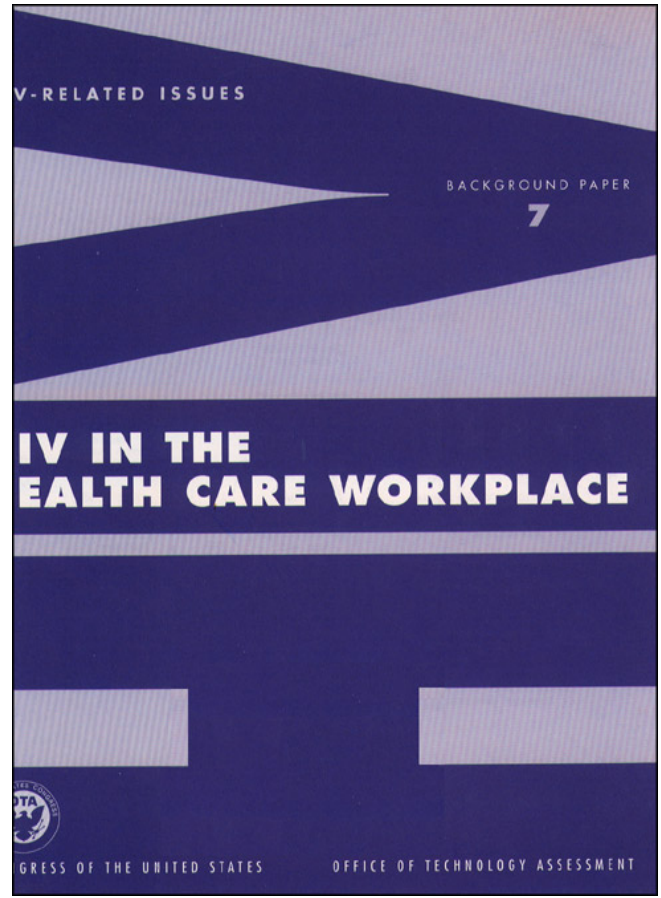
HIV in the Health Care Workplace

November 1991

OTA-BP-H-90
NTIS order #PB92-150333



Recommended Citation:

U.S. Congress, Office of Technology Assessment, *HIV in the Health Care Workplace, OTA-BP-H-90* (Washington, DC: U.S. Government Printing Office, November 1991).

For sale by the U.S. Government Printing Office
Superintendent of Documents, MaiI Stop: SSOP, Washington, DC 20402-9328
ISBN 0-16 -035991-0

HIV IN THE HEALTH CARE WORKPLACE

Background Paper

Prepared for OTA by:

Lawrence Mike
Professor of Medical Policy
University of Hawaii at Manoa
John A. Burns School of Medicine
Honolulu, HI .

and

Julia Ostrowsky
Chicago, IL

Clyde Behney, *Health Program Manager*

Maria E. Hewitt, Project Director, HIV-Related Series

This background paper was prepared as part of OTA's ongoing HIV-related assessment

November 1991

Foreword

Recent reports of five cases of HIV transmission within a dental practice have raised issues regarding patient safety and received much public attention. The Centers for Disease Control's reports of these cases and CDC'Ss subsequent recommendations for preventing transmission of HIV and the hepatitis B virus to patients during exposure-prone invasive procedures have in turn led Congress to consider several actions directed at HIV in the health care workplace.

This background paper examines evidence of the risk of HIV transmission in the health care workplace and discusses the policy implications of CDC guidelines and congressional actions in response to this risk. The issues discussed in this paper were the subject of a workshop conducted by OTA on July 25-26, 1991.

This background paper was prepared in response to a request by the Committee on Labor and Human Resources, U.S. Senate.

The background paper will be the seventh in the OTA's series of studies on HIV-related issues. The preceding papers in this series were Do *Insects Transmit AIDS?* (September 1987); *AIDS and Health Insurance-an OTA Survey* (February *1988); How Effective Is AIDS Education?* (June *1988); The Impact of AIDS on the Kaiser Permanence Medical Care Program (Northern California Region)* (July *1988); How Has Federal Research on AIDS/HIV Disease Contributed to Other Fields?* (April 1990); and *The Electiveness of Drug Abuse Treatment: Implications for Controlling AIDS/HIV Infection* (September 1990). Previous OTA reports addressing AIDS-related issues include: 1) *Blood Policy and Technology* (January 1985), 2) *Review of the Public Health Service's Response to AIDS* (technical memorandum, February 1985), 3) *The Costs of AIDS and Other HIV Infections; Review of the Estimates* (staff paper, May 1987), and 4) *Medical Testing and Health Insurance* (August 1988).

JOHN H. GIBBONS
Director

Workshop Participants: HIV in the Health Care Workplace

Lawrence Mike
Workshop Moderator
Professor of Medical Policy, University of Hawaii at Manoa
John A. Burns School of Medicine
Honolulu, HI

Joseph Alderman
Director, Office of Dental Health
Georgia Department of Human Resources
Atlanta, GA

Mark Barnes
Member
Bar Association of the City of New York
New York NY

Jeremiah Barondess
President
New York Academy of Medicine
New York NY

David Bell
Chief, AIDS Activity
Hospital Infections Program
Centers for Disease Control
Atlanta, GA

Peter Budetti
Hirsh Professor
Department of Health Services Administration
George Washington University
Washington, DC

James Curran
Director, Division of HIV/AIDS
Centers for Disease Control
Atlanta, GA

Nancy Dubler
Director
Legal & Ethical Issues in Health Care
Montefiore Medical Center
Bronx, NY

Theodore Eickhoff
Director, Internal Medicine
Presbyterian-St. Luke's Medical Center
Professor of Medicine
University of Colorado
School of Medicine
Denver, CO

Chai Feldblum
Professor of Law
Georgetown University Law Center
Washington, DC

Julie Louise Gerberding
Assistant Professor
San Francisco General Hospital
University of California, SF
San Francisco, CA

Lawrence Gostin
Executive Director
American Society of Law and Medicine
Boston, MA

David Henderson
Associate Director
Quality Assurance & Hospital Epidemiology
NIH Clinical Center
Bethesda, MD

Peter Huber
Senior Fellow
Manhattan Institute
Washington, DC

Sheldon Landesman
Associate Professor
Health Science Center
State University of New York
Brooklyn, NY

Donald Marianos
Dental Officer
Dental Disease Preventive Activities
National Center for Prevention Services
Centers for Disease Control
Atlanta, GA

Patricia McInturff
Director, Regional Division
Department of Public Health
Seattle-King County
Seattle, WA

Michael Osterholm
State Epidemiologist & Chief
Acute Disease Epidemiology Section
Minnesota Department of Health
Minneapolis, MN

Julia Ostrowsky
OTA Contractor
Chicago, IL

Craig Shapiro
Medical Epidemiologist
Hepatitis Branch
Centers for Disease Control
Atlanta, GA

Jane E. Sisk
Visiting Professor
School of Public Health
Columbia University
New York NY

Michael Tapper
Hospital Epidemiologist
Lenox Hill Hospital
New York, NY

NOTE: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the workshop participants. The workshop participants do not, however, necessarily approve, disapprove, or endorse this background paper. OTA assumes full responsibility for the background paper and the accuracy of its contents.

Contents

	Page
summary	1
Introduction	3
Expected Pattern of HIV Transmission to Patients	4
Magnitude of the Risk	5
Actions That Have Been Recommended	10
Impacts and Policy Implications	12
References	17

HIV in the Health Care Workplace

Summary

A cluster of HIV (human immunodeficiency virus) infections among five patients of an HIV-infected dentist has focused public attention on the possibility of HIV transmission from health care workers (HCWs) to patients. This background paper examines the evidence of the risk of HIV transmission in the health care workplace and discusses the policy implications of the Federal Centers for Disease Control (CDC) guidelines and congressional responses. The issues discussed in this paper were the subject of a workshop conducted by OTA on July 25-26, 1991. This background paper was prepared in response to a request by the Committee on Labor and Human Resources, U.S. Senate.

The cluster of HIV-infected patients of one Florida dentist represents the only known instance of HIV transmission to patients within a health care setting (aside from transfusion-associated HIV transmissions). How the dental patients were infected remains unknown. The possibility exists that the patients were infected directly through dentist-blood to patient-blood contact or indirectly by dental instruments contaminated with the dentist's or another infected patient's blood. The dentist and his five patients were all infected by a genetically similar HIV strain.

The CDC has concluded that estimating precise risks of HIV transmission from HCWs to patients is not yet possible, but that the available evidence points to a very small risk, much smaller than other known medical risks, such as the risk of dying due to an adverse reaction to anesthesia during surgery. On the basis of the analysis presented in this background paper, OTA agrees with this conclusion.

Two approaches have been used to assess the risk of HIV transmission in the health care setting—examining patients of HIV-infected health care providers in what are called "look-back studies," and developing risk assessment models.

