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Report and Recommendations

to the Legislature on the

Minnesota Department of Health

HIV and HBV Prevention Program

Minnesota Department of Health Disease Prevention and Control Division Acute Disease Epidemiology Section January 15, 1998



The Commissioner of Health's



Report and Recommendations

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to the Legislature on the

HIV and HBV Prevention Program

(Fulfilling 1997 Legislature Health and Human Services, Omnibus Bill Chapter 203, Section 34)

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January 15, 1998

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Executive Summary

Section 34 of the 1997 Legislature Health and Human Services Omnibus Bill Chapter 203 mandated the Commissioner of Health to evaluate the effectiveness of the "HIV and HBV Prevention Program." This is the program authorized under Minnesota Statutes section 214.17-214.25 which requires the Minnesota Department of Health (MDH) to review and monitor licensed health care workers infected with the human immunodeficiency virus (HIV) or hepatitis B virus (HBV). To date, 84 health care workers have been reported and evaluated including 78 with HIV infection and six with HBV infection.

In order to evaluate the program a number of activities were undertaken from August to December 1997. The MDH surveyed other state health departments, and with assistance of the licensing boards, surveyed licensing boards from other states and found that Minnesota's efforts were consistent with other states' efforts. Two focus groups were assembled whose participants had an interest in the program. The first group was comprised of physicians who had treated infected health care workers reviewed under the program. They recommended continuation of the program with more input by physician peers. The second focus group consisted of infection control practitioners. They also favored continuation of the program. Four (of 29) infected health care workers who had been involved in the program returned surveys that we mailed to them. They generally felt the program to be invasive, too restrictive, and overly inclusive. A survey of the general public revealed that most (89%) were unaware of the program but thought it was a good idea (95%). Sixteen persons representing a variety of organizations and professions were invited to serve on a review group. They recommended continuation of the program with modifications designed to make it more individually tailored, "user-friendly," and limited in its scope of review.

The MDH recommends that the HIV and HBV Prevention Program be continued. However, based on the comments and recommendations received, the MDH will make changes to the way it evaluates, assesses, and monitors infected licensed health care workers. The changes are designed to dramatically streamline the process for most persons, be less intrusive to the worker, and still protect patients from becoming infected with HIV or HBV. Health care workers will be evaluated based on an initial assessment of their scope of practice and assigned to one of three categories. Those persons not performing invasive or exposure-prone procedures (not placing patients at risk in coming into contact with their blood) will receive minimal evaluation and at most an annual monitoring by the MDH. Health care workers who perform invasive procedures but may or may not perform exposure-prone procedures will receive a moderate level of evaluation. The assessment will be less detailed than present and be more "user-friendly." The MDH will not require extensive health status updates as is currently done. Health care workers who perform exposure-prone procedures will receive a more detailed level of evaluation and monitoring. However, less detailed medical information will be required and the MDH will work closely with their attending physician to utilize them as an educator.

No legislative action is required. The modifications will be administrative changes in program management. Future considerations may require legislative action. These include expanding the program to non-licensed health care workers who perform exposure-prone procedures and to other bloodborne pathogens such as hepatitis C virus.

I. Glossary

A number of terms are used throughout this report which may be program-specific or technical in nature. This glossary may be referred to for clarification.

Assessment Phase/Evaluation/Review Process: After receiving a report that a regulated person is infected with HIV or HBV, the Commissioner of Health evaluates the past and current professional practice of the regulated person to determine whether there has been or there is a likelihood that patients may be exposed to his/her blood.

Attorney General's Office: Office of the Attorney General Health Division. Legal counsel to the HIV and HBV Prevention Program is provided by this Minnesota state agency. This assures that the Commissioner of Health's interests and obligations are fulfilled in promoting the health and safety of patients and regulated persons.

<u>CDC</u>: U.S. Public Health Services, Centers for Disease Control and Prevention. This is the federal agency that has issued recommendations concerning health care workers infected with HIV/HBV.

<u>Expert Review Panel (ERP)</u>: The panel provides expert assistance to the Commissioner of Health in the areas of infectious diseases, epidemiology, infection control, and practice techniques used by the regulated person.

Exposure-Prone Procedure: Exposure-prone procedures are defined according to the 1991 Centers for Disease Control and Prevention (CDC) "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures." Characteristics of exposure-prone procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site. Performance of exposure-prone procedures presents a recognized risk of percutaneous injury to the HCW, and—if such an injury occurs—the HCW's blood is likely to contact the patient's body cavity, subcutaneous tissues, and/or mucous membranes. (MMWR 1991;40[No.RR-8]:4)

<u>HBV</u>: Hepatitis B virus. Infection with this virus is associated with mild to severe illness; rarely it may result in liver cirrhosis and death. A small proportion of persons infected with HBV become chronic carriers. Some of these persons are positive for hepatitis B e antigen (HBeAg).

HBeAg: Hepatitis B e antigen or HBeAg. The presence of this antigen in the blood of a person positive for HBV is associated with a high level of infectivity.

<u>HIV</u>: Human immunodeficiency virus. Infection with this agent may progress to AIDS, a severe life-threatening condition, which most often results in progressive damage to the immune and other organ systems.

HIV and HBV Prevention Program: The program established under Minnesota Statute 214.17 - 214.25 intended to promote the health and safety of patients and regulated persons (certain licensed health care workers) by reducing the risk of infection in the provision of health care (refer to Appendix 1 for MN Statute 214.17-214.25 HIV and HBV Prevention Program).

Invasive Procedure: Invasive procedures are defined according to the CDC's 1987 "Recommendations for Prevention of HIV Transmission in Health-Care Settings." An invasive procedure is defined as "surgical entry into tissues, cavities, or organs or repair of major traumatic injuries 1) in an operating or delivery room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catherization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists." (MMWR 1987;36[suppl. no. 2S]:6S-7S.)

<u>Licensee/Licensed Health Care Worker</u>: A person licensed to perform duties by the Minnesota Board of Dentistry, Medical Practice, Nursing, or Podiatric Medicine, including a licensed dental hygienist, dentist, physician, nurse, podiatrist, registered dental assistant, or physician assistant (see Regulated Person).

<u>Licensing Boards</u>: The Boards of Dentistry, Medical Practice, Nursing, and Podiatric Medicine, and for the purposes of sections 214.19, subdivisions 4 and 5; 214.20, paragraph (1); and 214.24, of MN Statute 214.17-214.25, the board also includes the Board of Chiropractic Examiners.

MDH: Minnesota Department of Health

Monitoring Phase: The process of determining that a regulated person is complying with any monitoring plan.

Monitoring Plan or Stipulation and Agreement: A written document produced by the MDH. For the purposes of this report, it is an agreement between the Commissioner of Health and the licensee. It may address the scope of the regulated person's professional practice when the Commissioner of Health determines that the practice constitutes a risk of transmission of HIV or HBV from the regulated person to the patient. It may include the submission of regular reports at specified times related to the regulated person's health status, professional practice, and any other provision deemed necessary.

<u>Regulated Person</u>: Person licensed to perform duties according to the Minnesota Boards of Dentistry, Medical Practice, Nursing, or Podiatric Medicine, and for purposes of sections 214.19, subdivisions 4 and 5; 214.20, paragraph (1); and 214.24 of MN Statute 214.17-214.25, a chiropractor (see Licensee/Licensed Health Care Worker).

II. HIV and HBV Prevention Program

A. History of the Program

The Minnesota Department of Health (MDH) HIV and HBV Prevention Program for evaluating and monitoring infected licensed health care workers began in the fall of 1992 after the legislation became effective in July (Minnesota Statute 214.17-214.25) and funding was provided for hiring of staff. Funds are allocated to MDH from the health professional licensing boards (Boards of Medical Practice, Nursing, Dentistry, and Podiatric Medicine) to support the program. The program funds 1.5 FTEs (a full-time clinical nurse specialist with training in infection control and one half-time clerical position) The funding also provides for professional consultative fees and legal costs related to the program. Additional in-kind assistance is provided by staff of the Acute Disease Epidemiology Section including epidemiologists, an Epidemiologist Senior Supervisor, Medical Director, and Section Chief; the Director of the Division of Disease Prevention and Control; and the Executive Office.

The program was developed by the Acute Disease Epidemiology Section with guidance from the Attorney General's Office. This Section conducts surveillance for infectious diseases and had little or no experience in regulatory actions. Thus, the program was largely based on the investigative programs conducted by the licensing boards.

As of December 1997, 84 health care workers have been reported and evaluations initiated as part of the program. Approximately 10 to 15 new reports of infected health care workers are received annually.

B. General Procedures of the Program

The process for evaluating and monitoring a health care worker infected with human immunodeficiency virus (HIV) or hepatitis B virus (HBV) (hepatitis B e antigen [HBeAg] positive) infection begins with a report of the individual's HIV/HBV status to MDH. The report may be a self report from the health care worker, from the health care worker's personal attending physician, from an infection control practitioner at the facility employing the health care worker, or from other data supplied to MDH. Once a report is received, the license status of the health care worker is confirmed through the Attorney General's Office.

The statute authorizes the review and monitoring of the practice of certain licensed health care workers. An individual may be found not to qualify for review because he/she is not a licensed health care worker, his/her license to practice is on inactive status, or he/she has moved out of state and allowed his/her license to become inactive. In earlier times of the program, a number of health care workers died before or soon after an evaluation was initiated as they had been

living with HIV for some time before the statute became effective.

Once the health care worker's license has been verified, MDH staff send a letter to the licensee informing him or her that a case report has been received and directing him or her to meet with us. Included with the letter are data privacy information, a copy of Minnesota Statute 214.17-214.25, medical waiver forms, and information about how he/she may document his/her professional activities. Upon receipt of the waivers from the health care worker, medical records are obtained to confirm the person's infection status and to assess medical issues related to transmission of HIV or HBV from the health care worker to patients.

The health care worker is then interviewed regarding his/her clinical practice (education and training, practice history, current clinical practice); health status; and compliance with recommended infection control practices including routine infection control practices, and knowledge of procedures related to post-exposure management for patients. Waivers are signed to obtain further information about employment status and professional practice. Information is sought through record review and interviews with persons who can verify the information provided to MDH by the health care worker. This may involve interviews with supervisors, attending physicians, and/or colleagues. Documents are obtained related to his/her employment and practice history.

