# HIV / AIDS Course

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Take the Test

This course educates about modes of HIV/AIDS transmission, infection control procedures, clinical management, prevention, and current Florida law regarding HIV/AIDS and health care.

# Course Overview

## Part A

- Education in the modes of transmission
- Infection control procedures
- Clinical management
- Prevention of human immunodeficiency virus and acquired immune deficiency syndrome

## Part B

- current Florida law on acquired immune deficiency syndrome and its impact on testing,
- confidentiality of test results,
- treatment of patients,
- and any protocols and procedures applicable to human immunodeficiency virus counseling and testing,
- reporting,
- the offering of HIV testing to pregnant women,
- and partner notification issues pursuant to ss. 381.004 and 384.25

# HIV Modes of Transmission, Clinical Manifestations, and Cases in the Public

## HIV: Modes of Transmission

HIV can be transmitted from person to person through infected blood, semen or vaginal secretions, which have the highest concentrations of the virus and perinatally from mother to child. Breast milk has also been identified as a possible source of infection.

Although they may contain minute quantities of viral material, urine, tears, saliva and perspiration have never been implicated in the spread of HIV. To date the CDC has only investigated one case of HIV infection where transmission is believed to have occurred during kissing. However, the transmission was attributed to contact with blood, rather than saliva.

## Clinical Manifestations of HIV Infection

The course of HIV infection can vary considerably among individuals. The mean interval from infection to the development of AIDS is 10-11 years. The spectrum of HIV infection ranges from an asymptomatic state to severe immunodeficiency with associated opportunistic infections, neoplasms, and other conditions. Initial infection can be followed by an acute flu-like illness with fever, lymphadenopathy, sweats, myalgia, arthralgia, rash, malaise, sore throat, and headache.

The risk of disease progression increases with the duration of infection. Less than 5% of HIV-infected adults develop AIDS within 2 years of infection; without therapy, approximately 20-25 develop AIDS within 6 years after infection, and 50% within 10 years. Although over 23 diseases/conditions have been identified as AIDS indicators, P. carinii pneumonia, HIV wasting syndrome, and candidiasis of the esophagus are the most common.

# HIV Infection

Through June 30, 1997, a cumulative total of 612,078 persons with AIDS were reported to CDC by state and territorial health departments (table I ). Of these, 84 percent were adult/adolescent men, 15 percent were adult/adolescent women, and 1 percent were children (under 13 years of age). Of adults/adolescents reported during the 12 months period of July 1996-June 1997, 36 percent were white, 43 percent were black, and 20 percent were Hispanic. Men who have sex with men accounted for the largest proportion of reported cases (38 percent). Among 609 children reported in those 12 months, 15 percent were white, 63 percent were black, and 21 percent were Hispanic (table 6).Over 90 percent of these children were infected perinatally. In addition, 29 slates that conduct HIV case surveillance of adults, adolescents, and/or children reported 86,972 persons who were diagnosed with HIV (excluding persons tested anonymously) but not yet diagnosed with AIDS.

# Infection Control Procedures

The following is a summary of Centers for Disease Control Universal Precaution Recommendations:

1. Hands should be washed before and after patient contact and immediately if hands become contaminate with blood or other body fluids.
2. Gloves should be worn whenever there is a possibility of contact with body fluids.
3. Masks should be worn whenever there is a possibility of splashing or spattering of body fluids.
4. Gowns should be worn if soiling of exposed skin or clothing is likely.
5. To minimize the risks of exchange of body fluids during resuscitation procedures, pocket masks or mechanical ventilation devices should be readily available where these procedures are likely to be needed.
6. Spills of blood or blood-containing body fluids should be cleaned up using a solution of household bleach (sodium hypochlorite and water 1:10 to 1:100 solution for smooth surfaces and 1:10 solution for porous surfaces. Diluted bleach solutions should not be more than 24 hours old.
7. Health care workers who have open lesions, dermatitis, or other skin irritations should not participate in direct patient care activities and should not handle contaminated equipment.
8. Sharp objects represent the greatest risk for exposures. Contaminated needles should never be bent, clipped, or recapped. Immediately after use, contaminated sharp objects should be discarded into a puncture resistant "sharps" container designed for this purpose. Needle containers should never be overfilled; containers should be sealed and discarded when two-thirds to three-fourths full.
9. Contaminated equipment that is reusable should be cleaned of visible organic material, placed in an impervious container, and returned to central hospital supply or some other designated place for decontamination and reprocessing.
10. Instruments and other reusable equipment used in performing invasive procedures should be appropriately disinfected and sterilized as follows:
    - Equipment and devices that enter the patient's vascular system or other normally sterile areas of the body should be sterilized before being used for each patient
    - Equipment and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces should be sterilized when possible to undergo high level disinfection if they cannot be sterilized before being used for each patient.

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"Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Post-exposure Prophylaxis"

# Clinical Management

## Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis

Contents

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# Summary

This report updates and consolidates all previous PHS recommendations for the management of health-care workers (HCWs) who have occupational exposure to blood and other body fluids that may contain human immunodeficiency virus (HIV); it includes recommendations for HIV postexposure prophylaxis (PEP) and discusses the scientific rationale for PEP. The decision to recommend HIV postexposure prophylaxis must take into account the nature of the exposure (e.g., needlestick or potentially infectious fluid that comes in contact with a mucous membrane) and the amount of blood or body fluid involved in the exposure. Other considerations include pregnancy in the HCW and exposure to virus known or suspected to be resistant to antiretroviral drugs. Assessments of the risk for infection resulting from the exposure and of the infectivity of the exposure source are key determinants of offering PEP. Systems should be in place for the timely evaluation and treatment of HIV when using PEP.

Recommendations for PEP have been modified to include a basic 4-week regimen of two drugs (zidovudine and lamivudine) for most HIV exposures and an expanded regimen that includes the addition of a protease inhibitor (indinavir or nelfinavir) for HIV exposures that pose an increased risk for transmission or where resistance to one or more of the antiretroviral agents recommended for PEP is known or suspected. An algorithm is provided to guide clinicians and exposed health-care workers in deciding when to consider PEP.

Occupational exposures should be considered urgent medical concerns to ensure timely administration of PEP. Health-care organizations should have protocols that promote prompt reporting and facilitate access to postexposure care. Enrollment of HCWs in registries designed to assess side effects in HCWs who take PEP is encouraged.

# Introduction

Although preventing blood exposures is the primary means of preventing occupationally acquired human immunodeficiency virus (HIV) infection, appropriate postexposure management is an important element of workplace safety. In January 1990, CDC issued a statement on the management of HIV exposures that included considerations for zidovudine (ZDV) use for postexposure prophylaxis (PEP). At that time, data were insufficient to assess the efficacy of ZDV as a prophylactic agent in humans or the toxicity of this drug in persons not infected with HIV. Although there are still only limited data to assess safety and

efficacy, additional information is now available that is relevant to this issue.

In December 1995, CDC published a brief report of a retrospective case- control study of health-care workers (HCWs) from France, the United Kingdom, and the United States exposed percutaneously to HIV; the study identified risk factors for HIV transmission and documented that the use of ZDV was associated with a decrease in the risk for HIV seroconversion. This information, along with data on ZDV efficacy in preventing perinatal transmission and evidence that PEP prevented or ameliorated retroviral infection in some studies in animals, prompted a Public Health Service (PHS) interagency working group, with expert consultation, in June 1996 to issue provisional recommendations for PEP for HCWs after occupational HIV exposure.

Since the provisional recommendations were released, several new antiretroviral drugs have been approved by the Food and Drug Administration (FDA), and more information is available about the use and safety of antiretroviral agents in exposed HCWs. In addition, questions have been raised about the use of chemoprophylaxis in situations not fully addressed in the 1996 recommendations, including when not to offer PEP, what to do when the source of exposure or the HIV status of the source person is unknown, how to approach PEP in HCWs who are or may be pregnant, and considerations for PEP regimens when the source person's virus is known or suspected to be resistant to one or more of the antiretroviral agents recommended for PEP.

In May 1997, a meeting of expert consultants, convened by CDC to consider the new information, prompted a PHS interagency working group decision to issue updated recommendations. This document addresses the management of occupational exposure to HIV, including guidance in assessing and treating exposed HCWs, updates previous recommendations for occupational postexposure chemoprophylaxis, and updates and replaces all previous PHS guidelines and recommendations for occupational HIV exposure management for HCWs. Included in this document is an algorithm to guide decisions regarding the use of PEP for HIV exposures. The algorithm and these recommendations together address most issues that may be encountered during postexposure follow-up. As relevant information becomes available, updates of these recommendations will be published. Recommendations for nonoccupational (e.g., sexual or pediatric) exposures are not addressed in these guidelines.

## Definitions of Health-Care Workers and Exposure

In this report, "health-care worker" (HCW) is defined as any person (e.g., an employee, student, contractor, attending clinician, public-safety worker, or volunteer) whose activities involve contact with patients or with blood or other body fluids from patients in a health-care or laboratory setting. An "exposure" that may place an HCW at risk for HIV infection and therefore requires consideration of PEP is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object), contact of mucous membrane or non-intact skin (e.g., when the exposed skin is chapped, abraded, or afflicted with dermatitis), or contact with intact skin when the duration of contact is prolonged (i.e., several minutes or more) or involves an extensive area, with blood, tissue, or other body fluids. Body fluids include semen, vaginal secretions, or other body fluids contaminated with visible blood that have been implicated in the transmission of HIV infection; and fluids, which have an undetermined risk for transmitting HIV. In addition, any direct contact (i.e., without barrier protection) to concentrated HIV in a research laboratory or production facility is considered an "exposure" that requires clinical evaluation and consideration of the need for PEP.

Although one non-occupational episode of HIV transmission has been attributed to contact with blood-contaminated saliva, this incident involved intimate kissing between sexual partners and is not similar to contact with saliva that may occur during the provision of health-care services. Therefore, in the absence

of visible blood in the saliva, exposure to saliva from a person infected with HIV is not considered a risk for HIV transmission; also, exposure to tears, sweat, or non-bloody urine or feces does not require post-exposure follow-up.

Human breast milk has been implicated in perinatal transmission of HIV. However, occupational exposure to human breast milk has not been implicated in HIV transmission to HCWs. Moreover, the contact HCWs may have with human breast milk is quite different from perinatal exposure and does not require postexposure follow-up.

# Background

The rationale is provided here for the postexposure management and prophylaxis recommendations given at the end of the document. Additional details concerning the risk for occupational HIV transmission to HCWs and management of occupational HIV exposures are available elsewhere.

# Risk for Occupational Transmission of HIV to HCWs

Prospective studies of HCWs have estimated that the average risk for HIV transmission after a percutaneous exposure to HIV-infected blood is approximately 0.3% (95% confidence interval [CI]=0.2%-0.5%) and after a mucous membrane exposure is 0.09% (95% CI=0.006%- 0.5%). Although episodes of HIV transmission after skin exposure have been documented, the average risk for transmission by this route has not been precisely quantified because no HCWs enrolled in prospective studies have seroconverted after an isolated skin exposure. The risk for transmission is estimated to be less than the risk for mucous membrane exposures. The risk for transmission after exposure to fluids or tissues other than HIV-infected blood also has not been quantified.

As of June 1997, CDC has received reports of 52 U.S. HCWs with documented HIV seroconversion temporally associated with an occupational HIV exposure. An additional 114 episodes in HCWs are considered possible occupational HIV transmissions; these workers reported that their infection was occupationally acquired and no other risk for HIV infection was identified, but transmission of infection after a specific exposure was not documented. Of the 52 documented episodes, 47 HCWs were exposed to HIV-infected blood, one to a visibly bloody body fluid, one to an unspecified fluid, and three to concentrated virus in a laboratory. Forty-five exposures were percutaneous, and five were mucocutaneous; one HCW had both a percutaneous and a mucocutaneous exposure. The route of exposure for one person exposed to concentrated virus is uncertain. Of the percutaneous exposures, the objects involved included a hollow-bore needle, a broken glass vial (two), a scalpel (one), and an unknown sharp object (one) (CDC, unpublished data, 1998).