More than 4,000 patients of HIV-infected HCWs have so far been tested as part of look-back studies (some investigations are ongoing), with no cases of HIV infection yet attributable to medical or dental procedures except for the 5 Florida dental cases (the patients in these studies underwent a wide variety of procedures that were not specified according to whether they were exposure prone or not). While these results suggest that the risk of HIV transmission to patients is low, OTA notes that even if much larger numbers of patients are evaluated, these studies are unlikely to help determine the magnitude of risk because they are difficult to conduct and interpret. Years may often have elapsed between the performance of the medical procedure under investigation and the identification of the HIV-infected HCW, making it difficult to document important information on adherence to infection control, the nature of the procedure performed, and the occurrence of injury to the HCW in the performance of the procedure. Furthermore, if patients are identified as HIV-infected during the look-back study, it maybe impossible to determine whether infection was actually acquired from the particular HCW or from other generally more common sources.

OTA notes that carefully reasoned decisions on which situations warrant notification and testing of past patients will have to be made, given the limitations and the high cost of these studies. Resources and public policy solutions are also needed for the economic and social impacts that will affect HCWs and patients who are infected with HIV, and whose identities are made known during the course of such studies.

The CDC has developed a risk assessment model to estimate how often sporadic HIV transmission from HIV-infected HCWs to patients may have occurred. Estimates from modeling refer only to the risk of sporadic infection, not to the risk of infection clusters, such as the Florida dental case. The risk assessment model has three components:

1. the probability of percutaneous (through the skin) injury to the HIV-infected HCW during surgical and dental procedures;
2. the probability that the sharp object causing the HCW's injury will recontact the patient's open wound, resulting in blood exposure; and
3. the probability of HIV infection if such blood exposure occurs.

The estimates derived from this model are very uncertain, because reliable data are unavailable for

model components such as surgical and dental injury and recontact rates. Using what data are available, the CDC has estimated that from 13 to 128 patients may have been infected with HIV during dental and surgical procedures over the last 10 years. OTA agrees with CDC's conclusion that the risk is extremely small; but OTA finds that, while the CDC risk assessment model is methodologically acceptable, the available data are too preliminary and sketchy to provide estimates of the actual number of patients who might have been infected. Improved data on the risk assessment model's components are needed before specific numbers can be assigned to the risk.

Concern about the risk of transmission is limited to certain invasive procedures where there is a possibility that an HIV-infected HCW's blood may contaminate a patient's blood. This might occur when an HCW injured himself or herself, bled, and the HCW's blood then recontacted the patient's open incision. No injuries occur during most invasive procedures, and if injuries occur, there is usually no contamination of the patient's blood. Thus, noninvasive procedures and many invasive procedures pose virtually no risk to patients. During certain invasive procedures, however, it may be more difficult to avoid contaminating the patients' blood when the HCW is accidentally injured. An example of an "exposure-prone" invasive procedure is where a surgeon is using a sharp instrument or object, such as a suture needle, in a poorly visualized or highly confined anatomic site.

In July 1991, the CDC issued guidelines to limit the risk of HIV transmission in the health care workplace. The guidelines include:

1. adherence to infection control procedures ("universal precautions");
2. identification of exposure-prone procedures by medical/surgical/ dental organizations and the institutions at which the procedures are performed;
3. HCWs who perform exposure-prone procedures should know their HIV and HBV (hepatitis B virus) status; and
4. HCWs who are infected with HIV or HBV (and for HBV have serologic markers indicating potential infectivity-i. e., are hepatitis B e antigen positive) should seek counsel from an expert review panel and be advised under what circumstances, if any, they may continue to perform these procedures, and that prospective patients should be notified before undergoing exposure-prone procedures by these HIV- or HBV-positive HCWs.

Adherence to "universal precautions' that include appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments can greatly reduce the risk of HCW injury and, in turn, the risk of transmission of not just HIV but all blood-borne pathogens. A broad consensus exists among public health, medical, and professional organizations that strict adherence to infection control procedures is the most effective strategy for minimizing the risk of transmission. OTA notes that compliance with infection control practices can be greatly improved, using such incentives as continuing education courses as a condition of State relicensure and educational requirements as part of professional certification. These components of workplace safety will be enforced through the Occupational Safety and Health Administration's (OSHA) blood-borne disease standard that will go into effect on December 1, 1991.

The CDC recommends that HCWs engaged in exposure-prone invasive procedures know their HIV and HBV status, and if positive, seek the advice of expert panels on which procedures, if any, they may perform, and notify their prospective patients. OTA notes that adherence to these recommendations would likely end the practice of exposure-prone procedures by known HIV- and HBV-infected HCWs, possibly leading to disincentives for some HCWs to know their HIV and HBV status.

The CDC guidelines explicitly state, however, that there is no basis for restricting the practice of HIV- or HBV-infected HCWs in the performance of noninvasive procedures or of invasive procedures that are not exposure-prone. OTA therefore notes that the CDC guidelines could be the basis for creating "safe harbors" against liability actions for HIV- and HBV-infected HCWs who do not perform exposure-prone invasive procedures.

Initial investigations indicate that the types of "exposure-prone' invasive procedures can be greatly reduced through improvements in both technique and technology. Improved instrument design and innovative surgical technique play important roles in reducing the risk during exposure-prone invasive procedures. OTA notes that flexibility must be

preserved for expert panels not only to determine which and under what circumstances invasive procedures are "exposure-prone," but also to determine when they are no longer "exposure-prone." Liability concerns and public reaction, however, may make it difficult for expert panels to gain and maintain such flexibility.

The inclusion of HBV as well as HIV infection as a basis for restriction/exclusion of HCWs could temporarily reduce the availability of health services among certain health professions, specialties, geographical areas, and institutions. The number of HBV-infected HCWs should decline, however, as HBV vaccines are available and their use should increase.

The CDC guidelines state that mandatory testing of HCWs is not recommended given the extremely small risk of HIV transmission in the health care workplace. OTA agrees that the current assessment of the risk of HIV (and HBV) transmission in the health care workplace does not support the diversion of the resources required for broader testing.

The CDC guidelines, if widely implemented, are likely to have the intended effect of reducing further the very small risk of HIV transmission in the workplace. This would be due mainly to HCWs' improved compliance with universal precautions and to the development of improved technologies to prevent HCW injuries and blood recontacts during dental and surgical procedures. Improvements in compliance will be reinforced by the implementation of the OSHA blood-borne disease standard. It is unclear, however, whether the recommendations concerning voluntary HCW testing, the use of expert panels, and patient notification will ultimately also contribute to a reduction in the risk of HIV transmission, since HCWs' fear of disclosure, potential discrimination, and loss of livelihood may provide a disincentive to seek appropriate counseling and testing.

Introduction

Prior to the first identified cluster of HIV infections among five patients of a dentist infected with HIV, concerns over transmission of HIV in the health care workplace were focused on the risks to health care workers (HCWs) from HIV-infected patients. With conflation of these cases within a dental practice, public attention has shifted dramatically in the reverse direction.

Proposals to protect HCWs from patient-acquired HIV infections have been debated and examined extensively, and the actions that have been sanctioned have almost exclusively been directed at HCWs themselves-i.e., those exposed to the risk and not those who pose the risk—and what HCWs might do to reduce their risk of becoming infected with HIV from their patients. The principal bases for focusing exclusively on these prevention policies have been concerns over the countervailing privacy rights of patients, and the devastating social and economic consequences to people known to be HIV-infected. Other reasons include the need for HCWs to protect themselves against other blood-borne pathogens, and technical limitations of widespread patient testing, such as test results that are not available in time, and false negative tests.

Thus, calls for patients to be routinely and mandatorily tested for HIV infection have been resisted. In marked contrast, with the cluster of HIV-infected dental patients, public opinion has swiftly favored testing and restriction or exclusion of HIV-infected HCWs, leading legislators and professional societies to formulate responses as quickly as possible.

The issue is that the circumstances surrounding an HIV-infected HCW, or an HCW merely suspected of being HIV-infected, have changed the usual health care worker-patient relationship. Patients are in a vulnerable position in their relationships with health care providers, not only physically, but also consensually, reflected in such legal protections as the right to privacy and informed consent. However, privacy, and the consequences of losing that privacy, are as important to the HIV-infected HCW as they are to the HIV-infected patient. But HCWs also have at least a moral obligation to "do no harm.' Thus, in formulating policies to minimize the risk of HIV transmission in the health care workplace, policymakers must find workable and acceptable solutions after considering: 1) public health principles, which balance the individual's (usually the patient, but in the case of HIV, also the HCW) rights against the overall public health; 2) legal principles, which increasingly in recent years have emphasized the rights of individuals; and 3) ethical and moral principles, with their ideal and uncompromising goals.

The following issues are addressed in this background paper:

- the expected pattern of HIV transmission from HCW to patients, and whether the dental office cases fit this pattern;
- the magnitude of the risk of HIV transmission from HCWs to patients;
- the principal actions that have been recommended; and
- the impacts and policy implications of these actions.

Expected Pattern of HIV Transmission to Patients

Transmission of HIV has followed a pattern that is associated with transmission of hepatitis B virus (HBV); i.e., sexual contact, intravenous drug use, and other modes of blood-to-blood and other bodily fluid exchanges. Most of what is known about HBV transmission from HCWs to patients comes from clusters of cases associated with a single infected HCW performing invasive procedures. The reason is that the occasional, single cases of transmission, which constitute the underlying 'endemic' rate, are nearly impossible to detect. Thus, if and when cases of HIV transmission from HCWs to patients occurred, it would have been expected that they would be detected in a cluster, in which several patients of the HCW were infected during invasive procedures.