For those health care workers with complex clinical practices or medical conditions, expert consultants are retained. These might be professionals with the same specialty such as surgeons or dentists. They assist in the review and development of a monitoring plan tailored specifically to the health care worker. In addition, an expert review panel (ERP) as identified in statute may be convened. A professional(s) is enlisted from the local or national community with knowledge about infection control recommendations and expertise in the practice area of the infected health care worker. Additional members of the ERP include a representative from the appropriate licensing board, a physician specializing in the treatment of infectious disease, the Director of the MDH Disease Prevention and Control Division, the State Epidemiologist, the Disease Prevention and Control Medical Director, and staff from the MDH Acute Disease Epidemiology Section. The Attorney General's Office provides legal advice to the ERP. The comments and recommendations of the ERP form the basis to develop a monitoring plan for the health care worker.

Once all information from the health care worker has been synthesized, including recommendations from an ERP (if one was convened), a monitoring plan (called a Stipulation and Agreement) is developed. The monitoring plan is reviewed and approved by Acute Disease Epidemiology Section managers, the State Epidemiologist, the Director of the Division of Disease Prevention and Control, and the Assistant Attorney General. A final copy is sent to the Commissioner of Health for review and signature. The signed monitoring plan is then forwarded to

the health care worker for his/her signature, or presented in person, if necessary. A monitoring plan may require the health care worker to provide health status updates, practice updates, and/or address changes. Documentation of specific continuing education may be required. In limited instances where exposure-prone procedures are involved, restrictions or modifications may be placed on that person's practice. Once a health care worker has signed and returned the monitoring plan, follow-up occurs at specific intervals. Lack of cooperation or non-compliance with the monitoring plan may result in the health care worker being referred to the licensing board.

During the evaluation, drafting, and presentation of the monitoring plan, health care workers are reminded of their legal rights. They may choose to refer themselves to their licensing board and they may choose to seek legal counsel. The identity of the individual is kept confidential and revealed to as few persons as necessary.

C. Numbers and Types of Health Care Workers Evaluated from July 1992 through December 1997

To date, 84 health care workers (HCWs) have been reported and evaluated, including 78 with HIV infection and six with HBV infection.

The current status of these HCWs is as follows:

Cases dropped/not under jurisdiction (i.e., not licensed or other reason)

Dentist: 1 reported (dental student, not licensed)

Physicians: 1 reported as physician (not HBeAg positive, not licensed as an MD)

1 reported as a G-2 resident (HBeAg positive, no resident permit or license as an MD) 1 physician assistant reported (not HBeAg 17

13

positive)

Nurses: 11 reported as nurses (license inactive or never

licensed)

Operating Room Technician: 2 reported (not a regulated person as defined by statute)

HCWs who died during evaluation or after monitoring plan in effect

1 Physician

12 Nurses

HCWs evaluated and referred to the licensing board 1 Dentist 14 Nurses	15
HCWs to be referred to the licensing board 2 Nurses	2
HCWs currently alive with monitoring plans 1 Dentist 5 Physicians (specialties: orthopedic surgery, emergency medicine, cardiology, psychiatry [2]) 7 Nurses	13
HCWs in evaluation, license became inactive, licensing board to notify the MDH if license status changes 1 Physician (specialty: internal medicine) 1 Nurse	2
HCWs with monitoring plans, license became inactive, licensing board to notify the MDH if license status changes 1 Physician (specialty: pediatrics) 1 Nurse	2
HCWs evaluated, became HBeAg negative 1 Physician (specialty: vascular surgery)	1
HCWs currently being evaluated 1 Physician (specialty: psychiatry) 4 Nurses	5
HCWs to be evaluated 14 Nurses	. 14

III. Risk of HIV/HBV Transmission from Infected Health Care Workers to Patients

There have been two documented instances of HIV transmission from an infected health care worker to patient(s). In 1990-92, a U.S. Centers for Disease Control and Prevention (CDC) investigation demonstrated that a dentist with AIDS in Florida transmitted HIV to at least six of his patients¹⁻². The exact mechanism and specific events of transmission remain unknown but the evidence fully supports health care worker-to-patient transmission. An additional instance of HIV transmission from an orthopedic surgeon with AIDS to one of his patients was reported in January 1997 by health officials in France. The surgeon had performed hip surgery on the patient in 1992. Investigation revealed that the surgeon had sustained wounds or cuts during operative procedures which may have exposed patients to his blood³⁻⁴.

Multiple instances of HBV transmission to patients from infected health care workers have been and continue to be documented. These include transmissions from dentists, surgeons, obstetricians/gynecologists, a general practitioner, respiratory therapists, and a cardiac pump technician⁵. No transmissions from dentists have been reported since 1987 perhaps reflecting better infection control methods. Several situations deserve special mention. The first involves a cardiothoracic surgeon who transmitted HBV to 19 (13%) of 142 patients⁵⁻⁶. Seven of the transmissions occurred after his practice and techniques had been reviewed and he was approved to continue to practice. He normally wore a single pair of gloves and it is thought that he exposed patients through tying of surgical knots which resulted in separation of skin around his fingers. The second situation

¹Ciesielski C, Marionos D, Ou CY, et al. Transmission of human immunodeficiency virus in a dental practice. Ann Intern Med 1992;116(10):798-805.

²Centers for Disease Control and Prevention. Update: Investigations of persons treated by HIV-infected health-care workers-United States. MMWR 1993;42:329.

³Simons M. French doctor with AIDS said to have probably infected patient during surgery. New York Times, January 17, 1997.

⁴National Public Health Network of France (Reseau National deSante Publique) Press Release, January 17, 1997.

⁵Bell DM, Shapiro CN, Cieslieski CA, Chamberland ME. Preventing bloodborne pathogen transmission from health-care workers to patients. The CDC perspective. In: The Surgical Clinics of North America. Prevention of Transmission of Bloodborne Pathogens. Rhodes RS, Bell DM, eds. Vol. 75, No. 6, December 1995, W.B. Saunders Company, Philadelphia.

⁶Harpaz R, Von Seidlein L, Averhoff TM, et al. Transmission of hepatitis B virus to multiple patients from a surgeon without evidence of inadequate infection control. N Engl J Med 1996;334:549-54.

involves four separate instances of transmission of HBV to patients by surgeons who were hepatitis B e antigen negative. All four were infected with hepatitis B viruses that had mutations ("precore mutants")⁷.

Despite their best efforts, health care workers do suffer percutaneous injuries, estimated at 0.2 - 13 blood contacts per year depending on their occupation⁸. In certain circumstances, these percutaneous injuries are associated with recontact injuries, where the patient is potentially exposed to the injured health care worker's blood. If the health care worker is infected with HIV or HBV, the patient may become infected.

Thus, it is possible (and likely) that additional health care worker-to-patient transmissions of HIV and HBV will occur in the future. Although difficult to quantify, the risk of HIV transmission from a surgeon to a patient due to percutaneous injury during surgery has been estimated at 2.4 to 24 per million⁹. However, actual risk may vary with the procedures involved and this estimate may not apply to transmissions that occur in clusters, where multiple patients are infected (with HIV or HBV) from a single health care worker⁵. Since HBV is readily more transmissible than HIV, it is more likely that health care worker-to-patient transmissions of HBV will be seen in the future. However, the risks may be lessened as compliance with infection control procedures improves, new protective equipment is developed, and hepatitis B immunization among health care workers and patients increases.

⁷The Incident Investigation Teams and Others. Transmission of hepatitis B to patients from four infected surgeons without hepatitis B e antigen. N Engl J Med 1997;336:178-84.

⁸Bell DM. Occupational risk of human immunodeficiency virus infection in health care workers: An overview. Am J Med 1997;102(5B):9-15.

⁹Bell DM, Shapiro CN, Culver DH, et al. Risk of hepatitis B and human immunodeficiency virus transmission to a patient from an infected surgeon due to percutaneous injury during an invasive procedure: Estimates based on a model. Infect Agents Dis 1:263, 1992.

IV. Summary of the Charge to the Commissioner of Health

The charge to the Commissioner of Health is stated in Section 34 of the 1997 Legislature Health and Human Services Omnibus Bill Chapter 203:

"Sec. 34. [STUDY OF HIV AND HBV PREVENTION PROGRAM.] The commissioner of health shall evaluate the effectiveness of the HIV and HBV prevention program established under Minnesota Statutes, sections 214.17-214.25. The commissioner shall evaluate the effectiveness of the program in maintaining public confidence in the safety of health care provider settings, educating the public about HIV infection risk in such settings, prevention of HIV and HBV infections, and fairly and efficiently working with affected health care providers. The results in Minnesota shall be compared to similar efforts in other states. The commissioner shall present recommendations to the legislature by January 15, 1998, on whether the program should be continued, and whether modifications to the program are necessary if a recommendation is made to continue the program."

The evaluation was limited to MDH's program of reviewing and monitoring of health care workers infected with HIV and/or HBV. We did not review the infection control activities such as adoption of rules, largely undertaken by the licensing boards, under this statute. Since the statute seemed directed towards the MDH, we did not evaluate the assessment and monitoring activities of infected health care workers by the licensing boards. However, we did meet with the licensing boards, involved them with surveys, and invited them to serve on the HIV and HBV Prevention Program Review Group.

No funding was provided to carry out this charge. We utilized existing staff and resources. A number of activities were conducted from August 1997- January 1998 to complete this evaluation. We surveyed other state health departments and, with the assistance of our licensing boards, surveyed their counterparts in other states to compare their efforts and legislative mandate with ours. An independent contractor conducted two focus groups of health professionals who are affected by this program: infection control practitioners and physician care providers of HIV/HBV-infected health care workers. A convenience sample of the public was surveyed to determine their knowledge of the program and their perception of risk of HIV/HBV infection from health care workers. We also surveyed infected health care workers who have been evaluated by either the MDH or their licensing board. Results from these surveys are included here. In October 1997, we convened a review group to advise the Commissioner on the program. Their findings are also included.

V. Evaluation Activities

A. Survey of Health Departments

State health departments were surveyed by telephone/facsimile machine in August-December 1997 to determine what policies/activities they have in place to evaluate/monitor HIV/HBV-infected health care workers. Responses were received from all 50 states (including Minnesota). We reviewed answers to survey questions and materials and information sent to us to categorize state health department efforts. We looked specifically for statutes/rules governing their efforts and whether or not infected health care workers were required to be reported to the health department or a licensing board for the purposes of evaluation and monitoring. We organized efforts into seven categories.