Epidemiologic and laboratory studies suggest that several factors may affect the risk for HIV transmission after an occupational exposure. The one retrospective case-control study of HCWs who had percutaneous exposure to HIV found that the risk for HIV transmission was increased with exposure to a larger quantity of blood from the source patient as indicated by a device visibly contaminated with the patient's blood, a procedure that involved a needle placed directly in a vein or artery, or a deep injury. (A laboratory study that demonstrated that more blood is transferred by deeper injuries and hollow-bore needles lends further support for the observed variation in risk related to blood quantity). The risk also was increased for exposure to blood from source patients with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course of AIDS or other factors (e.g., the presence of syncytia-inducing strains of HIV). It was estimated that the risk for HIV transmission from exposures that involve a larger volume of blood, particularly when the source patient's viral load is probably high, exceeds the average risk of 0.3%. The utility of viral load measurements from a source patient as a surrogate for estimating the viral titer for

assessing transmission risk is not known. Plasma viral load measurement (e.g., HIV RNA) reflects only the level of cell-free virus in the peripheral blood. This measurement does not reflect the level of cell-associated virus in the peripheral blood or the level of virus in other body compartments (e.g., lymphatic tissue). Although a lower viral load, or results that are below the limits of viral quantification, in the peripheral blood probably indicates a lower titer exposure, it does not rule out the possibility of transmission; HIV transmission from persons with a plasma viral load below the limits of viral quantification (based to-infant transmission and in one HCW seroconversion (J .L. Gerberding, San Francisco General Hospital, unpublished data, May 1997).

There is some evidence that host defenses also may influence the risk for HIV infection. In one small study, HIV-exposed but uninfected HCW's demonstrated an HIV-specific cytotoxic T-lymphocyte (CTL) response when peripheral blood mononuclear cells were stimulated in vitro with HIV mitogens. Similar CTL responses have been observed in other populations with repeated HIV exposure without resulting infection. Among several possible explanations for this observation, one is that the host immune response sometimes may be able to prevent establishment of HIV infection after a percutaneous exposure; another is that the CTL response simply may be a marker for exposure.

# HIV Seroconversion in HCWs

Data on the timing and clinical characteristics of seroconversion in HIV- exposed HCWs are limited by the infrequency of infection following occupational exposure, variations in postexposure testing intervals, and differences over time in the sensitivity of HIV-antibody testing methods. Among the HCWs with documented seroconversions reported to CDC for whom data are available, 81% experienced a syndrome compatible with primary HIV infection a median of 25 days after exposure (CDC, unpublished data, 1998). In a recent analysis of 51 seroconversions in HCWs, the estimated median interval from exposure to seroconversion was 46 days (mean: 65 days); an estimated 95% seroconverted within 6 months after the exposure. These data suggest that the time course of HIV seroconversion in HCWs is similar to that in other persons who have acquired HIV through nonoccupational modes of transmission. Three instances of delayed HIV seroconversion occurring in HCWs have been reported; in these instances, the HCWs tested negative for HIV antibodies after more than 6 months postexposure but were seropositive within 12 months after the exposure (J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997). DNA sequencing confirmed the source of infection in one instance. Two of the delayed seroconversions were associated with simultaneous exposure to hepatitis C virus (BCV) (J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997). In one case, coinfection was associated with a rapidly fatal BCV disease course; however, it is not known whether BCV directly influences the risk for or course of HIV infection or is a marker for other exposure-related factors.

# Rationale for PEP

Considerations that influence the rationale and recommendations for PEP include the pathogenesis of HIV infection, particularly the time course of early infection; the biologic plausibility that infection can be prevented or ameliorated by using antiretroviral drugs and direct or indirect evidence of the efficacy of specific agents used for prophylaxis; and the risk/benefit of PEP to exposed HCWs. The following discussion considers each of these issues.

# Role of Pathogenesis in Considering Antiretroviral Prophylaxis

Information about primary HIV infection indicates that systemic infection does not occur immediately, leaving a brief "window of opportunity" during which postexposure antiretroviral intervention may modify viral replication. Data from studies in animal models and in vitro tissue studies suggest that dendritic cells in the mucosa and skin are the initial targets of HIV infection or capture and have an important role in initiating HIV infection of CD4+ T-cells in regional lymph nodes. In a primate model of simian immunodeficiency virus (SIV) infection, infection of dendritic-like cells occurred at the site of inoculation during the first 24 hours following mucosal exposure to cell-free virus. During the subsequent 24-48 hours, migration of these cells to regional lymph nodes occurred, and virus was detectable in the peripheral blood within 5 days. HIV replication is rapid (generation time: 2.5 days) and results in bursts of up to 5,000 viral particles from each replicating cell (; M.S. Saag, University of Alabama, personal communication, September 1997). The exponential increase in viral burden continues unless controlled by the immune system or other mechanisms (e.g., exhaustion of available target CD4+ T-cells). Theoretically, initiation of antiretroviral PEP soon after exposure may prevent or inhibit systemic infection by limiting the proliferation of virus in the initial target cells or lymph nodes.

# Efficacy of Antiretrovirals for PEP

Studies in animals and humans provide direct and indirect evidence of the efficacy of antiretroviral drugs as agents for postexposure prophylaxis. In human studies and in most animal studies, ZDV was the antiretroviral agent used for prophylaxis. However, in more recent animal studies, newer agents also have been reported to be. Data from animal studies have been difficult to model for humans. Most studies use a higher inoculum for exposure than would be expected in needlestick injuries. Among the animal studies, differences in controlled variables (e.g., choice of viral strain [based on the animal model used], inoculum size, route of inoculation, time of prophylaxis initiation, and drug regimen) make attempts to apply these results to humans difficult. In the animal studies that showed efficacy of pre-exposure and/or postexposure prophylaxis, reported outcomes have included:

**a)** Suppression of viremia or delayed antigenemia;
**b)** Drug-facilitated vaccine-type response (i.e., chemoprophylaxis sufficiently inhibited viral replication to permit formation of a long-lasting, protective cellular immune response); and
**c)** Definitive prevention of infection (i.e., chemoprophylactic efficacy).
    **1.** More recent refinements in methodology have enabled studies more relevant to humans; in particular, the viral inocula used in animal studies have been reduced to levels more analogous to human exposures. The results of these studies provide additional evidence of postexposure chemoprophylactic efficacy.

In studies of HIV-2 or SIV in nonhuman primates in which ZDV or 3'- fluorothymidine was used, suppression or delay of antigenemia was the most common outcome; prevention of infection was infrequent. However, two other antiretroviral agents, 2',3'-dideoxy-3'-hydroxymethyl cytidine (BEA-005) and (R)-9-(2-phosphonylmethoxypropyl) adenine (PMPA), used to study PEP in primates have been more effective in preventing infection. When PMPA was administered 48 hours before, 4 hours after, or 24 hours after intravenous SIV inoculation to long-tailed macaques, a 4-week regimen prevented infection in all treated animals. A 3-day regimen of BEA-005 prevented SIV infection in 12 of 12 pigtailed macaques when administered 1-8 hours after intravenous inoculation; infection also was prevented in four of four animals that received 3 days of BEA-005 within I 0 minutes after HIV-2 inoculation.

Animal studies have demonstrated that early initiation of PEP and small inoculum size are correlates of successful PEP. ZDV initiated 1 hour or 24 hours after intravenous exposure to a rapidly lethal variant of SIV in pigtailed macaques prevented infection in one of three animals and modified SIV disease in three

of six animals, respectively; PEP initiated at 72 hours had no effect (54). In macaques administered ZDV or BEA-005 1 to 72 hours after SIV intravenous challenge, earlier initiation of PEP was correlated with delayed onset and peak of antigenemia, decreased duration of antigenemia, and reduction in SIV serum titer; the most potent effect was evident when PEP was initiated within 8 hours of exposure. Studies in primates and murine and prophylactic efficacy. In addition, delaying initiation, shortening the duration, or decreasing the antiretroviral dose of PEP, individually or in combination, decreased prophylactic efficacy.

There is little information with which to assess the efficacy of PEP in humans. Seroconversion is infrequent after an occupational exposure to HIV-infected blood; therefore a prospective trial would need to enroll many thousands of exposed HCWs to achieve the statistical power necessary to directly demonstrate PEP efficacy. During 1987-1989, the Burroughs-Wellcome Company sponsored a prospective placebo- controlled clinical trial among HCWs to evaluate 6 weeks of ZDV prophylaxis; however, this trial was terminated prematurely because of low enrollment. Because of current indirect evidence of PEP efficacy, it is unlikely that a placebo-controlled trial in HCWs would ever be feasible.

In the retrospective case-control study of HCWs, after controlling for other risk factors for HIV transmission, the risk for HIV infection among HCWs who used ZDV as PEP was reduced by approximately 81% (95% CI=43%-94%). In addition, in a randomized, controlled, prospective trial (AIDS Clinical Trial Group [ACTG] protocol 076) in which ZDV was administered to HIV-infected pregnant women and their infants, the administration of ZDV during pregnancy, labor, and delivery and to the infant reduced transmission by 67%. Only 9%-17% (depending on the assay used) of the protective effect of ZDV was explained by reduction of the HIV titer in the maternal blood, suggesting that ZDV prophylaxis in part involves a mechanism other than the reduction of maternal viral burden.

The limitations of all of these studies must be considered when reviewing evidence of PEP efficacy. The extent to which data from animal studies can be extrapolated to humans is largely unknown, and the exposure route for mother-to-infant HIV transmission is not similar to occupational exposures; therefore these findings may not reflect a similar mechanism of ZDV prophylaxis in HCWs. Although the results of the retrospective case-control study of HCWs suggest PEP efficacy, the limitations of that study include the small number of cases studied and the use of cases and controls from different cohorts.

Failure of ZDV PEP to prevent HIV infection in HCWs has been reported in at least 14 instances (; G. Ippolito, AIDS Reference Center, Rome, Italy, and J. Hepton-stall, Communicable Disease Surveillance Center, London, United Kingdom, personal taken ZDV, laboratory assessment for ZDV resistance of the virus from the source patient was performed in only three instances, two of which demonstrated reduced susceptibility to ZDV. In addition to possible exposure to a ZDV-resistant strain of HIV, other factors that may have contributed to the apparent failures in these instances may include a high titer and/or large inoculum exposure, delayed initiation and/or short duration of PEP, and possible factors related to the host (e.g., cellular immune system responsiveness) and/or to the source patient's virus (e.g., presence of syncytia-forming strains).

# Antiretroviral Agents for PEP

Several antiretroviral agents from at least three classes of drugs are available for the treatment of HIV disease. These include the nucleoside analogue reverse transcriptase inhibitors (NRTIs), nonnuceloside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs) (See Appendix). Among these drugs, ZDV (an NRTI) is the only agent shown to prevent HIV transmission in humans. Although there are theoretical concerns that the increased prevalence of resistance to ZDV may diminish its utility for PEP, no data are available to assess whether this is a factor for consideration.

Clinical data from the ACTG protocol 076 study documented that despite genotypic evidence of maternal ZDV resistance, ZDV prevented perinatal transmission. Thus, based on the available information, it is still reasonable that ZDV should continue to be the first drug of choice for PEP regimens.