The conclusion that the dentist office in Florida was the site of HIV transmission for five patients is strongly supported by laboratory analyses of the HIV strains infecting the dentist and his patients. Tests consisted of: 1) comparisons of the DNA sequences of the HIV isolated from the dentist and 31 other HIV patients not associated with the dentist but from the same geographical area with the HIVs isolated from the dentist's patients; and 2) analysis of a particular portion of the HIV virus that is unique to each HIV strain (42).[1]

Seven of the dentist's patients were HIV-positive, but only five were infected by the same HIV strain as the dentist. These five patients included three females with no known HIV risk factors, and two males, one with no known risk factors and the other with unconfined risk factors. The two patients infected with a different HIV strain had known risk factors. One of the five patients (a female) did have sexual contact with another HIV-positive patient (a male) of the dentist. Tests determined that the female was infected with the HIV strain common to the dentist before the male with known risk factors was infected by another HIV strain.

A scientific interpretation of the data could only conclude that the HIV strain that infected the dentist was identical to that infecting five of his patients, but not that the dentist was the actual source. However, the dentist's office was the vector for transmission: i.e., the only identified common element among these five persons infected with the same HIV strain as the dentist was treatment by the dentist after the dentist was known to be infected with HIV.

When clusters of cases of HBV transmissions have been investigated, most of the causes remain unexplained, and the reports have indicated that "the potential existed for contamination of surgical wounds or traumatized tissue, either from a major break in standard infection-control practices (e.g., not wearing gloves during invasive procedures) or from unintentional injury to the infected HCW during invasive procedures (e.g., needle sticks incurred while manipulating needles without being able to see them during suturing)" (38).

How HIV transmission to the five dental patients actually occurred remains unknown. The CDC could only conclude that:

> Factors that may be associated with transmission of bloodborne pathogens from infected HCWs to patients . . . may reflect variations in the procedures performed and techniques used by the HCW, infection-control precautions used, and the titer of the infecting agent (37).

In other words, transmission may have resulted from the failure to follow preventive procedures, including proper sterilization of equipment, or from accidents that occurred despite preventive measures (e.g., gloves do not prevent injuries from sharp objects such as needles, teeth fragments, etc.), in combination with high titers of HIV in the dentist or one of the identified patients. It is known that HIV concentrations are high in the initial stages of infection, followed by low concentrations as the body's immune system defenses respond, then rise to high levels again as the immune system is

[1]Similar analyses on the particular "signature' associated with a specific strain of HIV have been used in determining tbat a strain of HIV from the Institut Pasteur was the same HIV strain that was used by the National Cancer Institute to successfully grow HIV, which in turn led to the development of HIV tests; see (42).

eventually overwhelmed and clinical AIDS appears. (With HBV, there are tests that can identify infectious individuals and those individuals with high levels of circulating HBV virus. Infectious individuals are those with circulating hepatitis B "surface" antigen or "HBsAg," and those with the "e" antigen of the hepatitis B virus or "HBeAg' who have higher levels of circulating virus. Besides these tests for identifying HBV-infected persons who would be more likely to transmit HBV infections, another difference between HBV and HIV is that a vaccine is available for HBV, while neither an infectivity test nor a vaccine is available for HIV.)

Magnitude of the Risk

Estimates of the risk of HIV transmission from HCWs to patients are currently derived in two ways: data from ongoing evaluations of patients treated by HIV-infected HCWs ("look-back" studies), and risk assessment models designed to estimate the frequency of sporadic HIV infection from invasive medical and dental procedures.

Several small look-back studies have been conducted, some of which have been reported in the published literature. In each of these studies, testing was voluntary, raising the possibility that individual selection bias may have influenced the results. The most systematic of these studies was reported in 1990 by Mishu and colleagues, (21) in which they notified and offered HIV antibody testing to all patients who had undergone operations by a general surgeon practicing in Nashville during the 7 years prior to his diagnosis of AIDS. Of 2,160 patients identified, 264 had already died, none reportedly of AIDS or other HIV-related causes. Of the remaining 1,896 patients, 1,652 were successfully contacted and offered HIV testing. A total of 616 patients were tested. One patient, an intravenous drug user who, on the basis of his medical history, may have had AIDS at the time of his surgery, tested positive. The investigators concluded that no cases of HIV transmission attributable to the surgery were found among the remaining 615 patients tested.

In a 1987 report, 75 patients of an air force surgeon with AIDS independently sought HIV antibody testing after publicity about the surgeon's HIV status (4). None of those patients tested positive. In a 1990 report, 76 patients of an English surgeon with AIDS independently sought HIV testing and none tested positive (29). Most of these patients were tested within 90 days of their surgery, however, before antibodies to HIV may have developed in any infected patient. In a 1991 report, 143 patients treated by a dental student with HIV infection were tested, with none testing positive (9).

These published studies, along with CDC's investigation of 850 patients of the Florida dentist and preliminary results from a number of unpublished, ongoing investigations of other patients of HIV-positive HCWs, indicate that over 4,000 patients have so far been tested, with no cases of HIV infection attributable to medical or dental procedures except for the 5 patients of the Florida dentist (6).

In the near future, the results of such look-back studies are unlikely to help define the magnitude of the risk. Not only would much larger numbers of patients who have undergone invasive procedures performed by HIV-infected HCWs have to be evaluated, but technical difficulties in conducting the studies and interpreting the results would prevent the studies from yielding clear-cut answers in many or most cases. Major difficulties pertain to confidentiality issues in testing patients and HCWs, retrospective investigation of the invasiveness of the procedures performed on each patient and of the **HCW's** use of infection control measures, and, in patients identified as HIV-infected, determination of whether infection was actually acquired from the particular HCW rather than from other generally more common sources.

Creation of risk assessment models is another method for estimating the risk to patients from HCWs. Such modeling can be used to generate average estimates or ranges of estimates of the number of patients who could be infected accidentally during invasive medical or dental procedures. These estimates refer to the risk of sporadic infection only, however. They do not refer to the risk of infection clusters such as the Florida dental case, which, almost by definition, would be virtually impossible to predict and quantify. Theoretically, other clusters of HIV infection among patients could arise on very rare occasions when several unusually risky elements occur simultaneously.

The usefulness of the results of a risk assessment model to estimate the risk of sporadic infection would depend largely on the quality of the data used to generate the estimates. At present, much of the data is incomplete and preliminary, so the risk

estimates based on these models would be limited accordingly. Further, since rare, sporadic cases of HIV infection are unlikely to be identified as cases derived from the health care workplace, the estimates generated by a risk assessment model maybe virtually impossible to validate. The results could, however, offer some information on the possible bounds of the risk, given current knowledge, and the assessment could be revised as new data become available.

In a draft discussion paper issued January 30, 1991, CDC described a preliminary risk assessment model that estimated: 1) the probability of sporadic HIV and HBV transmission to patients from an HIV- or HBV-infected surgeon or dentist; and 2) the number of patients who may have been infected by HIV- or HBV-infected surgeons and dentists. These estimates were for the underlying or sporadic rate, which would be in addition to the occasional cluster cases (35).

Key elements of the risk assessment were the following:

- the probability of percutaneous injury to a surgeon or dentist during the course of an invasive procedure;
- the probability that the sharp object causing the HCW's injury will recontact the patient's open wound, resulting in blood exposure; and
- the probability that HIV and HBV infection will occur following such blood exposure.

The risk of transmission to an individual patient—the product of these three probabilities-was then used to calculate the total number of patients who could have been infected by taking into account estimates of: the number of practicing surgeons and dentists who may be HIV- or HBV-positive, the number of invasive procedures performed per year, and the number of years surgeons and dentists might practice while infected with HIV or HBV.

For surgical procedures, four recently published studies have examined the occurrence of percutaneous injuries and other blood contacts during certain procedures (12,19,26,28). Taken together, these studies suggest that a percutaneous injury to one or more surgical staff members occurs in 1.7 to 5.6 percent of different surgical procedures under the various conditions described in each study. These studies are the frost to systematically describe and quantify the occurrence of such injuries. However, their small size and preliminary nature limit their usefulness for risk assessment.

A prospective, multicenter study of percutaneous injuries was recently undertaken by investigators at CDC and elsewhere in an attempt to generate data representative of teaching hospitals in large metropolitan areas that could also be used in risk assessment. At present, the report of the study has not yet been peer-reviewed and published, but some information about the study and its preliminary results was available to OTA (7,26).

The study was conducted at four hospitals with relatively high HIV seroprevalence in the patient population: two inner-city hospitals in New York and Chicago and two suburban teaching hospitals in the New York and Chicago areas. A total of 1,382 surgical procedures were observed in the cardiology, general surgery, gynecology, orthopedics, and trauma services. These included a range of invasive procedures without qualifying the degree of risk of HCW injury or other factors that might affect HIV transmission.

Ninety-nine percutaneous injuries to the HCW were reported in 95 of the 1,382 procedures. The majority of the injuries (77 percent) were caused by suture needles, mostly to the surgeon's nondominant hand, palm, or distal forefinger. The lowest injury rate was found in the orthopedic service (3.6 percent) and the highest in the gynecology service (10.1 percent). Within each service, the frequency of injury varied according to the specific surgical procedure performed.

