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MEMORANDUM July 27, 1992

TO: Members of the National Commission on AIDS

FROM: Thomas Brandt
Acting Executive Director

SUBJECT: 1) Commission's Report Entitled "Preventing HIV Transmission in Health Care Settings"

2) Letter of Support for the Principles and Objectives of the "Comprehensive Services for Youth Act of 1992"

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1) Please find enclosed a photocopied version of the Commission's latest report, "Preventing HIV Transmission in Health Care Settings," which is enroute to the printer. (Please disregard the several places in your copy that have printer's instructions).

We have an initial public release of the document tenatively planned for Thursday, July 30, followed by a larger mailing about August 6 when the professionally printed copies will be available. The July 30 release will primarily involve distribution of photocopies to principal AIDS journalists, state health officials, professional associations and a short list of experts who were either involved in the preparation of the report, or who would have strong interest in its content.

The National AIDS Information Clearinghouse will also be provided bulk copies by us to meet requests from the general public. However we are having only 4,000 copies of the report printed in order to contain printing and mailing costs. We can consider a second printing after the beginning of the new fiscal year. Also we are facilitating arrangements with the General Services Administration print shop so that groups wanting substantial numbers of copies can buy them directly.

2) Please find enclosed a copy of the letter from the Commission expressing support for the principles and objectives of the "Comprehensive Services for Youth Act of 1992." The committee, which is chaired by Senator Kennedy, was to have had the first hearing on the legislation July 28.

JULY 1992

Preventing HIV Transmission in Health Care Settings

National Commission on AIDS

WASHINGTON, DC ● UNITED STATES OF AMERICA

The National Commission on Acquired Immune Deficiency Syndrome (AIDS) was established by Public Law 100-607 "for the purpose of promoting the development of a national consensus on policy concerning AIDS and of studying and making recommendations for a consistent national policy" concerning the HIV epidemic. The Commission is a bipartisan body whose members were appointed by the President, the United States Senate, and the United States House of Representatives.

Additional copies of this report are available from the National Commission on AIDS, 1730 K Street, N.W., Suite 815, Washington, D.C. 20006, Tel. (202) 254-5125, TDD (202) 254-3816.

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Editor for *Preventing HIV Transmission in Health Care Settings*
Frances Porcher

PREFACE

The summer of 1991 marked the end of the first decade of acquired immune deficiency syndrome (AIDS) in the United States. It was also a time of great anxiety about the risk of transmitting human immunodeficiency virus (HIV) in the health care setting–so much so that a glance at the news headlines about AIDS might have left one with the mistaken impression that HIV disease is an illness largely visited upon dentists, surgeons, or their patients.

Although of serious concern, only a minute fraction of AIDS cases in the United States are linked to HIV transmission within the health care setting. The overwhelming risk of HIV infection in the United States remains in the modes of transmission already clearly established–unprotected sexual intercourse and the sharing of contaminated needles and syringes. The current, widespread application of sterile techniques has made the transmission of HIV in the health care setting extremely unlikely. Nevertheless, concerns about HIV transmission in the health care setting became the subject of intense scrutiny by the Centers for Disease Control, Congressional committees, and state health departments, as well as print and electronic media.

Enduring public anxiety concerning HIV transmission in the health care setting has prompted an array of policy responses. Although policy-makers share the same goal–protecting all patients and health care providers from harm while ensuring the continued delivery of quality health care–they have proposed widely divergent means of achieving that goal. Some proposed policy responses may result in diminishing, rather than enhancing, public safety and access to quality care. There remains a serious danger that policy-makers will react to fears with responses that will fail to make the health care setting safer, while needlessly putting careers in peril, jeopardizing access to care, and requiring disproportionate expenditures of scarce public funds. Continuing efforts will be necessary to allay untoward fears and put risks in perspective.

In this report the Commission seeks to provide general guidance in the form of enduring principles, as well as specific recommendations on particular aspects of the issue about which there is controversy. The report begins with those principles, followed by a review of the dimensions of risk and how these risks are perceived by the general public and health care professionals and includes Commission recommendations as to how to reduce risks and allay public fears. Finally, there is a discussion of some of the proposals to mandate testing and restrict the practice of HIV-infected health care workers. The conclusion of the Commission is that such approaches are not warranted and may be counterproductive, in that they may ultimately cause greater patient morbidity and mortality than they prevent.

David E. Rogers, M.D.
Vice Chairman

June E. Osborn, M.D.
Chairman

ACKNOWLEDGMENTS

The Commission held hearings on strategies to reduce the transmission of bloodborne infections in health care settings on November 5, 1991. The Commission's deliberations were greatly informed by the testimony and discussion of the witnesses at this hearing, who are named in Appendix A.

A number of individuals reviewed various versions of the draft report. Barbara Gerbert, Ph.D., and Robert E. Stein, LL.B., reviewed the entire document and made helpful suggestions. The Commission would also like to thank Mark Barnes, J.D., for his invaluable contribution to this report.

Research support for this project was also provided by the Center for AIDS Prevention Studies at the University of California at San Francisco. The assistance of the Center's staff and its director, Thomas J. Coates, Ph.D., is gratefully acknowledged.

EXECUTIVE SUMMARY

Preventing HIV Transmission in Health Care Settings

Since early in the AIDS epidemic, particularly after it became known that AIDS is the result of infection with the human immunodeficiency virus (HIV), a bloodborne agent, there have been concerns about the possible transmission of HIV infection in health care settings. In the late 1980s, there were sporadic reports of health care workers' being infected with HIV after coming in contact with infected patients' blood; now, at least 40 cases of health care professionals' becoming infected with HIV in health care settings have been documented.

In 1990, evidence was reported that patients of an HIV-infected dentist in Florida had contracted HIV infection; eventually five such patients with no other risk factors were identified. The virus isolates from the dentist and those patients had almost identical genetic fingerprints, which demonstrates a definite epidemiologic link among the cases. However, despite intensive investigation, it is unlikely we will ever know exactly how the infections resulted.

On the basis of that episode, the Centers for Disease Control (CDC) issued a series of recommendations designed to protect patients in health care settings. Those recommendations stressed as their centerpiece the careful and consistent use with *all* patients of standard infection control procedures for bloodborne agents–the so-called universal precautions. They also, however, recommended that HIV-infected health care workers cease doing what were termed "exposure-prone invasive procedures" and that appropriate professional medical and dental groups draw up lists of "exposure prone procedures" for their disciplines. CDC further recommended that HIV-infected health care workers consult with a panel of experts to determine what limits should be placed on their medical practices and further indicated that they should inform patients of their HIV-infection status before carrying out medical procedures.

CDC's recommendations had a series of unanticipated consequences. Professional groups, hospital attorneys, state courts, legislatures, and the U.S. Congress reacted with alarm to a perception of dangers to patients posed by infected health care professionals that was totally out of proportion to the largely theoretical risk. Indeed, for some time, the degree of attention given the issue by the media suggested that contact with a dentist or physician represented a major route of HIV transmission. Since then, professional groups and CDC have been attempting to ameliorate this unintended situation. Most medical professional associations refused to cooperate in developing a list of exposure-prone invasive procedures that carry a higher risk of virus transmission. On close inspection of the evidence, they found there were not enough data to support drawing up such a list.

Since the reporting of the Florida cluster, there has been intense and continuing nationwide effort to determine whether any other patients have become infected with HIV in any health care setting.

There have now been "look-back" studies involving more than 15,000 patients taken care of by 32 health care workers known to be HIV infected. Further, hundreds of thousands of invasive procedures have been performed on patients by health care professionals during literally millions of patient-health care worker interactions, and neither surveillance nor these studies have found a single patient with HIV infection resulting from care given by an infected health care worker. The instance involving the Florida dentist remains, to date, a single aberrant episode. Thus, while there is a theoretical risk of HIV's being transmitted from health care professionals to patients, there is at present no evidence that this has ever occurred, except in the puzzling Florida instance. Consequently, there remains no scientific justification for the original measures that recommended restricting the practice of HIV-infected health care workers on the basis of HIV status alone.

The central concern of the Commission continues to be ensuring patient safety. In all our deliberations, we have kept before us the central question: How can patients best be protected from possible infection with HIV or other bloodborne organisms? The scientific evidence, which is both extensive and persuasive, indicates that the following practices will best serve that purpose.

- **There must be consistent, meticulous, and universal use of well-understood infection control procedures.** Evidence developed from the study of another bloodborne infection, hepatitis B, which is at least one hundred times more infectious and probably 10 times more common in health professionals, suggests that this must be the centerpiece of patient protection. The Commission believes no effort should be spared to make sure that all health care professionals are trained in and apply proper infection control procedures in all health care settings, whether hospital, office, or home based.
- **Operative or other invasive procedures in which injury to health professionals occurs with any frequency should be eliminated or modified.** Studies today suggest that most of the procedures now viewed as potentially hazardous could be changed or forgone. This will involve developing and testing new instruments and investigating new operative techniques. It may also entail rethinking the advisability of performing certain operations where the operating field cannot be readily visualized.
- **All health care professionals should consider (based on behavioral or occupational exposure) the need to know their own HIV status. However, it is the Commission's belief that there is no current justification for restricting the practice of health care professionals on the basis of HIV status alone.**

Because of the understandable and continuing public concerns about possible transmission of infection from doctors or dentists, the reasons for this last recommendation bear elaboration. At first glance, it seems eminently reasonable to suggest that HIV-infected health care professionals should not engage in patient-care activities. However, the reasons for not going this route are compelling.

First, and most important, except for the case of the Florida dentist, health care worker-to-patient transmission simply has not occurred. There have been no other reported instances of health care worker-to-patient transmission and none have been found, despite intensive research. Thus, focusing on the health care setting puts unwarranted emphasis in the wrong place and deflects the nation from proper attention to sexual transmission, transmission via injection drug use, the problems of sexually active teenagers, and an epidemic that is worrisomely out of control and needs more committed health care professionals. As our late fellow Commissioner Belinda Mason said in a letter to President Bush, "Doctors don't give people AIDS, they take care of them."

Second, the costs entailed in testing health care professionals and what would inevitably follow, the testing of all patients, are enormous without any evidence that such testing would increase patient or health care worker safety. It is estimated that testing all health care workers in the nation could cost as much as $250 million and as much as $1.5 billion for testing all patients.

Third, because of the "window" period, in which an individual can be infected but not have detectable antibodies, mandatory testing and sidelining of health care workers on the basis of HIV status alone would not guarantee patient safety and, indeed, might yield a false sense of security. If surgeons were to seek testing each time they suffered needlestick injuries and forgo performing operations while awaiting confirmatory test results, they could effectively be sidelined for life.

Fourth, and most tragic, mandatory testing or sidelining of health care workers would send a most unfortunate message to all health care professionals. That message would read, "Don't take care of anyone who is HIV infected, or whom you even suspect of being HIV infected, because you may lose your professional life."

The Commission believes that the approaches embodied in the guidelines adopted by New York and Michigan hew most closely to the principles articulated in this document and are excellent examples for policy-makers in other states to follow. Those guidelines stress improvements in infection control and professional technique over blanket employment restrictions based on known or suspected HIV infection. The Michigan and New York guidelines address risks of all potential bloodborne transmissions between health care workers and patients, not merely HIV. Those guidelines therefore achieve the overall goal of improved safety for workers and patients, while avoiding the massive costs associated with mandatory testing, exclusion, and disclosure.

