Title of Course: HIV/AIDS: Ethical and Legal Issues

CE Credit: 2 Hours

Learning Level: Introductory

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Abstract:
Since the discovery of AIDS in 1981 and HIV in 1983, much has been learned about the complexities of caring for HIV-infected persons, how to keep them disease-free longer, and how to manage their symptoms more effectively. This course will explain important legal and ethical procedures that must be followed when working with persons infected with HIV and AIDS.

Learning Objectives:
1. Identify the types of information that are confidential and must be protected
2. Name the elements to be conveyed in the informed consent process in HIV/AIDS counseling
3. List the purposes of HIV/AIDS reporting and surveillance, including name-based reporting
4. Describe the ethical principles involved in caring for those with HIV/AIDS
5. Identify legal protections that are provided to individuals with disabilities such as HIV/AIDS
HIV/AIDS: Ethical and Legal Issues

Introduction

During the past 2 decades, HIV (human immunodeficiency virus) infection and severe HIV-related diseases such as AIDS (acquired immunodeficiency syndrome) have become a leading cause of illness and death in the United States. Since the discovery of AIDS in 1981 and HIV in 1983, much has been learned about the complexities of caring for HIV-infected persons, how to keep them disease-free longer, and how to manage their symptoms more effectively.

In addition, the development of new knowledge from HIV-related research also has helped to clarify aspects of the human immune response, behavioral interventions, public health strategies, and social and ethical approaches that contribute to the understanding and management of this disease and other sexually transmitted diseases (STDs). The effects of HIV infection and AIDS on individuals and society are staggering!

Healthcare professionals will continue to play a major and significant role in caring for those that are infected or affected by HIV and AIDS. This course will address confidentiality, informed consent, and legal reporting as well as ethical issues related to HIV and AIDS and the civil rights of those infected.

Topic 1: Confidentiality

Topic Introduction: Confidentiality of records, personal information gathered from clients, HIV testing, and test results, is of the utmost importance. It is imperative that healthcare providers ensure that this information remains confidential and that State laws and regulations be strictly adhered to. Upon completion of this topic, you should be aware of what confidential information is and understand the need to protect it.

Confidential Information

In the United States, all medical information generally is considered confidential and protected under the law. Because of the sensitivity of HIV-related information, many states have adopted laws that provide additional protection to HIV-related medical records. For example, HIV information may not be disclosed, in most instances, unless a specific written authorization for release of HIV-related information is obtained.

Confidential information includes any material, whether oral or recorded, in any form or medium that identifies (or can readily be associated with the identity of) an individual and is directly related to that person’s health and care.

Any data collected or recorded must be done so in a manner that ensures the privacy (confidentiality) of the client. Clear procedures and protocol manuals must be developed and implemented.
Healthcare providers should take extreme care in not violating the client’s confidence and obtain the client’s consent before sharing information about his or her health status. Physicians should ensure that HIV testing is conducted in a way that respects the individual’s autonomy and assures confidentiality as much as possible.

Individuals are frequently concerned about the confidentiality of test results. Testing may be conducted anonymously or confidentially.

- **Anonymous** testing ensures that no identifying information about the person being tested is connected to the test results.
- **Confidential** testing links the name with the results.

Information regarding a client’s use of HIV counseling, testing, and referral (CTR) services should remain confidential. Personal information should not be divulged to others in ways inconsistent with the client’s original consent. All staff involved with HIV testing and counseling information should sign a confidentiality agreement. By signing this agreement they are acknowledging their awareness and understanding of:

- the legal requirements under state and federal law not to disclose confidential HIV/AIDS information
- the legal and agency consequences of such a disclosure

**Confidentiality in Non-traditional Settings**

CTR should be provided in community-based and outreach settings as well as clinical settings. Data from publicly supported CTR programs have indicated that doing so could promote use of these services by persons at increased risk for HIV. When HIV CTR is not readily available, accessible, or acceptable, persons at increased risk might not take advantage of them.