The study also calculated injury rates by person-procedure (defined as one HCW present at a single procedure). Injury rates were found to be highest for residents and attending surgeons, for whom an average rate of 2.5 injuries per 100 person-procedures was found (88 injuries in 3,514 person-procedures); the range among the five specialties was 1.4 to 4.0 injuries per 100 person-procedures (35). CDC's risk assessment used 2.5 injuries per 100 person-procedures in their calculation of injury rates in surgery.

No prospective studies designed to record the rate of injuries during dental procedures have been published to date. One retrospective survey of the occupational risk for HIV infection among dental professionals practicing in the New York metropolitan area included data on the frequency of accidental

puncturing of the skin with sharp instruments and on the prevalence of HIV antibodies and HBsAg among dental staff (20). Subjects were recruited for the study through a mailing and through solicitation at professional meetings. A total of 1,309 dental professionals (including 1,132 dentists, 131 dental hygienists, and 46 dental assistants) without behavioral risk factors for HIV volunteered to complete a questionnaire.

Ninety-four percent (765 of 816) of the dentists and similarly high proportions of the hygienists and assistants reported accidental percutaneous injuries with sharp instruments during dental procedures. The dentists recalled an average of 1 such injury within 1 month prior to the questionnaire, 3 within 1 year, and 10 within 5 yearn. These data provide only rough estimates of the possible injury rate in dental procedures, since the results were based on the voluntary self-reporting of accidental injuries that could be recalled from memory.

In CDC's risk assessment, the rate of 1 injury per month was multiplied by 12 for a yearly rate, then divided by an estimate of 3,000 dental procedures per year having potential exposure to blood (based on 1989 testimony presented by the American Dental Association at Occupational Safety and Health Administration hearings), for a total rate of percutaneous injury to a dentist of 0.4 per 100 procedures (35).

The only other data available on dental injuries are unpublished data derived from other retrospective surveys conducted by the American Dental Association at their annual meetings. For the years 1988 through 1990, based on approximately 1,000 to 1,900 participants' responses per year, an average rate of 7 percutaneous injuries per year was reported by dentists in these surveys (23). Using another figure supplied by unpublished ADA data, an average of 3,820 invasive procedures are performed per dentist per year (2,23).

No matter how often injuries occur to HCWs during invasive procedures, blood transfer from HCW to patient must occur before there is the possibility of HIV infection. Some of the possible ways in which this could happen include: recontact with the patient of the sharp instrument that caused the HCW's wound; frank bleeding from the HCW's wound into the patient's open wound or onto the patient's mucous membranes or nonintact skin; the use of an instrument contaminated with the blood of the HCW or another patient following inadequate sterilization or disinfection procedures; and contact of the patient's open wound with secretions from the HCW's open lesions or exudative dermatitis (e.g., on the hands) (35).

Whether and how often any of these events occur during surgical and dental procedures are currently unknown. The possible contributory role of one or more of these factors was considered in CDC's evaluation of the cluster of HIV infections in five patients of the Florida dentist, but none were identified conclusively in that case (37). Observations of surgical procedures at one hospital in San Francisco suggest that the frequency of such recontacts is already very low and maybe further reduced with appropriate infection control practices (14).

None of the studies of injuries described above included data on these recontact factors, with the exception of the unpublished CDC data(7). In those data, one type of recontact during surgical procedures was observed and recorded: the frequency with which the sharp instrument that caused injury to the surgeon recontacted the patient's open wound or body cavity (also including the rate of injury of a HCW by a bone fragment or surgical wire freed in the patient's body). In relation to the number of procedures, recontact occurred in 2 percent (29) of 1,382 procedures (range among the 4 hospitals: 1.7 percent to 2.6 percent). In relation to the number of injuries, recontact was observed following 28 of 99 percutaneous injuries in 95 procedures: 1 recontact in 14 injuries during orthopedic surgery (7.1 percent); 6 in 31 injuries during general surgery (19 percent); 4 in 12 injuries during cardiac surgery (33 percent); 13 in 31 injuries during gynecologic surgery (42 percent); and 4 in 7 injuries during trauma surgery (57 percent). In relation to the number of surgeons, recontact was observed in 28 (32 percent) of 88 percutaneous injuries (the other 11 injuries occurred among other surgical team members). In 26 of the 29 instances, recontact was reportedly caused by continued use of the instrument that had injured the HCW, either because of a failure to recognize that it was contaminated or an inability to substitute another instrument quickly enough. This observation lends support to the suggestion that the majority of recontacts are potentially preventable.

It should be noted that the average recontact rate of 32 percent after percutaneous injury noted in

CDC's data is based on a small number of injuries observed (88). That problem, along with the fact that the data have not yet been examined by peer-review, suggests that the data may not be reliable enough to represent an overall recontact rate in a larger sample of U.S. health care facilities. In the absence of better information, however, this rate was used in CDC's risk assessment of HIV transmission during invasive surgical procedures.

There are no available data on recontact rates during invasive dental procedures, either published or unpublished. CDC's risk assessment applied the surgical recontact rate found in their data to the dental component of the analysis, since no other information was available. The use of the preliminary data on recontacts during surgery and their tenuous extrapolation to dental procedures contribute substantially to the overall uncertainty associated with estimates that can be derived at present from a risk assessment model, particularly as they apply to invasive dental procedures.

The risk for transmission of HIV after blood-to-blood contact has been studied fairly extensively because of the large number of reported cases in which HCWs (mostly nurses) have been injured by needles or other sharp objects contaminated with blood or blood-containing body fluids from patients with HIV infection. At present, a total of 14 prospective studies are being conducted to assess the magnitude of the risk to HCWs who have reported percutaneous exposures to blood or other body fluids from patients with HIV infection (18). Among 1,989 HCWs reporting a total of 2,119 such exposures (18), 6 cases have resulted in HIV infection; the overall risk per exposure derived from these data is approximately 0.30 percent (95 percent CI, 0.13 percent to 0.70 percent). Risks of transmission of HIV following mucous membrane and superficial cutaneous exposures is likely to be substantially smaller; anecdotal information suggests that seroconversion following mucous membrane exposure is possible, but no such cases have been documented among the HCWs being followed for such exposure in the prospective studies (17).

Factors that might influence the risk of transmission after exposure are not well understood, given the small number of seroconversions in these studies. The exposures in these prospective HCW studies include injuries considered to be severe, such as deep sticks or intramuscular lacerations, as well as those considered to be "trivial," such as superficial punctures. Factors that may influence the magnitude of the risk but which cannot yet be quantified include: the severity and type of injury, the presence or absence of barrier protections (e.g., double-gloving, which may reduce the amount of blood transmitted (22)), the stage of the source person's HIV infection (including the degree of viremia), and immunologic factors in the injured person.

In general, it can be assumed that such data on the risk of HIV transmission from infected patients to HCWs are also relevant to the risk of HIV transmission from an infected HCW to a patient following injuries and recontacts during invasive procedures. However, there are differences between the two situations that may influence the magnitude of the risk, such as the degree of viremia in the source person. An HIV-infected HCW who is asymptomatic may have a lower level of viremia than the average HIV-infected patient who is receiving treatment for AIDS or AIDS-related illnesses. In addition, injuries to HCWs involving suture needles may carry a smaller amount of infected blood than the hollow-bore injection needles that caused injuries to HCWs in these prospective studies, theoretically posing a smaller risk of infection. To date, no cases of HIV infection have been documented among HCWs injured by contaminated suture needles.

CDC's risk assessment used the combined data derived from the 14 studies, 0.3 percent risk of infection per percutaneous exposure, and also used a ten-fold lower estimate to approximate a potentially lower risk for infection under the conditions stated above for HCW-to-patient transmission. It is currently unknown, however, whether the risk for HCW-to-patient infection per exposure (e.g., by suture needles) is equivalent to or lower than the risk for patient-to-HCW infection per exposure (e.g., by hollow-bore needles), and if it is lower, by how much.

CDC estimated that as of September 30, 1990, there were reports of 42 cases of AIDS in surgeons and 156 cases of AIDS in dentists in the United States, based on national surveillance data for which occupational information was available. To estimate the number of HIV-infected surgeons and dentists from the number of AIDS cases, a factor of eight was applied, reflecting the ratio of an estimated one

million HIV-infected persons to the 122,159 cases of AIDS reported (35). In this way, it was estimated that there would be 336 HIV-positive surgeons and 1,248 HIV-positive dentists currently practicing in the United States.

The use of these data in the risk assessment may underestimate the number of surgeons and dentists with AIDS, since not all cases of AIDS are reported with occupational information. In addition, the ratio of eight cases of HIV infection for every reported case of AIDS represents only a rough approximation.

For surgical procedures, CDC estimated in its risk assessment that the average surgeon participates in 500 procedures per year (no data source given). Other available data point to a potentially lower number, e.g., 360 procedures per year, according to 1985 data from the American Medical Association (30).

For dental procedures, CDC's risk assessment used a figure of 3,000 invasive procedures per year (based on 1989 testimony presented by the American Dental Association at Occupational Safety and Health Administration hearings), whereas the American Dental Association reports unpublished data showing an average of 3,820 invasive procedures per year (2,23).