The determination that an HIV-infected health care worker is not able to continue to practice medicine or otherwise work with patients should be based upon an individualized determination that the worker is unable to comply with universal precautions and infection control guidelines and procedures, or lacks professional competence, or has been responsible for documented transmission of bloodborne infections.

The Commission is acutely aware of the magnitude and intensity of public alarm. Indeed, public polls have indicated that over 90% of Americans believe their doctors should tell them if they, the physicians, are HIV positive. Those polled further indicate that they would not make use of the services of an HIV-infected doctor. This is a reality we must face. It shows how poorly we have informed our citizenry.

The Commission believes it is important to acknowledge forthrightly fears concerning HIV transmission in the health care setting and address them, without allowing them to overwhelm rational judgment. Policies must be directed at eliminating risks that are significant rather than remote or theoretical. Policies must be grounded in scientific reality and be sufficiently flexible to respond to new scientific evidence. To this end, the Commission offers a set of guiding principles that will endure should new evidence come to light. The promotion of patient safety and access to health care must remain paramount concerns. The "cure" for the risk of HIV transmission in the health care setting must not be more damaging than the risk itself to the public's health.

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I

Principles for Evaluating Proposals to Reduce the Risk of Transmission of Bloodborne Infections in Health Care Settings

To support the development of sound policies based on science and public health, the National Commission on AIDS has developed the following principles, which are relevant to a wide range of circumstances and questions arising from concerns about transmission of HIV, hepatitis B virus (HBV), and other bloodborne pathogens in the health care setting. The principles will remain applicable as more becomes known about the scientific aspects of HIV transmission in the health care setting.

1. The primary objectives of any policy must be to protect all patients and health care providers from harm and to ensure the continued delivery of quality health care.

2. A policy must be based upon the best available scientific evidence regarding risk of transmission and methods to reduce or eliminate that risk. It should be sufficiently flexible to be revised in light of new scientific knowledge.

3. Strategies to reduce or eliminate risk of transmission must utilize the least restrictive available alternatives; i.e., those promoting the greatest safety with the fewest adverse consequences for both patients and health care providers and preserving, insofar as possible, other social values of autonomy, privacy, and justice.

4. A policy must be directed at eliminating risks that are significant, rather than remote, speculative, or theoretical.

5. Any policy involving testing or screening for infection must clearly distinguish between two separate rationales: testing for clinical or behavioral counseling purposes versus testing in order to secure results for infection control decisions. Testing for HIV (except for anonymous, unlinked epidemiologic screening) should proceed only with the explicit informed consent of the person tested or his or her legally authorized representative.

6. Physicians and other health care workers may not ethically avoid treating HIV-infected patients. Refusal of patients to undergo HIV testing should not jeopardize receiving care.

II

Historical Background

In the decade of experience with the human immunodeficiency virus (HIV), the virus that causes AIDS, much has been learned about how it is (and is not) transmitted. It is transmitted via unprotected sexual intercourse (anal or vaginal), by the sharing of contaminated drug injection equipment, from an infected woman to her fetus or infant (before, during, or shortly after birth), through breast-feeding, and through direct exposure to contaminated blood or blood products.

The Risk to Providers

Concerns arose in the late 1980s about the transmission of HIV in health care settings when several cases of HIV transmission from patients to health care providers were documented (CDC, 1987a,b; 1988a,b). Attention to occupationally acquired HIV infection sometimes obscured the fact that many more health care professionals have become infected through nonoccupational exposure. The Centers for Disease Control (CDC) reported that by September 20, 1991, 6,782 persons who had worked in health care or clinical laboratory settings had developed AIDS. Of these, an estimated 46 were surgeons and 190 were dental workers. CDC also estimates that to date there have been eight times as many HIV-infected health care workers as cases of AIDS in health care workers. The proportion of persons with AIDS who are health care workers has roughly paralleled the proportion of health care workers in the population at large. Approximately 6% of the U.S. population are employed in health care; health care workers have consistently made up 5% or less of the total AIDS cases reported to CDC.

CDC conducts extensive follow-up studies of health care workers with AIDS who are reported by state and local health departments to have unidentified risk factors. By the end of 1990, it had been established that approximately 40 health care workers in the United States had acquired HIV infection through occupational exposure (Chamberland et al., 1991). Practitioners have expressed skepticism about whether this number represents the full extent of occupationally acquired HIV infection, because fear of job loss may deter health care workers from reporting incidents of exposure to HIV-contaminated blood or from reporting their own infection status, if known (Kernodle, 1990). There is less-well-confirmed evidence of seroconversion following occupational exposure in approximately 140 cases (Bartlett, 1992a).

These 40 or so cases of known HIV transmission are a small numerator over a huge denominator. The denominator involves hundreds of thousands of provider-patient interactions involving hands-on procedures performed on HIV-infected patients. Although the risk of occupationally acquired HIV infection is remote, it is real. In some institutions, health care workers are in frequent contact with HIV-infected patients. A study at Johns Hopkins Hospital revealed a 13% rate of HIV seropositivity in patients admitted to the emergency room requiring emergency surgery (Kelen et al., 1989). The risk of exposure is greater for health care workers who work in units where persons with HIV disease predominate.

Shifting the Focus to Patients

Knowledge that health care workers had become infected in the workplace also provoked speculation about the risk *to patients* of acquiring HIV in health care settings, from either infected providers or other patients. The risks of transmitting HIV to patients in the health care setting moved from the theoretical to the real with the discovery that a woman subsequently identified as Kimberly Bergalis had become infected with HIV in the course of receiving dental care from a Florida dentist who later died of AIDS (CDC, 1990). The tragic episode involving Ms. Bergalis riveted the nation's attention and resulted in a paroxysm of policy-making activity. Medical professional associations, courts, legislatures, hospital administrators, and others sought to determine a prudent course of action in regard to HIV-infected health care workers and patients.

Until her death in December 1991, Ms. Bergalis occupied center stage as a proponent of instituting mandatory HIV testing of health care workers and restricting the practice of those found to be HIV positive (Breo, 1990). It was a phenomenon that has been witnessed repeatedly in the AIDS epidemic--the influence, not of the accretion of hundreds or thousands of cases, but of a single individual, suddenly entering the limelight because of HIV disease (Table 1). In dramatic Congressional testimony and in a letter to Florida health officials published in *Newsweek*, Ms. Bergalis blamed, but forgave, her dentist for her illness. She found it more difficult to forgive "[a]nyone that knew [my dentist] was infected and had full blown AIDS and stood by not doing a damn thing about it" (Kantrowitz et al., 1991:52).

The controversy that ensued in the wake of disclosures about Ms. Bergalis's illness raised a series of public policy questions:

- Should all health care workers or some specific categories of providers be routinely tested for HIV?
- Should patients be routinely tested for HIV?
- Should HIV-infected health care workers be required to inform patients and/or employers about their HIV status?
- Should HIV-infected health care providers be forbidden to perform certain types of procedures?

Another overarching question looms above all these particular concerns: how to act in the face of uncertainty? What response is appropriate in the face of an exceedingly remote risk of a dread disease? Four other patients of the same Florida dentist are believed to have acquired HIV infection in the course of receiving care (CDC, 1991a), although the other patients expressed views at odds with Ms. Bergalis on the policy implications of their tragedy and did not attract the same degree of media attention.

This single cluster of cases in Florida remains the *only* documented instance, to date, of HIV infection acquired by medical or dental patients presumably in the course of treatment. To what extent should a rare occurrence--one cluster of cases in more than a decade of an epidemic--dictate a broad policy response? The Bergalis case also raised questions about how to respond to public fears and "populist" political pressures when these are at odds with the advice of the public health and medical community.

Many of the issues addressed in this report have been dealt with elsewhere, as the burgeoning literature on the subject attests. In particular, the Office of Technology

TABLE 1 Chronology of Events

1990	
Jul 7	CDC discloses Florida dentist as source of infection in patient.
Aug 13-14	CDC convenes meeting of 70 health care groups; no consensus could be reached regarding recommendations.
1991	
Jan 10	AMA and ADA advocate practice restrictions for HIV-infected surgeons and dentists.
Jan 18-19	New York State Health Department and San Francisco Commissioners of Health challenge AMA guidelines claiming no grounds for practice restrictions.
Jan 18	CDC issues draft document with estimated risk of transmission of HIV and HCW-to-patient with surgery or dental procedures; the risk model proposed theorized that 13 to 128 patients may have acquired HIV infection from HCWs.
Feb 21-22	CDC convenes meeting for open review assessment and guidelines.
Mar 6	American Academy of Orthopedic Surgeons endorses AMA guidelines and tests 3,440 surgeons at annual meeting (48% of attendees); none of the 3,334 who denied other risk factors were seropositive.
Apr 4	CDC unofficial proposal for voluntary testing of HCWs who perform exposure-prone invasive procedures, with practice limitations on those who prove seropositive for HBeAg or HIV, is released to media.
Apr 26	New Jersey judge rules infected surgeons must notify patients of HIV infection; 5 days later the Medical Society of New Jersey requests testing of all hospital admissions, but denies any relationship to the NJ judge's decision.
Jun 12	Gallup poll shows 87% felt all physicians should be tested, 79% felt all patients should be tested, and 49% felt all HCWs with HIV infection should be banned from medical practice.
Jul 15	The CDC issues guidelines advocating voluntary testing for HIV and HBeAg by HCWs who perform "exposure-prone invasive procedures"; HCWs with positive results would have practice restrictions for "exposure-prone invasive procedures" or review by a local committee. "Exposure-prone invasive procedures" would be defined by appropriate representatives of surgical specialties.

TABLE 1 *Continued*

1991	
Aug	CDC has meeting with 20-25 groups including AMA and American College of Surgeons (ACS) to discuss process of defining exposure-prone invasive procedures by Nov. 15, 1991, deadline. A subsequent AMA-sponsored meeting of specialty groups showed opposition to developing a list; this includes the ACS, which claimed additional data were needed to quantify risk.
Aug-Sep	Congressional legislation introduced including (1) the "Helms amendment" for a $10,000 fine and 10-year prison sentence to a surgeon with HIV infection who performs surgery without informing the patient, (2) the Kennedy amendment that would mandate adoption of CDC guidelines, and (3) the Kimberly Bergalis amendment that would mandate testing of patients and health care workers involved in invasive procedures.
Oct 3	The Infectious Disease Society of America votes against CDC guidelines and endorses policy of no restriction on practice by HIV-infected HCWs.
Oct 3	Congress approves bill that will allow states to adopt either the CDC guidelines or some substitute measure. New York State and Michigan oppose CDC guidelines, testing, and practice restrictions; Illinois passes bill that mandates notification of patients of any health care worker with HIV infection.
Dec 14	The AMA and CDC agree that listing of "exposure prone" procedures is unnecessary. The CDC has withdrawn the prior guidelines for revision.
1992	
May 15	CDC publishes scientific report on the investigation of the Florida dental case in the *Annals of Internal Medicine*; reports in *MMWR* that no instances of HIV transmission were discovered in studies of more than 15,000 patients of HIV-infected health care workers.
Jun 18	Letter to state health directors from CDC Director, Dr. William L. Roper, states that CDC's review of state guidelines for equivalency will "give appropriate consideration to those states that decide that exposure-prone invasive procedures are best determined on a case-by-case basis, taking into consideration the specific procedure as well as the skill, technique, and possible improvement of the infected health-care worker."

