATIENT TO TEST A BLOOD SAMPLE OF
THE PATIENT FOR THE PRESENCE OF HIV WAS SOUGHT AND THE PATIENT REFUSED
TO CONSENT WAS UNAVAILABLE OR UNABLE TO CONSENT;

(3) (i) IN ACCORDANCE WITH HOSPITAL PROCEDURES, THE HEALTH
CARE PROVIDER INVOLVED IN THE EXPOSURE HAS GIVEN PROMPT NOTICE OF THE
EXPOSURE TO THE DESIGNATED HOSPITAL INFECTION DISEASE/COMMUNICABLE
DISEASE OFFICER WHERE THE EXPOSURE OCCURRED; OR

(ii) 1. THE FIRST RESPONDER INVOLVED IN THE EXPOSURE HAS
GIVEN PROMPT NOTICE TO THE MEDICAL DIRECTOR WITH JURISDICTION OVER THE
FIRST RESPONDER; AND

2. THE MEDICAL DIRECTOR HAS GIVEN PROMPT NOTICE TO
THE DESIGNATED HOSPITAL INFECTION DISEASE/COMMUNICABLE DISEASE
OFFICER WHERE THE PATIENT IS ADMITTED;

(4) THE HEALTH CARE PROVIDER OR FIRST RESPONDER INVOLVED IN
THE EXPOSURE HAS GIVEN INFORMED CONSENT AND HAS SUBMITTED A BLOOD
SAMPLE TO BE TESTED FOR THE PRESENCE OF HIV; AND

(5) THE DESIGNATED HOSPITAL INFECTION DISEASE/COMMUNICABLE
DISEASE OFFICER HAS MADE A DETERMINATION, IN ACCORDANCE WITH THE
CENTERS FOR DISEASE CONTROL AND PREVENTION RECOMMENDATIONS, THAT THE
TESTING OF BLOOD SAMPLES OR OTHER BODY FLUIDS OF THE PATIENT FOR THE
PRESENCE OF ANTIBODIES TO THE HUMAN IMMUNODEFICIENCY VIRUS (HIV)
WOULD BE HELPFUL IN MANAGING THE RISK OF DISEASE AND HEALTH OUTCOME OF
THE HEALTH CARE PROVIDER OR FIRST RESPONDER.

(C) IF THERE HAS BEEN AN EXPOSURE BETWEEN A FIRST RESPONDER AND
AN INDIVIDUAL BEFORE THE ADMISSION OF THE INDIVIDUAL TO A HOSPITAL:

(1) THE FIRST RESPONDER SHALL GIVE NOTICE TO THE FIRST
RESPONDER'S MEDICAL DIRECTOR IN ACCORDANCE WITH SUBSECTION (B)(3)(II) OF
THIS SECTION;

(2) THE MEDICAL DIRECTOR SHALL ACT AS AN INTERMEDIARY AT ALL
TIMES BETWEEN THE FIRST RESPONDER AND THE DESIGNATED HOSPITAL
INFECTION DISEASE/COMMUNICABLE DISEASE OFFICER; AND

(3) THE MEDICAL DIRECTOR AND THE DESIGNATED HOSPITAL
INFECTION DISEASE/COMMUNICABLE DISEASE OFFICER SHALL ENSURE THAT ALL
COMMUNICATIONS AND INFORMATION RELATED TO THE EXPOSURE OF THE FIRST
RESPONDER ARE CONFIDENTIAL.
HOUSE BILL 343

1 (C) (D) IF THE REQUIREMENTS OF SUBSECTION (B) SUBSECTIONS (B) AND (C) OF THIS SECTION ARE SATISFIED, THE DESIGNATED HOSPITAL INFECTIOUS DISEASE/COMMUNICABLE DISEASE OFFICER SHALL ORDER TESTS TO BE CONDUCTED FOR THE PRESENCE OF ANTIBODIES TO THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) USING A TEST PROCEDURE APPROVED BY THE DEPARTMENT ON:

7 (1) BLOOD SAMPLES ALREADY OBTAINED FROM THE PATIENT; OR

8 (2) BLOOD SAMPLES OR OTHER BODY FLUIDS COLLECTED FOR THE PURPOSE OF HIV TESTING UNDER THIS SECTION.