The risk to an individual patient undergoing an invasive procedure performed by an HIV-infected surgeon was calculated as the probability of injury to the surgeon during the procedure (2.5 percent) times the probability of the sharp instrument contaminated with the surgeon's blood recontacting the patient's open wound (32 percent) times the probability of HIV infection following such exposure (0.3 percent), resulting in; 0.0024 percent or 1 in 42,000, and ten-fold less (0.00024 percent or 1 in 420,000). For invasive dental procedures, the corresponding results were 0.00038 percent or 1 in 263,000, and 0.000038 percent or 1 in 2,630,000.[2]

The individual risks were then used to estimate the potential number of patients infected over the past 10 years. For surgery, the risk to an individual patient (both high and low estimates) was multiplied by the estimated number of HIV-infected surgeons (336), times the number of procedures such surgeons perform per year (500), times the number of years an HIV-infected surgeon would likely practice with the infection (7), to get a range of 3 to 28 patients potentially infected through surgery during this period. For dentists, the individual risks were multiplied by the number of dentists (1,248), times the number of invasive procedures per year (3,000), times the number of years working with HIV infection (7), to get a range of 10 to 100 patients potentially infected through dentistry during this period. Combining the number of patients, a total range of 13 to 128 patients potentially infected through invasive surgical and dental procedures performed from 1981 through 1990 was derived.

Similar estimates were made by CDC for hepatitis B (HBV) transmission from HCWs to patients. Their results were based on the same injury and recontact rates as for the HIV estimates, but other data were used for the probability of HBV transmission and the number of HBV-infected surgeons and dentists. The risk of HBV transmission was estimated to be approximately 100 times higher than the risk of HIV transmission, or approximately 1 in 420 to 1 in 4,200 for surgeons, and 1 in 2,630 to 1 in 26,300 for dentists.[3]

The broadness of the ranges found in the CDC analysis reflect the large uncertainty in the data and the inability to generate anything better than crude estimates with the data currently available. Furthermore, the risk estimates, which could well fall at the low end of the range in many health care settings, could be further reduced by more thorough adoption of infection control practices.

These estimates were extensively critiqued in a February 21-22, 1991, open meeting at the CDC. On July 12, 1991, when the CDC issued its "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures,' it qualfied its draft estimates by stating that "a precise assessment of the risk is not yet avail-

?For an HIV-positive dentist, the American Dental Association also provided estimates. For HIV transmission, the ADA estimated the risk at 1 in 4,762,000 to 1 in 47,620,000. These estimates, however, were based on the number of total procedures per year of 8,649 per dentist; whereas the ADA's estimates of total invasive procedures per year was 3,820 per dentist, thus the estimates should have been 1 in 2,500,000 to 1 in 25,000,000 (23)

[3]For an HBV-positive dentist, the American Dental Association also provided estimates, For HBV transmission, the ADA estimated the risk at 1 in 47,600 to 1 in 476,000. These estimates, however, were based on the number of total procedures per year of 8,649 per dentist; whereas the ADA's estimates of total invasive procedures per year was 3,820 per dentist, thus the estimates should have been 1 in 25,000 to 1 in 250,000 for HBV (23).

able." The CDC also summarized its review of 20 published studies of transmission of HBV from HCWs to patients, and its review of the dental office HIV cases and 4 other instances of patients treated by HIV-infected HCWs.

Referring to HBV, the CDC stated that:

> [M]ost reported clusters in the United States occurred before awareness increased of the risks of transmission of blood-borne pathogens in health care settings and before emphasis was placed on the use of universal precautions and hepatitis B vaccine among HCWs.

For HIV, the CDC stated that:

> [T]he limited number of participants and the differences in procedures associated with these five investigations limit the ability to generalize from them and to define precisely the risk of HIV transmission from HIV-infected HCWs to patients. A precise estimate of the risk of HIV transmission from infected HCWs to patients can be determined only after careful evaluation of a substantially larger number of patients whose exposure-prone procedures have been performed by HIV-infected HCWs.

Actions That Have Been Recommended

The recommendations that have been made by various organizations and bodies have addressed the following issues:

- education and enforcement of universal precautions;
- procedural changes (e.g., better infection control, surgical techniques and monitoring);
- exclusion or restriction of practice in specific types of procedures (e.g., invasive procedures on patients in which the HCW may accidentally be injured);
- identification of infected HCWs, including (voluntary or mandatory) testing and safeguards on keeping such information confidential; and
- disclosure and notification of the infected status of the HCW to others, such as to the institution in which he/she practices, State licensing authorities, and prospective patients of invasive procedures performed by the infected HCW.

These latter recommendations are often accompanied by a recognition of the need for compensatory actions such as health insurance, compensation for lost income, and retraining because of the potential consequences of testing and subsequent practice restrictions.

On July 12, 1991, the Centers for Disease Control issued recommendations, which conclude:

"Investigations of HIV and HBV transmission from HCWs to patients indicate that, when HCWs adhere to recommended infection-control procedures, the risk of transmitting HBV from an infected HCW to a patient is small, and the risk of transmitting HIV is likely to be even smaller. However, the likelihood of exposure of the patient to an HCW's blood is greater for certain procedures designated as exposure-prone. To minimize the risk of HIV or HBV transmission, the following measures are recommended:

- All HCWs should adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments. HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment and devices used in performing invasive procedures until the condition resolves. HCWs should also comply with current guidelines for disinfection and sterilization of reusable devices used in invasive procedures.
- Current available data provide no basis for recommendations to restrict the practice of HCWs infected with HIV or HBV who perform invasive procedures not identified as exposure-prone, provided the infected HCWs practice recommended surgical or dental techniques and comply with universal precautions and current recommendations for sterilization/disinfection.
- Exposure-prone procedures should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed.
- HCWs who perform exposure-prone procedures should know their HIV antibody status. HCWs who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.
- HCWs who are infected with HIV or HBV (and are HBeAgpositive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been

advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures.

- Mandatory testing of HCWs for HIV antibody, HBsAg, or HBeAg is not recommended. The current assessment of the risk that infected HCWs will transmit HIV or HBV to patients during exposure-prone procedures does not support the diversion of resources that would be required to implement mandatory testing programs. Compliance by HCWs with recommendations can be increased through education, training, and appropriate confidentiality safeguards." (38)

"Invasive Procedures" are defined as:

> [S]urgical entry into tissues, cavities, or organs or repair of major traumatic injuries' associated with any of the following: 1) 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 caesarean 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 (38).

"Exposure-prone procedures" are described as follows:

> Characteristics of exposure-prone procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site. Performance of exposure-prone procedures presents a recognized risk of percutaneous injury to the HCW, and—if such an injury occurs-the HCW's blood is likely to contact the patient's body cavity, subcutaneous tissues, and/or mucous membranes. (38)

On August 16, 1991, the CDC announced that it had begun a process to develop a list of exposure-prone invasive procedures that CDC will publish as a national reference, with completion of that process anticipated by November 15, 1991 (39). There will probably be gray areas of exposure-prone invasive procedures, such as root-canal treatments. Such gray areas need to be minimized, because they will probably be grouped with the clearly exposure-prone invasive procedures (l).

The distinction between "invasive procedures" and "exposure-prone invasive procedures" is significant, because it is a key area in which the risk of HIV or HBV transmission can be further minimized. For example, in the CDC draft estimates of the risk of HIV and HBV transmission from HCWs to patients, a key element in the estimates was the use of a 32-percent recontact rate, or the percent of injuries during surgery in which the sharp object causing the injury recontacts the patient's open wound (35). The 32-percent recontact rate was the average; the recontact rate ranged from 8 to 57 percent among specialties and from 24 to 42 percent among hospitals.

Given the wide range of recontact rates among specialties and hospitals, just in this single study, significant reductions in recontacts and, thus, the risks -of transmission, seem not only possible, but achievable. Preliminary results from studies being conducted in San Francisco indicate that the recontact rates there are much lower than the 32-percent rate used in the CDC estimates, and may approach zero with appropriate precautions (12).

The largely preventable nature of transmission from infected HCWs to patients logically calls for strengthening of preventive measures. These measures can be grouped into techniques and technologies. Preventive techniques to eliminate the risk of injuries from sharp objects can be encouraged through continuing education in universal precautions, infection control procedures, and knowledge of HIV and HBV transmission as a condition of professional certification and for relicensure by State licensing boards. Technologies for prevention include improved devices, instrumentation, and personal protective equipment (e.g., gloves).

The Occupational Safety and Health Administration (OSHA) is currently in the process of finalizing rules and regulations concerning occupational exposures to blood-borne pathogens. The final standard will be based on a proposed rule (41), which in turn, is based on CDC guidelines concerning universal precautions. The OSHA standard, which will by statute become final by December 1, 1991, will not only be generally consistent with the universal precautions section of the CDC guidelines, but will also authorize enforcement through onsite inspections and imposition of civil and criminal penalties

for violators. The standard will affect an estimated 5.3 million workers (including 4.6 million HCWs) in 616,000 worksites (including 585,000 health care settings). This includes not only hospitals, but also physicians' offices, dentists' offices, medical and dental laboratories, nursing homes, outpatient facilities, and other sites. The OSHA standard requires employers to implement universal precautions, including the development of infection control plans and the provision of personal protective equipment, safe work practices, clean worksites, HBV vaccines and post-exposure follow-up, and worker information and training.