There are no data to directly support the addition of other antiretroviral drugs to ZDV to enhance the effectiveness of the PEP regimen. However, in HIV-infected patients, combination regimens have proved superior to monotherapy regimens in reducing HIV viral load. Thus, theoretically a combination of drugs with activity at different stages in the viral replication cycle (e.g., NRT's with a PI) could offer an additive preventive effect in PEP, particularly for occupational exposures that pose an increased risk for transmission.

Determining which agents and how many agents to use or when to alter a PEP regimen is largely empiric. Guidelines for the treatment of early HIV infection recommend the use of three drugs (two NRTIs and a PI); however, the applicability of these recommendations to PEP remains unknown. In addition, the routine use of three drugs for all occupational HIV exposures may not be needed. Although the use of an increased risk for transmission, it is uncertain whether the potential additional toxicity of a third drug is justified for lower-risk exposures. For this reason, the recommendations at the end of this report provide guidance for two- and three-drug PEP regimens that are based on the level of risk for HIV transmission represented by the exposure. NRTIs that can be considered for use with ZDV for PEP are lamivudine (3TC), didanosine (ddI), and zalcitabitie, each of which has been included in recommended regimens that include ZDV. In previous CDC recommendations, 3TC was recommended as a second agent for PEP based on greater antiretroviral activity of the ZDV/3TC combination and its activity against many ZDV-resistant HIV strains without substantially increased toxicity. Also, data suggest that ZDV-resistant mutations develop more slowly in patients receiving the ZDV/3TC combination than those receiving ZDV alone, and in vitro studies indicate that the mutation associated with 3TC resistance may be associated with reversal of ZDV phenotypic resistance. No additional information has emerged to warrant altering the original recommendation of 3TC as the second agent for PEP. In addition, because ZDV and 3TC are available in a combination formulation (Combivir™, manufactured by Glaxo Wellcome, Inc., Research Triangle Park, NC), the use of 3TC may be more convenient for HCWs. However, individual clinicians may prefer other NRTIs or combinations of other antiretroviral agents based on local knowledge and experience in treating HIV infection and disease. The addition of a PI as a third drug for PEP following high-risk exposures is based on the site of activity in the replication cycle (i.e., after viral integration has occurred) and demonstrated effectiveness in reducing viral burden. Previously, indinavir (IDV) was recommended as the PI for PEP because of its increased bioavailability when compared with saquinavir and its more favorable immediate toxicity profile compared with ritonavir. In addition, requirements for dose escalation when initiating ritonavir make it less practical for use in PEP. Since the 1996 PEP recommendations were published, nelfinavir (NEL) was approved for use by FDA and is now included in regimens recommended for the treatment of primary HIV infection. Also, FDA recently approved a soft-gel formulation of saquinavir (Fortovase™, manufactured by Hoffmann-LaRoche, Inc., Nutley, New Jersey) that has improved bioavailability relative to its hard-gel formulation (Invirase™, manufactured by Hoffmann-LaRoche, Inc.). However, the recommended dose of soft-gel saquinavir (1200 mg three times a day) is twice that of the hard-gel formulation (600 mg three times a day) and necessitates taking 18 pills a day, a factor that may influence HCW compliance if used for PEP. Based on these considerations, either IDV or NEL is recommended as first choice for inclusion in an expanded soft-gel formulation (Fortovase™) should be used. Also, differences in the side effects associated with IDV and NEL, discussed below, may influence which of these agents is selected in a specific situation.

The NNRTIs (i.e., nevirapine and delavirdine) have not been included in these recommended regimens for PEP. As a class of antiretroviral agents, the NNRTIs are fast-acting and very potent, making them appealing in concept for PEP. In addition, there is some evidence of prophylactic efficacy. However, concerns about side effects and the availability of alternative agents argue against routinely using this

class of drugs for initial PEP, although with expert consultation, an NNRTI might be considered.

## Side Effects and Toxicity of Anti-retroviral Agents

An important goal of PEP is to encourage and facilitate compliance with a 4-week PEP regimen. Therefore, the toxicity profile of antiretroviral agents, including the frequency, severity, duration, and reversibility of side effects, is a relevant consideration. All of the antiretroviral agents have been associated with side effects (See Appendix).

However, studies of adverse events have been reported primarily for persons with advanced disease (and longer treatment courses) and therefore may not reflect the experience of persons with less advanced disease or those who are uninfected (74). Side effects associated with many of the NRTIs (e.g., ZDV or ddI) are chiefly gastro-intestinal (e.g., nausea or diarrhea), and in general the incidence of adverse effects has not been greater when these agents are used in combination.

All of the approved PIs may have potentially serious drug interactions when used with certain other drugs, requiring careful evaluation of concomitant medications being used by an HCW before prescribing a PI and close monitoring for toxicity when an HCW is receiving one of these drugs (See Appendix). PIs may inhibit the metabolism of nonsedating antihistamines and other hepatically metabolized drugs; NEL and ritonavir may accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs). The use of PIs also has been associated with new onset of diabetes mellitus, hyperglycemia, diabetic ketoacidosis, and exacerbation of pre-existing diabetes mellitus. Nephrolithiasis has been associated with IDV use (including in HCWs using the drug for PEP); however, the incidence of this potential complication may be limited by drinking at water throughout the day). Rare cases of hemolytic anemia also have been associated with the use of IDV. NEL, saquinavir, and ritonavir have been associated with the development of diarrhea; however, this side effect usually responds to treatment with antimotility agents that can be prescribed for use, if necessary, at the time any one of these drugs is prescribed for PEP. The manufacturer's package insert should always be .consulted for questions about potential drug interactions.

Among HCWs receiving ZDV PEP, usually at doses of 1,000-1,200 mg per day (i.e., higher than the currently recommended dose), 50%-75% reported one or more subjective complaints and approximately 30% discontinued the drug because of symptoms. Common symptoms included nausea, vomiting, malaise or fatigue, headache, or insomnia. Mild decreases in hemoglobin and absolute neutrophil count also were observed. All side effects were reversed when PEP was discontinued.

Preliminary information about HCWs receiving combination drugs for PEP (usually ZDV plus 3TC with or without a PI) suggests that approximately 50%-90% of HCWs report subjective side effects that caused 24%-36% to discontinue PEP. One study documented that combination regimens that included ZDV at a lower dose (600 mg per day) were better tolerated than high-dose ZDV used alone (l,000- 1,200 mg per day). However, serious side effects, including nephrolithiasis, hepatitis, and pancytopenia, have been reported with the use of combination drugs for PEP (; J.L. Gerberding, San Francisco General Hospital, personal communication, May 1997).

## Resistance to Antiretroviral Agents

Known or suspected resistance of the source virus to antiretroviral agents, particularly to one or more agents that might be included in a PEP regimen, is a concern for those making decisions about PEP. Resistance of HIV has been reported with all available antiretroviral agents. However, the relevance of exposure to a resistant virus is not understood. Although transmission of resistant strains has been

reported, in the perinatal clinical trial that studied vertical HIV transmission (ACTG protocol 076), ZDV prevented perinatal transmission despite genotypic resistance of HIV to ZDV in the mother. In addition, patients generally take more than one antiretroviral drug and, unless testing is performed, often it is difficult to know to compound by the frequency of cross-resistance within drug classes.

Resistance should be suspected in source patients when there is clinical progression of disease or a persistently increasing viral load and/or a decline in CD4 T-cell count despite therapy, or a lack of virologic response to a change in therapy. Nevertheless, in this situation it is unknown whether a modification in the PEP regimen is necessary or will influence the outcome of an occupational exposure.

# Antiretroviral Drugs in Pregnancy

Considerations for the use of antiretroviral drugs in pregnancy include their potential effect on the pregnant woman and on her fetus or neonate. The pharmacokinetics of antiretroviral drugs has not been completely studied in pregnant women. Some of the antiretroviral drugs are known to cross the placenta, but data for humans are not yet available for others (particularly the PIs). In addition, data are limited on the potential effects of antiretroviral drugs on the developing fetus or neonate. Decisions on the use of specific drugs in pregnancy also are influenced by whether a drug has specific adverse effects or might further exacerbate conditions associated with pregnancy, (e.g., drugs that cause nausea may be less tolerated when superimposed on the nausea normally associated with pregnancy). There are data on both ZDV and 3TC from clinical trials in HIV-infected pregnant women. The most extensive experience has been with the use of ZDV after 14 weeks of gestation in pregnant HIV-infected women in phase I studies and the perinatal ACTG protocol 076. The dose of ZDV for pregnant women is the same as that in nonpregnant persons, and ZDV appears safe and well tolerated in both women and their infants who have had a follow-up period of several years. Data from the Antiretroviral Pregnancy Registry have not documented an increased risk for birth defects in infants with in utero exposure to ZDV. There are limited data on use of 3TC alone or in combination with ZDV in late gestation
in pregnant HIV-infected women. As with ZDV, the pharmacokinetics and dose of 3TC appear to be similar to those for nonpregnant persons. The drug appears safe during pregnancy for women and infants, although long-term safety is not known. Carcinogenicity and/or mutagenicity is evident in several in vitro screening tests for ZDV and all other FDA-licensed nucleoside antiretroviral drugs. In some in vivo rodent studies, high-dose lifetime continuous ZDV exposure or very high dose in utero ZDV exposure has been associated with the development of tumors in adult females or their offspring. The relevance of these animal data to humans is unknown. However, in 1997 benefits of ZDV in preventing perinatal transmission, where the risk for transmission without ZDV is 25%-30%, outweigh the hypothetical concerns about transplacental carcinogenesis.

No data are available regarding pharmacokinetics, safety, or tolerability of any of the PIs in pregnant women. The use of PIs in HIV-infected persons has been associated with hyperglycemia; it is unknown whether the use of these agents during pregnancy will exacerbate the risk for pregnancy-associated hyperglycemia. Therefore, close monitoring of glucose levels and careful instruction regarding symptoms related to hyperglycemia are recommended for pregnant HCWs receiving a PI for PEP. IDV is associated with infrequent side effects in adults (i.e., hyperbilirubinemia and renal stones) that could be problematic for the newborn. As the half-life of IDV in adults is short, these concerns may be relevant only if the drug is administered shortly before delivery.

# Recommendations for the Management of Potentially Exposed HCWs

Health-care organizations should make available to their workers a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and follow-up of occupational exposures that may place HCWs at risk for acquiring any blood borne infection, including HIV. Employers also are required to establish exposure- control plans, including postexposure follow-up for their employees, and to comply with incident reporting requirements mandated by the Occupational Safety and Health Administration. Access to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. Antiretroviral agents for PEP should be available for timely administration (i.e., either by providing access to PEP drugs on site or creating links with other facilities or providers to make them available offsite). Persons responsible for providing post-exposure counseling should be familiar with evaluation and treatment protocols and the facility's procedures for obtaining drugs for PEP. HCWs should be educated to report occupational exposures immediately after they occur, particularly because PEP is most likely to be effective if implemented as soon after the exposure as possible. HCWs who are at risk for occupational exposure to HIV should be taught the principles of postexposure management, including options for PEP, as part of job orientation and ongoing job training.

# Exposure Report

If an occupational exposure occurs, the circumstances and postexposure management should be recorded in the HCWs confidential medical record (usually on a form the facility designates for this purpose). Relevant information includes:

- Date and time of exposure
- Details of the procedure being performed, including where and how the exposure occurred, and if the exposure was related to a sharp device, the type of device and how and when in the course of handling the device the exposure occurred
- Details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected
- Or for a skin or mucous membrane exposure, the estimated volume of material and duration of contact and the condition of the skin [e.g., chapped, abraded, or intact])
- Details about the exposure source (i.e., whether the source material contained HIV or other blood borne pathogen[s]), and if the source is an HIV-infected person, the stage of disease, history of antiretroviral therapy, and viral load, if known; and details about counseling, postexposure management
- Follow-up.