Category I: Mandatory report/review to/by health department-statutory authority

- 11 states: Minnesota, Alabama, Colorado, Georgia, Illinois, Iowa, Nebraska, North Carolina, Ohio, South Carolina, South Dakota
- Authority by statute or rule specific to infected health care workers (HCWs)
- Mandatory reporting of HCW to health department
- Monitoring activities retained by health department

Category II: Mandatory report/review to/by health department-general public health authority

- 2 states: Idaho, Utah
- Authority under general public health code in policy, recommendations, or guidelines
- Policy states HCWs will or shall be reviewed (implying mandatory reporting and review as opposed to voluntary reporting and review)

Category III: Mandatory report/review to/by licensing board, not health department

- 3 states: Arkansas, Louisiana, Mississippi
- Authority by statute or rule
- Investigation and monitoring activities performed by the licensing board
- Health department provides technical assistance

Category IV: Voluntary report/review to/by licensing board, not health department

- 2 states: Connecticut, Kentucky
- Health department provides technical assistance to licensing board

Category V: Voluntary report/review to/by health department-statutory authority

- 6 states: Missouri, New Hampshire, Oklahoma, Oregon, New York, Tennessee
- Authority by statute or rule
- Voluntary reporting of HCW to health department
- Monitoring activities retained by the health department

Category VI: Voluntary review by health departmentguidelines/recommendations

- 19 states: Arizona, California, Florida, Hawaii, Maine, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, North Dakota, Pennsylvania, Rhode Island, Vermont, Washington, West Virginia, Wisconsin, Wyoming
- Guidelines/recommendations issued by health department-no apparent statute/rule
- In most instances health departments have adopted the CDC 1991 guidelines on infected health care workers nearly verbatim as their own
- Voluntary reporting of HCW to health department

Category VII: No review process by either the health department or the licensing board

• 7 states: Alaska, Delaware, Indiana, Kansas, Maryland, Virginia, Texas

In summary, 16 states have some type of mandatory reporting system for infected health care workers and 27 have a voluntary reporting system. Seven states have no review process of infected health care workers; this is in apparent violation of federal law which requires some program at least equivalent to the 1991 CDC recommendations for infected health care workers.

B. Survey of Licensing Boards

The Boards of Dentistry and Podiatric Medicine (Podiatry) surveyed other state boards by mail; 39 and 29 boards responded respectively (including Minnesota). The Boards of Nursing and Medical Practice surveyed other boards electronically in August with 35 and 9 responding, respectively. Results are displayed in Appendix 2. In summary, only a few state licensing boards report being involved in reviewing and evaluating infected health care workers. Those findings are consistent with the survey of state health departments.

C. Focus Groups of Physicians and Infection Control Practitioners

Two focus groups were held in October 1997. One group included physicians who provide care for health care workers with HIV/HBV infection who had been reviewed or involved in the program. The other group included hospital infection control practitioners (ICPs) who worked at facilities where health care workers with HIV/HBV infection had practiced. An independent facilitator asked both groups for their views on the public perception of HIV/HBV-infected health care workers, their experience with the MDH program, and recommendations for changes to the program.

The full report for the focus groups is included as Appendix 3. To summarize, the following themes and recommendations emerged from the focus groups:

1. Fears of HIV/HBV in Health Care Workers and Changes in the Past Five Years

Over the past five years, there has been a marked shift from hysteria to a more educated public. The public still shows concern about HIV/HBV transmission, but seems to be more educated about the low risk of HIV/HBV transmission.

2. Experiences and Concerns with the Program

Experiences related by the physicians contained both positive and negative comments. Many of the negative experiences occurred when the program was first initiated. The positive experiences with the program occurred more recently as the program evolved.

3. Role of the Program in Preventing the Transmission of HIV/HBV from Health Care Workers to Patients

The consensus of both groups was that the program heightened awareness, but it probably did not play much of a role in the prevention of transmission. In fact, there does not seem to be a means to measure whether or not this program prevents transmission.

4. Maintaining Public Confidence in the Safety of Health Care Provider Setting

Both groups acknowledged a need for maintaining public confidence in the health care setting and that this program is perceived as providing oversight, monitoring, and protection. Both groups also indicated that the program provides reassurance to the public on this issue.

5. Recommendations of the Focus Groups

Given the above themes, the consensus of both groups was that the program is necessary for consistency of practice and reassurance of the public. Both groups agreed that more flexibility is needed in order for the program to be more consistent with the experience gained in the five years the program has existed. However, the groups differed in how they would like the program modified.

a. Physician Group Recommendations

The physician group recommended a new model for the program. In the substance abuse arena, one model used is the physicians serving physicians model. This model is seen as more user-friendly, educational, and helpful, rather than simply regulatory. The model could be modified to suit this situation, in that the peer system could be the entry point into the system. The health care worker would connect with a peer from the same field or practice. This peer would spend time educating and acting as an advocate for the infected health care worker.

Structured as a pyramid, the next step would be a committee of experts to look at the practice of the health care worker to educate the individual on infection control practices and discuss restriction of practice. The experts could be paid stipends for their time when the group is convened. The MDH would become an administrator of the program, acting as a resource. The expert panel would report in aggregate to the MDH, boards, and the community on a regular basis, and maintain the confidentiality of the infected health care worker, while the health care worker complies with their recommendations. If a health care worker failed to comply with the recommendations set forth by this panel, he/she would be reported to the board of practice for board action.

b. Infection Control Practitioner Group Recommendations

The infection control practitioner group had several recommendations. First, the program needs to share information between the MDH and the medical facility where the health care worker practices. Second, the scope of the program should be expanded to include non-licensed health care workers (e.g., surgical technicians). Third, the information, decisions, and recommendations from the MDH should be provided in a timely manner. Fourth, provide ongoing reporting to medical facilities of the number of health care workers who are HIV/HBV-infected, and their field of practice. Last, additional education to all health care workers and the community is needed on an annual basis in reference to the legislation, the roles of the medical providers and the MDH, and the status of the program.

D. Survey of the Public

Between September 1997 and January 1998, we utilized a convenience sample of the general public and surveyed them about their knowledge and attitudes related to HIV/HBV-infected health care workers and the program. One hundred and nine interviews were completed (50 male, 59 female; age range 18-74). The following is a summary of the data.

1. Are you aware that the Minnesota Department of Health has a program to evaluate and monitor physicians, dentists, and nurses infected with HIV? HIV is the virus that causes AIDS.

No. Responding	Yes (%)	No (%)
109	20 (18)	89 (82)

2. In theory do you think this is a good program that the Minnesota Department of Health should have?

No. Responding	Yes (%)	<u>No (%)</u> .	<u>Undetermined (%)</u>
109	104 (95)	4 (4)	1 (1)

3. Are you worried or afraid that a physician, dentist, or nurse with HIV infection may be providing health care?

No. Responding	Yes (%)	No (%)	Undetermined (%)
109	40 (37)	68 (62)	1* (1)

^{*}It depends on specialty

Selected comments:

Yes, I've heard about it on the news before.

I see mine take precautions, I trust them.

I wasn't until now.

4. If "YES", to question 3., does it decrease your level of concern/fear to know that the Minnesota Department of Health has this program?

Selected comments:

- -I would be less worried if knew own doctor's HIV status.
- -It might increase protection or precautions.
- -No, but getting the awareness is good.
- -I'm not sure.
- -If patients aren't informed of names-what good is it?
- -It helps.
- -It's better to know there is a program.
- -If they have HIV they shouldn't be working.
- -They should inform patients and get a signed consent form.

If "NO", to question 3., is it because the Minnesota Department of Health has this program that you are not concerned or afraid?

Yes - 16 No - 52

Selected comments:

- -Not really, because if the information isn't public we don't know anyway.
- -I'm a health care worker and I am educated about precautions to take.
- -It's good to know somebody is monitoring these workers.
- -The odds of having an infected doctor are low.
- -Military doctors provide my care, I know they are checked regularly and dismissed if positive.
- -Has HIV been transmitted in this way?
- -I don't always see people using protective equipment.
- -Workers need follow-up, but consider it's a two-sided issue.

In summary, most (82%) of the public respondents were unaware of the HIV and HBV Prevention Program but favored such a program (95%). One-third of the people surveyed were concerned about HIV/HBV-infected health care workers, and nearly three-fourths of those reporting concern were less afraid knowing that this program exists.

E. Survey of Infected Health Care Workers

Twenty-nine health care workers who have been evaluated by MDH (14) or by their licensing board (15) were sent surveys to be returned anonymously. Four responses (a,b,c,d) were received. The following are their answers:

1. Is the HIV and HBV Prevention Program process fair in evaluating and monitoring affected health care professionals?

- a) I don't believe it's fair at all. As a nurse, I have lost jobs because my supervisor knows and has to send letters to the Minnesota Board of Nursing. Eventually word leaks out to other staff, and this to me is a privacy issue. I worked my last two jobs in Board & Care (unskilled). I did no I.V.'s, tube feedings, insulin, shots or intrusive cares. I just pass pills. I don't feel people working in my position should be monitored.
- b) I firmly believe that the purpose of the HIV monitoring statute is purely political, meant to appease voters and not based upon good science. Since the single case of an infected Florida dentist in 1991, there hasn't been a single other case (of which I am aware) of a dentist or surgeon passing HIV on to a patient. Certainly, time has demonstrated that the requirements of these statutes are far too restrictive.

Therefore, to answer your question, no, I don't believe the statute and process are fair.

I am..., and have been forced to virtually give up...of my practice as a result of this law. Minnesota is one of only a few (perhaps two) states in the country that has such a restrictive law. (Parts deleted to maintain anonymity.)

- c) Too detailed to unemployed or disabled...i.e., not working.
- d) No answer.
- 2. Is the HIV and HBV Prevention Program process efficient in evaluating and monitoring affected health care professionals?
 - a) I also say no. There are many health professionals that have hidden to protect losing their jobs.
 - b) In my own personal situation, the answer to this question is a resounding no. I wouldn't call 18-20 months to come up with a monitoring agreement an example of efficient evaluating and monitoring.

I cannot comment on how efficient the Department of Health has been in performing an evaluation of others.

- c) Too much detail until one does invasive procedures.
- d) Should all professionals be monitored the same? Should there be set guidelines concerning certain practices, i.e., surgery or invasive radiology vs. non-invasive medicine? Should it be adequate that health

providers fill out a yearly statement about their health and not require multiple letters be filed by employers and physicians who care for them? The current system is not efficient by any means.