Reductions in recontact rates would also affect the definition of 'exposure-prone invasive procedures.' The CDC guidelines recommend that identification of such exposure-prone procedures be the responsibility of "medical/surgical/dental organizations and institutions at which the procedures are performed,' and, as described earlier, CDC has now begun a process "to develop a list of exposure-prone invasive procedures that CDC will publish as a national reference" (39).

By contrast, several State health departments and professional organizations have issued their own guidelines to reduce the risk of HIV transmission in health care settings. The policies of New York and Michigan stress education and improved infection control measures, and reject mandatory disclosure of HCW HIV serostatus. Other States are in the process of developing policies with provisions that are at variance with the CDC guidelines. Some of these are more restrictive than the CDC guidelines (e.g., Illinois) while others are similar to the policies of New York and Michigan. A number of professional organizations have contested the CDC category of exposure-prone procedures as the sole criterion for categorical exclusion of HIV positive HCWs, observing that no firm scientific basis exists to guide such a restrictive policy.

A few days after these CDC recommendations were published, the U.S. Senate voted:

1. to require States to adopt the guidelines within 1 year as a condition of receiving Public Health Service funds, and to make failure by an HCW to comply with the guidelines grounds for disciplinary action by the appropriate State licensing agency;
2. to make it a criminal act (punishable by a fine of not more than $10,000, imprisonment of not less than 10 years, or both) for HCWs who know that they are infected with HIV, to engage in treatment involving invasive physical contact, without prior notification to the patient (H.R. 2622);
3. to allow testing of patients in order to protect Hews (H.R. 2608); and
4. to require the OSHA blood-borne disease standard to go into effect.

In the House of Representatives legislation was introduced to require testing of HCWs-and notification of patients if HCWs are infected, and to provide HCWs with the right to know the HIV status of their patients (H.R. 2788).

In October, the House and Senate rejected criminal sanctions and mandatory testing provisions and adopted a compromise that requires States to adopt the CDC guidelines or equivalent State-initiated guidelines and requires the OSHA standard be in effect by December 1, 1991 (34).

Impacts and Policy Implications

The Senate and House compromise requires the States to forfeit their Public Health Service Act funds if the CDC or equivalent State guidelines are not adopted by regulation or legislation within 1 year (with a time extension for State legislatures that meet on a biennial basis). The congressional action would make adoption of the CDC or equivalent State guidelines mandatory rather than advisory, but the language of the guidelines themselves is still couched in advisory terms ("should" rather than "shall' '), so arguably the principal difference would be that each State would have to explicitly recognize and develop specific policies on how the guidelines would be implemented. However, the CDC guidelines have only recently been issued and made available for examination, and there already are apparent a number of highly probable and major effects of the guidelines, of which policymakers should be aware and which they should be prepared to address.

Congress did not specifically require States to adopt the CDC guidelines themselves. Rather, States can adopt equivalent guidelines designed to reduce the transmission of HIV and HBV in the health care workplace. Therefore, States may wish to analyze the various ramifications of the CDC guidelines before deciding what type of State guideline to implement.

First, it has been argued that certain parts of the CDC guidelines go beyond what is supported on public health grounds. The explanation accompanying the CDC guidelines states that it is not possible at this time "to define precisely the risk of HIV transmissions from HIV-infected HCWs to patients,' and that, "when HCWs adhere to recommended infection-control procedures, the risk of transmitting HBV from an infected HCW to a patient is small, and the risk of transmitting HIV is likely to be even smaller.' Nevertheless, the CDC guidelines recommend, in addition to infection-control procedures, that HCWs who perform exposure-prone procedures know their HIV status; seek counsel from expert review panels on what circumstances, if any, they may continue to perform these procedures; and that prospective patients be notified of the HCW's seropositivity before undergoing exposure-prone invasive procedures.

Similarly, the Association for Practitioners in Infection Control and the Society of Hospital Epidemiologists of America state that:

> HIV infection, per se, does not constitute a basis for barring an HIV-infected person from any patient care activity, including invasive procedures. However, HCWs who are known to have chronic transmissible bloodborne infections should be counseled to avoid procedures that have been epidemiologically linked to the transmission of HBV or other bloodborne infections voluntarily (5).

However, the CDC guidelines go a step further by raising the issue of whether there are circumstances, "if any," in which HIV- or HBV-infected HCWs may continue to perform exposure-prone procedures, and the review panels must ensure that prospective patients be notified of the HCW's seropositivity. It is highly unlikely that infected HCWs will be able to perform exposure-prone invasive procedures once they identify themselves and the review panel and patient notification procedures are followed (except for circumstances where the patients themselves are HIV-positive).

With imprecise information available regarding the true risk of HCW-to-patient transmission of HBV and HIV, the CDC has attempted to target any HCW practice restrictions to those clinical situations most likely to be associated with the potential for transmission. Some argue, however, that the patient notification requirement in the CDC guidelines go beyond what the CDC itself concludes are small HBV and even smaller HIV risks. Clearly, the balancing of risks is a difficult matter of informed judgment.

The legal system defers to public health experts in areas of expertise the courts deem themselves incompetent to address. For example, in the landmark U.S. Supreme Court case of *School Board of Nassau County v. Arline (480* U.S. *273 (1987))*, the U.S. Supreme Court stated that, whether a person loses job protection because of a contagious disease would be based on facts on which lower courts "normally should defer to the reasonable medical judgments of public health officials." If public health policies are not based on reasoned risk estimates, but instead are conservative responses to uncertain risk, the courts may be in the position of basing their legal conclusions on scientifically unsubstantiated "public health' policies.

Some leading legal analysts argue that the circumstances do not require 'informed consent. ' The risk must be material to a reasonable person, and involve remoteness/likelihood as well as severity; and if the HCW's right to privacy is to be breached, there must be a compelling public health benefit, which has not been demonstrated (16). Further, a consistent application of the patient's "right to know" would require the disclosure of all risks in health care delivery (20a). Another analyst argues that the issue of remote risks associated with a provider is completely outside the doctrine of informed consent; i.e., the doctrine applies to the patient's choice to undergo specific treatment and has not traditionally been applied to the disclosure of relatively remote risks associated with the provider (11).

The intermingling of public health and legal issues in the informed consent area is further compounded by statements from medical (not public health) sources. They may infer a legal basis, such as contained in a recent, influential editorial:

> [B]ecause it is remotely possible that there could be an exchange of blood during a medical procedure, patients *have a right to know* whether a doctor or nurse who performs invasive procedures is infected with HIV (emphasis added) (3).

This statement is based on the ethical principle of "physician do no harm," which is not concerned with the public health responsibility of balancing benefits and risks. The editorial writer made this clear when she went on to state:

> Clearly, HIV-infected persons need to be protected against discrimination and hysteria, but doing so requires social and political measures, not epidemiologic ones.

Yet, at the same time, an accompanying editorial that considered a balancing test concluded:

> For now, given the small risk of transmission, it appears that the balance between utility and risk does not warrant mandatory testing of HCWs or reporting by them. Instead, voluntary testing and subsequent voluntary action seem to be most appropriate (8).

Second, although the CDC guidelines specifically state that mandatory testing of HCWs is not recommended, the recommendations that HCWs should know their HIV (and HBV) status, that counsel should be sought from review panels, and prospective patients should be notified, have created a liability need to test for HIV (and HBV), and these recommendations make it more likely that voluntary testing will be made mandatory.[4] Testing, whether labeled mandatory or voluntary, is bound to increase dramatically.

Testing and disclosure policies have been the focus of most of the policy discussions concerning HIV in the health care workplace.[5] Disclosure of HCW test results to patients, ostensibly to give patients the choice of seeking care from noninfected HCWs,[6] can have multiple negative effects. First, is the potential loss of HCW confidentiality possibly resulting in loss of their profession. Societal impacts include loss of health care personnel and avoidance of practice specialties and geographic areas in which HCWs have a higher probability of being exposed to HIV-infected patients, high dislocation costs for HCWs no longer able to engage in exposure-prone procedures, and lack of health insurance coverage for HCWs and patients whose HIV-infection status becomes known.[7]

Policies should be considered that: 1) minimize the social and economic impacts on infected HCWs who are identified and restricted or excluded from their professions, as well as on infected patients who are also identified; and 2) create "safe harbors" from legal liability for infected HCWs whose risk of transmitting disease to patients is not an issue.

Some protection for some infected HCWs maybe addressed in part by the private sector,[8] but there clearly are impacts that only government can address. Such an area is health insurance for HIV-infected persons, but for which a disease-specific approach does not seem feasible, given the greatly expanded and escalating cost experiences of the end-stage renal disease program under Medicare, and the competing interests of other major diseases (i.e., cancer, heart disease, Alzheimer's, etc.). Health insurance legislation that eliminates exclusion of pre-existing conditions and experience-rating, would address the health insurance needs of HIV-infected persons, but such proposals will be decided in a much broader context than the HIV situation.