SOURCE: Adapted from Bartlett (1992b:Table 18).

Assessment (OTA, 1991) has completed a useful analysis of many of the issues involved, especially as they relate to what is known about risk. Some individual states such as Michigan (Ad Hoc Committee on HIV-Infected Health Care Workers, 1991) and New York (New York State Department of Health, 1992) have developed sound policy approaches, and the U.S. Congress has adopted legislation that requires states by October 28, 1992, to enact either CDC guidelines on preventing infection in the health care setting, or some substitute measure, or risk losing federal funds as stipulated in the Treasury, Postal and General Government Act, 1992, Pub. L. 102-141 § 634 (1991). The Commission realizes that there is no single policy document that will entirely dispose of the myriad issues posed by the risk of transmission of HIV and other bloodborne pathogens in the health care setting. In the U.S. system for regulating the delivery of medical care and public health practice, state and local policy-makers have much discretion in decisions about HIV-infected health care practitioners. This discretion allows for considerable variability in decision-making; it may also risk inequitable results.

III

Identifying and Minimizing Risks in Health Care Settings

Sources of Risk to Health Care Workers

Most health care providers who have become infected with HIV in the course of rendering care have experienced a needlestick or other puncture wound from hollow-bore needles or, more rarely, other "sharps" while treating HIV-infected patients. A few cases have involved blood-to-mucous membrane contact (CDC, 1987a). Transmission from an infected patient to a previously uninfected health care worker is most likely to occur when there is a breach in infection control procedures, such as when a needle used on an HIV-infected patient is recapped or improperly disposed of, puncturing the skin of the worker.

Any health care worker who comes in contact with the blood or body fluids of an HIV-infected patient is at risk. This includes not only physicians, surgeons, and dentists performing so-called invasive procedures (see Glossary, Appendix B), but also nurses and phlebotomists who risk needlestick injuries. Health care workers not involved in direct patient care may also be at risk.

"First responders" such as emergency medical technicians, police, and fire fighters may also risk exposure to infected blood in situations where protective clothing is unavailable or not feasible to use. A study in a New York hospital found that "needlestick injuries occurred most frequently among the housekeeping staff, followed by nursing and laboratory personnel. Housekeeping personnel sustained these injuries while handling trash bags and linen with protruding needles, and while disposing of needles in over-filled receptacles" (Askari and Alexander, 1989:110). Housekeeping and other ancillary personnel in the health care setting have often been overlooked in training programs devoted to the prevention of occupational exposure to HIV and HBV.

Risks to Patients

As noted above, the cluster of five dental patients in Florida remains the only instance to date of HIV transmission to patients in the course of rendering care. It is understandable that there would be far fewer cases of health care provider-to-patient accidental transmission of HIV than patient-to-provider. For provider-to-patient HIV transmission to occur, the infected health care worker would have to sustain an injury and bleed into a patient's wound, or after sustaining an injury during an invasive procedure, have the sharp object causing the injury then recontact the patient's open wound or otherwise nonintact skin, resulting in the patient's exposure to the health care worker's blood. This type of occurrence is likely to happen only during certain types of invasive surgical or dental procedures. Needles or instruments used in treating patients do not normally come in contact with blood and body fluids of health care workers. If such an incident occurs, health care workers can typically interrupt the procedure and discard the contaminated equipment or cover their own wounds to protect patients, since, in most instances, the health care workers will be aware of injury to themselves. There is also a risk of patient-to-patient transmission of bloodborne pathogens if equipment contaminated with infected blood is reused. This risk is eliminated if universal precautions and basic infection control procedures are applied.

There are also risks involved when providers ignore or grossly violate the universal precautions (see below) and basic infection control standards and practices. In a few widely publicized cases, HIV-infected health care workers with exudative lesions have inappropriately continued to practice; however, no HIV transmission to patients has been documented as a result.

In the Florida dental case, it is doubtful that the manner in which the virus was transmitted to the five patients will ever be determined with certainty. The patients and the dentist appeared to have all been infected with the same strain of the virus, substantiating an epidemiologic link among the six cases. Investigators examining the case found that the dentist and his assistants had on numerous occasions ignored basic sterilization and infection control procedures as well as universal precautions (Ciesielski et al., 1992).

Universal Precautions and Infection Control Procedures

CDC has issued a series of guidelines on precautions regarding HIV in the health care workplace. CDC recommends that all hospitals adopt an infection control policy known as "universal precautions." Under this concept, all blood of health care workers and patients is presumed to be potentially infectious, whether laboratory tests are positive or negative or have not been conducted. Likewise, all instruments and equipment that have come into contact with blood are presumed to be potentially contaminated with bloodborne pathogens such as HIV or HBV and must be carefully handled, cleaned, and sterilized or disinfected, or disposed of safely (Wong et al., 1991).

To observe universal precautions, health care workers protect themselves and their patients with barrier devices when anticipating contact with blood and body fluids. Barrier equipment for universal precautions includes protective gowns, latex and vinyl gloves, disposable face masks, and protective eye wear. Particular caution is urged when handling hollow-bore needles and other "sharps." CDC recommends that used needles not be bent, broken, or recapped by hand, but rather that they should be discarded promptly in a puncture-resistant container placed near the point of use.

The Commission believes compliance with universal precautions and basic infection control practices should be aggressively pursued and carefully monitored in all health care settings. This includes private physicians' and dentists' offices and ambulatory surgery centers as well as hospitals, clinics, and clinical laboratories. It also includes private homes where health care is provided. Further research is necessary to substantiate further the types of universal precautions and alterations to professional techniques that best reduce the risk of all blood-to-blood exposure between workers and patients. Health care institutions must accept greater responsibility for providing proper training for workers on infection control procedures and alterations to professional techniques. In-service education should be supplemented with enhanced procedures for monitoring compliance with scientifically accepted infection control standards and proper professional techniques.

Various studies have examined the effectiveness of universal precautions and infection control practices in reducing HIV and HBV transmission risks (Gauthier et al., 1991; Linnemann et al., 1991; Whitby, Stead, and Najman, 1991). One study of universal precautions in hospitals cited the "frequent shortages of isolation materials (especially 'rubber' gloves)" (Doebbeling and Wenzel, 1990:2083).

The Commission believes infection control improvements are necessary to save lives. This is one area where there can be no cutting corners. There is no justification for allowing lapses in universal precautions and infection control procedures because of lack of necessary equipment, such as protective barrier clothing or convenient receptacles for the disposal of needles.

The increased need for disposable equipment will inevitably add expense to the cost of delivering health care. For example, there is resistance to some simple new technologies, such as needles with special sheaths that help avoid needlesticks, because of the added cost at a time of skyrocketing health care expenditures. Increased expenditures on infection control are, however, likely to save money ultimately by reducing disease transmission and eliminating the need for more costly alternatives, such as sidelining health care professionals or denying or delaying care for patients with bloodborne infections.

Much of the recent focus on infection control has been on so-called "invasive procedures," which, as defined by CDC would include most surgical, obstetrical, and dental procedures, as well as diagnostic procedures such as cardiac catheterization and angiography. CDC also attempted to designate a narrower category of "exposure-prone invasive procedures," (see Glossary, Appendix B) but this was abandoned when most medical professional associations refused to cooperate, citing the limitations of the data on which to base such categorization (Altman, 1991).

The limited epidemiologic evidence about which procedures might be classified as "exposure prone" comes from experience with hepatitis B virus (HBV), a bloodborne virus that is transmitted in the same manner as HIV. Since the early 1970s, there have been 33 reports of health care worker-to-patient transmission of HBV. Infected dentists and surgeons accounted for 29 of these clusters, 16 of which were reported in the United States. Slightly more than one-third of the reported clusters involved health care workers who did not routinely wear gloves. Twenty clusters were associated with surgery and occurred despite glove use, which cannot eliminate all percutaneous injuries.

The occurrence of clusters of HBV has remained constant, occurring an average of one or two worldwide per year since 1977. Although HBV transmission from health care worker to patient has not been eliminated entirely, even with the advent of universal precautions, it is noteworthy that the risk of HBV transmission through percutaneous exposure to blood is approximately 100 times greater than that of HIV. Moreover, the prevalence of HBV infection among health care professionals is about 10 times greater than that of HIV infection. Additionally, more rigorous efforts can be made to encourage use of universal precautions.

There are ongoing efforts to develop safer needles and syringes and more convenient receptacles for disposal. Also under way are studies of improvements in gloves to provide better protection against punctures and surface contamination and in other protective coverings for use during performance of invasive procedures. According to Dr. John Bartlett, Chief of Infectious Diseases at Johns Hopkins University:

> One of the problems with many of the efforts in developing better protective gear is the lack of standards for testing. Protective wear including gowns fall in FDA class 2, which requires "consensus performance standards" that have

> never been developed for most products. Difficulties in developing such standards are based in part on the fact that gloves, masks, gowns, and footwear have no established merit in preventing infection in the operating room so that goals for standard testing are necessarily based on arbitrary theories and controversial test models (Bartlett, 1992b:247).

There is a great deal of activity among surgical subspecialists to develop refinements that will provide greater protection for health care workers and patients alike (Raahave and Bremmelgaard, 1991). There is still room for creativity in minimizing the risk of bloodborne infection by training in proper techniques, designing new equipment, teaching new ways of handling equipment, and developing new procedures or variations on old ones.

OSHA Regulations

With prodding from Congress, the Occupational Safety and Health Administration (OSHA) in December 1991 adopted a long-awaited final rule addressing occupational exposure to bloodborne pathogens (Table 2). OSHA received more than 3,000 comments on the proposed rule, and more than 400 people testified at five public hearings. As of July 6, 1992, all employers of individuals whose jobs can be "reasonably anticipated" to require contact with human blood or other potentially infectious materials must comply with the OSHA standard, which is sensibly grounded in the need to adhere to universal precautions. This involves implementing a written exposure-control plan that covers such areas as methods of compliance, access to HBV vaccination, postexposure evaluation and follow-up, and record keeping.

The OSHA regulations are noteworthy, in part because of the breadth of coverage. They apply not only to workers in hospitals, nursing homes, and physicians' and dentists' private offices, but also to employees in many other types of settings such as correctional institutions, funeral services, and infectious-waste disposal sites.

The extent to which OSHA regulations apply to certain types of workers may vary from state to state. OSHA regulations do not apply to state, county, or municipal employees except in the 25 states where state OSHA programs have been approved by the federal government. Thus, employees of the medical system of the University of California would be covered, although their Texas counterparts would not, because California has a state OSHA program and Texas does not. Medical, nursing, dental, and allied health students do not come within the purview of the regulations unless they are also employees. Nor are hospital or institutional volunteers included.

The success of OSHA regulations in enhancing the safety of health care workers and patients will depend on how well the educational requirements of the regulations are implemented and how aggressive the agency is in ensuring compliance.

Monitoring and educational efforts related to implementation of the OSHA regulations deserve top priority. Moreover, new federal legislation should be considered to clarify and expand the employee groups reached by the regulations to include all of those at risk of occupational exposure to bloodborne pathogens.