10 (D) (E) WHEN THE DESIGNATED HOSPITAL INFECTIOUS DISEASE/COMMUNICABLE DISEASE OFFICER OBTAINS THE RESULTS OF AN HIV TEST CONDUCTED IN ACCORDANCE WITH THE PROVISIONS OF SUBSECTION (C) (D) OF THIS SECTION, THE DESIGNATED HOSPITAL INFECTIOUS DISEASE/COMMUNICABLE DISEASE OFFICER SHALL DIRECTLY NOTIFY THE PATIENT OF THE RESULTS OF THE HIV TEST AND, TO THE EXTENT POSSIBLE, IN A MANNER THAT WILL PROTECT THE CONFIDENTIALITY OF THE HEALTH CARE PROVIDER OR THE FIRST RESPONDER AND THE PATIENT.

18 (E) (F) IF THE RESULTS OF AN HIV TEST CONDUCTED IN ACCORDANCE WITH THE PROVISIONS OF SUBSECTION (C) (D) OF THIS SECTION ARE POSITIVE, THE DESIGNATED HOSPITAL INFECTIOUS DISEASE/COMMUNICABLE DISEASE OFFICER SHALL PROVIDE OR ARRANGE FOR THE PROVISION OF APPROPRIATE COUNSELING AND TREATMENT RECOMMENDATIONS TO THE HEALTH CARE PROVIDER OR FIRST RESPONDER AND THE PATIENT.

24 (F) (G) (1) NOTWITHSTANDING THE PROVISIONS OF TITLE 4, SUBTITLE 3 OF THIS ARTICLE, THE MEDICAL RECORDS, INCLUDING ANY PHYSICIAN ORDER FOR AN HIV TEST OR THE RESULTS OF AN HIV TEST CONDUCTED UNDER THIS SECTION, MAY NOT BE DOCUMENTED IN THE MEDICAL RECORD OF THE PATIENT OR, HEALTH CARE PROVIDER, OR FIRST RESPONDER.

29 (2) THE HOSPITAL WHERE THE EXPOSURE OCCURRED SHALL MAINTAIN A SEPARATE CONFIDENTIAL RECORD OR INCIDENT REPORT FOR ALL HIV TESTS CONDUCTED UNDER THIS SECTION.

32 (3) EACH HOSPITAL SHALL ADOPT PROCEDURES FOR THE CONFIDENTIAL HIV TESTING OF BLOOD SAMPLES OR OTHER BODY FLUIDS USED OR COLLECTED FOR PURPOSES OF THIS SECTION.

35 (4) EXCEPT AS PROVIDED IN PARAGRAPH (5) OF THIS SUBSECTION, THE MEDICAL RECORDS, INCLUDING ANY PHYSICIAN ORDER FOR AN HIV TEST OR THE RESULTS OF ANY HIV TEST CONDUCTED UNDER THIS SECTION, ARE:

38 (I) CONFIDENTIAL; AND

39 (II) NOT DISCOVERABLE OR ADMISSIBLE IN EVIDENCE IN ANY CRIMINAL, CIVIL, OR ADMINISTRATIVE ACTION.
HOUSE BILL 343

(5) IF THE IDENTITY OF THE PATIENT OR ANY OTHER INFORMATION
THAT COULD BE READILY ASSOCIATED WITH THE IDENTITY OF THE PATIENT IS NOT
DISCLOSED, THE RESULTS OF AN HIV TEST CONDUCTED ON A PATIENT FOR
PURPOSES OF THIS SECTION MAY BE INTRODUCED INTO EVIDENCE IN ANY
CRIMINAL, CIVIL, OR ADMINISTRATIVE ACTION INCLUDING THE ADJUDICATION OF A
WORKERS' COMPENSATION CLAIM.

(6) THE COSTS INCURRED IN PERFORMING AN HIV TEST ON A PATIENT
IN ACCORDANCE WITH THE PROVISIONS OF THIS SECTION SHALL BE PAID BY THE
HOSPITAL.

(6) EACH HOSPITAL SHALL DEVELOP WRITTEN PROCEDURES TO
IMPLEMENT THE PROVISIONS OF THIS SECTION.