# Exposure Management

## Treatment of an Exposure Site

Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. There is no evidence that the use of antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk for HIV transmission. However, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended. Exposure-control plans, including postexposure follow-up for their employees, and to comply with incident reporting requirements mandated by the Occupational Safety and Health Administration. Access

to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. Antiretroviral agents for PEP should be available for timely administration (i.e., either by providing access to PEP drugs on site or creating links with other facilities or providers to make them available offsite). Persons responsible for providing post-exposure counseling should be familiar with evaluation and treatment protocols and the facility's procedures for obtaining drugs for PEP. HCW should be evaluated to determine the need for HIV PEP. Follow- up for hepatitis B virus and hepatitis C virus infections also should be conducted in accordance with previously published CDC recommendations.

## Evaluation of Exposure

The exposure should be evaluated for potential to transmit HIV based on the type of body substance involved and the route and severity of the exposure. Exposures to blood, fluid containing visible blood, or other potentially infectious fluid (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardia, and amniotic fluids) or tissue through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are situations that pose a risk for blood borne transmission and require further evaluation (Figure 1). In addition, any direct contact (i.e., personal protective equipment either was not used or was ineffective in protecting skin or mucous membranes) with concentrated HIV in a research laboratory or production facility is considered an exposure that requires clinical evaluation to assess the need for PEP.

For skin exposures, follow-up is indicated if it involves direct contact with a body fluid listed above and there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound). However, if the contact is prolonged or involves a large area of intact skin, postexposure follow-up may be considered on a case-by-case basis or if requested by the HCW.

For human bites, the clinical evaluation must consider possible exposure of both the bite recipient and the person who inflicted the bite. HIV transmission only rarely has been reported by this route (100,101; CDC, unpublished data, 1998). If a bite results in blood exposure to either person involved, postexposure follow-up, including consideration of PEP, should be provided.

## Evaluation and Testing of an Exposure Source

The person whose blood or body fluids are the source of an occupational exposure should be evaluated for HIV infection. Information available in the medical record at the time of exposure (e.g., laboratory test results, admitting diagnosis, or past medical history) or from the source person may suggest or rule out possible HIV infection. Examples of information to consider when evaluating an exposure source for possible HIV infection include laboratory information (e.g., prior HIV testing results or results of immunologic testing [e.g., CD4+ count]), clinical symptoms (e.g., acute syndrome suggestive of primary HIV infection or undiagnosed immediately after they occur, particularly because PEP is most likely to be effective if implemented as soon after the exposure as possible.
HCWs who are at risk for occupational exposure to HIV should be taught the principles of postexposure management, including options for PEP, as part of job orientation and ongoing job training.

## Exposure Report

If an occupational exposure occurs, the circumstances and postexposure management should be recorded in the HCWs confidential medical record (usually on a form the facility designates for this purpose). Relevant information includes:

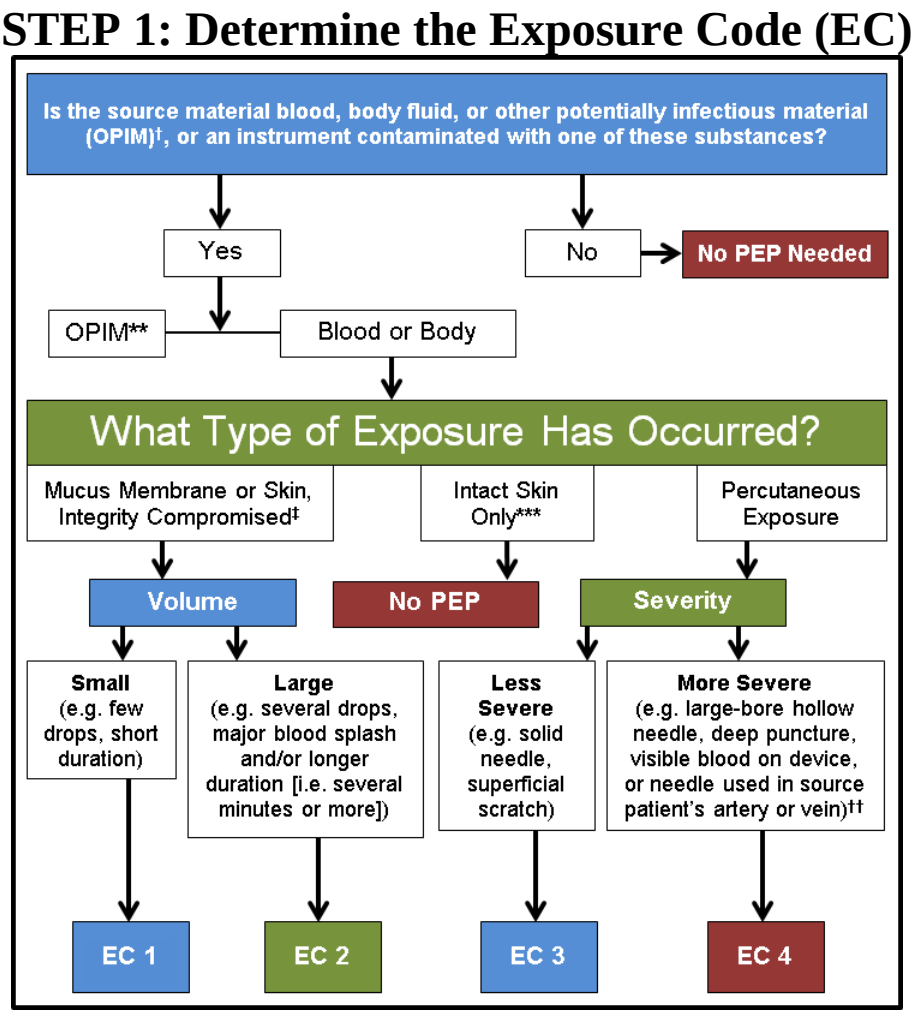
• date and time of exposure; details of the procedure being performed, including where and how the exposure occurred, and if the exposure was related to a sharp device, the type of device and how and when in the course of handling the device the exposure occurred; details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected; or for a skin or mucous- membrane exposure, the estimated volume of material and duration of contact and the condition of the skin [e.g., chapped, abraded, or intact]); details about the exposure source (i.e., whether the source material contained HIV or other blood borne pathogen[s ]), and if the source is an HIV-infected person, the stage of disease, history of antiretroviral therapy, and viral load, if known; and details about counseling, postexposure management, and follow-up.

Exposure Management Treatment of an Exposure Site
Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. There is no evidence that the use of antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk for HIV transmission. However, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

Assessment of Infection Risk injecting-drug use, sexual contact with a known HIV-positive partner, unprotected sexual contact with multiple partners [heterosexual and/or homosexual], or receipt of blood or blood products before 1985).

If the source is known to have HIV infection, available information about this person's stage of infection (i.e., asymptomatic or AIDS), CD4+ T-cell count, results of viral load testing, and current and previous antiretroviral therapy, should be gathered for consideration in choosing an appropriate PEP regimen. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate.

**FIGURE 1.** Determining the need for HIV postexposure prophylaxis (PEP) after an occupational exposure*




* This algorithm is intended to guide initial decisions about PEP and should be used in conjunction with other guidance provided in this report.

† Semen or vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids: or tissue.

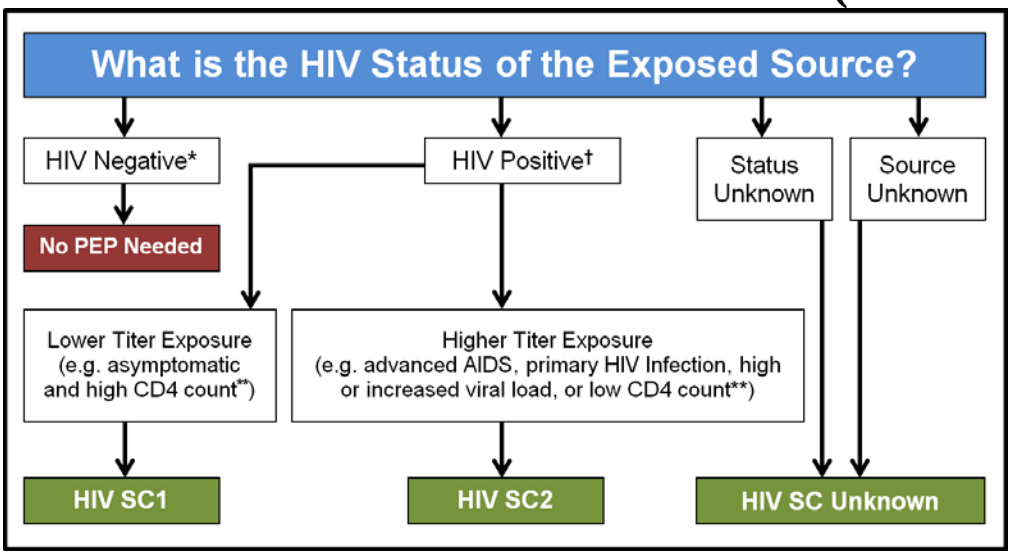
** Exposure to OPIM must be evaluated on a case by case basis. In general, these body substances are considered a low risk for transmission in health care settings. Any Unprotected contact to concentrated HIV in a research laboratory or production facility is considered an occupational exposure that requires clinical evaluation to determine the need for PEP.

‡ Skin integrity is considered compromised if there is evidence of chapped skin, dermatitis, abrasion, or open wound.

*** Contact with intact skin is not normally considered a risk for HIV transmission, However, if the exposure was to blood, and the circumstance suggests a higher volume exposure (e.g., an extensive area of skin was exposed or there was prolonged contact with blood) the risk of HIV transmission should be considered.

†† The combination of these severity factors (e.g. large-bore hollow needle and deep puncture) contribute to an elevated risk for transmission if the source person is HIV-positive.

# STEP 2: Determine the HIV Status Code (HIV SC)




* A source is considered negative for HIV infection if there is laboratory documentation of a negative HIV antibody, HIV polymerase chain reaction (PCR), or HIV p24 antigen test result from a specimen collected at or near the time of exposure and there is no clinical evidence of recent retroviral like illness.

† A source is considered infected with HIV (HIV positive) if there has been a positive laboratory result for HIV antibody, HIV PCR, or HIV p24 antigen or physician-diagnosed AIDS.

** Examples are used as surrogates to estimate the HIV titer in an exposure source for purposes of considering PEP regimens and do not reflect all clinical situations that may be observed. Although a high HIV titer (HIV SC2) in an exposure source has been associated with an increased risk for transmission, the possibility of transmission from a source with a low HIV titer also must be considered.



Take the Test

# STEP 3: Determine the PEP Recommendation

| EC | HIV SC | PEP Recommendation |
|---|---|---|
| 1 | 1 | PEP may not be warranted. Exposure type does not pose a known risk for HIV transmission. Whether the risk for drug toxicity outweighs the benefit of PEP should Ire decided by the exposed HCW and treating clinician. |
| 1 | 2 | Consider basic regimen.*Exposure type poses a negligible risk for HIV transmission. A high HIV titer in the source may justify consideration of PEP. Whether the risk for drug toxicity outweighs the benefit of PEP should be decided by the exposed HCW and treating clinician. |
| 2 | 2 | Recommend basic regimen. Most HIV exposures are in this category; no Increased risk for HIV transmission has been observed but use of PEP is appropriate. |
| 2 | 2 | Recommend expanded regimen.† Exposure type represents an increased HIV transmission risk. |
| 3 | 1 or 2 | Recommend expanded regimen. Exposure type represents an increased HIV transmission risk. |
| ► Unknown ◄ | | If the source or, in the case of on unknown source, the setting where the exposure occurred suggests a possible risk for HIV exposure and the EC is 2 or 3, consider PEP basic regimen. |

***** Basic regimen is four weeks of zidovudine, 600 mg per day in two or three divided doses, and lamivudine, 150 mg twice daily.