Estimating Risk

There are a few basic sources of information from which it is possible to estimate the risk of HIV transmission in the health care setting. CDC surveillance of AIDS cases includes efforts to determine what risk factors were associated with transmission. Attempts are made to distinguish occupational-exposure infection from infection that

TABLE 2 Summary of OSHA Procedures for Occupational Exposure to Hepatitis B (HBV) and HIV

Exposure Determination: Employer will identify all employees who are exposed to potentially infectious materials, including blood, blood products, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid.

Control Methods

A. Universal precautions (see Appendix B).
B. Engineering controls: should be used in preference to other methods to minimize exposure; they include puncture-resistant sharp instrument containers, splash guards, and self-sheathing needles.
C. Work practice controls: alterations in task performance to reduce exposure, including: (a) hand washing after removing gloves and after contact with body fluids; (b) personal protective equipment should be removed after leaving work area and placed in appropriate area for storage, decontamination, or disposal; (c) needles and other sharp instruments shall not be sheared, bent, broken, recapped, or resheathed by hand; (d) procedures shall be done in a fashion that minimizes splashing and spraying.
D. Personal protective equipment
    1. Employer will provide appropriate protective equipment, including gloves, gowns, head and foot coverings, face shield or masks, eye protection, and fluid-resistant aprons.
    2. Equipment must be available in a variety of sizes.

HBV vaccination: This must be provided at no cost to all employees at risk and should be given according to recommendation for standard medical practice.

Postexposure evaluation:

1. Employer must make a confidential medical evaluation and follow-up.
2. Employer shall notify source patient and attempt to obtain consent to test source blood for HIV and HBV.
3. Employer shall offer exposed worker serologic testing for HIV and HBV as soon as possible after exposure; repeat testing for HIV will be offered at 6 weeks, 12 weeks, and 6 months.
4. Exposed worker will be offered counseling, medical evaluation of any febrile illness during the 12 weeks after exposure, and use of postexposure measures according to standard medical practice.

SOURCE: Bartlett (1992b:Table 11); see also OSHA (1991).

occurred as a result of sexual or drug-injecting behavior. Seroprevalence surveys have also been undertaken to establish the level of HIV disease among health care providers and patients in various settings (St. Louis et al., 1990). A number of retrospective (so-called "look back") investigations have been conducted in which patients of HIV-infected health care providers have been tested for HIV antibodies retrospectively (Mishu et al., 1990; Danila et al., 1991). Prospective studies have also been conducted of health care workers who are exposed to the blood and body fluids of HIV-infected patients. Finally, predictions have been made from projection models supported by extrapolations from what is known about other bloodborne infections, such as HBV.

Although hepatitis transmission may remain the most relevant comparison, there are a number of factors limiting the value of HIV/HBV comparisons. The mononucleosis-like symptoms associated with acute HIV disease are less obvious than the symptoms (hepatitis) associated with acute HBV infection. And the period between acquisition of infection and onset of symptoms is much longer for diseases that define AIDS than for those associated with hepatitis B virus infection (hepatoma and cirrhosis). Finally, although HIV is transmitted at a much lower rate than HBV, HBV is much less frequently fatal–1% to 2% of those infected with HBV ultimately die of the infection or its consequences (Figure 1).

Risk to Providers. A number of studies assessing the frequency of needlestick and other "sharps" injuries that might risk HIV or HBV transmission have been published (McCormick et al., 1991; Panlilio et al., 1991; Wright et al., 1991). The risk of a health care worker's becoming infected after a needlestick with a needle used on an HIV-infected patient is estimated to be 0.3% to 0.4% (Henderson et al., 1990). This estimate is based on studies of exposures involving hollow-bore needles contaminated with blood from individuals in advanced stages of illness. In fact, however, most needlesticks are caused by suture needles that are not hollow, with the risk of HIV transmission therefore being even more remote. The chances of seroconverting following exposure will depend on the needle type, size, depth of penetration, and the blood volume transferred. Glove material of any type will reduce the amount of contamination considerably, since during punctures, the glove itself acts as a sheath, stripping some blood from the needle's exterior. Other factors may influence the degree of risk of seroconversion, but are difficult to quantify, such as the stage of HIV disease and the degree of viremia of the "source patient" and the immunologic competence of the individual who is injured. The prevalence of HIV and/or HBV infection among patients is also an important consideration in assessing the cumulative risk to health care professionals over time.

Risk to Patients. Attempts also have been made to estimate the risk to patients of becoming infected with HIV in the health care setting. The absence of documented instances of HIV transmission, other than the case of the Florida dentist, shows the risk to be very low.

CDC has developed a model of the risk of HIV transmission to patients, based in part on what is known about the transmission of HBV. In the CDC theoretical model, it was estimated that the risk of a patient's being infected by an HIV-infected surgeon during a single operation is between 1/42,000 and 1/420,000. This risk is considerably less than that associated with many other hazards associated with medical care that are borne daily without comment by patients and health care regulators, as well as risks in everyday life. CDC used a model to estimate further that the lifetime chance of an HIV-infected surgeon who continues to operate infecting a patient would be from 0.8% to 8.1%; however, CDC acknowledged many limitations of its model. The CDC model may underestimate risk in situations where infection control procedures are ignored and clusters of infection may occur, or overestimate risk in other settings. It also relied

FIGURE 1 Hepatitis B (HBV) and HIV in health care workers: Annual experience. The data for HBV in health care workers is from the 1970s and may be lower at the present time due to HBV vaccine, universal precautions, and other factors. The HIV data are based on assumptions of 400,000 sharp instrument injuries per year in U.S. hospitals, average seroprevalence rates of 1.3%, efficiency of transmission of 0.3%, and the observation that sharp instruments account for 31 of 37 documented occupationally acquired HIV infections (400,000 X 0.013 X 37/31 = 19) (Bartlett, 1992b:Figure 5).

on unpublished and controversial estimates of recontact rates. Because of data limitations, however, this model must necessarily be considered highly speculative.

In addition to theoretical models of risks to patients, a number of retrospective studies have been conducted with patients of HIV-infected health care workers. According to an update published by CDC on May 15, 1992 (CDC, 1992), HIV test results have been obtained from 15,795 patients of 32 HIV-infected health care workers. *No* HIV infections have been uncovered that could be attributed to medical or dental care, except the five patients of the Florida dentist. Published studies include:

- Testing of 616 patients of a Nashville surgeon from 7 years prior to his AIDS diagnosis. One patient tested HIV positive; the most likely source of his infection was his own injection drug use (Mishu et al., 1990).
- Seventy-five patients of an Air Force surgeon with AIDS sought testing; not one was HIV positive (Armstrong et al., 1987).
- Seventy-six patients of an English surgeon with AIDS were tested and none was HIV positive; most were tested too soon after surgery for the results to have been absolutely conclusive (Porter et al., 1990).

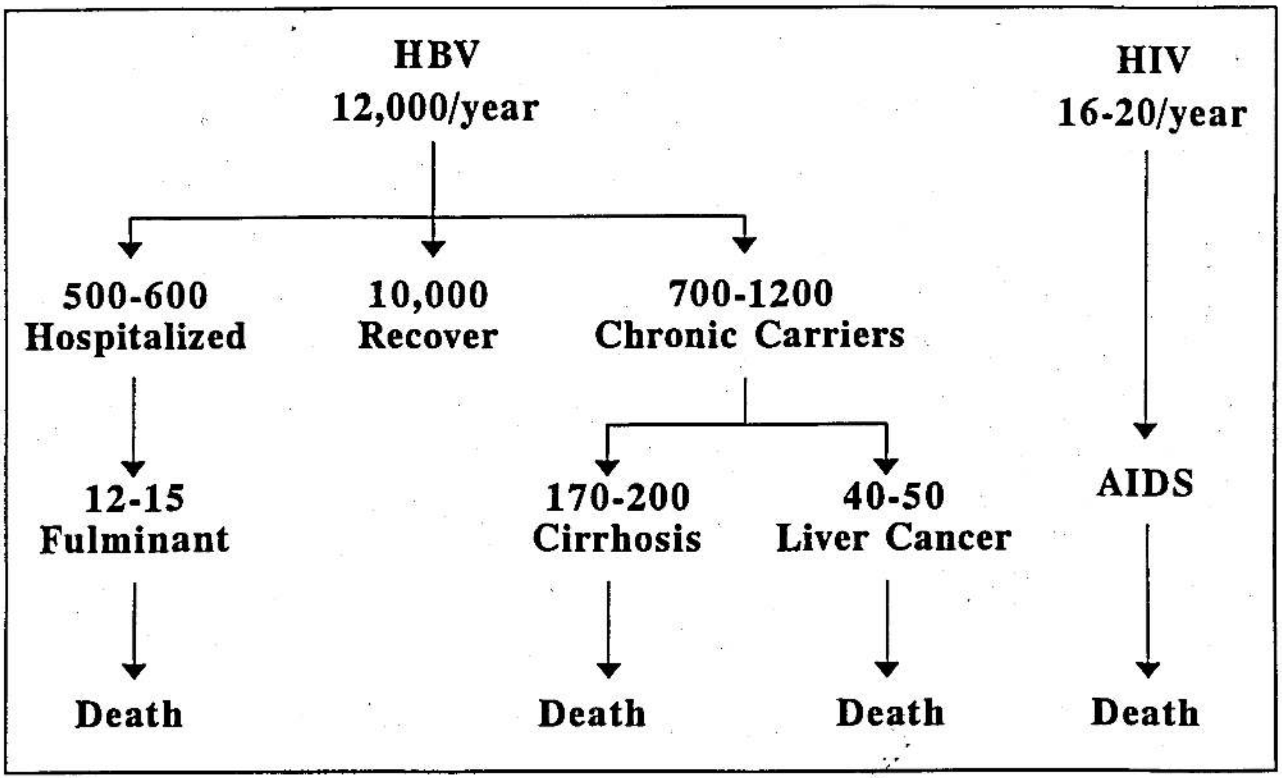
HBV
12,000/year
500-600
Hospitalized
10,000
Recover
700-1200
Chronic Carriers
12-15
Fulminant
170-200
Cirrhosis
40-50
Liver Cancer
Death
Death
Death
HIV
16-20/year
AIDS
Death

Figure 1

- One hundred forty-three patients of an HIV-positive dental student were tested; none was positive (Comer et al., 1991).
- Three hundred twenty-five patients of an HIV-infected Minnesota family physician were tested. The physician had continued to practice despite severe dermatitis caused by *Mycobacterium marinum* on his hands and forearms. All of these patients tested negative, despite the breach of infection control standards (Danila et al., 1991).

The OTA report (OTA, 1991) also summarized the limitations of such retrospective studies. They are fraught with difficulties that render them difficult to interpret. It is costly and labor-intensive to notify patients. It may be difficult to secure patient consent to testing. The need to assure voluntary, informed consent introduces selection biases that could influence results. For those who do consent to be tested and test positive, there is further difficulty in ascertaining with certainty whether the virus was transmitted in the course of treatment. Retrospective determinations of the invasiveness of procedures involved and adherence to infection control guidelines are also problematic.