(6) A HEALTH CARE PROVIDER, FIRST RESPONDER, OR HOSPITAL OR
DESIGNEE OF A HOSPITAL ACTING IN GOOD FAITH TO PROVIDE NOTIFICATION OR
MAINTAIN THE CONFIDENTIALITY OF THE RESULTS OF A TEST CONDUCTED UNDER
THIS SECTION MAY NOT BE HELD LIABLE IN ANY CAUSE OF ACTION RELATED TO A
BREACH OF PATIENT OR HEALTH CARE PROVIDER, OR FIRST RESPONDER
CONFIDENTIALITY.

SECTION 2. AND BE IT FURTHER ENACTED, That the AIDS Administration
in the Department of Health and Mental Hygiene, in consultation with the Maryland
Hospital Association and AIDS advocacy organizations, shall study the issue of HIV
testing of individuals who refuse to consent to HIV testing when there has been an
exposure involving a health care provider or a first responder, as defined in §
18-338.3 of the Health - General Article, as enacted by Section 1 of this Act. The
AIDS Administration shall report its finding and recommendations, in accordance
with § 2-1462 of the State Government Article, to the Senate Education, Health, and
Environmental Affairs Committee and the House Health and Government Operations
Committee on or before December 1, 2003.

SECTION 3. AND BE IT FURTHER ENACTED, That Section 1 of this Act shall
take effect October 1, 2003.

SECTION 2: 4. AND BE IT FURTHER ENACTED, That, except as provided in
Section 3 of this Act, this Act shall take effect October 1, 2003.
Workgroup to Study the Issue of HIV Testing of Individuals Who Refuse to Consent to HIV Testing in the Event of an Occupational Exposure Involving a Health Care Worker or First Responder

Member List

1. Dr. Liza Solomon
   AIDS Administration

2. Jenny Bolster, RN
   AIDS Administration

3. Daniel Bruner, Esq.
   Whitman Walker Clinic

4. Elizabeth Fuss, RN, MS, CIC
   Association of Professionals in Infection Control and Epidemiology

5. Meg Garrett, RN, JD
   Johns Hopkins Hospital

6. Dr. Patricia Hawkins
   Whitman Walker Clinic

7. Rev. Debra Hickman
   Sisters Together and Reaching

8. Indira Kotval, LCSW-C, MPH
   HERO

9. Dr. Merle McCann
   AIDS Action Baltimore

10. Denise Matricciani
    Maryland Hospital Association

11. David Rocah, Esq.
    ACLU of Maryland

12. David Shippee
    Chase Brexton Health Services

13. Holly Taylor, MPH, PhD
    Bloomberg School of Public Health and Bioethics Institute – Johns Hopkins

    University of Maryland School of Law
Survey of Occupational Exposures to Blood or Body Fluids

Please refer to the back of this sheet for definitions of key terms.

During the period of January 1, 2001 through January 1, 2002 (or the most recent twelve-month period for which data is available):

1. How many health care providers reported any occupational exposures to blood or body fluids within your hospital during the twelve-month period? ______________________

2. Of those health care providers who reported any occupational exposures, how many of the exposures met the definition of exposure given on the attached sheet? __________

3. For exposures that met the definition cited above, how many health care providers requested information about the HIV status of the individual who was the source of the exposure ("source patient")? __________

4. How many patients were approached and requested to undergo testing? __________
   a. How many patients agreed to testing? __________
   b. How many patients refused to have an HIV test? __________
   c. How many patients did not undergo testing because the patient indicated that their status was already known? __________

5. How many source patients were not approached because their medical record indicated their HIV status? __________

6. In how many cases was the patient, by virtue of his/her physical or mental condition, judged to be not competent to give informed consent to an HIV test? __________

7. In those cases where a patient was judged not competent to give informed consent (due to physical or mental condition), how often was substitute consent:
   a. Requested? __________
   b. Obtained? __________
   c. Refused? __________

8. In how many cases was the patient or individual with the authority to consent to medical care for the patient unavailable to give consent? __________

9. In your facility, who is responsible for requesting consent for HIV testing in the case of an occupational exposure?
   a. Designated individual from employee health? __________
   b. The infection control nurse? __________
   c. The attending physician? __________
   d. The physician on call? __________
   e. Someone else? __________ (Please describe) __________

10. When this person is not available, who is responsible for requesting consent?
    a. Designated individual from employee health? __________
    b. The infection control nurse? __________
    c. The attending physician? __________
    d. The physician on call? __________
    e. Someone else? __________ (Please describe) __________

11. Do you have a policy or protocol for requesting HIV testing in the case of an occupational exposure?
    a. Yes __________ (Please send policy/procedures )
    b. No __________