The creation of "safe harbors" could use the CDC guidelines as its basis. Those guidelines already state that, among the considerations on which the recommendations are based, is the following: "Infected HCWs who adhere to universal precautions and who do not perform invasive procedures pose no risk for transmitting HIV or HBV to patients. " This is the type of "reasonable medical judgment of public health officials" that should legitimately be deferred to by the courts, and the conclusiveness of this statement could be codified by statute. The CDC guidelines also state that there is no basis for restricting the practice of infected HCWs who perform invasive procedures not identified as exposure-prone. These infected HCWs could also be provided a safe harbor, but the standard would have to be different, as procedures not identified as "exposure-prone" still leave the possibility of infection through carelessness or (gross) negligence. However, the standard of proof that would be required in these actions could also be

---

[4]For example, the Minnesota Board of Medical Examiners is considering requiring proof of I-IN-negative status as a condition of relicensure (25).

[5]CDC recently issued draft guidelines for voluntary HIV testing services for patients in acute-care hospital settings to increase access to early intervention for those identified as HIV-positive (40).

[6]Whether this "informed choice" has a basis in the legal doctrine of "informed consent" is discussed below.

[7]For example, if a mandatory HIV and HBV testing and restriction program for HCWs performing invasive procedures were implemented at a 350-bed university-affiliated public teaching hospital in San Francisco, in the first year, 1,080 HCWs would have to be tested, and direct costs are estimated at $860,000. (13)

[8]For example, the American Medical Association is reportedly preparing to offer an insurance policy for a lump-sum $500,000 payment designed to provide a degree of financial security to infected physicians who may want to quit or limit their practice before they become eligible for disability insurance; reported in: (24).

defined by statute, as for other malpractice provisions.

Third, an unintended effect of the CDC guidelines might be the loss of protection of antidiscrimination laws for persons infected with HIV (and HBV), including both HCWs and patients. A contagious disease is a disability for the purposes of the Rehabilitation Act of 1973 (as amended in 1988) and the Americans with Disabilities Act of 1990. However, the definition of an individual with a handicap (under the Rehabilitation Act) does not include someone:

> [W]ho has a currently contagious disease or infection and who, by reason of such disease or infection, would constitute a direct threat to the health or safety of other individuals or who, by reason of the currently contagious disease or infection, is unable to perform the duties of the job (29 U.S.C. 706(8)(c)).

A "direct threat" is "a significant risk to the health or safety of others that cannot be eliminated by reasonable accommodation," (Americans With Disabilities Act, Sec. 101(3).) and the factors to be considered in determining "significant risk" are, according to the decision of the Supreme Court *(School Board of Nassau County v. Arline 480 U.S. 273 (1987)):* 1) the nature of the risk (how the disease is transmitted); 2) the duration of the risk (how long is the carrier infectious); 3) the severity of the risk (what is the potential harm to third parties); and 4) the probabilities the disease will be transmitted and will cause varying degrees of harm.[9]

These factors were considered in a recent Maryland Attorney General Opinion about the legality of a requirement that contractors providing health care services in State correctional facilities determine whether any of their employees are infected with HIV. (76 *Opinions of the Attorney General* (Opinion No. 91-027 (June 25, 1991)), State of Maryland.) The Maryland Attorney General's Opinion was that there was no reasonable dispute as to whether the first three factors are present in invasive procedures. As to the fourth, "the probabilities the disease will be transmitted," the Opinion concluded: "This assessment of probabilities requires knowledge of the latest epidemiologic and clinical evidence. It is for an expert in the field to make, not the Attorney General."

This Opinion was issued on June 25, 1991. What would the Attorney General have concluded if CDC's July 12, 1991, recommendations had been previously issued? On one hand, the CDC: 1) stated that the risks of HBV transmission are small, and the risks of HIV transmission even smaller; and 2) further concluded that a precise estimate of the risk of HIV transmission from infected HCWs to patients could not be determined at this time. On the other hand, the CDC nevertheless offered recommendations beyond universal precautions, including voluntary testing of HCWs engaged in exposure-prone invasive procedures, counsel with expert review panels, and notification of prospective patients.

In short, for the purposes of antidiscrimination statutes, the CDC guidelines provide mixed signals to the courts on whether the risk of HIV transmission in the health care workplace reaches the level of 'a significant risk to the health or safety of other individuals or who, by reason of the currently contagious disease or infection, is unable to perform the duties of the job." As noted above, it is questionable whether the courts should use the CDC conclusions if such conclusions have not been accurately based on "public health risks. " If such a significant risk is nevertheless found, HIV-infected workers engaged in exposure-prone invasive procedures would no longer be protected in their right to perform such procedures. As for HIV-infected patients, the Rehabilitation Act and the Americans with Disabilities Act do not explicitly make a distinction in the term "significant risk" between employees and clients for services. Thus, the fear exists that HIV-infected patients will lose the identical antidiscrimination protection that is lost by HIV-infected providers. The General Counsel to the American Medical Association, however, has noted that HIV-infected patients would not be found to pose a "significant risk" to their providers, even in exposure-prone procedures, because the risk of transmission from a patient to a provider in just one procedure is extremely low—much lower than the cumulative risk of an HIV-infected provider operating over time (32).

[9] Recent regulations established by the Equal Employment Opportunity Commission (EEOC) in promulgation of the Americans with Disabilities Act set standards identical to the standards set forth by the U.S. Supreme Court in ***School Board of Nassau County v. Arline, 480*** U.S. ***273 (1987),*** although the language is slightly different. The EEOC's ADA version read as follows: 1) the duration of the risk; 2) the nature and severity of the potential harm; 3) the likelihood that the potential harm will occur; and 4) the imminence of the potential harm. The EEOC regulations require that, to pose a significant risk, a person with a disability must pose a "high probability of substantial harm." (56 ***F.R.*** 35726 (July 26, 1991).)

It is unclear, at this point, what ramifications the CDC guidelines will have on the "significant risk" standard for either providers or patients. CDC may wish to clarify the purpose of its guidelines and note that they were not meant to affect the "significant risk' standard of the disability statutes, or may wish to clarify specifically that different risks are to be assumed by providers and patients under such statutes (10).

Fourth, while it is logical and reasonable to link preventive strategies for HBV with those for HIV, the impact on health care services due to restriction or exclusion from practice for HBV-infected HCWs could have serious consequences in specific specialties and institutions. For the long term, vaccines are available for HBV, and HCWs could avoid restriction or exclusion through vaccination. There are also indications that resolution of infection may be possible through treatment (27).

Little information is available, however, on the impact for specific types of HCWs, specialty practices, geographic areas, and institutions.

At the American Academy of Orthopedic Surgeons' annual meeting in March 1991, 3,420 of 7,121 orthopedists attending the meeting participated in a CDC survey of their HIV and HBV status (36). The characteristics of these participants were also compared to survey respondents (10,411 of 20,625 who were mailed a questionnaire) of all known orthopedists in training, practice, or retired in practice in the United States and Canada. The participants were more likely to be in residency or fellowship training; have trained or practiced in one or more geographic areas of high AIDS incidence since 1977; have operated on one or more patients with known HIV infection; have had a patient's blood contact their skin the previous month; and have sustained a percutaneous injury (e.g., needlestick or cut) from a sharp object contaminated with a patient's blood in the previous month. Fifty-one percent of the participants had been tested previously for HIV. Two (0.06 percent) participants were HIV seropositive, both of whom reported nonoccupational risk factors for HIV infection.

As for HBV seropositivity, CDC's findings (31) indicate that the carrier rate among the orthopedic surgeons tested was similar to CDC estimates that approximately 0.6 percent of surgeons in the United States are HBV carriers, of whom 20 percent are estimated to be positive for HBeAg (denoting higher infectivity) (35).

Fifth, identification of HIV- and HBV-infected workers and notification of patients who have had exposure-prone procedures performed by these HCWs will be costly and require major resources.

While the CDC recommendations on notification apply specifically to all prospective patients who would undergo exposure-prone procedures performed by HIV- and HBV-infected HCWs, the CDC guidelines also comment on notification and follow-up studies on patients who have had exposure-prone procedures performed by infected HCWs. The CDC states that the public health benefit of such "look-back' notification:

> . . . should be considered on a case-by-case basis, taking into consideration an assessment of specific risks, confidentiality issues, and available resources. Carefully designed and implemented follow-up studies are necessary to determine more precisely the risk of transmission during such procedures. Decisions regarding notification and follow-up studies should be made in consultation with State and local public health officials (38).

Such follow-up studies are already being conducted on an ad hoc basis by health institutions as individual cases of HIV-infected HCWs become public. Whether the legal and public opinion environment will allow a careful consideration of "specific risks, confidentiality issues, and available resources' may already be a moot question for HIV-infected HCWs, but perhaps not for HBV-infected HCWs. However, as pointed out by CDC, there is still a need for more specific guidance by public health agencies on when such follow-up studies should take place (whether or not nonpublic health forces compel such studies to take place), and the design of such studies. Furthermore, the point is not whether CDC itself should have been more specific and prescriptive on when such follow-up studies should take place and the design of such studies. There will always be two sides of the question on the role-balancing between the Federal CDC and State public health authorities.

Look-back studies are unlikely to help define the magnitude of risk because they are difficult to conduct and interpret. Years may often have elapsed between the performance of the medical procedure under investigation and the identification of the HIV-infected HCW, making it difficult to document

important information on adherence to infection control, the nature of the procedure performed, and the occurrence of injury to the HCW in the performance of the procedure. Furthermore, if patients are identified as HIV-infected during the look-back study, it may be impossible to determine whether infection was actually acquired from the particular HCW or from other generally more common sources. Carefully reasoned decisions on which situations warrant notification and testing of past patients will have to be made given the limitations and the high cost of these studies.