† Expanded regimen is the basic regimen plus either indinavir, 800 mg every 8 hours, or nalfinavir, 750 mg three times a day.

If the HIV serostatus of the source person is unknown, the source person should be informed of the incident and, if consent is obtained, tested for serologic evidence of HIV infection. If consent cannot be obtained (e.g., patient is unconscious), procedures should be followed for testing source persons according to applicable state and local laws. Confidentiality of the source person should be maintained at all times.

HIV -antibody testing of an exposure source should be performed as soon as possible. Hospitals, clinics, and other sites that manage exposed HCWs should consult their laboratories regarding the most appropriate test to use to expedite these results. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by enzyme immunoassay (EIA) cannot be completed within 24-48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorcscent antibody is not necessary for making initial decisions about postexposure management but should be done to complete the testing process. If the source is HIV seronegative and has no clinical evidence of acquired immunodeficiency syndrome (AIDS) or symptoms of HIV infection, no further testing of the source is indicated. It is unclear whether follow-up testing of a source who is HIV negative at the time of exposure, but recently (i.e., within the last 3-6 months) engaged in behaviors that pose a risk for HIV transmission, is useful in postexposure management of HCWs; HCWs who become infected generally seroconvert before repeat testing of a source would normally be performed.

If the exposure source is unknown, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for risk for transmission of HIV. Certain situations, as well as the type of exposure, may suggest an increased or decreased risk; an important consideration is the

prevalence of HIV in the population group (i.e., institution or community) from which the contaminated source material is derived. For example, an exposure that occurs in a geographic area where injecting-drug use is prevalent or on an AIDS unit in a health- care facility would be considered epidemiologically to have a higher risk for transmission than one that occurs in a nursing home for the elderly where no known HIV-infected residents are present. In addition, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher- risk exposure than exposure to a needle that was most likely used for giving an injection. Decisions regarding appropriate management should be individualized based on the risk assessment.

HIV testing of needles or other sharp instruments associated with an exposure, regardless of whether the source is known or unknown, is not recommended. The reliability and interpretation of findings in such circumstances are unknown.

## Clinical Evaluation and Baseline Testing of Exposed HCWs

Exposed HCWs should be evaluated for susceptibility to blood borne pathogen infections. Baseline testing (i.e., testing to establish serostatus at the time of exposure) for HIV anti body should be performed. If the source person is seronegative for HIV, baseline testing or further follow-up of the HCW normally is not necessary. If the source person has recently engaged in behaviors that are associated with a risk for HIV transmission, baseline and follow-up HIV-antibody testing (e.g., 3 and/or 6 months postexposure) of the HCW should be considered. Serologic testing should be made available to all HCWs who are concerned that they may have been exposed to HIV. For purposes of considering HIV PEP, the evaluation also should include information about medications the HCW may be taking and any current or underlying medical conditions or circumstances (i.e., pregnancy, breast feeding, or renal or hepatic disease) that may influence drug selection. Pregnancy testing should be offered to all nonpregnant women of child bearing age whose pregnancy status is unknown.

# HIV PEP

The following recommendations apply to situations where an HCW has had an exposure to a source person with HIV or where information suggests that there is a likelihood that the source person is HIV-infected. These recommendations are based on the risk for HIV infection after different types of exposure and limited data regarding efficacy and toxicity of PEP. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity must be carefully considered when prescribing PEP. When possible, these recommendations should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission.

## Explaining PEP to HCWs

Recommendations for chemoprophylaxis should be explained to HCWs who have sustained occupational HIV exposures (Figure 1). For exposures for which PEP is considered appropriate, HCWs should be informed that a) knowledge about the efficacy and toxicity of drugs used for PEP are limited; b) only ZDV has been shown to prevent HIV transmission in humans; c) there are no data to address whether adding other antiretroviral drugs provides any additional benefit for PEP, but experts recommend combination drug regimens because of increased potency and concerns about drug-resistant virus; d) data regarding toxicity of antiretroviral d rugs in persons without H IV infection or in pregnant women arc limited for ZDV and not known regarding other antiretroviral drugs; and e) an y or all drugs for PEP may be declined by the HCW. HCWs who have HIV occupational exposures for which PEP is not recommended should be informed that the potential side effects and toxicity of taking PEP outweigh the

negligible risk of transmission posed by the type of exposure.

## Factors in Selection of a PEP Regimen

Selection of the PEP regimen should consider the comparative risk represented by the exposure and information about the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4+ T-lymphocyte counts, viral load measurements, and current disease stage. Most HIV exposures will warrant only a two- drug regimen, using two NRT's, usually ZDV and 3TC. The addition of a third drug, usually a PI (i.e., IDV or NEL), should be considered for exposures that pose an increased risk for transmission or where resistance to the other drugs used for PEP is known or suspected.

## Timing of PEP Initiation

PEP should be initiated as soon as possible. The interval within which PEP should be started for optimal efficacy is not known. Animal studies have demonstrated the importance of starting PEP within hours after an exposure. To assure timely access to PEP, an occupational exposure should be regarded as an urgent medical concern and PEP started as soon as possible after the exposure (i.e., within a few hours rather than days). If there is a question about which antiretroviral drugs to use, or whether to use two or three drugs, it is probably better to start ZDV and 3TC immediately than to delay PEP administration. Although animal studies suggest that PEP probably is not effective when started later than 24-36 hours postexposure, the interval after which there is no benefit from PEP for humans is undefined. Therefore, if appropriate for the exposure, PEP should be started even when the interval since exposure exceeds 36 hours. Initiating therapy after a longer interval (e.g., 1-2 weeks) may be considered for exposures that represent an increased risk for transmission; even if infection is not prevented, early treatment of acute HIV infection may be beneficial. The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in HCWs, PEP probably should be administered for 4 weeks, if tolerated.

## PEP if Serostatus of Source Person is Unknown

If the source person's HIV serostatus is unknown at the time of exposure (including when the source is HIV negative but may have had a recent HIV exposure), use of PEP should be decided on a case-by-case basis, after considering the type of exposure and the clinical and/or epidemiologic likelihood of HIV infection in the source (Figure I ). If these considerations suggest a possibility for HIV transmission and HIV testing of the source is pending, it is reasonable to initiate a two-drug PEP regimen until laboratory results have been obtained and later modify or discontinue the regimen accordingly.

## PEP if Exposure Source is Unknown

If the exposure source is unknown, use of PEP should be decided on a case-by-case basis. Consideration should include the severity of the exposure and the epidemiologic likelihood that the HCW was exposed to HIV.

## PEP for Pregnant HCWs

If the HCW is pregnant, the evaluation of risk and need for PEP should be approached as with any other HCW who has had an HIV exposure.
However, the decision to use any antiretroviral drug during pregnancy should involve discussion between

the woman and her health-care provider regarding the potential benefits and potential risks to her and her fetus.

# Follow-up of HCWs Exposed to HIV

## Postexposure Testing

HCWs with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they receive PEP. HIV-antibody testing should be performed for at least 6 months postexposure (e.g., at 6 weeks, 12 weeks, and 6 months). It is unclear whether an extended follow-up period (e.g., 12 months) is indicated in certain circumstances. Although rare instances of delayed HIV seroconversion have been reported (J.L. Gerberding, San Francisco General Hospital, unpublished data, May 1997), the infrequency of this occurrence does not warrant adding to HCWs' anxiety by routinely extending the duration of postexposure follow-up. Circumstances for which extending the duration of follow-up have been suggested include the use of highly potent antiretroviral regimens (i.e., more than two drugs) because of theoretical concerns that HIV seroconversion could be delayed, or simultaneous exposure to HCV. Data are insufficient for making a general recommendation in these situations. However, this should not preclude a decision to extend follow-up in an individual situation based on the clinical judgment of the HCW's health-care provider. HIV testing should be performed on any HCW who has an illness that is compatible with an acute retroviral syndrome, regardless of the interval since exposure. HIV-anti body testing using EIA should be used to monitor for seroconversion. The routine use of direct virus assays (e.g., HIV p24 antigen EIA or polymerase chain reaction for HIV RNA) to detect infection in exposed HCWs generally is not. Although direct vims assays may detect HIV infection a few days earlier than EIA, the infrequency of HCW seroconversion and increased costs of these tests do not warrant their routine use in this setting. Also, HIV RNA is approved for use in established HIV infection; its reliability in detecting very earl y infection has not been determined.

## Monitoring and Management of PEP Toxicity

If PEP is used, drug-toxicity monitoring should be performed at baseline and again 2 weeks after starting PEP. Clinical judgment, based on medical conditions that may exist in the HCW and any toxicity associated with drugs included in the PEP regimen, should determine the scope of testing. Minimally these should include a complete blood count and renal and hepatic chemical function tests. Monitoring for evidence of hyperglycemia should be included for HCWs whose regimen includes any PI; if the HCW is receiving IDV, monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis also should be included. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies may be indicated. HCWs who fail to complete the recommended regimen often do so because of the side effects they experience (e.g., nausea and diarrhea). These symptoms often can be managed without changing the regimen by prescribing antimotility and antiemetic agents or other medications that target the specific symptoms. In other situations, modifying the dose interval (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), may help promote adherence to the regimen.

# Counseling and Education

Although HIV infection following an occupational exposure occurs infrequently, the emotional impact of the exposure often is substantial. In addition, HCWs are given seemingly conflicting information. All though HCWs are told that there is a low risk for HIV transmission, a 4-week regimen of PEP is recommended and they are asked to commit to behavioral measures (i.e., sexual abstinence or condom use) to prevent secondary transmission, all of which influence their lives for several weeks to months. Therefore, access to persons who are knowledgeable about occupational HIV transmission and who can deal with the many concerns an HIV exposure may raise for the HCW is an important element of postexposure management.

HIV-exposed HCWs should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially during the first 6-12 weeks after the exposure when most HIV-infected persons are expected to seroconvert: use sexual abstinence or condoms to prevent sexual transmission and to avoid pregnancy; and refrain from donating blood, plasma, organs, tissue, or semen. If the exposed HCW is breastfeeding, she should be counseled about the risk for HIV transmission through breast milk, and discontinuation of breastfeeding should be considered, especially following high-risk exposures. If the HCW chooses to receive PEP, temporary discontinuation of breastfeeding while she is taking PEP should be considered to avoid exposing the infant to these agents. NRT's are known to pass into breast milk; it is not known whether this also is true for PIs.

There is no need to modify an HCW's patient-care responsibilities to prevent transmission to patients based solely on an HIV exposure. If HIV seroconversion is detected, the HCW should be evaluated according to published recommendations for HIV-infected HCWs.

Exposed HCWs should be advised to seek medical evaluation for any acute illness that occurs during the follow-up period. Such an illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy, may be indicative of acute HIV infection but also may be due to a drug reaction or another medical condition.

Exposed HCWs who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided about potential drug interactions and the drugs that should not be taken with PEP, the side effects of the drugs that have been prescribed (See Appendix), measures to minimize these effects, and the methods of clinical monitoring for toxicity during the follow-up period.

They should be advised that the evaluation of certain symptoms should not be delayed (e.g., back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia [i.e., increased thirst and/or frequent urination]).

# Recommendations for the Selection of Drugs for PEP

The selection of a drug regimen for HIV PEP must strive to balance the risk for infection against the potential toxicity of the agent(s) used. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for transmission (Figure 1). Also, there is insufficient evidence to recommend a highly active regimen for all HIV exposures. Therefore, two regimens for PEP are provided (Table 1): a "basic" two-drug regimen that should be appropriate for most HIV exposures and an "expanded" three-drug regimen that should be used for exposures that pose an increased risk for transmission (Figure 1) or where resistance to one or more antiretroviral agents is known or suspected. When possible, the regimens should be implemented in consultation with persons having expertise in

antiretroviral treatment and HIV transmission.