- 3. Please discuss any additional issues or concerns related to the HIV and HBV Prevention Program.
 - a) I think it should include CNA's, social workers, dietary-anybody in contact with patients.
 - b) With the recent advances in new medications to treat HIV infection, if the statute is to be continued or modified, I think it should address the question as to whether or not an individual who is HIV positive and has an undetectable viral load is truly infectious. I ask you to consider as an example HBV, where only those who are HBeAg positive are considered infectious.
 - c) Staff have been friendly. Again-simplify procedure for initial and follow up info. Remind HCW by mail when MD notification is required. If disabled, should not be required unless working again.
 - d) The program should change from a punitive agency, i.e., "You're going to lose your license if..." to a support agency for health professionals. It should be a source of information for employees and employers to protect patients and health professionals from spreading HIV and HBV. In the seven years I've been involved in the program I've received no information whatever about incidence, vectors, and spread of these viruses among health care workers. The agency needs to be equipped to handle any general hysteria which could be raised by the media during "low news" periods. I have no idea how our stated policies compare with those of other states. There is no "information line" or information diary house on the subject...education is the only way to combat fear.

F. Prevention of HIV and HBV Infections

Ideally, we would like to know how many HIV and HBV infections were prevented because of this program. Due to the extremely low risk of transmission and the relatively small number of health care workers who conduct invasive or exposure-prone procedures the probability that any infections would have occurred is extremely low, even in the absence of a program. If the program has prevented infections, we are not able to measure this.

We do know that we have reviewed health care workers who were putting patients at risk because they performed procedures that are exposure-prone. Their practices were restricted so that the risk to patients was reduced. This includes two dentists

(one who was referred to the Board of Dentistry), an emergency room physician who performed surgical procedures, and an orthopedic surgeon. If these individuals had not had their practices, skills, and techniques reviewed, it is possible that they may have exposed a patient to their blood and infected the patient.

VI. HIV and HBV Prevention Program Review Group

A. Introduction and Members

In order to receive broad based community response for the evaluation of the program, we convened a review group. It was composed of 16 members representing a variety of organizations and professions (see below). The review group met three times: October 30, November 20, and December 18, 1997. Comments from individual members of the review group taken from the minutes are attached in Appendix 4.

Review Group Members List:

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Frank Fly Policy & Planning Coordinator Board of Administrative Services 2829 University Ave. SE, Suite 530 Minneapolis, MN 55414 (612) 617-2121

Patricia Franklin Minnesota Medical Association 3433 Broadway St. NE Minneapolis, MN 55413-1761 (612) 362-3739 Robert Leach, Executive Director Board of Medical Practice 2829 University Ave. SE, Suite 400 Minneapolis, MN 55414-3246 (612) 617-2149

Susan Stout Minnesota Nurses Association 11295 Bandana Blvd. N. St. Paul, MN 55108-5115 (612) 646-4807

Meghan Morton Care Providers of Minnesota City of Lakes Transitional Care 110 E. 18th St. Minneapolis, MN 55403

Jeanne Pfeiffer
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Lorraine Teel, Executive Director Minnesota AIDS Project 1400 Park Ave. S. Minneapolis, MN 55404 (612) 373-2400 Patricia Glasrud, Executive Director Board of Dentistry 2829 University Ave. SE, Suite 450 Minneapolis, MN 55414 (612) 617-2250

Debra Kildahl, Executive Director Minnesota Homecare Association 1711 County Road B W. Roseville, MN 55113-4036 David Williams, MD Hennepin County Medical Center Department of Medicine Mail Code 865B 701 Park Ave. Minneapolis, MN 55415

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B. Charge to the Review Group

The charge to the review group was to recommend to the Commissioner of Health whether the MDH HIV and HBV Prevention Program should be continued with no modifications, be continued with modifications, or be discontinued. The recommendations were to be formulated based on evaluation of the above information, and with consideration of the following issues: maintaining public confidence in the health care setting, public education about the risk of HIV infection in health care settings, prevention of HIV and HBV infections, and fairly and efficiently working with affected health care providers.

C. Recommendations of the Review Group

The review group recommended continuing the program with modifications.

- 1. The program needs to be modified so that it no longer focuses on a "one-size fits all" approach. Program activities need to be tailored to the individual health care worker, with minimal evaluation and monitoring of those health care workers who do not perform invasive or exposure-prone procedures. Only those health care workers who do perform such procedures should have a detailed evaluation and monitoring plan, as appropriate based on the scope of work.
- 2. The program needs to be more "user-friendly." This includes: 1) being less punitive; 2) continuing to protect the confidentiality/identify of health care workers; 3) providing an opportunity for health care workers to grieve the process without risk of losing their license; 4) minimizing the intrusiveness of the program; 5) conducting the evaluation over a short time period so the stress to the health care worker is minimized; and 6) assuring that those working on the program from the licensing boards are knowledgeable about HIV/HBV and risk of transmission of these agents.

- 3. The scope of review of medical history for the health care worker should be limited to medical records which cover the period of time following HIV/HBV seroconversion and only include those records which relate to the actual risk of transmission (e.g., results of viral load testing, presence of skin lesions on hands/forearms, peripheral neuropathy). Routine monitoring of mental status is beyond the scope of this statute; such monitoring is accomplished through other existing programs.
- 4. The program should cover any HIV/HBV-infected health care worker, regulated or not, who engages in exposure-prone procedures (e.g., surgical technicians). This change would require legislative action which the review group did not recommend be pursued.

VII. Summary of Evaluation Activities and MDH Staff Comment

Section 34 of the 1997 Legislature Health and Human Services Omnibus Bill Chapter 203 required the evaluation of the HIV and HBV Prevention Program by the Commissioner of Health. The issues to be addressed included: the effectiveness of the program in maintaining public confidence in the safety of health care provider settings, educating the public about HIV infection risk in such settings, prevention of HIV and HBV infections, fairly and efficiently working with affected health care providers, and a comparison of similar efforts in other states. In response to this mandate several activities were undertaken by MDH staff and are summarized below.

A. Survey of Health Departments and Licensing Boards:

All other state health departments and licensing boards were surveyed to determine their role in this area. Including Minnesota, 16 states have mandatory reporting and some follow-up; 27 states have some form of voluntary reporting and follow-up; and seven states do not have any activities in place, although federal law requires states to be in compliance with the 1991 CDC recommendations for infected health care workers. In most instances, the responsibility in this area lies with the health department rather than the licensing board.

MDH Staff Comment:

Minnesota's program is consistent with other states' efforts.

B. Focus Groups of Infection Control Practitioners and Physicians:

Two separate focus groups were held by an independent contractor of the MDH. Four infection control practitioners and six physicians attended, respectively. The following themes emerged from these meetings: 1) there is less concern from the general public regarding HIV/HBV infection in health care workers than there was five years ago; 2) more positive experiences have occurred with the program in the last few years as it has matured; 3) it is unclear whether or not the program actually prevents transmission; there is no effective way to truly measure prevention of infections; and 4) the program provides public assurance and protection. The infection control practitioner group suggested: increased sharing of overall program and individual case information, and conducting a public and provider education initiative about the program.

The physician group recommended a new model for the program similar to the physicians serving physicians model that is used in managing substance abuse. A peer from the same field of practice would educate and act as an advocate for the health care worker. A panel of experts would examine the health care worker's infection control practices and discuss restriction of practice. The MDH would administer and act as a resource for the program. The panel would regularly report to MDH, the licensing boards, and the community while the health care worker complies with their recommendations. Failure to comply by the

health care worker would be reported to the appropriate licensing board for action.

MDH Staff Comment:

Both groups favor retaining the program in some fashion. The physicians' proposal is not possible under the current legislative mandate. However, by making the program more "user-friendly" and communicating with the primary care provider more about infection control issues, we may incorporate some aspect of their suggestions. Particularly, we will request more active participation of the health care worker's primary care provider to serve as an advocate for the health care worker. The infection control practitioners' request for individual case information is not possible without a health care worker's prior knowledge and consent due to data privacy laws.

C. Survey of Health Care Workers:

An open-ended survey was sent to 29 participants in the program to be returned anonymously. Four surveys were returned. Generally, the respondents felt that the program is invasive, too restrictive, and overly inclusive for health care workers who do not perform exposure-prone procedures. One respondent felt the program exists to appease the public given the small number of documented transmissions.

MDH Staff Comment:

The recommended changes in the program are designed to respond to concerns of health care workers and will make it less intrusive, invasive, and more "user-friendly."

D. Survey of the General Public:

Individuals from the community participating in an unrelated interview conducted by MDH staff were asked to respond to questions about the HIV and HBV Prevention Program. Questions about awareness and feelings about the program, the level of concern about health care worker HIV/HBV status, and the impact of the program, were asked of 109 participants. Most respondents (82%) were unaware of the program. Of those surveyed, 95% believe the program is a good idea. One-third worry about the HIV infection status of a health care worker, and the majority who have this worry believe that having the program helps with that concern.

MDH Staff Comment:

The program appears to increase public confidence in promoting a safe health care environment, and there appears to be general public support of this effort.

VIII. Recommendations and Rationale for Program Changes

Based on recommendations from the two focus groups, infected health care workers who returned surveys, and the review group, we will make changes to the way we evaluate, assess, and monitor infected licensed health care workers. We will continue the program but with substantial procedural changes. These changes are designed to dramatically streamline the process for most persons, be less intrusive to the worker, and still protect patients from infections with HIV or HBV. These changes have been reviewed and approved by the Attorney General's Office. The initial evaluation and follow-up monitoring will be tailored according to the likelihood that the health care worker performs invasive and exposure-prone procedures. The following is a description of the recommended components and actions of the MDH in refocusing the HIV and HBV Prevention Program.

Licensed health care workers reported to MDH will be evaluated based on an initial assessment of their scope of practice; each health care worker will be assigned to one of three categories outlined below. The health care worker may be moved to another category during the process if the initial assessment is not accurate or the scope of practice changes during the evaluation. The verification of employment and position responsibilities will be done with as little intrusion as possible. Prior to any contact of employers or others to verify employment or scope of practice, the health care worker will be asked to sign a waiver identifying the individual(s) to be contacted. In no case is (or will) the status of the health care worker be disclosed by MDH staff without the health care worker's prior knowledge and consent, unless explicitly authorized by law.

Category I. Health Care Workers not Performing Invasive or Exposure-Prone Procedures

Category I will involve minimal evaluation and at most an annual monitoring of the health care worker.