Finally there is an issue regarding the resource support that the Federal Government should provide. If resources are limited to these direct consequences, then they could be provided for design and conduction of the follow-up studies, and for notification costs. The compromise bill that would require "the States to adopt CDC or equivalent guidelines may increase notification and follow-up activities.

References

1. Alderman, E.J., Georgia Department of Human Resources, Division of Public Health, personal communication, Aug. 19, 1991.
2. American Dental Association, Bureau of Economic and Behavioral Research, unpublished data.
3. Angell, M., "A Dual Approach to the AIDS Epidemic," New *England Journal of Medicine, 324, 1498-1499 (1991).*
4. Armstrong, F.P., Miner, J. C., and Wolfe, W.H., "Investigation of a Health-Care Worker With Symptomatic Human Immunodeficiency Virus Infection: An Epidemiologic Approach," *Milit. Med. 152(8): 414-418, 1987.*
5. *The* Association for Practitioners in Infection Control & The Society of Hospital Epidemiologists of America (Henderson, D.K., cd.), "Position Paper: The HIV-Infected Healthcare Worker," *Infect. Control Hosp. Epidemiol., 11,647-656 (1990).*
6. Bell, D., comments made at a workshop on "HIV in the Health Care Workplace," Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.
7. Bell, D.M., Chief, AIDS Activity, Hospital Infections Program, Center for Infectious Diseases, CDC, Atlanta, GA, personal communication to OTA, August/September, 1991.
8. Brennan, T., "Transmission of the Human Immunodeficiency Virus in the Health Care Setting-Time for Action,' New *England Journal of Medicine, 324, 1504-1506* (1991).
9. Comer, R.W., Myers, D.R., Steadman, C.D., et al., "Management Considerations for an HIV Positive Dental Student," *Journal Dent. Education 55: 187-191, 1991.*
10. *Curran,* J., comments at a workshop on "HIV in the Health Care Workplace," Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.
11. Feldblum, C., "A Response to Gostin, "The HIV-Infected Health Care Professional: Public Policy, Discrimination, and Patient Safety" (in press) (1991); also, comments made at a workshop on "HIV in the Health Care Workplace," Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.
12. Gerberding, J.L., San Francisco General Hospital, comments made at a workshop on "HIV in the Health Care Workplace," Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.
13. Gerberding, J.L., "Expected Costs of Implementing a Mandatory Human Immunodeficiency Virus and Hepatitis B Virus Testing and Restriction Program for Healthcare Workers Performing Invasive Procedures," *Infect. Control Hosp. Epidemiol. 12, 443-447 (1991).*
14. Gerberding, J.L., Littell, C., Tarkington, A., et al., "Risk of Exposure of Surgical Personnel to Patients' Blood During Surgery at San Francisco General *Hospital, ''New England Journal of Medicine 322(25): 1788-1793, 1990.*
15. Gerberding, J.L., and Schecter, W.P., "Surgery and AIDS, Reducing the Risk (editorial)," *Journal of American Medicine Association, 265(12), 1572-1573* (Mar. *27, 1991);* commenting on Panlilio, A.L., Fey, D.R., Edwards, J.R., et al., "Blood Contacts During Surgical Procedures," *Journal of American Medicine Association, 265, 1533-1537 (1991).*
16. Gostin, L., "HIV-Infected Physicians and the Practice of Seriously Invasive Procedures," *Hastings Center Report,* 19(1), 32-39, 1989; also, comments at a workshop on "HIV in the Healthcare Workplace,' Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.
17. Henderson, D. K., comments made at a workshop on "HIV in the Health Care Workplace," Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.
18. Henderson, D.K., Fahey, B.J., Winy, M., et al., "Risk for Occupational Transmission of Human Immunodeficiency Virus Type 1 (HIV-1) Associated With Clinical Exposures: A Prospective Evaluation," *Annuals of Internal Medicine 113: 740-746, 1990.*
19. Hussain, S.A.,Latif,A.B.A., and Choudhary, A.A.A.A., "Risk to Surgeons: A Survey of Accidental Injuries During Operations," *Br. J. Surg. 75: 314-316,1988.*

20. Klein, R. S., Phelan, J.A., Freeman, K., **et al., "Low** Occupational Risk of Human Immunodeficiency Virus Infection Among Dental Professionals," New *England Journal of Medicine 318(2): 86-90, 1988.*

20a. Louden, N.M. (letter), New *England Journal of Medicine 325* **(11).**

21. Mishu, B., Schaffner, W., Horan, J.M., **et al., "A Surgeon** With AIDS: Lack of Evidence of Transmission **to** Patients, ' *Journal of American Medicine Association 264(4): 467470, 1990.*

22. **Nast, S.T,** and Gerberding, **J.L., "Factors Predicting Infectivity Following Needlestick Exposure to HIV: An In Vitro Model" (abstract),** *Clinical Research 39(2): 381A, 1991.*

23. **Neidle, E.A., American Dental Association, "Statement of the American Dental Association on Estimates of the Risk of Endemic Transmission of Hepatitis B Virus and Human Immunodeficiency Virus to Patients by the Percutaneous Route During Invasive Surgical and Dental Procedures," typescript, presented at CDC, Feb. 21,**1991.

24. *Newsweek,* **p.** 5, Aug. 12, 1991.

25. Osterholm, M., **comments made at a** workshop **on "HIV in the Health Care** Workplace," Office of Technology Assessment, U.S. Congress, Washing**ton, DC,** July 25-26, 1991.

26. Panlilio, A.L., Fey, D.R., Edwards, J.R., **et al., '** 'Blood Contacts During Surgical Procedures,' *Journal of American Medicine Association 265(12), 1533-1537, 1991.*

27. **Perrillo, R.P., Schiff, E.R., Davis, G.L., et al., "A Randomized, Controlled Trial of Interferon Alfa-2b Alone and After Prednisone Withdrawal for the Treatment of Chronic Hepatitis B," New** *England Journal of Medicine, 323,295-301* **(1990).**

28. **Popejoy, S.L., and Fry, D.E., "Blood Contact and Exposure in the Operating Room,"** *Surg. Gynecol Obstet. 172(6): 480483, 1991.*

29. **Porter, J.D., Cruikshank, J.G., Gentle, P.H., et al., "Management of Patients Treated by a Surgeon** With HIV Infection" **(letter), Lancet 335: 113-114, 1990.**

30. **Reynolds, R. S.,** *Socioeconomic Characteristics of Medical Practice: 1985* **(Chicago, IL: American Medical Association, 1985).**

31. **Shapiro, C., Hepatitis Branch, Centers for Disease Control, comments at a workshop on "HIV in the Health Care Workplace," Office of Technology Assessment, U.S. Congress, Washington, DC, July 25-26, 1991.**

32. **Statement of Kirk Johnson, American Bar Association Coordinating Committee on AIDS Panel, ABA Annual Meeting, Chicago, IL, Aug. 10, 1991.**

33. **Tokars, J., Bell, D., Marcus, R., et al., "Percutaneous Injuries During Surgical Procedures" (abstract), VII International Conference on AIDS, vol. 2, Florence, Italy, June 16-21,** 1991, p. 83.

34. U.S. Congress, House of Representatives, *Making Appropriations for the Treasury Department, the U.S. Postal Service, the Executive Office of the President, and Certain Independent Agencies, for the Fiscal Year Ending September 30, 1992, and for Other Purposes, Conference Report,* **H. Rpt. 102-235 (Washington, DC: U.S. Government Printing Office, 1991).**

35. **U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Estimates of the Risk of Endemic Transmission of Hepatitis B Virus and Human Immunodeficiency Virus to Patients by the Percutaneous Route During Invasive Surgical and Dental Procedures" (draft), typescript, dated Jan. 30, 1991.**

36, **U.S. Department of Health and Human Service, Public Health Service, Center of Disease Control, "Preliminary Analysis: HIV Serosurvey of Orthopedic Surgeons,** 1991," *Journal of American Medi"-cine Association 265(21):2779-2781,* **June 5, 1991.**

37, **U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Update: Transmission of HIV Infection During Invasive Dental Procedures-Florida,"** *Morbidity and Mortality Weekly Report 40(23):377-381,* **June 14, 1991.**

38. **U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures,"** *Morbidity and Mortality Weekly Report 40 (No. RR- 8),* **July 12, 1991.**

39. **U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Process for Identifying Exposure-Prone Invasive Procedures,"** *Morbidity and Mortality Weekly Report 40(32):565-566,* **Aug. 16, 1991.**

40. **U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Draft Guidelines for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings," Sept. 20, 1991.**

41. **U.S. Department of Labor, OSHA, "Occupational Exposure to Bloodborne Pathogens; Proposed Rule and Notice of Hearing," 29 CFR Part 1910,** *Federal Register, 54-102,* **May 30, 1989.**

42. **Wain-Hobson, S., Vartanian, J.P., Henry, M., et al., "LAV Revisited: Origins of the Early HIV-1 Isolates From Institut Pasteur,"** *Science 252:961-965,* **May 17, 1991.**