Time period of these statistics: Start date ___________ End date ___________

Name of facility: __________________________________________

Name of person completing form: __________________________________

Telephone number: ______________________ Date: ______________________

Return form by August 22, 2003

ATTN: Georgette Lavetsky, M.H.S.
Department of Health and Mental Hygiene
AIDS Administration
500 N. Calvert Street – Baltimore, MD 21202
FAX (410) 333-6333
Please use the following guidelines for determining who is a "health care provider" for purposes of responding to this questionnaire:

Include:

A. Any individual who is an employee of the hospital;

B. Any individual licensed or certified under the Health Occupations Article who provides health or medical care in your hospital, including house staff and attending physicians;

C. Any individual in an approved education program under the Health Occupations Article who provides health or medical care in your hospital;

Do not include:

Any police, firefighters, emergency medical technicians, or other first responders who treat patients before they reach your facility.

Please use the following definition of "exposure" when answering questions 3 through 6:

Exposure "between a patient and a health care provider:

I. Percutaneous contact with blood or body fluids;
II. Mucocutaneous contact with blood or body fluids;
III. Open wound, including dermatitis, exudative lesions, or chapped skin, contact with blood or body fluids for a prolonged period; or
IV. Intact skin contact with large amounts of blood or body fluids for a prolonged period
(Health-General Article, §18-338.1, Annotated Code of Maryland).
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HB 343 Workgroup on HIV Testing of Individuals Who Refuse to Consent

Survey of Occupational Exposures to Blood or Body Fluids

- All 45 acute care hospitals in Maryland with ≥ 30 beds.
  - Omitted two smallest hospitals with 9 and 12 beds each.
  - 35 sites responded (represents 36 hospitals).
- Most recent available one-year period.
- Trying to ascertain the following:
  - How common are occupational exposures?
  - How often do you request patient consent for HIV testing?
  - How often do patients refuse HIV testing?
  - How often is substitute consent requested?
  - How often is substitute consent refused?
  - Who requests consent?
  - What is your policy?
- Policies were received from 32 of 35 responding sites.
How common are exposures?

- 2,409 reported exposures.
- 2,320 of those (96%) met the criteria for an occupational exposure to blood or body fluids.
  - 90% in very large facilities (>500 beds)
  - 95% in large facilities (201-500 beds)
  - 94% in medium facilities (101-200 beds)
  - 76% in small facilities (30-100 beds)
- Health care workers requested patient information on HIV status for 2,142 of the 2,320 exposures (92%).
  - Similar percents in facilities of all sizes.

Patient Consent Sought

- 1,935 source patients who could be identified, whose HIV status was unknown, and who were competent to provide consent.
- 1,913 (99%) of 1,935 source patients consented to HIV testing.
- 22 (1%) of 1,971 source patients refused.
Reasons why source patients were not approached for testing

- 114 source patients had status recorded in their medical charts
  - 65 (57%) of these were in two very large sites.
  - An additional 19 source patients indicated their status when approached for testing
- In a number of cases, individual patients were not identifiable, or exposures occurred through contact with sharps boxes or packed blood.
- 112 patients were not competent to give consent. (according to 28 of 35 sites which keep track of this)

Substitute Consent Sought

- 112 source patients in 28 sites not competent to give consent.
- Substitute consent was requested for 108 (96%) of the 112 patients.
- Substitute consent was requested but not possible for 4 patients due to inability to contact family or due to patient death.
- Substitute consent was granted for 103 (99%) of 104 patients who lived and whose next of kin were available.
- Substitute consent was refused for 1 (1%) of 104 patients.
Major Findings

- 99% of patients agreed to consent
- 99% of substitutes agreed to consent
- Results do not differ by size of hospital

Who requests consent?

- 17 of 35 responding sites indicated >1 individual with primary responsibility for requesting HIV testing for occupational exposures.
  - Percents will not add to 100%.
  - 18 (51%) indicated a designated individual from employee health
  - 17 (49%) indicated the attending physician
  - 7 (20%) indicated the infection control nurse
  - 4 (11%) indicated the physician on call
  - 12 (34%) indicated “someone else”: e.g., charge nurse, patient’s nurse, surgical or medical resident, etc.
- When primary person not available, 20 (57%) of sites indicated “someone else” with responsibility: e.g., charge nurse, etc.