Licensed health care workers who are HIV/HBV-infected who do not perform invasive or exposure-prone procedures pose little or no risk of HIV/HBV transmission to patients; most nurses and many physicians will be included in this category. Health care workers who do not provide direct patient care as part of their responsibilities also pose little or no risk of transmission. For individuals in either of these situations, the MDH evaluation will include the following components:

Assessment Phase:

- Verify licensure status
- Verify HIV or HBV infection status
- Personal interview with the health care worker about his/her employment and practice responsibilities and the method(s) to verify that information

- Review the position description and/or other documentation of the health care worker's scope of practice
- Verify employment status and scope of practice

Monitoring Phase:

When MDH staff conclude that invasive or exposure-prone procedures are not part of the scope of practice of the health care worker, he/she is sent a **minimal** monitoring plan indicating that he/she is required to report to MDH any change in scope of practice that may involve exposure-prone procedures. If no report is forwarded to MDH, contact will be made with the health care worker at least annually to document that no change in practice has occurred.

Changes from Current Program:

The assessment phase will be considerably shortened and be less detailed than present. We will require fewer details and independent verification as to the scope of practice of the health care worker. The monitoring phase will also be dramatically limited. We will provide a "consumer-friendly" form for health care workers to use in annually reporting changes in their practice. The form will be attached to a reminder letter rather than as a non-compliance notification. In addition, we will not require health status updates as has been done in the past, since these are not relevant, given the scope of practice. We anticipate this will speed up the review process.

Category II. Health Care Workers Who Perform Invasive Procedures and May or May Not Perform Exposure-Prone Procedures

Category II will involve a moderate level of evaluation and monitoring of the health care worker.

The scope of practice of some health care workers may include invasive procedures and exposure-prone procedures; most surgeons, dentists, emergency room physicians, podiatrists, nurse-midwives, and surgical nurses will be included in this category. Some invasive procedures have the potential to be exposure-prone depending on the circumstances or techniques used. For individuals in these situations, the MDH evaluation will include the following components:

Assessment Phase:

- Verify licensure status
- Verify HIV or HBV infection status
- Review medical records related to risk of HIV/HBV transmission to patients (e.g., dermatologic problems, peripheral neuropathy or other neurological problems)
- Personal interview with the health care worker about their employment and practice responsibilities and the methods to verify that information

- Review the position description and/or other documentation of the health care worker's scope of practice
- Verify employment status and scope of practice
- Evaluate infection control practices in general and specific patient care procedures, if indicated by scope of practice

Monitoring Phase:

The outcomes of initial Category II evaluation are twofold: 1) the health care worker <u>does not</u> perform exposure-prone procedures or 2) the health care worker <u>does</u> perform exposure-prone procedures. Health care workers who <u>do not</u> perform exposure-prone procedures will remain in Category II; those who <u>do</u> will move to Category III. Those who remain in Category II will be sent a monitoring plan similar to Category I. As in Category I, the health care worker will be asked to report any change in scope of practice and to provide an update to MDH annually. The health care worker may also be requested to obtain and provide documentation to MDH of infection control training related to his/her scope of practice.

Changes from Current Program

The assessment phase will be shortened and less detailed than present. We will narrow the scope of the medical record review. The monitoring plan will be much shorter and more "user-friendly." When possible, we will enlist the attending physician to serve as an advocate/educator for infection control improvement in their patient who is the licensee. We will provide a "consumer-friendly" form for the licensee to use in reporting changes in their practice attached to a reminder letter rather than a non-compliance notification. We will not require health status updates as we have in the past. As in Category I, these are not relevant given the scope of practice.

Category III. Health Care Workers Who Perform Exposure-Prone Procedures

Category III will involve a more detailed level of evaluation and monitoring of the health care worker.

Some health care worker's scope of practice includes the performance of exposure-prone procedures. For health care workers who are performing such procedures at the time the MDH is contacted about their HIV/HBV infection status, the MDH evaluation will include the following components:

Assessment Phase:

- Verify licensure status
- Verify HIV or HBV infection status
- Review medical records related to risk of HIV/HBV transmission (e.g., dermatologic problems, and peripheral neuropathy or other neurological problems)

- Personal interview with the health care worker about his/her employment and practice responsibilities and the methods to verify that information
- Review the position description and/or other documentation of the health care worker's scope of practice
- Verify employment status and scope of practice
- Evaluate infection control practices in general and specific patient care procedures, if indicated by scope of practice
- Consult with content experts about information to be collected and assessed

Modifications to Scope of Practice:

Convene an expert review panel (ERP) to discuss infection control practices, skills, and training, the scope of practice of the health care worker, practice restrictions such as prohibitions to perform certain potentially high-risk procedures, modifications in performing other procedures, and other recommendations indicated by the scope of the health care worker's practice.

Monitoring Phase:

The health care worker is expected to provide the following information to MDH:

- Agreement to the recommendations of the ERP to no longer perform certain high-risk procedures, to perform some procedures with modifications, and to not begin performing other exposure-prone invasive procedures
- A plan with identified individuals responsible for managing a potential exposure situation (i.e., where blood from the health care worker may have contacted a patient)
- A report about the scope of practice and employment status from each place of employment or institution in which the health care worker practices at least annually or at the time of any change
- Documentation of infection control training recommended by the ERP
- A health status update from the health care worker's health care provider(s) at least annually or at the time of any change in health status related to transmission of HIV/HBV infection such as hand-eye coordination, deficits or reduction in dexterity, upper extremity peripheral neuropathy affecting tactile sensation, retinitis affecting visual acuity or depth of visual field, and skin infections on the hands or forearms that may increase the risk of HIV/HBV transmission

Changes from Current Program:

We will provide health care workers with a "consumer-friendly" form for them to use in reporting changes in practice. In addition, we will require less detailed medical information and will develop forms for their attending physician to use to highlight pertinent changes in their health status. When possible, we will enlist the attending physician to serve as an advocate/educator for infection control improvement in his or her patient who is the licensee.

General Program Changes:

Health care workers can initiate a request to the Commissioner to amend the monitoring plan and the Commissioner can also recommend amendments to the health care worker on the basis of new scientific or medical information related to HIV or HBV, or new information concerning the health care worker's health status or practice. Either the Commissioner or the health care worker may refer the matter to the licensing board if the Commissioner or health care worker refuses to incorporate the proposed amendments.

The MDH staff will be available to consult with licensing boards for health care workers who choose to be reviewed by their licensing boards or who are referred by MDH to their licensing board.

IX. Future Considerations

Two areas were briefly discussed by the focus groups and review group but have not been fully developed by the MDH. Both would require legislative change and thus may need to be addressed in the future. First, it may be reasonable to expand the scope of the program to include certain non-licensed health care workers who may perform exposure-prone procedures. For example, surgical technicians may perform such procedures but are not covered under the existing statute since they are non-licensed. At present, there are other methods that allow the MDH to review and evaluate such workers. However, changing the statute may clarify and simplify the mandate to do so.

Second, additional bloodborne pathogens may need to be considered in health care worker-to-patient transmission. In particular, hepatitis C virus (HCV) has been recently found to be an occupational hazard to health care workers. HCV causes chronic liver disease. There have been documented transmissions of HCV from infected health care workers to patients. The risk of transmission appears to be intermediate between HIV and HBV. Again, statutory change may clarify the legal mandate the MDH has with respect to HCV-infected health care workers.

X. Appendices

Minnesota Statute 214.17-214.25

HIV AND HBV PREVENTION PROGRAM

214.17 HIV AND HBV PREVENTION PROGRAM; PURPOSE AND SCOPE.

Sections 214.17 to 214.25 are intended to promote the health and safety of patients and regulated persons by reducing the risk of infection in the provision of health care.

History: 1992 c 559 art 1 s 9

214.18 DEFINITIONS.

Subdivision 1. Board. "Board" means the boards of dentistry, medical practice, nursing, and podiatric medicine. For purposes of sections 214.19, subdivisions 4 and 5; 214.20, paragraph (1); and 214.24, board also includes the board of chiropractic examiners.

- Subd. 2. Commissioner. "Commissioner" means the commissioner of health.
- Subd. 3. HBV. "HBV" means the hepatitis B virus with the e antigen present in the most recent blood test.
 - Subd. 4. HIV. "HIV" means the human immunodeficiency virus.
- Subd. 5. Regulated person. "Regulated person" means a licensed dental hygienist, dentist, physician, nurse, podiatrist, a registered dental assistant, a physician's assistant, and for purposes of sections 214.19, subdivisions 4 and 5; 214.20, paragraph (a); and 214.24, a chiropractor.

History: 1992 c 559 art 1 s 10

214.19 REPORTING OBLIGATIONS.

Subdivision 1. Permission to report. A person with actual knowledge that a regulated person has been diagnosed as infected with HIV or HBV may file a report with the commissioner.

- Subd. 2. Self-reporting. A regulated person who is diagnosed as infected with HIV or HBV shall report that information to the commissioner promptly, and as soon as medically necessary for disease control purposes but no more than 30 days after learning of the diagnosis or 30 days after becoming licensed or registered by the state.
- Subd. 3. Mandatory reporting. A person or institution required to report HIV or HBV status to the commissioner under Minnesota Rules, parts 4605.7030, subparts 1 to 4 and 6, and 4605.7040, shall, at the same time, notify the commissioner if the person or institution knows that the reported person is a regulated person.
- Subd. 4. Infection control reporting. A regulated person shall, within ten days, report to the appropriate board personal knowledge of a serious failure or a pattern of failure by another regulated person to comply with accepted and prevailing infection control procedures related to the prevention of HIV and HBV transmission. In lieu of reporting to the board, the regulated person may make the report to a designated official of the hospital, nursing home, clinic, or other institution or agency where the failure to comply with accepted and prevailing infection control procedures occurred. The designated official shall report to the appropriate board within 30 days of receiving a report under this subdivision. The report shall include specific information about the response by the institution or agency to the report. A regulated person shall not be discharged or discriminated against for filing a complaint in good faith under this subdivision.
- Subd. 5. Immunity. A person is immune from civil liability or criminal prosecution for submitting a report in good faith to the commissioner or to a board under this section.

History: 1992 c 559 art 1 s 11

214.20 GROUNDS FOR DISCIPLINARY OR RESTRICTIVE ACTION.

. A board may refuse to grant a license or registration or may impose disciplinary or restrictive action against a regulated person who:

- (1) fails to follow accepted and prevailing infection control procedures, including a failure to conform to current recommendations of the Centers for Disease Control for preventing the transmission of HIV and HBV, or fails to comply with infection control rules promulgated by the board. Injury to a patient need not be established;
 - (2) fails to comply with any requirement of sections 214.17 to 214.24; or
 - (3) fails to comply with any monitoring or reporting requirement.