The OTA concluded that "in the near future, the results of such look-back studies are unlikely to help define the magnitude of the risk" (OTA, 1991:5). The OTA conclusion was echoed by authors of one recent look-back study who concluded that such studies are "limited in their ability to demonstrate transmission," because of the relatively small number of patients studied, the probability of a low risk of transmission in a given procedure, and the potential for a cluster of cases of HIV transmission in association with a single practitioner rather than random infrequent transmission by all HIV-infected health care workers" (Danila et al., 1991:1409).

The authors further noted that, with thousands of HIV-infected practitioners at work, there is potential for a dramatic increase in the number of look-back investigations. For example, in a case where there were known failures to adhere to universal precautions and infection control procedures, a New York trial court ordered the estate of a dentist who had died of AIDS to turn over more than 3,000 patient records to the state health department. The court rejected arguments that the records were protected under state doctor-patient privilege provisions or HIV-specific confidentiality statute, *McBarnette* v. *Estate of Feldman* No. 15978/91 (N.Y. Sup. Ct. Jan. 30, 1992) (Schemo, 1992). The authors recommend that "before a look-back investigation is undertaken, there should be a clearly identifiable risk of transmission of the infection, substantially higher than the risk requiring limitation of an HIV-infected health care worker's practice prospectively" (Danila et al., 1991:1406).

The Commission encourages the continued monitoring of HIV and HBV transmission in order to understand the sources of risk and to refine risk estimates. Such studies can help to establish the knowledge base for the development of sound future policies. A limited number of carefully designed and controlled studies is preferable to engaging in look-back investigations each and every time a health care practitioner dies of HIV-related causes.

Risk Perception

Despite the remote nature of the risk to patients from HIV-infected health care providers in most circumstances, people express considerable fear and anxiety when queried in public-opinion polls. A poll conducted for *Newsweek* by the Gallup Organization in June 1991 interviewed a representative nationwide sample of 618 adults. Ninety percent said that all health care workers should be required to tell their patients if they are infected with the AIDS virus. An even greater percentage supported disclosure for dentists and surgeons (94% and 95%, respectively) (Kantrowitz et al., 1991).

The fears reflected in the recent polls are not entirely attributable to the case of the Florida dentist. A telephone survey of a random probability sample of 2,000 adults conducted in the summer of 1988, before any cases of health care worker-to-patient HIV transmission had been identified, revealed that 45% of those surveyed believed that HIV-infected physicians should not be allowed to continue to practice. More than half of the respondents said they would seek care elsewhere if they discovered their physician or dentist was HIV infected (Gerbert et al., 1989).

Perhaps the most disturbing finding was that nearly one-third of those polled said they would change physicians if their doctor merely treated people with HIV disease (Gerbert et al., 1989; see also, Daniels, 1992). As the researchers note, answers to public opinion polls depend greatly on how questions are framed, and answers to opinion poll questions do not necessarily translate directly into behavior. Many respondents who stated they would seek to change doctors may have little latitude in choice of provider. Nevertheless, "[e]ven if only a small proportion of those who expressed the intention to switch [health care providers] acts on these views . . . the impact on medical services could still be substantial" (Gerbert et al., 1989:1971).

These concerns are not merely conjectural:

> A pair of New York private investigators said they would "tail" a patient's surgeon to find out whether he's gay.
>
> Their press release--titled "Learning if Your Doctor Has AIDS"--describes their work for a woman who wanted them to check out her "effeminate" surgeon before she had cancer surgery. When they reported that the man went to a gay bar, she switched surgeons (Krieger, 1992:A2).

The public reaction to the threat of HIV transmission in the health care setting is not necessarily surprising, given what is known about risk perception and risk communication (National Research Council, 1989). In making risk calculations, people tend to overlook palpable, everyday risks, such as those associated with driving a car or smoking cigarettes, as compared with more remote, but dreaded risks. Perceptions of risk are heightened if the source of the risk is not observable or detectable. Unfamiliar risks or those involving scientific unknowns are particularly dreaded, as are risks from sources beyond one's control (Slovic, 1987).

Risks of daily life may seem less overwhelming in part because of assumptions about the role of government in ensuring public health and safety. The food we eat, the air we breathe, and the cars we drive--in each of these instances risk/benefit calculations have entered into decisions about what kind of resources to invest in making them safer. Seldom is the general public privy to the specific data involving risk that informed such decisions; nor is there much interest in knowing the details. There are, however, notable exceptions in which the public takes great interest in risk assessment and risk management--for example, the location of nuclear power plants and landfills.

HIV transmission in the health care setting is one example of a risk in which the public has taken great interest. As knowledge about HIV has evolved and as experts have publicly disagreed on many aspects of HIV transmission, there has been much public skepticism. Some pronouncements by experts and government officials have fueled public fears unnecessarily. A number of witnesses who appeared before the

Commission were critical of the way in which the CDC report attempting to model the extent of risk of HIV transmission to patients was released to the press and promoted by the agency. Because of the public prominence accorded the document, rather than serving as a "useful starting point for further discussions," it was "taken out of context and used as factual information" (Gerberding, 1991a:64). CDC estimated that between 3 and 28 surgical patients and between 10 and 100 dental patients had been infected in the course of receiving care. This was reported in many newspapers as fact, with little or no qualification or any indication that this was a wholly "theoretical extrapolation."

Witnesses testifying before the Commission made a number of useful suggestions based on psychological studies of how health care providers and patients perceive the risk of HIV (Gerbert et al., 1988, 1989, 1991a). Attempts to increase knowledge of mechanisms of transmission and risk probabilities are necessary (but not sufficient) steps in helping to allay fears of patients and providers alike. Simple empirical assessments of risk will not solve the problems at hand, even when they show the risks are extremely remote. Such assessments fail to account for patients' value preferences in deciding which risks to avoid and which to assume.

The Commission was urged to heed a recipe for successful risk communication penned by Dr. Paul Slovic:

> [R]isk communication and risk management efforts are destined to fail unless they are structured as a two-way process. Each side, expert and public, has something valid to contribute. Each side must respect the insights and intelligence of the other (Slovic, 1987:285).

Education and training programs must be directed at changing not only knowledge, but also attitudes, beliefs, and behaviors. Experts cannot wish away risk by describing it as low or by attaching other synonyms, such as *remote, vanishingly small, exquisitely rare,* etc. It is appropriate to acknowledge frankly the risk of HIV and HBV transmission, admitting that accidents may happen, while seeking ways of minimizing such accidents.

The Commission believes it is important to acknowledge fears concerning HIV transmission in the health care setting forthrightly and address them, without allowing them to overwhelm rational judgment. Policies must be directed at eliminating risks that are significant, rather than remote, speculative, or theoretical.

A much more concerted effort is needed to educate the public and health care providers about the risk of HIV and hepatitis B virus transmission and the most cost-effective ways to lower it. Leadership must be assumed at a number of levels. Health care professional schools are important settings for teaching about risks of disease transmission in the course of delivering care. An important aspect of medical, nursing, and allied health professional education is learning to respect universal precautions and infection control guidelines. These lessons must be imparted and reinforced regularly.

It is especially discouraging to note that a substantial fraction of medical students, interns, and even practicing physicians are not vaccinated against infectious diseases that might pose a threat to patients. A 1990 survey of medical schools found that one-third do not require their medical students to be vaccinated. Up to 20% of medical students have not been immunized against measles and rubella, and 40% to 90% have not been immunized against hepatitis B (Nazario, 1990; Poland and Nichol, 1990).

Individual health care providers and hospital patient education coordinators also have an important role to play in shaping public perceptions of risk. They can explain universal precautions and infection control procedures in the course of rendering care. This can help allay patients' anxieties and encourage patients to voice unspoken questions and fears.

The public health and scientific communities have a special responsibility, not only to conduct research to refine risk estimates further, but also to communicate risks in a responsible fashion, taking into account uncertainties and complexities. Social psychological research must be supported to gain a more sophisticated understanding of the public's response to these issues and to enhance the ability to communicate effectively about risks. Behavioral research can also illuminate the most effective means of ensuring health care workers' adherence to universal precautions and infection control measures.

IV

HIV-Antibody Testing and Restrictions on Health Care Workers Performing Invasive Procedures

The Bergalis case prompted numerous calls for widespread mandatory testing of health care workers for evidence of HIV infection. Testing has been proposed as a means of identifying those whose medical or dental practice should be restricted. The Commission previously rejected such suggestions (National Commission on AIDS, 1991). Despite the superficial appeal of programs of widespread HIV-antibody testing of health care workers, such an endeavor is unlikely to provide greater protection for patients than less intrusive or restrictive alternatives.

The Commission believes that strategies to reduce or eliminate the risk of HIV/HBV transmission must utilize the least restrictive alternatives; i.e., those promoting the greatest safety with the fewest adverse consequences for both patients and health care providers and preserving, insofar as possible, other social values.

Mandatory testing of health care workers and patients would be more intrusive than voluntary testing and would carry a greater risk of breaches of confidentiality and discrimination. Moreover, even mandatory or routine testing of health care workers or patients would be unlikely to identify all who are HIV infected. The social stigma attached to a diagnosis of HIV infection is still considerable–individuals who think they might be HIV infected and fear job loss or other forms of discrimination may even avoid seeking health care where HIV testing is mandated.

Economic and Social Costs of Testing

The cost of mandatory testing would of course include the direct costs of the tests themselves. Testing costs would vary depending on the frequency of retesting and the range of providers to be included. Such costs would necessarily include the expense of establishing an administrative mechanism to ensure that the blood sample is actually obtained from the health care provider in question and a means of recording test results, maintaining confidentiality, and providing pre- and post-test counseling.

The cost of instituting widescale HIV-antibody testing as an infection control measure was estimated in one study to be $860,750 for a program in a 350-bed teaching hospital. The estimate includes the testing of 1,080 health care workers and 5,715 patients undergoing invasive procedures. The cost estimate also includes resulting practice proscriptions on a single infected surgeon, a dental student, and a paramedic (Gerberding, 1991b).

The Pennsylvania Department of Health has estimated that the cost of one round of testing for all of its 443,000 health care workers would be $4 million. With pre- and post-test counseling, the estimated cost would rise to $13.8 million. The costs of testing all 1.7 million Pennsylvania hospital inpatients is estimated at $53.7 million. Extrapolation from these figures yields a total national cost of $1.5 billion to test all hospitalized patients and $250 million to test all health care workers. Even making the perilous assumption that the risk justifies such a program and that it will be 100% successful, such an endeavor is likely to prevent only an estimated four to five cases of HIV infection per year based on the highest risk estimates. This represents a projected expenditure of $50 million per case of HIV infection averted. A projection performed for a screening program suggested for the state of Maryland estimated one case of HIV infection would be averted in 25-250 years. The cost per case prevented would be $440 million to $4.4 billion. These estimates represent a highly questionable diversion of resources at a time when many people living with HIV disease encounter formidable financial barriers to care. Such an expenditure would do nothing to alter the course of the epidemic. As an exhaustive monograph on the subject of proposed policies regarding HIV-infected surgeons concluded, "There is no doubt that this entire issue will have essentially no impact on the epidemic of HIV" (Bartlett, 1992b:271).