Expanding CTR into non-traditional settings can be accomplished through partnership with community-based service providers and use of new, FDA-approved HIV test technologies that offer portability, less-invasive sample collection, less-complex sample collection and processing, and reduced biohazard risks. To ensure effective CTR that is responsive to client needs, providers should develop and implement written quality assurance protocols and procedures specifically for services provided in non-traditional settings.

Ensuring clients’ privacy and confidentiality during CTR is essential, but could present unique challenges in some non-traditional settings. Confidentiality can more easily be breached in settings where clients and providers can be seen or heard by others. Suggested strategies for maintaining privacy and confidentiality in non-traditional settings include the following:

- Use a separated area in a mobile van
- Use rooms with locking doors
- Mark a specific room with a "do not disturb" or "occupied" sign
- Designate an area in the setting that provides physical privacy
- In parks and similar locations, seek areas with as much privacy as possible
- Provide counseling and testing services in the client’s home or other secure setting
- Have clients return to the setting to receive test results and counseling and referral

**Exceptions to ‘Confidentiality’ Rules**
Exceptions to the legal and ethical obligation to maintain the confidentiality of HIV-related information exist. For example, healthcare providers in the United States have a duty to report HIV infections and AIDS cases to public health authorities. The benefits to the public health of this reporting are felt to outweigh the risk to infected individuals.

In some states, healthcare providers may also be permitted to disclose a patient's HIV infection to persons at risk of infection without legal penalty. For example, in some states, a healthcare provider may not warn sexual or drug-using partners of infected patients without first informing the patient of the intended disclosure. Check your state laws for specific information you may or may not be allowed to share.

Confidentiality of medical information means that information which can be related to a specific patient may not be disclosed to anyone except under specific circumstances. Usually, this requires the individual’s written authorization by signing a release of information form. However, exceptions to confidentiality are appropriate when necessary to protect the public health or when necessary to protect individuals, including healthcare workers, who are endangered by persons infected with HIV.

The most common circumstances for disclosure of confidential information are:

- if there is a separate, signed release of information form
- to another health care provider for related on-going medical care
- in a life-or-death emergency
- to a third party payor (insurance provider)
- in the case of reporting notifiable conditions to the local health jurisdiction or the Department of Health (DOH)

Another exception to the general rule of confidentiality of HIV-related information concerns HIV-infected healthcare workers. U.S. government policy has recommended that HIV-infected healthcare workers who perform exposure-prone invasive procedures have their cases reviewed by an expert panel, which will decide whether they may continue to perform such procedures and whether they must inform patients of their infection. States are required to adopt this policy or its "equivalent."

Because the government has taken a flexible view on "equivalency," there is wide variation in state law and not all states require disclosure of HIV infection by health care workers. Those who favor the federal policy argue that disclosure of healthcare workers' HIV infection is necessary to meet the obligation of informed consent. They also argue that the health care workers' obligations to act in patients' best interests also mandate disclosure of HIV infection and, in some cases, restrictions on clinical activities. Those who are against the federal policy argue that such disclosure or restrictions are inappropriate because they violate health care workers' privacy and because the risks to health care workers, for example from discrimination, far outweigh the benefits to patients, given that the risk of infection from a seropositive health care worker is very small.

Maintaining Confidential Information

All medical records are confidential and must be maintained in a manner that protects that confidentiality. Client information must be kept strictly confidential and records should be managed and stored in a secure manner. All client information and records must be maintained using an approach consistent with specific state laws and regulations pertaining to persons with HIV and the release of confidential information and, if applicable, the Privacy and Security Requirements promulgated by the federal government in the Health Insurance Portability and Accountability Act (HIPAA).

Agencies providing-HIV testing must develop confidentiality policies and procedures that prevent unauthorized persons from learning information shared in confidence. All information relating to an individual’s HIV/AIDS status is protected under medical
confidentiality guidelines and legal regulations. Case reports are kept in locked files with access limited to only a few authorized personnel who are trained in maintaining confidentiality and security of these records.