**TABLE 1.Basic and Expanded Postexposure Prophylaxis Regimens**

| Regimen Category | Application | Drug Regimen |
|---|---|---|
| **Basic** | Occupational HIV exposures for which there is a recognized transmission risk (Figure 1). | 4 weeks (28 days) of both zidovudine 600 mg every day in divided doses (i.e., 300 mg twice a day, 200 mg three times a day, or 100 mg every 4 hours) and lamivudine 150 mg twice a day. |
| **Expanded** | Occupational HIV exp1isurns that pose an increased risk for transmission (e.g., larger volume of blood and/or higher virus titer in blood) (Figure 1). | Basic regimen plus either indinavir 800 mg every 6 hours or nelfinavir 750 n1g three times a day.***** |

***** Indinavir should be taken on an empty stomach (i.e., without food or with a light meal) and with increased fluid consumption (i.e., drinking six 8 oz. glasses of water throughout the day); nelfinavir should be taken with meals.

# Situations That Require Special Consideration

## Resistance of the Source Virus to Antiretroviral Drugs

It is unknown whether drug resistance influences transmission risk; however, transmission of drug-resistant HIV has been reported and is therefore a theoretical concern when choosing PEP regimens. If the source-person's virus is known or suspected to be resistant to one or more of the drugs included in the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended. If the resistance is to one class of antiretroviral drugs, the addition to the basic PEP regimen of a drug from another class might be considered (e.g., addition of a PI when a source patient has not been treated with a PI but has virus resistant to one or more NRT's). It is strongly recommended that PEP be started regardless of the resistance status in the source virus; if resistance is known or suspected, a third or fourth d rug may be added to the regimen until consultation with a clinical expert in the treatment of HIV infection or disease can be obtained.

## Known or Suspected Pregnancy in the HCW

Pregnancy should not preclude the use of optimal PEP regimens, and PEP should not be denied to an HCW solely on the basis of pregnancy. However, as discussed previously, an occupationally exposed pregnant HCW must be provided with full information about what is known and not known regarding the potential benefits and risks associated with use of the antiretroviral drugs to her and her fetus for her to make an informed decision regarding the use of PEP. The choice of antiretroviral drugs to use for PEP in pregnant HCWs is complicated by the potential need to alter dosing because of physiologic changes associated with pregnancy and the potential for short- or long-term effects on the fetus and newborn. Thus, considerations that should be discussed with a pregnant HCW include the potential risk for HIV transmission based on the type of exposure; the stage of pregnancy (the first trimester being the period of maximal organogenesis and risk for teratogenesis); and what is known about the pharmacokinetics, safety, and tolerability of the drug or combination of drugs in pregnancy.

# Postexposure Registries

Health-care providers in the United States are encouraged to enroll HCWs who receive PEP in a confidential registry developed by CDC, Glaxo Wellcome Inc., and Merck & Co., Inc., to assess toxicity; telephone (888) 737-4448 ([888] PEP-4HIV), or write the HIV PEP Registry, 1410 Commonwealth Drive, Suite 215, Wilmington, NC 28405. Unusual or serious and unexpected toxicity from antiretroviral drugs should be reported to the manufacturer and/or FDA, telephone (800) 332-1088.

Health-care providers also should report instances of prenatal exposure to antiretroviral agents to the Antiretroviral Pregnancy Registry. The registry is an epidemiologic project to collect observational, nonexperimental data on antiretroviral drug exposure during pregnancy to assess potential teratogenicity. Referrals should be directed to the Antiretroviral Pregnancy Registry, 1410 Commonwealth Drive, Suite 215, Wilmington, NC 28405; telephone (800) 258-4263 or (800) 722-9292, ext. 39437; fax (800) 800-1052.

A protocol has been developed to evaluate HIV seroconversion in an HCW who received PEP. These events can be reported to CDC, telephone (404) 639-6425.

# Resources for Consultation

Clinicians who seek consultation on HIV PEP for assistance in managing an occupational exposure should access local experts in HIV treatment as much as possible. In addition, the "National Clinicians' Post-Exposure Prophylaxis Hotline (PEP-Line)" has been created to assist clinicians with these issues; telephone (888) 448-4911. Other resources and registries include the HIV Postexposure Prophylaxis Registry, the Antiretroviral Pregnancy Registry, FDA, and CDC (Table 2).

**TABLE 2. HIV postexposure prophylaxis resources and registries**

| Resource or Registry | Contact Information | |
|---|---|---|
| National Clinicians' Postexposure Hotline | Telephone: | (888) 448-4911 |
| HIV Postexposure Prophylaxis Registry | Telephone: | (888) 737-4448 ([888] PEP4HIV) |
| | Write: | 1410 Commonwealth Drive, Suite 215 Wilmington, NC 28405 |
| Antiretroviral Pregnancy Registry | Telephone: | (800) 258-4263 |
| | Fax: | (800) 800-1052 |
| | Write: | 1410 Commonwealth Drive, Suite 215 Wilmington, NC 28405 |
| Food and Drug Administration (for reporting unusual or severe toxicity to antiretroviral agents) | Telephone: | (800) 332-1008 |
| CDC (for reporting HIV seroconversions in health-care workers who received PEP) | Telephone: | (404) 639-6425 |

# Administrative Considerations

Effective implementation of the elements of postexposure management detailed in these recommendations may require various types of expertise. The assessment of the severity of an exposure

generally requires clinical training and experience (i.e., medical or nursing). However, the assessment of HIV infection risk and initiation of a basic PEP regimen necessitates knowledge or experience in clinical epidemiology, infection control, occupational health, or the clinical treatment of HIV. Decisions about HIV PEP are particularly complex if PIs are used or there is concern about drug-resistant virus. Thus, expert consultation when prescribing PEP is strongly encouraged. PEP protocols should list the names of readily available resources for consultation and could include policies that require infectious disease evaluation before prescribing an expanded antiretroviral regimen.

# CDC Factsheet: Preventing Occupational HIV Transmission to Health Care Workers

As of June 30, 1998, CDC is aware of 54 health care workers (HCWs) in the United States who have had documented HIV seroconversion following occupational exposures, which means they tested negative for HIV infection around the time of exposure, but tested HIV positive within a year after the exposure. Another 133 HIV-infected health care workers have been classified as having possible cases of occupational transmission. These 133 health care workers have a history of occupational exposure to blood, other body fluids, or HIV-infected laboratory material and report no other risk factors for HIV infection, but do not have documentation of seroconversion after the occupational exposure.

**U.S. Health Care Workers with Documented and Possible Occupationally Acquired HIV Infection and AIDS, Reported Through June 1998**

| Occupation | Documented Transmission | Possible Transmission |
|---|---|---|
| Dentist/Dental Worker | 0 | 6 |
| Embalmer/Morgue Tech. | 1 | 2 |
| EMT/Paramedic | 0 | 12 |
| Health Aide/Attendant | 1 | 14 |
| Housekeeper/Maint. Worker | 1 | 12 |
| Lab Tech.-Clinical | 16 | 16 |
| Lab Tech.-Nonclinical | 3 | 0 |
| Nurse | 22 | 33 |
| Physician, Nonsurgical | 6 | 11 |
| Physician, Surgical | 0 | 6 |
| Respiratory Therapist | 1 | 2 |
| Technician, Dialysis | 1 | 3 |
| Technician, Surgical | 2 | 2 |
| Technician, Other | 0 | 10 |
| Other Healthcare Occupations | 0 | 4 |
| **TOTAL** | **54** | **133** |

## Types of Exposures and Risk for HIV Transmission

Of the 54 HCWs with documented transmission, 46 (85%) were exposed to HIV through percutaneous injuries (injuries penetrating the skin, such as from a needlestick). Another 5 had mucocutaneous exposures (they were exposed to body fluids from an HIV-infected person through the mucous membranes or skin); 2 HCWs had both percutaneous and mucocutaneous exposures; and 1 had an unknown route of exposure. Forty-nine of the 54 HCWs were exposed to the blood of an HIV-infected person, 1 to visibly bloody fluid, I to an unspecified fluid, and 3 to concentrated virus in a laboratory. Studies suggest that several factors may affect the risk for HIV transmission through an occupational exposure, including the quantity of blood or body fluid, the concentration of HIV in the blood or fluid, and the exposed person's underlying health and immune status.

## Preventive Strategies

The primary means of preventing the HCWs' occupational exposure to HIV and other blood borne pathogens is to follow infection control precautions with the assumption that the blood and other body fluids from all patients are potentially infectious. These precautions include the routine use of barriers (such as gloves and/or goggles) when anticipating contact with blood or body fluids, immediately washing hands and other skin surfaces after contact with blood or body fluids, and careful handling and disposal of sharp instruments during and after use.

Safety devices also have been developed to help prevent needle-stick injuries. If used properly, these types of devices may reduce the risk of exposure to HIV through percutaneous injuries. Furthermore, because many percutaneous injuries are related to sharps disposal, strategies for safer disposal, including safer design of disposal containers and placement of containers, are being developed.

Although the most important approach toward reducing the risk of occupational HIV transmission is to prevent occupational exposures, there also should be plans for postexposure management for HCWs. One consideration in postexposure management is the administration of antiretrovirals as postexposure prophylaxis (PEP). The use of zidovudine as PEP has been shown to be safe and associated with decreased risk for occupationally related HIV infection. Newer antiretrovirals also may be effective, although there is less experience with their use as PEP; therefore, data are continually being collected on the use of the newer antiretrovirals. CDC recently issued guidelines for the management of HCW exposures to HIV and recommendations for PEP. These guidelines outline a number of considerations in determining whether or not an HCW should receive PEP and in choosing the type of PEP regimen.

## Building Better Prevention Programs for Health-Care Workers

Continued work in the following areas is needed to reduce the risk of occupational HIV transmission to health care workers:

**Continue administrative efforts.** All health organizations should continue to support infection control measures that prevent HCWs from becoming exposed to blood and other body fluids. Training and monitoring HCWs and reporting occupational exposures are essential to prevention efforts.

**Develop and promote the use of safety devices.** Effective and competitively priced safety devices are needed for HCWs who frequently come into contact with potentially HIV-infected blood and other body fluids. The use of safety devices should be evaluated to determine if they are being used properly and consistently.

**Monitor the effects of PEP.** More data are needed on the safety and tolerability of different regimens of PEP, particularly those regimens that consist of new antiretroviral agents. Furthermore, improved communication regarding side effects before starting treatment and close follow-up of HCWs are needed to increase compliance with the PEP.

CDC, in collaboration with hospitals and other health care organizations, will continue to promote a safe and healthy health care work environment through surveillance activities, epidemiologic and laboratory research, and the development of guidelines and recommendations for the prevention and management of occupational exposures and infections in health care workers.

*Last Updated: October 1998*
*Centers for Disease Control & Prevention*
*National Center for HIV, STD, and TB Prevention*
*Divisions of HIV/AIDS Prevention*
*Please send comments/suggestions/requests to:*

# Part B

## 381.004 HIV testing--

**(2) Legislative Intent**--The Legislature finds that the use of tests designed to reveal a condition indicative of human immunodeficiency virus infection can be a valuable tool in protecting the public health. The Legislature finds that despite exiting laws, regulations, and professional standards which require or promote the informed, voluntary, and confidential use of test designed to reveal human immunodeficiency virus infection, many members of the public are deterred from seeking such testing because they misunderstand the nature of the test or fear that test results will be disclosed without their consent. The Legislature finds that the public health will be served by facilitating informed, voluntary, and confidential use of tests designed to detect human Immunodeficiency virus infection.