History: 1992 c 559 art 1 s 12

214.21 TEMPORARY SUSPENSION.

The board may, without hearing, temporarily suspend the right to practice of a regulated person if the board finds that the regulated person has refused to submit to or comply with monitoring under section 214.23. The suspension shall take effect upon written notice to the regulated person specifying the statute or rule violated. The suspension shall remain in effect until the board issues a final order based on a stipulation or after a hearing. At the time the board issues the suspension notice, the board shall schedule a disciplinary hearing to be held under chapter 14. The regulated person shall be provided with at least 20 days' notice of a hearing held under this section. The hearing shall be scheduled to begin no later than 30 days after the issuance of the suspension order.

History: 1992 c 559 art 1 s 13

214.22 NOTICE; ACTION.

If the board has reasonable grounds to believe a regulated person infected with HIV or HBV has done or omitted doing any act that would be grounds for disciplinary action under section 214.20, the board may take action after giving notice three business days before the action, or a lesser time if deemed necessary by the board. The board may:

- (1) temporarily suspend the regulated person's right to practice under section 214.21;
- (2) require the regulated person to appear personally at a conference with representatives of the board and to provide information relating to the regulated person's health or professional practice; and
- (3) take any other lesser action deemed necessary by the board for the protection of the public.

History: 1992 c 559 art 1 s 14

214.23 MONITORING.

Subdivision 1. Commissioner of health. The board shall enter into a contract with the commissioner to perform the functions in subdivisions 2 and 3. The contract shall provide that:

(1) unless requested to do otherwise by a regulated person, a board shall refer all regulated persons infected with HIV or HBV to the commissioner;

- (2) the commissioner may choose to refer any regulated person who is infected with HIV or HBV as well as all information related thereto to the person's board at any time for any reason, including but not limited to: the degree of cooperation and compliance by the regulated person; the inability to secure information or the medical records of the regulated person; or when the facts may present other possible violations of the regulated persons practices act. Upon request of the regulated person who is infected with HIV or HBV the commissioner shall refer the regulated person and all information related thereto to the person's board. Once the commissioner has referred a regulated person to a board, the board may not thereafter submit it to the commissioner to establish a monitoring plan unless the commissioner of health consents in writing;
- (3) a board shall not take action on grounds relating solely to the HIV or HBV status of a regulated person until after referral by the commissioner; and
- (4) notwithstanding sections 13.39 and 13.41 and chapters 147, 148, 150A, 153, and 214, a board shall forward to the commissioner any information on a regulated person who is infected with HIV or HBV that the department of health requests.
- Subd. 2. Monitoring plan. After receiving a report that a regulated person is infected with HIV or HBV, the board or the commissioner acting on behalf of the board shall evaluate the past and current professional practice of the regulated person to determine whether there has been a violation under section 214.20. After evaluation of the regulated person's past and current professional practice, the board or the commissioner, acting on behalf of the board, shall establish a monitoring plan for the regulated person. The monitoring plan may:
- (1) address the scope of a regulated person's professional practice when the board or the commissioner, acting on behalf of the board, determines that the practice constitutes an identifiable risk of transmission of HIV or HBV from the regulated person to the patient;
- (2) include the submission of regular reports at a frequency determined by the board or the commissioner, acting on behalf of the board, regarding the regulated person's health status; and
- (3) include any other provisions deemed reasonable by the board or the commissioner of health, acting on behalf of the board.

The board or commissioner, acting on behalf of the board, may enter into agreements with qualified persons to perform monitoring on its behalf. The regulated person shall comply with any monitoring plan established under this subdivision.

Subd. 3. Expert review panel. The board or the commissioner acting on behalf of the board may appoint an expert review panel to assist in the performance of the responsibilities under this section. In consultations with the expert review panel, the commissioner or board shall, to the extent possible, protect the identity of the regulated person. When an expert review panel is appointed, it must contain at least one member appointed by the commissioner and one professional member appointed by the board. The panel shall provide expert assistance to the board, or to the commissioner acting on behalf of the board, in the subjects of infectious diseases, epidemiology, practice techniques used by regulated persons, and other subjects determined by the board or by the commissioner acting on behalf of the board. Members of the expert review panel are subject to those provisions of chapter 13 that restrict the commissioner or the board under Laws 1992, chapter 559, article 1.

Subd. 4. Immunity. Members of the board or the commissioner acting on behalf of the board, and persons who participate on an expert review panel or who assist the board or the commissioner in monitoring the practice of a regulated person, are immune from civil liability or criminal prosecution for any actions, transactions, or publications made in good faith and in execution of, or relating to, their duties under sections 214.17 to 214.24, except that no immunity shall be available for persons who have knowingly violated any provision of chapter 13.

History: 1992 c 559 art 1 s 15

214.24 INSPECTION OF PRACTICE.

Subdivision 1. Authority. The board is authorized to conduct inspections of the clinical practice of a regulated person to determine whether the regulated person is following accepted and prevailing infection control procedures. The board shall provide at least three business days' notice to the clinical practice prior to the inspection. The clinical practice of a regulated person includes any location where the regulated person practices that is not an institution licensed and subject to inspection by the commissioner of health. During the course of inspections the privacy and confidentiality of patients and regulated persons shall be maintained. The board may require on license renewal forms that regulated persons inform the board of all locations where they practice.

- Subd. 2. Access; records. An inspector from the board shall have access, during reasonable business hours for purposes of inspection, to all areas of the practice setting where patient care is rendered or drugs or instruments are held that come into contact with a patient. An inspector is authorized to interview employees and regulated persons in the performance of an inspection, to observe infection control procedures, test equipment used to sterilize instruments, and to review and copy all relevant records, excluding patient health records. In performing these responsibilities, inspectors shall make reasonable efforts to respect and preserve patient privacy and the privacy of the regulated person. Boards are authorized to conduct joint inspections and to share information obtained under this section. The boards shall contract with the commissioner to perform the duties under this subdivision.
- Subd. 3. Board action. If accepted and prevailing infection control techniques are not being followed, the board may educate the regulated person or take other actions. The board and the inspector shall maintain patient confidentiality in any action resulting from the inspection.
- Subd. 4. Rulemaking. A board is authorized to adopt rules setting standards for infection control procedures. Boards shall engage in joint rulemaking. Boards must seek and consider the advice of the commissioner of health before adopting rules. No inspections shall be conducted under this section until after infection control rules have been adopted. Each board is authorized to provide educational information and training to regulated persons regarding infection control. All regulated persons who are employers shall make infection control rules available to employees who engage in functions related to infection control.

History: 1992 c 559 art 1 s 16

214.25 DATA PRIVACY.

Subdivision 1. Board data. (a) All data collected or maintained as part of the board's duties under sections 214.19, 214.23, and 214.24 shall be classified as investigative data under section 13.39 except that inactive investigative data shall be classified as private data under section 13.02, subdivision 12, or nonpublic data under section 13.02, subdivision 9, in the case of data not on individuals.

- (b) Notwithstanding section 13.05, subdivision 9, data addressed in this subdivision shall not be disclosed except as provided in this subdivision or section 13.04; except that the board may disclose to the commissioner under section 214.23.
- Subd. 2. Commissioner of health data. (a) All data collected or maintained as part of the commissioner of health's duties under sections 214.19, 214.23, and 214.24 shall be classified as investigative data under section 13.39, except that inactive investigative data shall be classified as private data under section 13.02, subdivision 12, or nonpublic data under section 13.02, subdivision 9, in the case of data not on individuals.
- (b) Notwithstanding section 13.05, subdivision 9, data addressed in this subdivision shall not be disclosed except as provided in this subdivision or section 13.04; except that the commissioner may disclose to the boards under section 214.23.
- (c) The commissioner may disclose data addressed under this subdivision as necessary: to identify, establish, implement, and enforce a monitoring plan; to investigate a regulated person; to alert persons who may be threatened by illness as evidenced by epidemiologic data; to control or prevent the spread of HIV or HBV disease; or to diminish an imminent threat to the public health.

History: 1992 c 559 art 1 s 17

Results of Surveys of Other State Licensing Boards

1) Does your state board have a procedure for reviewing and evaluating the clinical practice of an HIV-infected practitioner? (If no, go to question 3.)

Dentistry: Yes - 7 No - 32 Missing - 0
Podiatry: Yes - 3 No - 25 Missing - 1
Nursing: Yes - 5 No - 29 Missing - 1

Medical Pract: Yes - 6 No - 2 Missing - 1

2) Once an HIV-infected practitioner has been evaluated, does your state board have a procedure for monitoring or following the HIV-infected person?

Dentistry: Yes - 6 No - 1 Missing - 0 Yes - 3 No - 0 Podiatry: Missing - 0 Yes - 4 No - 0 Nursing: Missing - 0 Unk - 1 Medical Pract: Yes - 6 No - 0Missing - 3

3) Does your board have a procedure for reviewing and evaluating the clinical practice of a hepatitis B virus HBV-infected practitioner? (If no, go to question 5.)

Dentistry: Yes - 7 No - 32 Missing - 0

Podiatry: Yes - 3 No - 25 Missing - 1

Nursing: Yes - 5 No - 28 Missing - 2

Medical Pract: Yes - 4 No - 4 Missing - 1

4) Once an HBV-infected practitioner has been evaluated, does your board have a procedure for monitoring or following the HBV-infected person?

Dentistry: Yes - 7

Podiatry: Yes - 3

Nursing: Yes - 4 Unk - 1

Medical Pract: Yes - 4

5) If no, does any other regulatory agency evaluate and/or monitor these practitioners?

Dentistry:

Yes - 18 No - 17 Missing - 4

Podiatry:

Yes - 6 No - 16

Missing - 6

Unk - 1

Nursing:

Yes - 9

No - 10 Missing - 10

Unk - 6

Medical Pract:

Yes - 3

No - 4

Missing - 2

. 0 01111

a) Which agency?

Dentistry:

Health dept - 16

Missing - 2

Podiatry:

Health dept - 6

Nursing:

Health dept - 8

Employer - 1

Medical Pract:

Health dept - 3

b) Is the board involved at all?