In recognition of the very sensitive nature of these conditions, medical record protection for HIV and AIDS, like those for substance abuse and mental health, are protected more rigorously than other medical information because disclosure of this information to the wrong person or agency could mean additional harm to the patient. It has been determined that there exists a level of prejudice, fear and discrimination directed at people with these medical conditions. Therefore, these regulations create a balance between civil protection and information access.

Minimum professional standards for any agency handling confidential information should include providing employees with appropriate information regarding confidentiality guidelines and legal regulations.

It is the responsibility of the county’s health officer to investigate potential violations in confidentiality of HIV identifying information and report those to the Department of Health.

**Learning Activity 1:**

Mr. Green comes into the clinic where you work and requests an HIV test. He has a history of injecting drugs and has been experiencing flu-like symptoms for the past month. He is concerned because his friend recently tested positive for HIV. Later that day a man who identifies himself as Mr. Green’s friend calls and asks you the result of Mr. Green’s HIV test. Is it permissible for you to tell him?

Write down your answer and the reason then turn to the last page for the answer.

**Topic Summary:** Confidential information is any material, either oral or written, that identifies (or can readily be associated with the identity of) an individual and is directly related to that person’s health and care. It is imperative for healthcare providers to maintain confidentiality of all medical information as mandated by state laws and regulations with few exceptions. Clients with HIV, AIDS, and other STDs may be subject to additional harm if this information is divulged due to prejudice, fear, and discrimination which may be directed toward them. Anyone who violates the provisions to assure confidentiality will be subject to disciplinary action and a fine.

**Topic 2: Informed Consent**

**Topic Introduction:** Early knowledge of HIV infection is now recognized as a critical component in controlling the spread of HIV infection. It is believed that many people who are infected have not been tested and are, therefore, unaware of their HIV-positive status. The array of HIV testing technologies available and the assurance of confidentiality possibly enhance a person's willingness to be tested. HIV testing should be voluntary and free of coercion. When you complete this topic you should understand the importance of informed consent in HIV testing and know the information provided in pre-test counseling, the process of obtaining consent, and the exceptions to informed consent.

**Pre-Test Counseling**

Because the physical risks are minimal, blood tests in the United States typically do not require extensive informed consent discussions, and consent often is implied rather than explicit. However, early in the AIDS epidemic, HIV testing was recognized as different from other blood tests because it presented serious psychosocial risks, such as:

- rejection by family
- discrimination in employment

Some states require written signed consent for HIV testing.
Moreover, because there was no proven treatment at that time, the benefits of early diagnosis to individual patients were uncertain. In recognition of these circumstances and to encourage testing, special procedures were adopted for obtaining consent for an HIV test, such as pre-test counseling and specific informed consent. Special protections for confidentiality of HIV test results also were enacted.

For the most part, these special requirements remain in effect. Nearly one-fifth of states require pre-test counseling, which, typically, is in addition to any requirements for informed consent. The majority of states require specific informed consent to HIV testing, and many of these require that consent be written. In addition, a number of these states specify the information that must be conveyed during the informed consent process, including:

- the nature of the test
- the risks and benefits of testing
- the nature of the illness caused by HIV
- risk behaviors
- prevention measures
- the confidentiality of HIV test results
- reporting requirements
- other circumstances under which test results may be disclosed
- the voluntary nature of the test
- the ability to withdraw consent
- the availability of anonymous testing

CDC’s Revised Guidelines for HIV Counseling, Testing and Referral November 2001 provide guidance and require a “client-centered” approach, meaning:

- Counseling must be based on an assessment of the individual patient’s risk.
- The counselor should help the client set realistic behavior change goals that would reduce the risk of transmitting or acquiring HIV.
- The counselor should create opportunities to build appropriate risk reduction skills.
- CDC’s 2001 Revised Guidelines for HIV Counseling, Testing and Referral, November 2001 can be found at: www.cdc.gov/hiv/topics/testing/index.htm

Unless a person has been previously tested for HIV and declines receipt of information, all persons to be tested for HIV should receive pre-test counseling. During the pre-test counseling session the following information is recommended:

- the benefits of learning HIV status and the potential dangers of the disease,
- the ways in which HIV is transmitted and ways in which it can be prevented,
- the procedure for the HIV test,
- the meaning of HIV test results and the importance of obtaining test results,
- the possible effects of HIV testing and a positive HIV result related to employment, insurance, housing, and other potential legal, social, and personal consequences, and
• as appropriate, the availability of anonymous HIV testing, the differences between anonymous testing and confidential testing, and the location of anonymous test sites. For example, anonymous testing may not be a medically appropriate option for a patient presenting with signs or symptoms of HIV infection.