The full economic, social, and personal costs of widespread mandatory testing of health care workers are far broader than the exposure of the testing program itself. Mandatory testing of health care workers who engage in "exposure-prone," invasive procedures (however defined) may lead ineluctably to the testing of health care workers who do not perform invasive procedures. For example, "[c]oncerned about liability, one New York hospital board decided that removing sutures was an exposure-prone procedure (exceeding the CDC intent). They discharged an emergency department physician and notified patients that they might have been treated by an HIV-infected health care worker" (Daniels, 1992:1368).

There is no scientific consensus as to how often HIV-antibody tests would need to be repeated for infection control purposes. There is a lag time between acquiring infection with HIV and the production of measurable antibodies, i.e., a "window period" during which infected individuals will test negative. A negative test is no guarantee that an individual will not become infected in the future. Nevertheless, one state medical association, in an ostensible effort to calm public fear, issued certificates that could be posted in the offices of doctors who tested HIV negative. Even more deplorable is the marketing gimmick of a few dentists and other practitioners who have advertised that they and their staff are HIV negative. For example, a New York City dentist who "maintains a dental practice in Greenwich Village . . . . has not waited for the debate about testing health care workers for HIV-antibodies to be decided one way or the other. In an advertising flyer sent out to potential patients, [he] has stated that he and his staff have been tested for the AIDS virus, and are AIDS free" (Jones, 1992).

And a Washington, D.C.-based company, Partners for AIDS-Free America (PAFA), was established in December 1991 to issue laminated cards to certify that the bearer is HIV negative (for a fee of $29.95) and *HIV-negative framed wall certificates for doctors and dentists for $79.95* (Anonymous, 1992).

If the argument for testing health care workers and restricting their practice were taken to its illogical extreme, HIV-negative providers could be sidelined for months after each percutaneous exposure to patients' blood, as they await confirmatory tests to ensure they have not become infected as a result of their occupational exposure. Nor would such a program take into account percutaneous exposures that sometimes occur unbeknownst to the health care provider (Gerberding et al., 1990).

Mandatory testing of health care workers in order to limit the practice of those who are HIV infected for infection control purposes is both misguided and unworkable in practice. Routine or mandatory testing of health care workers should not be a

condition of employment or licensure. Nor should insurers require a negative HIV antibody test as a condition of malpractice coverage.

Losing Professional Resources

The costs associated with testing and sidelining HIV-infected health care workers also include the loss of their services to society, as well as their own loss of income. Exclusionary employment practices will inevitably result in the loss of dedicated, qualified health care workers, a precious social commodity. Society also loses the money and effort invested in training health care workers, a great deal of which is underwritten by public funds.

The loss envisioned here would be enormous. CDC currently estimates that of the 4.5 million health care workers in the United States, 360 surgeons, 1,200 dentists, 5,000 physicians, and 35,000 other health care workers are infected with HIV. Excluding or sidelining even a fraction of these workers would result in the loss of their current services and future availability, forgoing the considerable private and public investment in their educational training.

There have been suggestions that HIV-infected practitioners be accommodated by reassigning them to positions where they have less patient contact or do not practice invasive procedures. This may be impossible, however, with surgeons or dentists. Reassigning health care workers to jobs with little or no patient contact would still result in significant social costs when direct patient-care services are lost. Barbara Fassbinder, an Iowa nurse infected with HIV in the workplace, described her situation vividly at the November 1991 hearing of the Commission:

> As concerns my employment, this was a difficult situation for all concerned, [since the] policies and knowledge in place in January of 1987 were vague.
>
> I was transferred to an administrative position, for which I was not prepared, and it was not a part of my overall career goals. It was done partly out of fear of public reaction, if my HIV infection should become known in the community. And although I tried very hard to succeed in this job, my heart was not in it, which only added to my already deepening depression. I missed my old job. I missed the patient contact. I missed my former co-workers. I missed my life as it used to be and I mourned for my lost future.
>
> It was all enveloped in a cloud of secrecy. HIV counseling was not readily available in our rural area, and it was not until I sought care at a major teaching hospital a couple of hours drive away, that I began to feel hope again. But as my energies began to wain, tensions increased with my employer over responsibilities for compensation, as well as job expectations, and my health dictated that I finally resign in 1989 (Fassbinder, 1991:84-85).

Many HIV-infected providers are gay men whose practices include large numbers of individuals with HIV disease; diverting them from practice would further undermine efforts to respond to the epidemic. Sidelining health care professionals who have chosen to work in HIV care would have a disproportionate impact on areas of high HIV seroprevalence. These areas tend to be medically underserved, especially certain urban epicenters such as New York City where people with HIV disease and those from communities with high rates of HIV disease already have difficulties securing access to care.

One suggested alternative has been to allow HIV-infected practitioners to work only with HIV-infected patients (or perhaps, medically indigent individuals). This cynical proposal would set a dangerous precedent for demanding that workers with a particular infectious disease be allowed to treat only patients with that disease. The proposal would also widen the already growing gap in health care access between the "haves" and "have nots."

The Symmetry of Provider/Patient Testing

Any proposal for mandatory widespread screening of health care workers is unlikely to garner support of the medical community without a parallel program for preprocedure testing of patients. Commentators have noted the "peculiar dialectic" involved in the development of policies for testing of health care workers and patients (Barnes et al., 1990:322). Providers have argued that, if they are to be tested, then patients should be tested as well, because the risk of HIV infection in the health care setting is significantly greater flowing from patient to provider than in the reverse direction.

Some health care providers have also argued that, even when following universal precautions, they can be "extra careful" when they know the patients are HIV infected. There is no evidence that knowledge of seropositivity reduces the rate of percutaneous exposures to patients' blood (Gerberding et al., 1990). Moreover, the corollary of this argument implies that health care workers might somehow be less careful or vigilant with patients who have not tested HIV positive. Because of the "window period" between acquisition of infection and positive test results, it is a risky course of action to base decisions about how to proceed on patients' presumed serostatus. The strategy of universal precautions makes more sense–assuming blood to be potentially infectious whether HIV-antibody test results are positive, negative, or unavailable. If mandatory HIV testing of patients resulted in refusal to provide care or in the provision of substandard care, health care providers and the institutions employing them would risk substantial liability.

The Commission believes it is important to distinguish clearly between HIV-antibody testing for clinical and/or behavioral purposes, on the one hand, and testing in order to secure results for infection control purposes, on the other. Individuals have a right to know if they are being tested for other than their own benefit.

The Impact on Willingness to Provide Care

The Commission believes that physicians and other health care workers may not ethically refuse to treat patients because of the patients' HIV infection. Patients' refusal to undergo HIV testing should not jeopardize receiving care.

Yet many health care providers are reluctant to treat individuals with HIV disease. The HIV epidemic is already adversely affecting the ability to recruit and retain health care workers and students (Gauch, Feeney, and Brown, 1990; Gerbert et al., 1991b; Cooke, 1992).

There are a variety of complicated reasons for health care providers' willingness or refusal to treat HIV disease, including attitudes about homosexuality and drug use, sense of duty, competence in HIV care, and concerns about the impact on the ability to practice (i.e., hiring and retaining staff and attracting patients). Risk of occupational acquisition of infection also factors into this mix of concerns. Health care workers who risk acquiring HIV in the health care setting know that exposure to HIV may mean illness and possibly death. If becoming HIV infected also means practice restrictions and loss of ability to make a living long before illness would make it inadvisable or impossible to work, there will be further reason to avoid such care. Such fears could result in more widespread refusal to take care of HIV-infected patients or in substandard care in HIV disease.

Professor Molly Cooke, a physician who has studied caregivers' attitudes toward HIV care, has cautioned against assuming "that people who are willing to treat AIDS patients are for some reason less concerned with the risk of occupational infection than 'non-treaters'" (Cooke, 1992:247). Dr. Cooke has studied concerns about occupational risk among committed providers.

> Regarding health care workers who are providing care to HIV patients as fearless or unconcerned about occupational transmission does not do justice to the tension that these professionals feel between their desire to help their patients and the justifiable desire to preserve their own health and safety and that of their families . . . . Practitioners in high prevalence areas alternate between finding reassurance in the published statistics on seroconversion rates after needlestick injuries and finding the same statistics worrisome. Concern about occupational infection fluctuates; certain events, either in the practice setting or outside events reported in the media, can lead to the reappearance of fear (Cooke, 1992:249-250).

The need for health care workers to be given support in their willingness to take care of people with HIV disease was recognized by ethicist Albert R. Jonsen in arguing that individual responsibility of health care providers is by itself an "insufficient basis for public confidence:"

> Their individual responsibility to act in accord with prudent recommendations for professional behavior must be surrounded by the strengthening bonds of collegial, professional, corporate, and social responsibility . . . . Nothing would do more to assure that infected professionals either reveal their status in an appropriate way or act in accord with recommended standards than programs of psychological and economic support . . . . The organized professions should assure ways exist to compensate responsible individuals for any loss of practice arising from disclosure of status (Jonsen, 1991:661-662; see also, Schatz, 1991).

The Commission believes that health care workers who limit or modify their range of professional activities because of HIV infection should be provided with opportunities to continue appropriate patient care activities. Professional associations and employers should be encouraged to promote the continued use of HIV-infected health care workers' skills and knowledge through career counseling and, where necessary, job retraining and placement. Adequate disability insurance should be available to those who suffer occupationally acquired HIV infection.

V

Disclosing HIV Status to Prospective Patients

Informed Consent and the Right to Know

There has been considerable debate as to the extent of the patient's "right to know" the HIV or HBV status of health care providers. The CDC guidelines published in July 1991 recommend that health care workers who perform exposure-prone invasive procedures find out their HIV status, and, if they are HIV positive, seek advice from local expert panels on under what circumstances, "if any," they may continue to perform such procedures (CDC, 1991c). In a provision added at the behest of Senator Orrin Hatch (R-Utah) just before the guidelines were going to press (Sternberg, 1991), CDC also recommended informing patients in each instance in which an HIV-infected worker performs an invasive procedure, even though that worker has been certified to work by an expert review panel. Once such actions are taken, it is unlikely that HIV-infected health care workers will be able to perform invasive procedures (or even noninvasive ones), except perhaps on patients who are, likewise, HIV infected.

Health care workers who know or suspect they are HIV infected are less likely to seek care or counsel in a health care system that seeks to weed them out. HIV-infected practitioners have been forced to abandon their practices when their status was disclosed, even when no invasive procedures were involved and there were no additional risks posed to their patients as a result of their infection status. In 1988, a Texas pediatrician was forced to abandon his practice when his HIV serostatus became known to his local community (Kinsella, 1989).

Professor Larry Gostin noted other such cases:

> [A] director of anesthesia was denied contact with patients and was then disciplined when he personally assisted a patient who had vomited and was in immediate danger of aspirating; a gynecologist was forced out of a lucrative medical partnership despite his offer to do no "hands on" work. Even health care professionals who contracted HIV from occupational exposure have been dismissed or penalized by the hospital where the exposure took place (Gostin, 1990:305, citations omitted).

Some analysts have argued for disclosure, based on the principle of *primum non noccere* ("first, do no harm"). This conclusion acknowledges that the overwhelming majority of those polled say they would want to know their providers' HIV status. Under the doctrine of "informed consent," which is based both on common and statutory law, physicians and other providers are obliged to disclose risks when they are "material" to patients (Appelbaum, Lidz, and Meisel, 1987). A leading case defined material as, "when a reasonable person in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risks or cluster of risks in deciding whether or not to forego the proposed therapy" *Canterbury* v. *Spence*, 464 F.2d 72 (1972).