**(3) Definitions**--As used in this section:

**(a)** **"HIV test"** means a test ordered after July 6, 1988, to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.

**(b)** **"HIV test result"** means a laboratory report of a human immunodeficiency virus test result entered into a medical record on or after July 6, 1988, or any report or notation in a medical record of a laboratory report of a human immunodeficiency virus test. As used in this section, the term "HIV test result" does not include test results reported to a health care provider by a patient.

**(c)** **"Significant exposure"** means:

**1.** Exposure to blood or body fluids through needlestick, instruments, or sharps;

**2.** Exposure of mucous membranes to visible blood or body fluids, to which universal precautions apply according to the National Centers for Disease Control and Prevention, including, without limitations, the following body fluids:

**a.** Blood,
**b.** Semen,
**c.** Vaginal secretions,
**d.** Cerebra-spinal fluid (CSF),
**e.** Synovial fluid,
**f.** Pleural fluid,
**g.** Peritoneal fluid,
**h.** Pericardial fluid,
**i.** Amniotic fluid,
**j.** Laboratory specimens that contain HIV (e.g., suspensions of concentrated virus); or

**3.** Exposure of skin to visible blood or body fluids,' especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.

**(d)** **"Preliminary HIV test"** means an antibody screening test, such as the enzyme- linked immunosorbent assays (ELISAs) or the Single-Use Diagnostic System (SUDS).

**(e)** **"Test subject"** or **"subject of the test"** means the person upon whom an HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.

**(4) Human Immunodeficiency Virus Testing; Informed Consent; Results; Counseling; Confidentiality--**

**(a)** No person in this state shall order a test designed to identify the human immunodeficiency virus, or its antigen or antibody, without first obtaining the informed consent of the person upon whom the test is being performed, except as specified in paragraph (h). Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Information shall also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (4)(c), each county health department shall maintain a list of sites at which anonymous testing Is performed, including the locations, phone numbers, and hours of operation of the sites. Consent need not be in writing provided there is documentation in the medical record that the test has been explained and the consent has been obtained.

**(b)** Except as provided in paragraph (h), informed consent must be obtained from a legal guardian or other person authorized by law when the person:

**1.** Is not competent, is Incapacitated, or is otherwise unable to make an informed judgment; or

**2.** Has not reached the age of majority, except as provided in s. 384.30.

**(c)** The person ordering the test or that person's designee shall ensure that all reasonable efforts are made to notify the test subject of his or her test result. Notification of a person with a positive test result shall include Information on the availability of appropriate medical and support services, on the Importance of notifying partners who may have been exposed, and on preventing transmission of HIV. Notification of a person with a negative test result shall Include, as appropriate, Information on preventing the transmission of HIV. When testing occurs in a hospital emergency department, detention facility, or other facility and the test subject has been released before being notified of positive test results, informing the county health department for that department to notify the test subject fulfills this responsibility.

**(d)** No test result shall be determined as positive, and no positive test result shall be revealed to any person, without corroborating or confirmatory tests being conducted except in the following situations:

**1.** Preliminary test results may be released to licensed physicians or the medical or nonmedical personnel subject to the significant exposure for purposes of subparagraphs (h) 10., 11., and 12.

**2.** Preliminary test results may be released to health care providers and to the person tested when decisions about medical care or treatment of, or recommendation to, the person tested and, in the case of an intrapartum or postpartum woman, when care, treatment, or recommendations regarding her newborn, cannot await the results of confirmatory testing. Positive preliminary HIV test results shall not be characterized to the patient as a diagnosis of HIV Infection. Justification for the use of preliminary test results must be documented in the medical record by the health care provider who ordered the test. This subparagraph does not authorize the release of preliminary test results for the purpose of routine Identification of HIV-Infected Individuals or when HIV testing Is Incidental to the preliminary diagnosis or care of a patient. Corroborating or confirmatory testing must be conducted as follow-up to a

positive preliminary test. Results shall be communicated to the patient according to statute regardless of the outcome. Except as provided in this section, test results are confidential and exempt from the provisions of s. 119.07(1).

**(e)** Except as provided in this section, the identity of any person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1). No person who has obtained or has knowledge of a test result pursuant to this section may disclose or be compelled to disclose the identity of any person upon whom a test is performed, or the results of such a test in a manner which permits identification of the subject of the test, except to the following persons:

**1.** The subject of the test or the subject's legally authorized representative.

**2.** Any person, including third-party payors, designated in a legally effective release of the test results executed prior to or after the test by the subject of the test or the subject's legally authorized representative. The test subject may in writing authorize the disclosure of the test subject's HIV test results to third party payors, who need not be specifically identified, and to other persons to whom the test subject subsequently Issues a general release of medical information. A general release without such prior written authorization is not sufficient to release HIV test results.

**3.** An authorized agent or employee of a health facility or health care provider if the health facility or health care provider Itself Is authorized to obtain the test results, the agent or employee participates In the administration or provision of patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a need to know such Information. The department shall adopt a rule defining which persons have a need to know pursuant to this subparagraph.

**4.** Health care providers consulting between themselves or with health care facilities to determine diagnosis and treatment. For purposes of this subparagraph, health care providers shall include licensed health care professionals employed by or associated with state, county, or municipal detention facilities when such health care professionals are acting exclusively for the purpose of providing diagnoses or treatment of persons in the custody of such facilities.

**5.** The department, in accordance with rules for reporting and controlling the spread of disease, as otherwise provided by state law.

**6.** A health facility or health care provider which procures, processes, distributes, or uses:

**a.** A human body part from ii deceased person, with respect to medical information regarding that person; or
**b.** Semen provided prior to July 6, 1988, for the purpose of artificial insemination.

**7.** Health facility staff committees, for the purposes of conducting program monitoring, program evaluation, or service reviews pursuant to chapters 395 and 766.

**8.** Authorized medical or epidemiological researchers who may not further disclose any identifying characteristics or information.

**9.** A person allowed access by a court order which is issued in compliance with the following

provisions:

**a.** No court of this state shall issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public Interest which may be disserved by disclosure which deters blood, organ, and semen donation and future human immunodeficiency virus-related testing or which may lead to discrimination. This paragraph shall not apply to blood bank donor records.

**b.** Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially in documents not filed with the court.

**c.** Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.

**d.** Court proceedings as to disclosure of test results shall be conducted in camera, unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

**e.** Upon the issuance of an order to disclose test results, the court shall impose who may have access to the information, the purposes for which the information shall be used and appropriate prohibitions on future disclosure.

**10.** A person allowed access by order of a judge of compensation claims of the Division of Administrative Hearings. A judge of compensation claims shall not issue such order unless he or she finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means.

**11.** Those employees of the department or of child-placing or child-caring agencies or of family foster homes, licensed pursuant to s. 409.175, who are directly involved In the placement, care, control, or custody of such test subject and who have a need to know such information; adoptive parents of such test subject; or any adult custodian, any adult relative, or any person responsible for the child's welfare, if the test subject was not tested under subparagraph (b)2. and if a reasonable attempt has been made to locate and Inform the legal guardian of a test result. The department shall adopt a rule to implement this subparagraph.

**12.** Those employees of residential facilities or of community-based care programs that care for developmentally disabled persons, pursuant to chapter 393, who are directly involved in the care, control, or custody of such test subject and who have a need to know such information.

**13.** A health care provider Involved in the delivery of a child can note the mother's HIV test results in the child's medical record.

**14.** 14. Medical personnel or nonmedical personnel who have been subject to a significant exposure during the course of medical practice or In the performance of professional duties, or individuals who are the subject of the significant exposure as provided In subparagraphs (h)10.-12.

**15.** The medical examiner shall disclose positive HIV test results to the department In accordance with rules for reporting and controlling the spread of disease.

**(f)** Except as provided in this section, the identity of a person upon whom a test has been performed is confidential and exempt from the provisions of s. 119.07(1). No person to whom the results of a test have been disclosed may disclose the test results to another person except as authorized by this subsection and by ss. 951.27 and 960.003. Whenever disclosure is made pursuant to this subsection, it shall be accompanied by a statement in writing which includes the following or substantially similar language: "This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other Information is NOT sufficient for this purpose. An oral disclosure shall be accompanied by oral notice and followed by a written notice within 10 days, except that this notice shall not be required for disclosures made pursuant to subparagraphs (e)3. and 4.

**(g)** Human immunodeficiency virus test results contained in the medical records of a hospital licensed under chapter 395 may be released in accordance with s. 395.3025 without being subject to the requirements of subparagraph (e)2., subparagraph (e)9., or paragraph (f); provided the hospital has obtained written informed consent for the HIV test in accordance with provisions of this section.

**(h)** Notwithstanding the provisions of paragraph (a), informed consent is not required:

**1.** When testing for sexually transmissible diseases is required by state or federal law, or by rule including the following situations:
- **a.** HIV testing pursuant to s. 796.08 of persons convicted of prostitution or of procuring another to commit prostitution.
- **b.** Testing for H V by a medical examiner In accordance with s. 406.11.

**2.** Those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue pursuant to s. 381.0041.

**3.** For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies when the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent, as supported by documentation in the medical record. Notification of test results In accordance with paragraph (c) is required.

**4.** For the performance of an HIV-related test by licensed medical personnel for medical diagnosis of acute illness where, In the opinion of the attending physician, obtaining informed consent would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested. Notification of test results In accordance with paragraph (c) is required If It would not be detrimental to the patient. This subparagraph does not authorize the routine testing of patients for HIV Infection without Informed consent.

**5.** When HIV testing is performed as part of an autopsy for which consent was obtained pursuant to s. 872.04.

**6.** For the performance of an HIV test upon a defendant pursuant to the victim's request In a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to the provisions of s. 775.0877, s. 951.27, or s. 960.003; however, the results of any HIV test performed shall be disclosed solely to the victim and the defendant, except as provided in ss. 775.0877, 951.27, and 960.003.

**7.** When an HIV test is mandated by court order.

**8.** For epidemiological research pursuant to s. 381.0032, for research consistent with Institutional review boards created by 45 C.F.R. part 46, or for the performance of an HIV-related test for the purpose of research, if the testing is performed In a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

**9.** When human tissue is collected lawfully without the consent of the donor for corneal removal as authorized by s. 765.5185 or enucleation of the eyes as authorized by s. 765.519.

**10.** For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample Is available that was taken from that individual voluntarily by medical personnel for other purposes. The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under chapter 483; personnel of a blood bank or plasma center; a medical student or other. student who is receiving training as a health care professional at a health care facility; and a paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23.

**a.** Prior to performance of an HIV test on a voluntarily obtained blood sample, the individual from whom the blood was obtained shall be requested to consent to the performance of the test and to the release of the results. The individual's refusal to consent and all information concerning the performance of an HIV test and any HIV test result shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the individual's medical record.

**b.** Reasonable attempts to locate the individual and to obtain consent shall be made, and all attempts must be documented. If the Individual cannot be found, an HIV test may be conducted on the available blood sample. If the individual does not voluntarily consent to the performance of an HIV test, the individual shall be informed that an H. V test will be performed, and counseling shall be furnished as provided in this section. However, HIV testing shall be conducted only after a licensed physician documents, in the medical record of the medical personnel, that there has been a significant exposure and that, in the physician's medical judgment, the Information Is medically necessary to determine the course of treatment for the medical personnel.

**c.** Costs of any HIV test of a blood sample performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel. However, costs of testing or treatment not directly related to the Initial HIV tests or costs of subsequent testing or treatment shall not be borne by the medical personnel or the employer of the medical personnel.

**d.** In order to utilize the provisions of this subparagraph, the medical personnel must either be tested for HIV pursuant to this section or provide the results of an HIV test taken within 6 months prior to the significant exposure if such test results are negative.