Persons at high risk for HIV infection should receive information regarding:

• personalized risk reduction education including abstinence from sex and/or drugs, mutual monogamy, use of condoms consistently and correctly, cleaning works or using a syringe exchange
• the need to notify sex and/or needles sharing partners (including spouses), if the test is positive
• not to donate blood or blood products
• the possible need to re-test

Pre-test counselors are also to provide a non-judgmental environment, develop and maintain a system for referrals, obtain informed consent for testing, and adhere to disclosure and confidentiality regulations.

Pre-test counseling can be a time when patients learn about their personal risk of HIV and obtain skills-building (partner negotiation skills, correct condom use and/or cleaning of injection supplies) to assist in their behavior change.

All persons tested for HIV should be offered an opportunity to receive post-test counseling if the individual to be counseled tests positive for HIV infection.

Obtaining Informed Consent

According to CDC’s “Guidelines for HIV Counseling, Testing and Referral,” obtaining informed consent before HIV testing is essential. HIV testing should be voluntary, informed, and consented. Accepting or refusing testing must not have detrimental consequences to the quality of care offered. State or local laws and regulations governing HIV testing should be followed.

In 2001, CDC issued revised “Recommendations for HIV Screening of Pregnant Women” which emphasize HIV testing as a routine part of prenatal care and strengthen the recommendation that all pregnant women be tested for HIV. It is also advised that HIV testing and treatment be done at the time of labor and delivery for women who have not received prenatal testing and retroviral drugs, as necessary. These guidelines maintain a voluntary approach to HIV testing. This voluntary approach preserves a woman’s right to make decisions regarding testing and supports a woman’s right to refuse testing if she does not think it is in her best interest.

Many healthcare providers are encouraging pregnant women to be tested for HIV because of a lack of awareness about risks. However, at this time, testing for HIV during pregnancy still requires a separate consent. Women may not be “automatically” tested for HIV. HIV-infected women can reduce the chance of transmitting the virus to their children if they take AZT during pregnancy and delivery.

Information provided regarding informed consent:

• May be presented orally or in writing
• Should use language the client can understand
• Should be specific to HIV testing
• Cannot be inferred from a general consent to treatment
• May be presented separately from or combined with other consent to procedures for health services (e.g., as part of a package of tests or care for certain conditions). However, if consent for HIV testing is combined with
consent for other tests or procedures, the inclusion of HIV testing must be specifically discussed with the client who must agree to HIV testing before the test is done.

- Should be documented in writing, preferably with the client’s signature

Verbal consent is often used in anonymous testing situations. If verbal consent is used, procedures and protocols should clearly identify and describe the process of how counselors will document the consent.

Staff members providing CTR services should be sensitive to barriers that can interfere with obtaining true informed consent, including alcohol and drug use, mental illness, and peer pressure in venues where persons congregate or socialize. Suggested strategies for obtaining informed consent in non-traditional settings include the following:

- Schedule an appointment to test at a later date/time.
- Follow up at a later time with the client if contact information is available.
- Read the informed consent form to the client.
- Use verbal prompts to ensure that the client understands information in the informed consent form.

Exceptions to Informed Consent

Some states permit HIV testing without informed consent under specified circumstances. For example, many states permit testing of patients without permission after a significant exposure to emergency response workers or healthcare providers occurs, although permission generally must be sought. In addition, some states permit the testing of prisoners and persons accused of sex crimes. Some states also require mandatory HIV testing of newborns which indirectly reveals maternal HIV status.