The informed consent case law involves disclosures related to patients' choices to undergo procedures or diagnostic interventions. Little attention in the development of the law on informed consent was paid to the extent to which physicians or other providers must disclose risks involving disabilities or conditions affecting those health professionals themselves. Professor Chai Feldblum has concluded that in the absence of a compelling public health justification, which has not yet been demonstrated because of the remoteness of the risk, there is no justification under informed consent doctrines for health care workers to disclose their HIV status (Feldblum, 1991).

Some commentators have suggested how misplaced patients' desires to know about their providers' HIV status are by enumerating a litany of conditions or disabilities that are much more likely to compromise patient care: "e.g., aging, stress, fatigue, marital problems, psychiatric treatment, medication side effects, drug or alcohol use" (Barnes et al., 1990:315). These commentators have noted that no statute or regulation yet requires that these much more serious risks to patients be disclosed.

Philosopher Norman Daniels has characterized the problems related to the disclosure of health care workers' HIV status as the "switching dilemma." In the clash of conflicting rights, he argues that dismissing a patient's desires to know his or her provider's HIV status by relying on arguments about remote probabilities of risk is "strongly paternalistic. . . . We cannot simply dismiss the fear as pure prejudice since there is a real mechanism for transmission." According to Daniels:

> The point of appealing to patient rights is to protect patients against "expert" judgments by physicians who may be so sure the risks they impose are worth taking that they fail to inform patients about them. To preserve the right of patients to decide what risks are worth taking means refusing to let expert or objective assessments of risks and benefits carry the day and requiring instead that the subjective assessment by the patient is decisive (Daniels, 1992:1370).

The result can be described as a "problem of the commons," an instance in which if we collectively refrain from acting on what we perceive to be in our individual self-interest (in this instance, demanding to know the HIV status of surgeons or other health care workers) we will all be better off. Daniels makes the analogy to fishermen respecting limits on catches. If an individual fisherman or even a few fishermen violate the limit and catch more fish than allowed, they will prosper. Yet, if all try and catch as many as they can, they each suffer when the fish population collapses. In the case of HIV-infected health care workers, "we will each be worse off if we give unrestricted play to patient rights to engage in switching behavior, or if we adopt policies that are equivalent to people so exercising those rights" (Daniels, 1992:1370).

The Commission believes that a blanket policy of disclosure of health care providers' HIV status to patients would not only fail to make the health care workplace any safer, it would also have a deleterious impact on access to health care. Mandatory disclosure of a health care worker's HIV serostatus does little, if anything, to enhance the patients' safety. It inflates the risk of HIV transmission out of proportion to other risks and is inconsistent with the principles and practice of informed consent.

VI

Guidance for Health Care Workers at Risk for HIV Infection

All health care workers should consider their need to undergo HIV testing voluntarily. Some health care workers may, in their personal lives, practice behaviors that place them at risk for HIV infection. Others may be at risk because of aspects of their medical practice that may increase the likelihood of percutaneous exposure to patients' blood through needlesticks or other injuries. They may practice in geographic areas or clinical settings in which a large proportion of patients are HIV infected.

Health care workers who are concerned about their HIV status should initiate discussions with their personal physician to review high-risk behaviors as well as risks associated with the transmission of HIV/HBV in the health care setting. As with anyone who is at risk for HIV, health care workers who believe they may be at risk should take steps to find out their HIV status and receive appropriate counseling to preserve their status if negative, or make assessments regarding clinical care and prophylactic interventions, if positive.

HIV testing may also be considered whenever clearly documented significant exposures to blood and other body fluids occur between health care workers and patients. Testing incident to such exposures must always be preceded by counseling and written informed consent of the person tested or his or her legally authorized representative. When a patient has suffered an exposure to the blood or body fluid of a health care worker, the patient has a right to know the HIV status of the health care worker. This will help the patient decide what steps to take regarding HIV testing, prophylactic treatment, and follow-up care. The patient should also be counseled to prevent subsequent transmission of infection.

Determinations about HIV-infected health care workers' abilities to continue to practice medicine should be based on an individualized assessment of an array of factors, not merely HIV status. The practice of an infected health care worker should be evaluated by his or her physician and modified only if there is clear evidence that the health care worker poses a significant risk of transmitting infection through the inability to meet universal precautions and basic infection control standards.

All HIV-infected health care workers are encouraged to seek counseling from their personal physicians, as needed, to understand the risk of HIV transmission in any invasive or exposure-prone procedures, and receive advice on appropriate special precautions. In addition, infected health care workers should seek appropriate medical care and periodic evaluations of health status, counseling on the advisability of continuing to work in the health care setting, and information on safer sex and partner notification.

Limiting the practice of HIV-infected health care workers is not justified on the basis of scientific evidence, as discussed above. It is not necessary because of the extremely low risk of disease transmission and the many negative consequences that will flow from restricting the health care practice.

HIV infection alone does not constitute a reason for limiting the practice of HIV-infected health care workers, including the performance of invasive or exposure-prone procedures. Any practice restrictions or work modifications should be based on an individualized assessment of the health care worker's ability to comply with universal precautions and infection control guidelines and procedures, his or her professional competence, or documented previous transmission of bloodborne infections. Monitoring by the individual health care worker's personal physician should be sufficient to determine whether such conditions exist for HIV-infected health care workers who do not perform invasive or exposure-prone procedures. For infected health care workers who perform invasive or exposure-prone procedures, the personal physician may wish to consult public health officials and other experts.

VII

Preserving a Precious Resource: HIV-Infected Health Care Workers

Protecting the Civil Rights of Workers

Administrators in both medicine and dentistry have expressed the sentiment that the issue of HIV-infected health care workers leaves them "between a rock and a hard place." They have responsibilities for quality of care, including hiring and staff credentialing. They fear adverse publicity and lawsuits if they allow HIV-infected practitioners to continue to practice or if they fail to disclose the infected person's status to current or former patients (and indeed, even HIV-negative patients have sued, alleging emotional distress because of not having been told that their provider was HIV infected). On the other hand, privacy, confidentiality, and civil rights provisions protect the rights of HIV-infected providers.

Federal civil rights laws protect the employment rights of HIV-infected health care workers. There are two relevant federal statutes: the Federal Rehabilitation Act (1973) 29 U.S.C. Sec. 794(a) and the Americans with Disabilities Act (1990) Pub. L. 101-336, 104 Stat. 327 (1990); in addition, at least 34 states have disability laws specifically prohibiting discrimination based on HIV infection in a variety of contexts (Hunter, 1990).

Section 504 of the Federal Rehabilitation Act of 1973 provides that no otherwise-qualified individual with disability shall be subject to discrimination because of his or her disability under programs receiving federal funds. A qualified person with a disability is one who, with reasonable accommodations, can perform essential functions of a job, despite physical or mental impairment. This statute applies to most hospitals, by virtue of their receipt of federal Medicare or Medicaid funds. The statute obliges hospitals to make reasonable accommodations for otherwise qualified employees with disabilities, unless doing so would impose an "undue hardship" on the institution or a "significant risk" to the health and safety of others.

In a 1987 Supreme Court case involving a school teacher with tuberculosis, *School Board of Nassau County, Florida* v. *Arline* 480 U.S. 273 (1987), the court held that having an infectious disease qualified as a disability under the Federal Rehabilitation Act, and that Section 504 protections against discrimination therefore extended to contagious diseases. Under *Arline*, one cannot be dismissed summarily merely because of fear of contagion. Although the Supreme Court declined to address whether an HIV-infected person would be within the scope of the Rehabilitation Act, lower federal courts have subsequently held that HIV-infected individuals or those perceived as being HIV infected fall within the protection of the Rehabilitation Act.

In *Arline*, the court adopted a "significant risk" standard urged by the American Medical Association (AMA) in an *amicus curiae* brief. The AMA's proposed four-pronged significant-risk test is as follows:

- The nature of the risk (how is the disease transmitted);

- The duration of the risk (how long is the carrier infectious);
- The severity of the risk (what is the potential harm to third parties); and
- The probabilities the disease will be transmitted.

The civil rights protections of the Rehabilitation Act were extended to most employees, not merely those who work for organizations that receive federal funds, by the landmark Americans with Disabilities Act (ADA) passed in 1990. Currently being phased into effect, the ADA prohibits employers from discriminating against otherwise qualified individuals with disabilities, including HIV infection. If a significant risk of substantial harm cannot be eliminated by reasonable accommodation, then the ADA does not afford protection against discrimination. The ADA represents a hard-fought social consensus on discrimination and risk. It is also noteworthy because it defines private physicians' and dentists' offices as places of public accommodation.

Regulations promulgated under the ADA establish a four-pronged test of significant risk similar to the test in the Supreme Court decision in *Arline*. The legislative history of the ADA clearly shows that Congress intended that "speculative or remote risk" or "merely elevated risk of injury" would not rise to the level of "significant risk." Evaluation of risk should not be based on "generalizations, misperceptions, ignorance, irrational fears, patronizing attitudes, or pernicious mythologies" *U.S. Code Cong. & Adm. News*, Supp. 6, at 303, 338, 446-447 (Sept. 1990).

One question sure to be addressed in the near future is the implication of the federal antidiscrimination provisions for HIV-infected health care workers employed in certain inner-city hospitals and correctional facilities where they may face serious risks of exposure to multidrug-resistant tuberculosis (MDR-TB). This is a special concern for those whose immune systems are compromised by HIV infection. It is not clear to what extent the risk formulations in the ADA apply to risk to oneself. Section 504 of the Rehabilitation Act has been interpreted to allow risk to self as a basis for discriminatory hiring practices. Although the ADA is silent on this, the regulations pursuant to the ADA promulgated by the Equal Employment Opportunity Commission (EEOC) include a risk-to-self defense against discrimination charges.

AIDS legal advocates have maintained that "even if courts were to recognize the risk to self as a basis for employment discrimination under the ADA, employers would be required to meet an exacting standard before they could discriminate against an employee for his or her own good." Employers have been urged to avoid paternalism in this context. "While workers are entitled to full disclosure of health risks associated with their jobs, properly informed workers should have the right to determine on their own whether they desire to work in the presence of disclosed risks. Disclosure, not discrimination, should remain the touchstone for employment policy in the age of MDRTB" (Lambda Legal Defense and Education Fund, Inc., 1992).

Bearing the Economic Burden of Occupational Injuries

The cost of occupational exposure to HIV and other bloodborne diseases is both a societal issue and a concern for health care workers and patients. Questions about how to pay for costs of HIV disease resulting from infection occurring in the health care setting point up the shortcomings of a health care financing system so intimately tied to the workplace. Traditional means of shifting the costs of unintentional injuries may not work well with HIV disease. The need to establish the source of a potentially work-related illness or disability before receiving needed care has particular limitations in this instance (Brennan, 1991).

Workers' compensation claims made by HIV-infected health care workers or damage suits brought directly against employers will encounter significant obstacles. It may be difficult to prove infection was a result of occupational injury, because HIV is much more commonly transmitted by unprotected sexual intercourse or the sharing of contaminated equipment used for injecting illicit drugs. Hospitals and workers' compensation boards will fight against any presumption that the infection occurred at work and may go to great lengths to uncover details about plaintiffs' personal lives–there have been anecdotal accounts of hospitals' hiring private detectives to inquire about the sex lives of tort litigants and disability claimants.