Dentistry:

Yes - 9

Podiatry:

Yes - 4

Missing - 1

Nursing:

Yes - 4

No - 2

No - 1

Missing - 2

Medical Pract: Yes - 3

c) In what capacity?

Dentistry: Compliance issues, violations, monitoring, advisory

Podiatry: Advisory, compliance issues, violations, may monitor

Nursing: Compliance issues, monitoring, advisory, violations

Medical Pract: Advisory, compliance issues, violations, monitoring

6) Does your board require continuing education in infection control for practitioners as a pre-requisite for continuing or renewal of authority to practice?

Dentistry:

Yes - 10 No - 26 Missing - 3

Podiatry:

Yes - 5 No - 23 Missing - 1

Nursing: Yes - 3 No - 28 Missing - 4

Medical Pract: Yes - 1 No - 7 Missing - 1

7) Does your board require continuing education in infection control for only HIV/HBV-infected practitioners as a pre-requisite for relicensure?

Dentistry: Yes - 1 No - 36 Missing - 2

Podiatry: Yes - 28 No - 0 Missing - 1

Nursing: Yes - 0 No - 29 Missing - 6

Medical Pract: Yes - 7 No - 1 Missing - 1

Focus Group Report to Evaluate the HIV/HBV Prevention Program

Focus Group Report to Evaluate the HIV/HBV Health Care Worker Program

October, 1997

Focus Group Facilitator and Author of Report:

Terry Lauer, MA Consultant

Executive Summary

During the 1997 legislative session, the legislature mandated an evaluation of the infected Health Care Worker program, which began in 1992. The Minnesota Department of Health (MDH) used the following to complete this evaluation:

- written surveys of the Health Care Workers (HCW) who have participated in the program;
- written surveys to health departments and the various boards, including: medical practice, nursing, dentistry, and podiatry, from all of the states discussing their programs;
- phone interviews with a convenience population in the state;
- physicians focus group;
- infection control practitioner focus group; and
- an advisory group to evaluate the information and make final recommendations on the program.

This report discusses the focus group portion of the evaluation. The following themes and recommendations emerged from the focus groups and they are highlighted in this summary.

Fears of HIV/HBV in Health Care Workers and Changes in the Past Five Years

Over the past five years, there has been a marked shift from hysteria to a more educated public. The public shows concern about HIV/HBV transmission, but seems to be more educated about the risks of HIV/HBV transmission.

Experiences and Concerns with the Program

The experiences relayed from patients of the focus groups contained both positive and negative experiences. Many of the negative experiences occurred when the program was first initiated, and the positive experiences with the program occurred more recently.

Role of the Program in Preventing the Transmission of HIV/HBV from Health Care Workers to Patients

The consensus of both groups was that the program heightened awareness, but it probably did not play much of a role in the prevention of transmission. In fact, there does not seem to be a means to measure how this program prevents transmission. A need for more data is evident.

Maintaining Public Confidence in the Safety of Health Care Provider Setting

Both groups acknowledged a need for maintaining public confidence in the health care setting and that this program is perceived as the protection in which the public can place their trust. Based on the feedback from the focus groups, the belief of the public is that the program's existence is the reassurance needed.

Recommendations

Given the above themes, the consensus of both groups was that the program was necessary for consistency of practice, and the reassurance of the public. Both groups agreed that more flexibility was needed in order for the program to be more consistent with the experience gained in the five years since the program began. However, the groups differed in how they would like the program modified, so this will be discussed separately.

Physicians Group Recommendations

The physicians group recommended a new model for the program. In the substance abuse arena, the model used is the physicians serving physicians model. This model is well respected and seen as more user friendly, educational, and helpful, rather than simply regulatory. This model could be modified to suit this situation, in that the peer system could be the entry point into the system. The HCW would connect with a peer from the same field of practice. This peer would spend time educating and acting as an advocate for the infected HCW.

Structured as a pyramid, the next step would be a committee of experts to look at the practice of the HCW to educate the individual on infection control practices and discuss restriction of practice. The experts could be paid stipends for their time when the group is convened. The MDH would become an administrator of the program, acting as a resource. The expert panel would report in aggregate to the MDH, Boards, and the community on a regular basis, maintaining the confidentiality of the infected HCW, while the HCW complies with their recommendations. If a HCW fails to comply with the recommendations set forth by this panel, then the HCW would be reported to the Board of Practice for enforcement issues.

Infection Control Practitioners Group Recommendations

The infection control practitioners group had several recommendations. First, the program needs to share information between the MDH and the medical facility where the HCW practices. Second, expanding the scope of practice to include non-licensed HCWs is needed. Third, make sure that the information, decisions, and recommendations that come from the MDH are timely. Fourth, there is a need for ongoing reporting to medical facilities of the number of HCWs who are HIV/HBV infected, including their field of practice. Last, additional education to all HCWs and the community in reference to the legislation, the roles of the medical providers and the MDH, how the program is working, and the statistics is needed on an annual basis.

Focus Group Report to Evaluate the HIV/HBV Health Care Worker Program

Statement of Need

In 1992, the Minnesota Department of Health was mandated by the state legislature to create the HIV/HBV Health Care Worker Program. The intention of the program was to promote the health and safety of patients and regulated persons by reducing the risk of infection in the provision of health care. In 1997, the state legislature gave the following mandate to evaluate the effectiveness of this program:

The commissioner of health shall evaluate the effectiveness of the HIV and HBV prevention program established under Minnesota Statutes, sections 214.17 to 213.25. The commissioner shall evaluate the effectiveness of the program in maintaining public confidence in the safety of health care provider settings, educating the public about HIV infection risk in such settings, prevention of HIV and HBV infections, and fairly and efficiently working with affected health care providers. The results in Minnesota shall be compared to similar efforts in other states. The commissioner shall present recommendations to the legislature by January 15, 1998, on whether the program should be continued, and whether modifications to the program are necessary if a recommendation is made to continue the program.

The evaluation includes the following:

- written surveys of the Health Care Workers (HCW) who have participated in the program;
- written surveys to health departments and the various boards, including: medical practice, nursing, dentistry, and podiatry, from all of the states discussing their programs;
- phone interviews with a convenience population in the state;
- physicians focus group;
- infection control practitioner focus group; and
- an advisory group to evaluate the information and make final recommendations on the program.

This report discusses the focus group portion of the evaluation. The remaining portions of the evaluation will be covered in the full report.

Two focus groups were held during the month of October, 1997. One focus group included infection control practitioners, and the other included physicians from various medical facilities in the state. The participants were selected based on their experience in working with this program some time in the past five years. Four people attended the infection control practitioner group, and six people attended the physicians group.

Results

The following themes and recommendations emerged from the focus groups.

Fears of HIV/HBV in Health Care Workers and Changes in the Past Five Years

In both of the groups, they discussed that in 1992, when the program first began, there seemed to be a lot of public hysteria about the possible risk of health care worker transmission. Over the past five years, there has been a marked shift from hysteria to a more educated public. The public shows concern, but seems to be more educated about the risks of HIV/HBV transmission.

Some of the patients are now saying, "What is my risk of exposure?" They don't just automatically take the incident as a HCW exposure, but they want to know...they want to have reassurance...that they were not exposed to the HCW's blood. So, the public is certainly much more informed about the mode of transmission, and that there could be a potential for their exposure as well. -- infection control practitioner

There has been a big change since the early 1990's. Part of what has helped is that there are literally no cases of transmission in the news. There has been some assimilation by the public, as far as what messages have been repetitively put across on media and physician/patient interactions. I think over a period of time, with the positive reinforcment that nobody's being endangered by health care workers, that that is what is keeping things on an even keel. -- physician

Experiences and Concerns with the Program

The experiences relayed from patients of both focus groups contained both positive and negative experiences. One physician stated that several people, who have been involved in the program, were fairly and objectively treated. Possibly, because of this treatment, they were more likely to be interested in doing the right thing, but also doing what they were supposed to do (which were one in the same), the physician stated. One physician told of an opposite experience. A patient felt that he was under a microscope, scrutinized inappropriately, and when the yearly letter from the physician did not arrive at the MDH, he received threatening letters. These experiences contrasted one another, with the latter happening early on in the program, and the former, more recently.

The legal aspect of the program is very intimidating to the infected HCW, according to the physicians group. "The most intimidating factor is that the attorney general's office will be there." Because the first step of the process is the legal component, rather than something that happens if the HCW does not comply with the regulations set forth, the program is intimidating to everyone involved. It seems like a huge amount of regulation for a relatively small issue, with only 80

licensed HCWs in five years infected, with no likelihood of transmission, according to the physicians present.

According to the infection control practitioner group, although the program offers a body of expertise from the MDH and confidentiality is maintained in all cases, it has been somewhat frustrating for medical facilities to access. As much of the information collected in this program by the MDH is classified as private, the medical facilities cannot access this information without consent of the HCW. This was not always relayed to the medical personnel requesting information. So, in some cases, the reason the MDH staff did not answer specific questions was misconstrued that "they (are) just so unwilling to cooperate," instead of respecting the confidentiality of the HCW. In summary, although the HCW may be restricted from some privileges because of his/her infectious disease status, the facility where he/she is practicing does not have access to those restrictions placed on the HCW by this program. According to the infection control practitioners present, this is frustrating to the medical facilities where a HCW practices.

Medical personnel charged with infection control feel that there is duplication of roles within the medical facility and the MDH. Although the medical facility has ultimate authority to investigate, and monitor infection control, the MDH must follow the legislation, conduct an investigation, and, in some cases, restrict privileges of the HCW. From an infection control practitioner's perspective, this is a duplication of roles. The program needs more clarity of these roles to avoid duplication and create a better understanding of how the two are linked.

From the infection control practitioner's perspective, another concern with the program is that it is only for licensed HCWs. Non-licensed HCWs who do invasive procedures are not part of this program, and they do not require an investigation by the MDH. As non-licensed HCWs can put people at risk, the legislation needs to be expanded to include them.

Role of the Program in Preventing the Transmission of HIV/HBV from Health Care Workers to Patients

The consensus of both groups was that the program did heighten awareness, but it probably did not play much of a role in the prevention of transmission. In fact, there does not seem to be a means to measure how this program prevents transmission. A need for more data is evident due to this dearth of information.

Maintaining Public Confidence in the Safety of Health Care Provider Setting

Both groups acknowledged a need for maintaining public confidence in the health care setting and that this program is perceived as the protection in which they can place their trust. Both groups agreed that the public needs to know that there is a vehicle to place their trust in. By having this program in place ensures that there are no anticipated transmissions. The belief in the public is that the program's existence is the reassurance needed.