Partner Notification

Partner notification, a component of STD control programs for many years, is a means to identify and target risk-reduction education to individuals at high risk for contracting or transmitting HIV infection. When applied to HIV infection, the term "partner" includes not only sex partners but also intravenous drug users who share needles. Partner notification for HIV infection or AIDS, as for all STDs, is highly confidential and depends upon the voluntary cooperation of the patient and state law.

CDC currently recommends the following: "Persons who are HIV-antibody positive should be instructed on how to notify their partners and to refer them for counseling and testing. If they are unwilling to notify their partners or if it cannot be assured that their partners will seek counseling, physicians or health department personnel should use confidential procedures to assure that the partners are notified." Two complementary notification processes can be used to identify partners:

**Patient referral**

- HIV-infected patients choose to inform their own partners directly of their risk of infection.
- Trained health department personnel can help instruct patients how to inform sex and needle-sharing partners sensitively about their potential risk for infection.

**Provider referral**

- Infected patients request assistance in notifying some or all of their partners.
- Patients voluntarily provide names, descriptions, and addresses so that the notification process can be carried out by trained health department staff.
• Patient names are never revealed to sex or needle-sharing partners.

Because of resource limitations, patient referral, rather than provider referral, has played an increasingly important role in STD control.

In the AIDS prevention and surveillance projects supported by CDC, states have been required to implement procedures for confidential notification of sex and needle-sharing partners of AIDS patients and HIV-seropositive individuals. All these states currently counsel HIV-infected clients seen in public counseling and testing sites about ways to reduce the risk of transmitting HIV. These states also counsel HIV-infected clients about the need to inform sex and needle-sharing partners of their risk of infection.

When the partner-notification model is applied to the control of HIV infection, certain differences must be considered. The incubation period for HIV is long. Therefore, sex partners or needle-sharing partners from months or years earlier may potentially have been the sources of infection. Partner notification for patients with hepatitis B, which has an epidemiologic pattern similar to that of HIV infection, has proven difficult because of the prolonged period of infectivity, the large number of anonymous sex partners among many homosexual men, and the inaccessibility of the intravenous drug-using population.

Partner-notification data from several states reveal a high seroprevalence rate, ranging from 11% to 39%, among persons identified as sex or needle-sharing partners, many of whom are themselves engaging in high-risk behavior. By identifying such individuals, the partner-notification process can target risk-reduction messages to those at greatest risk of acquiring or transmitting infection. Thus, partner notification provides both primary and secondary prevention of HIV infection.

Notification of unsuspecting partners is especially important because it enables persons who may not have been reached through other AIDS education programs to receive risk-reduction education. For example, the partner-notification process can identify female and male partners of intravenous drug users or female partners of bisexual males who may have been exposed to HIV infection but who may be unaware of their risk. Partner-notification activities targeted toward women of childbearing age contribute additionally by potentially preventing the perinatal transmission of HIV.

Homosexual men who voluntarily request counseling and HIV testing may be at lower risk for infection than those who have refused testing. Through the partner-notification process, these high-risk partners who otherwise might not request risk-reduction education can receive counseling. Also, counseling of partners provides an opportunity to offer other beneficial services to those at risk, including drug treatment, STD treatment, tuberculosis testing and treatment, adult immunizations, psychosocial support services, and contraceptive counseling.

The type of partner-notification services provided by different health departments will depend on local resources and the number of seropositive persons identified. State and local health departments are encouraged to develop evaluation programs to identify the most effective partner-notification strategies for different clinical and sociocultural settings in both areas with high and low HIV seroprevalence rates.

Efforts to contact and communicate with infected patients, partners, and spouses must be carried out in a manner that preserves the confidentiality and privacy of all involved. This includes:

• counseling partners in a private setting
• trying to notify exposed partners face-to-face
• never revealing the name of the original patient to the partner
• not leaving verbal messages that include STD/HIV on answering machines
• not leaving written messages that include any mention of STD/HIV
• not giving confidential information to third parties (roommates, neighbors, parents, spouses, children)

The assurances of confidentiality and protection against discrimination, which are critical in dealing with any STD, have become legal issues in the case of HIV infection. These issues may influence the success of programs based on patient referral alone. Confidentiality is essential to ensure that individuals at risk continue to seek counseling, testing, or partner-notification services.