Providers who acquire HIV infection on the job may be precluded from suing employers because of the availability of workers' compensation and provisions that bar tort litigation for those for whom such benefits are available. Workers' compensation benefits tend to be quite limited and more suited to providing for injuries than chronic diseases. Moreover, they are pegged to salaries at the time of the injury, which may be extremely modest for providers in training such as medical, dental, and nursing students or for part-time workers as testified to by witnesses at Commission hearings. The Commission heard dramatic testimony on the shortcomings on the workers compensation system from a nurse who was infected as a result of an occupational injury:

> [T]he workers compensation system . . . falls far short of even my most modest expectations. It is important to note that the responsibility is on the health care worker to prove infection in the workplace. For me, that was not difficult, but for many health care workers it is very difficult, and workers compensation denies [benefits].
>
> The compensation system, which does vary from state to state, is a classic good news/bad news story. The good news is that all and only HIV-related expenses are covered, after close scrutiny, I might add. The bad news is that disability payments are based on a portion of one's wages at the time of the accident. I was working half-time in 1986, so, therefore, I am compensated at half-time 1986 wages, 60 percent of half-time 1986 wages, I might add . . . .
>
> In addition, since I, like most Americans . . . purchased my health insurance through my employer–my husband is employed in agriculture–when I was no longer able to work, because of my illness, we were no longer able to pay the premiums on health insurance, so then we began the task of trying to find health insurance for my husband and children, who are free of HIV disease . . . . Many companies would not even consider them. The ones that were kind enough to consider them were likely to ask for bizarre assurances, such as a notarized statement from my husband that he would not have sexual relations with me.
>
> I was outraged, by the way, by this request. My husband's [response] was much more humorous, but profound. His statement was, "Do you mean it is okay with them if I sleep with strangers or I shoot drugs, but I just can't sleep with my wife [of] 15 years, who I already know is HIV infected?" Needless to say, we didn't take that policy.
>
> The company that did finally agree to insure my husband and children still will not cover them for anything HIV related, even though the scientific evidence is overwhelming that household contact is extremely safe, and my

> children are safer in my own home than they are in the outside world, as teenagers (Fassbinder, 1991:82-84).

The American Medical Association developed a disability insurance policy that would pay a lump sum benefit of up to $500,000 for a physician who tests HIV positive at an annual premium of less than $1,000 (Orentlicher, 1991). Very few hospitals have addressed these issues with comprehensive policies (Hauptman and Feinberg, 1990). Many have established policies that cover only a fraction of the work force, such as house staff.

VIII

CDC Guidelines

On July 12, 1991, CDC issued a set of recommendations that concluded that the risk of transmitting HBV from an infected health care worker to patient is "small" and the risk of transmitting HIV "even smaller" (CDC, 1991c:7). CDC also stated that the likelihood of patients' being exposed to a health care worker's blood is greater for certain procedures, designated as "exposure prone." The July recommendations can be summarized as follows:

- All health care workers should adhere to universal precautions.
- Available data provide no justification for restricting the practice of HIV- or HBV-infected health care workers who perform invasive procedures, unless they are exposure prone.
- Health care workers who perform exposure-prone procedures should know their HIV status (and HBeAg status if there is no evidence of immunity conferred by vaccination).
- HIV- or HBV-infected workers should consult with local expert panels as to under what circumstances, if any, they may continue to perform exposure-prone procedures. Prospective patients of HIV- or HBV-infected health care workers should be notified before undergoing exposure-prone, invasive procedures.

On August 16, 1991, CDC announced that it was developing a process to enumerate specifically a list of exposure-prone procedures to guide health care workers, health care facility administrators, and the designated local review panels in determining from which procedures HIV-infected health care workers should withdraw themselves or notify prospective patients of the workers' HIV status (CDC, 1991b). Medical professional associations balked at cooperating in developing the CDC list, pointing to a lack of evidence as to what procedures pose risks, given the rarity of health care worker-to-patient transmission (Altman, 1991).

CDC Activity, State Activity, and "Equivalency"

CDC's activities in this area are a key source of policy guidance, even if they are not the only or the last word. Although recommendations appearing in the CDC's *Morbidity and Mortality Weekly Report* are often labeled "guidelines," they carry substantial weight. Most significantly, Congress enacted a law that directs states to adopt guidelines "equivalent" to those published by CDC within a year or risk loss of federal funds. Unless an extension is granted, October 28, 1992, is the deadline for states to adopt an "equivalent" set of guidelines, Treasury, Postal Services and General Government Appropriations Act, 1992, Pub. L. 102-141 § 634 (1991). Congress has empowered the Director of CDC to make a determination of such equivalency. CDC began to revise substantially its July 1991 guidelines, but ultimately decided, on advice of Health and Human Services attorneys, not to issue new, less restrictive guidelines.

Courts have frequently looked to CDC guidelines to establish standards of medical practice in litigation. CDC guidelines have already been invoked to uphold practice restrictions on an HIV-infected surgeon, *Behringer* v. *Princeton Medical Center* 592 A.2d 1251 (N.J. Super. 1991), or to otherwise sideline health care workers (Wolff, 1991). In a disturbing case, a previous version of CDC guidelines was misinterpreted in a case upholding the firing of a nurse who refused to convey the results of his HIV testing, *Leckelt* v. *Board of Commissioners of Hospital District No. 1*, 714 F. Supp. 1377 (E.D. La. 1989), *aff'd* 909 F.2d 820 (5th Cir. 1990). In a more recent case, CDC's July 1991 guidelines were invoked in a Pennsylvania decision rejecting the privacy claims of an HIV-infected OB/GYN surgical resident under the Pennsylvania Confidentiality of HIV-Related Information Act. The court upheld the hospital's decision to notify more than 400 previous patients that the resident was HIV positive, without adequately addressing questions related to whether he had actually put them at risk, *Doe* v. *Hershey Medical Center*, __ Pa. Super. __, 595 A. 2d 1290 (Pa. Super. Ct. 1991).

Congress obviously did not mean for the states simply to adopt the CDC guidelines word for word, or the equivalency concept would have been neither necessary nor meaningful. The "equivalency" language clearly was meant to allow states considerable leeway in fashioning guidelines to minimize the transmission of HIV and HBV in the health care workplace, while choosing different routes to this same endpoint. Dr. William Roper, Director of the Centers for Disease Control, told the *New York Times*, "We think we will learn more by letting states do various things on a state-to-state basis and seeing what we learn over the next few years" (Altman, 1992:C7). In a June 18, 1992 letter to state health officers, Dr. Roper stated that the review of state guidelines regarding their equivalency to the July 12, 1991 CDC guidelines "will give appropriate consideration to those states that decide that exposure-prone invasive procedures are best determined on a case-by-case basis, taking into consideration the specific procedure as well as the skill, technique, and possible impairment of the infected health-care worker."

The Commission believes the approaches embodied in the guidelines adopted by New York (New York State Department of Health, 1992) and Michigan (Ad Hoc Committee, 1991) hew closely to the principles set forth at the beginning of this document and are excellent examples for policy-makers in other states.

Importantly, those guidelines stress improvements in infection control and professional technique over blanket employment restrictions based on known or suspected HIV infection. The Michigan and New York guidelines address risks of all potential bloodborne transmissions between health care workers and patients, not merely HIV. Those guidelines therefore achieve the overall goal of improved safety for workers and patients, while avoiding the massive costs, human hardship, and disruption of services associated with mandatory testing, exclusion, and disclosure.

The Commission feels strongly that measures adopted to prevent potential HIV transmission between health care workers and patients must be the least costly, least restrictive alternatives consistent with protection of the public health. Keeping these objectives of cost reduction and minimal intrusiveness in mind is consistent with our society's deepest constitutional and legal traditions, while simultaneously respecting essential principles of public health and medical practice. The "cure" to the risk of HIV transmission in the health care workplace must not be more damaging to the public's health than the risk itself. In the Commission's view, federal, state, and local policy-makers therefore must gauge carefully any unintended secondary and tertiary

consequences of policies adopted in this area, to ensure that such policies do not create more difficulties than they solve. *Primum non nocere*–"first, do no harm"–even while acknowledging, frankly, that risks to public health in the HIV epidemic from transmission in the health care setting pale by comparison to the continued spread through unprotected sexual activity and risky drug use.

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APPENDIX A

Witnesses at the Commission Hearing on Making the Health Care Environment Safer: Strategies to Reduce the Risk of Transmission of Bloodborne Infections
November 5, 1991, Washington, DC

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James R. Winn, M.D., Executive Vice President, Federation of State Medical Boards, Ft. Worth, TX

APPENDIX B

Glossary of Terms

acute HIV disease or infection–may occur as early as a week after infection starts and ordinarily precedes seroconversion; clinical manifestations: fever, lymphadenopathy, night sweats, skin rash, headache, and cough; also called *primary HIV infection* and *acute phase of HIV infection.*

body fluids–from which HIV has been isolated: blood, semen, breast milk, vaginal/cervical secretions, tears, saliva, urine; only blood, semen, vaginal/cervical secretions, and breast milk are known to transmit HIV.

degree of viremia–concentrations of virus particles in the blood stream.

exposure-prone invasive procedures–CDC defined these as "procedures during which there is a recognized risk for percutaneous injury to the health-care worker (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". (CDC 1991a:565).

exposure-prone procedures–CDC defined exposure-prone procedures as follows: "Characteristics of exposure-prone procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the health care worker'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 health care worker, and–if such an injury occurs–the health care worker's blood is likely to contact the patient's body cavity, subcutaneous tissues, and/or mucous membranes" (CDC, 1991b:4).

HIV-infected–term used 1) to denote a person with a diagnosis of HIV infection based on clinical signs/symptoms (not laboratory-confirmed) or 2) to denote a woman's HIV status when she has an infant who tests HIV-positive; can also be used as an inclusive term for persons who test *HIV-positive* (see also).

HIV-negative–having no serologic evidence of HIV antibody.

HIV-positive–having confirmed serologic evidence (antibody or virus isolate) of HIV infection; the primary test for antibody to HIV is the ELISA, confirmation is with another ELISA or a supplementary test, usually Western blot.

invasive procedures–CDC defined "invasive procedures" 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 catheterization 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" (CDC, 1987b:6S-7S).

transmission–there are three modes of transmission of HIV: 1) *sexual*; 2) *parenteral*–through blood, including (a) blood transfusions, (b) blood products, (c) injections and skin-piercing instruments, (d) organ and semen donation; and 3) *perinatal*–from an HIV-infected woman to her fetus or infant before, during, or shortly after birth.

universal precautions–measures taken in health care settings to prevent transmission of HIV whether patients are known to be HIV infected or not; blood and certain body fluids (such as semen and vaginal secretions) of all patients are considered potentially HIV-infected; universal precautions are intended to help prevent parenteral exposures including mucous membrane and nonintact skin exposures, to blood in health care settings.

window period–the time between acquisition of an infectious agent (HIV) and the appearance of specific antibody; with HIV, the window period lasts about 6-8 months but may last as long as a year; the virus is transmissible from the time of acquisition.