Recommendations

Given the above, the consensus of both groups was that the program was necessary for consistency of practice, and the reassurance in the public. Both groups agreed that more flexibility was needed in order for the program to be more consistent with the experience gained in the five years since the program began. However, the groups differed in how they would like the program modified, so this will be discussed separately.

Physicians Group Recommendations

The physicians group recommended a new model for the program. In the substance abuse arena, the model used is the physicians serving physicians model. This model is well respected and seen as more user friendly, educational, and helpful, rather than simply regulatory. This model could be modified to suit this situation, in that the peer system could be the entry point into the system. The HCW would connect with a peer from the same field of practice. This peer would spend time educating and acting as an advocate for the infected HCW.

Structured as a pyramid, the next step would be a committee of experts to look at the practice of the HCW to educate the individual on infection control practices and discuss restriction of practice. The experts could be paid stipends for their time when the group is convened. The MDH would become an administrator of the program, acting as a resource. The expert panel would report in aggregate to the MDH, Boards, and the community on a regular basis, maintaining the confidentiality of the infected HCW, while the HCW complies with their recommendations. If a HCW fails to comply with the recommendations set forth by this panel, then the HCW would be reported to the Board of Practice for enforcement issues.

These ideas need to be expanded, but the bottom line is that a more user friendly and flexible program is needed. As most of us know, changes in the science of HIV are quick and often dramatic. As stated above, more data is needed to see if this program does indeed prevent transmission, and a recommendation for research was made. With Hepititis C on the horizon, flexible thinking, and a foundation for quick response is critical. Also, the law, as written, needs to have the foresight to be able to respond quickly to the current science. Politically, these changes should be eased into over the next couple of years.

Infection Control Practitioners Group Recommendations

The infection control practitioners group had several recommendations. First, the program needs to share information between the MDH and the medical facility where the HCW practices. As the program has been disjointed, by coming together to create a consistent set of clearly defined roles for the medical facilities and the MDH, there would be less confusion. In addition, confidentiality needs to be maintained; however, relevant information needs to be shared with those in the medical facilities that are charged with infection control. Whether consent is given by the HCW,

or some other means is employed to transfer this information to the most appropriate people, this shared information is necessary for the success of this program.

Second, expanding the scope of practice to include non-licensed HCWs is needed. The legislation only allowed for licensed HCW to become part of this program. As non-licensed HCW do invasive procedures, the infection control practitioners group thought it important that this group become part of the program. Third, make sure that the information, decisions, and recommendations that come from the MDH are timely. Medical facilities need this information quickly, and, at times, the MDH did not respond promptly.

Fourth, there is a need for ongoing reporting to medical facilities of the number of HCWs who are HIV/HBV infected, including their field of practice. Medical facilities would like this information on an annual basis for general information and to help alleviate fears. Last, additional education to HCWs and the community in reference to the legislation, the roles of the medical providers and the MDH, how the program is working, and the statistics is needed. Although the HCWs are somewhat knowledgeable about the program, the community and HCWs need to have updated information about these issues.

Limitations

The focus groups were sparsely attended in both instances. However, those that attended were well versed in the existing program, and had had numerous experiences working with patients who had participated in the program. Therefore, the feedback gained by these groups was tremendously insightful and thoughtful. The suggestions offered to modify the existing program were based on years of working with patients in this program.

Summary

In summary, based on the feedback from the focus group participants, the program needs to be continued, but modified to afford more flexibility within it. In the case of the physician's group, they recommended less regulation and a move to a peer controlled program, with the MDH playing an administrative role. The infection control practitioners group desired more of an exchange of information among the different parties involved, and an expansion of the legislation to include non-licensed health care workers.

Focus Group Questions

1.	What have your patients said to you about fears of HIV/HBV in health care workers, and how have citizen concerns changed over time (1987 compared to today)?
2.	What have been your experiences and concerns with the Minnesota Program?
3.	<u>Infection control practitioners</u> : How would it affect your practice if this program were eliminated?
	Physicians: In some states without such a program, the only review of a health care worker with HIV infection would be done by the person's physician. Thus you would be responsible for their practice, their infection control, and ultimately the safety of their patients. How would this work for you?

	a.	1992 alternative, mandatory testing with potential practice review or mandatory practice exclusion (suspension).
·		Pros: Cons:
	b.	The current program as is.
	·	Pros: Cons:
	c.	Modify the program.
		List recommendations for change:
		Pros: Cons:
	d.	Eliminate program.
		Pros Cons:
5.	What HIV/	is your opinion regarding the role of this program in preventing the transmission of HBV from health care workers to patients?
6.	What in he	t is your opinion regarding the role of this program in maintaining public confidence alth care workers?

Review Options:

4.

Participants in the Focus Groups:

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Comments From the Review Group Members About the Program
Taken from Minutes of Review Group Meetings
Fall/Winter 1997

Individual Comments:

- 1) I am surprised the legislature didn't ask for an analysis of the costs of the program (cost to the board, MDH, practitioner). This is a cost of doing business and while it's fee based, the costs eventually go back to the public through increased health care costs. If the program continues, it should be through the general fund.
- 2) The program should reflect who does exposure-prone procedures and should include surgical technicians.
- 3) The public should be educated about the program so there is less confusion.
- 4) We need to include information about the infection control rules and how they protect the public. That should be included in any report of how the public is protected.
- 5) The program provides some oversight of HIV/HBV infected health care workers so they do not engage in procedures that place people at risk. HIV and HBV are treated the same, yet HBV has a more significant risk. If a provider monitors themself, protecting the public's health is not addressed.
- 6) What is the risk threshold? Can we use information from research on when the person is likely to be stuck (bony fragments exposed) and concentrate on that?
- 7) MDH didn't develop rules and based the program on the statute which can be interpreted in many ways.
- 8) If Minnesota had adopted CDC guidelines as other states have done, could we respond effectively?
- 9) The law provides legal protections and clarifies authority. Also, the statute provides for enforcement, which currently isn't there or isn't clear.
- If we continue to have a monitoring program how do we respond to the issues of controversy that the investigation process jeopardizes the health care worker's privacy and their jobs and is overly burdensome? Can we streamline that process to respond to that controversy? For instance, can the investigation and monitoring plan be different if the person doesn't engage in any exposure-prone procedures? (In response to this comment, MDH staff discussed that if the MDH/Board assumes the risk, they need some freedom in verifying information. In this program, the MDH has had more than one experience of being given incorrect information by the health care worker and the Board of Nursing commented they have received incorrect information in other investigations.)

- 11) The Board of Nursing completes the cases the MDH doesn't want (the health care worker is being investigated for another reason, the person is not being responsive, or is not being cooperative). Because it's being handled by the regulatory agency who has power over the health care worker's practice, they have not had significant problems.
- The monitoring plan is very legalistic and is hard to be user friendly with all the legal components. (In response to this comment, MDH staff explained that the monitoring plan contains approximately three pages of boiler-plate language that is given to all participants. Each monitoring plan contains a section that applies only to that health care worker.)
- 13) We need to focus on risk and the health care workers who perform risky procedures. They need more intensive investigation and monitoring plan but one size doesn't fit all. It's hard to distinguish a mini-monitoring plan for non-invasive from the plan being used for the health care workers who do risky procedures.
- 14) One health care worker said they were reviewed by the licensing board and the review panel used by the board wasn't knowledgeable about HIV and the health care worker was concerned about a monitoring plan developed by a review panel who wasn't up to date on the issues.
- 15) The scope of the medical review should be limited (really focus on HIV-related transmission).
- 16) People face suspension of their license if they grieve this and they really have no recourse if they disagree with the monitoring plan either in process or at the final stage.
- 17) What is the public health benefit of monitoring people who do not do invasive procedures?
 - Create public confidence in the health system (is this a public health benefit?)
 - Monitor cognitive status. (This isn't done for other conditions that have equal or greater cognitive implications such as MS or diabetes.)
- 18) One of the outcomes of the program is that health care workers with HIV/HBV have been able to continue to work in Minnesota.

Although the blood supply is not completely safe, most people say they've done everything they could do to make it safe. This program is similar to 'doing everything we reasonably can.'

How do we sort out nonexposure-prone procedures with a small risk from exposure-prone procedures? How do we respond to or prevent public fear of transmission?

- 19) MDH should more easily distinguish exposure-prone; focus on infections/risk/cognitive risk.
- 20) One Review Group member expressed these points:
 - The primary reason to not have such a program remains the absence of evidence regarding transmission risk. Of the nearly 600,000 cases of AIDS reported in the U.S., six (one site) are linked to a health care worker. Only one additional case (in France) has been demonstrated to have occurred through a breach of latex or other protective means. (Note: see III. Risk of HIV/HBV Transmission from Infected Health Care Workers to Patients. The actual event causing transmission is unknown.) We have in place an expensive program which at its heart works to artificially assure the public that there is no, or little, risk of HIV transmission in the health care setting. In fact, such is the case without such a program.
 - The impracticality of monitoring a health care worker's career for 25-30 years—a possibility given the new treatments for HIV and the length of time a worker may remain gainfully employed post-HIV seroconversion.
 - Such a program continues to stigmatize those health care workers living with HIV. There are no guarantees of confidentiality protections and once confidentiality has been broken, such a breach may well result in difficulty for this worker to ever again find gainful or satisfactory employment—especially with any career ladder piece attached. The Appellate Court is currently split on their ruling whether or not HIV (absent a diagnosis of AIDS) is covered by the Americans With Disabilities Act—therefore an HIV positive worker who felt discriminated against has no legal recourse to discriminatory acts.
 - While the risk of transmission from a worker to a patient is infinitesimally low, it is indeed a bit higher the reverse way-from a patient to a worker. For the health care profession to know that seroconversion may not only dramatically affect their life, but may well ruin their career, could for some workers serve as a disincentive to treat those living with HIV out of fear of seroconversion.
 - Having such a program continues to misinform the public, or at the least lead them away from understanding the true risk of HIV infection. Such a program reinforces the belief that HIV is a virus which is easy to "catch" and indeed can occur in a setting as safe as your doctor's office.
 - Finally, such a program creates for the public an impression that the public health officials can create a perfect world where HIV risk never occurs. They can't. I worry that if indeed a transmission did occur, it would come from an unregulated worker or someone who didn't even know their HIV status and the public outcry would be enormous about the failure of this program.



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