**e.** A person who receives the results of an H V test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).

**f.** If the source of the exposure will not voluntarily submit to HIV testing and a blood sample is not available, the medical personnel or the employer of such person acting on behalf of the employee may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, In the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

**11.** For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice of the medical personnel while the medical personnel provides emergency medical treatment to the individual; or who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency. For the purposes of this subparagraph, a medical emergency means an emergency medical condition outside of a hospital or health care facility that provides physician care. The test may be performed only during the course of treatment for the medical emergency.

**a.** An Individual who is capable of providing consent shall be requested to consent to an HIV test prior to the testing. The individual's refusal to consent, and all information concerning the performance of an HIV test and its result, shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the Individual's medical record.

**b.** HIV testing shall be conducted only after a licensed physician documents, in the medical record of the medical personnel or nonmedical personnel, that there has been a significant exposure and that, in the physician's medical judgment, the information Is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

**c.** Costs of any HIV test performed with or without the consent of the Individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment shall not be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel.

**d.** In order to utilize the provisions of this subparagraph, the medical personnel or nonmedical personnel shall be tested for HIV pursuant to this section or shall provide the results of an HIV test taken within 6 months prior to the significant exposure if such test results are negative.

**e.** A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the Information received and of the persons tested. Such confidential Information is exempt from s. 119.07(1).

**f.** If the source of the exposure will not voluntarily submit to HIV testing and a blood sample was not obtained during treatment for the medical emergency, the medical personnel, the employer of the medical personnel acting on behalf of the employee, or the nonmedical personnel may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing Is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

**12.** For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care.

**a.** HIV testing may be conducted only after a licensed physician documents in the medical record of the medical personnel or nonmedical personnel that there has been a significant exposure and that, in the physician's medical judgment, the Information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

**b.** Costs of any HIV test performed under this subparagraph may not be charged to the deceased or to the family of the deceased person.

**c.** For the provisions of this subparagraph to be applicable, the medical personnel or nonmedical personnel must be tested for HIV under this section or must provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative.

**d.** A person who receives the results of an HIV test pursuant to this subparagraph shall comply with paragraph (e).

**13.** For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant when, after a reasonable attempt, a parent cannot be contacted to provide consent. The medical records of the infant shall reflect the reason consent of the parent was not initially obtained. Test results shall be provided to the parent when the parent is located.

**14.** For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive.

**15.** For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

**(5) County Health Department Network of Voluntary Human Immunodeficiency Virus Testing Programs--**

**(a)** The Department of Health shall establish a network of voluntary human Immunodeficiency virus testing programs in every county in the state. These programs shall be conducted in each health department established under the provisions of part of chapter 154. Additional programs may be contracted to other private providers to the extent that finances permit and local circumstances dictate.

**(b)** Each county health department shall have the ability to provide counseling and testing for human immunodeficiency virus to each patient who receives services and shall offer such testing on a voluntary basis to each patient who presents himself or herself for services in a public health program designated by the State Health Officer by rule.

**(c)** Each county health department shall provide a program of counseling and testing for human immunodeficiency virus infection, on both an anonymous and confidential basis. Counseling provided to a patient tested on both an anonymous and confidential basis shall include informing the patient of the availability of partner-notification services, the benefits of such services, and the confidentiality protections available as part of such services. The Department of Health or its designated agent shall continue to provide for anonymous testing through an alternative testing site program with sites throughout all areas of the state. Each county health department shall maintain a list of anonymous testing sites. The list shall include the locations, phone numbers, and hours of operation of the sites and shall be disseminated to all persons and programs offering human immunodeficiency virus testing within the service area of the county health department, including physicians licensed under chapter 458 or chapter 459. Except as provided in this section, the Identity of a person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1).

**(d)** The result of a serologic test conducted under the auspices of the Department of Health shall not be used to determine if a person may be insured for disability, health, or life insurance or to screen or determine suitability for, or to discharge a person from, employment. Any person who violates the provisions of this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

**(6) Human Immunodeficiency Virus Testing Requirements; Registration With the Department of Health; Exemptions from Registration --**No county health department and no other person in this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:

**(a)** The program must be directed by a person with a minimum number of contact hours of experience in the counseling of persons with acquired immune deficiency syndrome or human immunodeficiency virus infection, as established by the Department of Health by rule.

**(b)** The program must have all medical care supervised by a physician licensed under the provisions of chapter 458 or chapter 459.

**(c)** The program shall have all laboratory procedures performed in a laboratory licensed under the provisions of chapter 483.

**(d)** The program must meet all the informed consent criteria contained in subsection (3).

**(e)** The program must provide the opportunity for pretest counseling on the meaning of a test for human immunodeficiency virus, including medical indications for the test; the possibility of false positive or false negative results; the potential need for confirmatory testing; the potential social, medical, and economic consequences of a positive test result; and the need to eliminate high-risk behavior.

**(f)** The program must provide supplemental corroborative testing on all positive test results before the results of any positive test are provided to the patient. Except as provided in this section, the identity of any person upon whom a test has been performed and test results are confidential and exempt from the provisions of s. 119.07(1).

a. (g) The program must-provide the opportunity for face-to-face posttest counselling on the meaning of the test results; the possible need for additional testing; the social, medical, and economic consequences of a positive test result; and the need to eliminate behavior which might spread the disease to others.

**(g)** Each person providing posttest counseling to a patient with a positive test result shall receive specialized training, to be specified by rule of the department, about the special needs of persons with positive results, including recognition of possible suicidal behavior, and shall refer the patient for further health and social services as appropriate.

**(h)** When services are provided for a charge during pretest counseling, testing, supplemental testing, and posttest counseling, the program must provide a complete list of all such charges to the patient and the Department of Health.

**(i)** Nothing in this subsection shall be construed to require a facility licensed under chapter 483 or a person licensed under the provisions of chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 466, or chapter 467 to register with the Department of Health If he or she does not advertise or hold himself or herself out to the public as conducting testing programs for human Immunodeficiency virus infection or specializing in such testing.

**(j)** The department shall deny, suspend, or revoke the registration of any person or agency that violates this section, or any rule adopted under this section, constituting an emergency affecting the immediate health, safety, and welfare of a person receiving service.

**(7) Penalties--**

**(a)** Any violation of this section by a facility or licensed health care provider shall be a ground for disciplinary action contained in the facility's or professional's respective licensing chapter.

**(b)** Any person who violates the confidentiality provisions of this section and s. 951.27 commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

**(c)** Any person who obtains information that Identifies an individual who has a sexually transmissible disease including human immunodeficiency virus or acquired immunodeficiency syndrome, who knew or should have known the nature of the information and maliciously, or for monetary gain, disseminates this information or otherwise makes this information known to any other person, except by providing it either to a physician or nurse employed by the department or to a law enforcement agency, commits a felony of the third degree, punishable as provided in s.

775.082 or s. 775.083.

**(8) Exemptions,**--Except as provided in paragraph (4)(d) and ss. 627.429 and 641.3007, insurers and others participating In activities related to the insurance application and underwriting process shall be exempt from this section.

**(9) Model Protocol for Counseling and Testing for Human Immunodeficiency Virus**--The Department of Health shall develop, by rule, a model protocol consistent with the provisions of this section for counseling and testing persons for the human immunodeficiency virus. The protocol shall include criteria for evaluating a patient's risk for human immunodeficiency virus infection and for offering human immunodeficiency virus testing, on a voluntary basis, as a routine part of primary health care or admission to a health care facility. The Department of Health shall ensure that the protocols developed under this section are made available to health care providers.

**(10) Fees**--

**(a)** Each person or private organization registered as an AIDS or HIV testing site shall pay the department a fee which shall be set by rule of the department.

**(b)** Fees established pursuant to paragraph (a) shall be an amount sufficient to meet all costs incurred by the department in carrying out its registration, data collection, complaint monitoring, and administrative responsibilities under this section, for all private AIDS or HIV testing sites, but shall not exceed $100.

**(c)** No other fees shall be charged by other governmental agencies for these purposes.

**(11) Rules**--The Department of Health may adopt rules to implement this section, including definitions of terms, procedures for accessing confidential information, requirements for testing, and requirements for registered testing sites.

**(12) Testing As a Condition of Treatment or Admission**--

**(a)** It is unlawful for any facility the operation of which, or for any person engaged in an occupation the practice of which, requires a license by the Agency for Health Care Administration, the Department of Health, or the Department of Business and Professional Regulation, to require any person to take or submit to a human immunodeficiency virus-related test as a condition of admission to any such facility or as a condition of purchasing or obtaining any service or product for which the license is required. This subsection shall not be construed to prohibit any physician in good faith from declining to provide a particular treatment requested by a patient if the appropriateness of that treatment can only be determined through a human immunodeficiency virus-related test.

**(b)** The Agency for Health Care Administration, the Department of Health, and the Department of Business and Professional Regulation shall adopt rules implementing this subsection.

**(c)** Any violation of this subsection or the rules implementing It shall be punishable as provided in subsection (6).

**History.**--s. 21, ch. 88-380; s. 2, ch. 89-289; s. 6, ch. 89-350; s. 3, ch. 90-210; s. 3, ch. 90-292; s. 3, ch. 90-344; ss. 17, 67, ch. 91-297; s. 12, ch. 92-33; s. 2, ch. 92-171; s. 64, ch. 92-289; s. 10, ch. 93-227; s. 3, ch. 93-230; s. 4, ch. 93-264; s. 39, ch. 94-218; s. 94, ch. 95-143; s. 1032, ch. 95-148; s. 1,

# Chapter 384 Sexually Transmissible Diseases

**384.25 Reporting required--**

**(1)** Each person who makes a diagnosis of or treats a person with a sexually transmissible disease and each laboratory that performs a test for a sexually transmissible disease which concludes with a positive result shall report such facts as may be required by the department by rule, within a time period as specified by rule of the department, but In no case to exceed 2 weeks.

**(2)** The department shall adopt rules specifying the Information required in and a minimum time period for reporting a sexually transmissible disease. In adopting such rules, the department shall consider the need for information, protections for the privacy and confidentiality of the patient, and the practical ability of persons and laboratories to report in a reasonable fashion. To ensure the confidentiality of persons Infected with the human Immunodeficiency virus (HIV), reporting of HIV infection and acquired immune deficiency syndrome (AIDS) must be conducted using the HIV/AIDS Reporting System (HARS) developed by the Centers for Disease Control and Prevention of the United States Public Health Service.

**(3)** The department shall require reporting of physician diagnosed cases of AIDS based upon diagnostic criteria from the Centers for Disease Control and Prevention.

**(4)** The department may require physician and laboratory reporting of HIV Infection. However, only reports of HIV Infection Identified on or after the effective date of the rule developed by .the department pursuant to this subsection shall be accepted. The reporting may not affect or rerate to anonymous HIV testing programs conducted pursuant to s. 381.004(4) or to university-based medical research protocols as determined by the department.

**(5)** After notification of the test subject under subsection (4), the department may, with the consent of the test subject, notify school superintendents of students and school personnel whose H V tests are positive.

**(6)** The department shall by February 1of each year submit to the Legislature an annual report relating to all Information obtained pursuant to this section.

**(7)** Each person who violates the provisions of this section or the rules adopted hereunder may be fined by the department up to $500 for each offense. The department shall report each violation of this section to the regulatory agency responsible for licensing each health care professional and each laboratory to which these provisions apply.

**History.--**s. 90, ch. 86-220; s. 28, ch. BB-380; s. 8, ch. 89-350; s. 1,ch. 93-264; s. 675, ch. 95-148; s. 2, ch. 96-179; s. 5, ch. 96-221; s. 189, ch. 97-101; s. 3, ch. 98-171.