Partner notification is provided using a variety of strategies to make sure exposed partners, including spouses, are notified of their exposure to HIV and receive appropriate counseling in a way that protects confidentiality of the source patient.

It is a federal law that a good faith attempt be made to notify the spouse of an HIV infected individual. “Spouse” is defined as the person(s) in a marriage relationship with the infected person up to 10 years prior to the test.

**Learning Activity 2:**

As a healthcare provider in a public health clinic, you are responsible for pre-test counseling. List the 3 essential factors which pertain to HIV testing then turn to the last page for the answer.

**Topic Summary:** Obtaining informed consent prior to HIV testing is essential. HIV testing should be voluntary, informed, and consented. Pre-test counseling should assess a person’s individual risk for HIV and provide an individual counseling session prior to testing. Verbal or written consent must be obtained prior to performing the test and documented, preferably with the client’s signature. Partner notification is a means to identify and target risk-reduction education to individuals at high risk for contracting or transmitting HIV infection.

**Topic 3: Legal Reporting Requirements**

**Topic Introduction:** All states require reporting of AIDS cases to public health authorities. This information is important for disease surveillance and is used as a basis for allocation of federal funding. HIV reporting requirements vary by state. Strict confidentiality requirements protect access to reported information. Each state has outlined a limited list of individuals who can legally access test results. A substantial penalty may be imposed if a healthcare provider willfully or negligently discloses the HIV status of a patient. When you complete this topic, you should be aware of the purpose of HIV/AIDS reporting and surveillance, name-based reporting and its impact on federal funding.

**Purpose of Reporting and Surveillance**

The purpose of reporting notifiable conditions is to:

• identify those who are infected
• offer HIV prevention, care, and partner notification services to those found to be infected
• generate epidemiologic data to be used to plan, target, evaluate, and allocate resources for HIV prevention and care services

This information is necessary for public health officials to protect the public's health by tracking communicable diseases and other conditions. These data are critical to local health departments and the departments of health and labor and industries in their efforts to prevent and control the...
spread of diseases and other conditions. Public health officials take steps to protect the public, based on these notifications.

Key ways public health officials protect the public include:

- treating persons already ill
- providing preventive therapies for individuals who came into contact with infectious agents
- investigating and halting outbreaks
- removing harmful health exposures

Public health workers also use these data to assess broader patterns, including historical trends and geographic clustering. By analyzing the broader picture, officials are able to take appropriate actions, including outbreak investigation, re-direction of program activities, or policy development.

Reporting of HIV and AIDS cases assists local and state officials in tracking the epidemic. It also allows for effective planning and intervention to be provided in the effort to reduce the transmission of HIV. Agencies providing confidential HIV testing should develop policies and procedures (including roles and responsibilities) to ensure the timely reporting of HIV cases to the local health department.

**Name-Based Reporting**

Reporting of AIDS cases has always included the patient's name and other identifying information. Although reporting of HIV infections initially was not done by name, there has been a recent and controversial movement in the United States toward name-based reporting of HIV infection. The debate over name-based reporting has focused on the need for more accurate epidemiological information regarding the spread of the epidemic, especially as antiretroviral therapies have proven successful in delaying progression to AIDS versus concerns about deterring testing and the risk of discrimination.

CDC has made specific recommendations for keeping reporting confidential. However, because HIV testing carries the risk of discrimination if confidentiality is breached, the CDC and commentators on this issue have recommended that anonymous testing, from which name reporting is not possible, continue to be offered.

CDC has clearly communicated that only HIV case data reported through a name-based system will be accepted in the national database. In the fiscal year 2007, Federal Ryan White CARE Act (RWCA) funding will be calculated on the proportion of states' HIV cases. Many states previously used a name to code system. Under this system, providers who received a confirmed HIV positive diagnosis reported the positive test to the local health jurisdiction within 3 work days. The local health jurisdiction then assigned a computer-generated code (a combination of letters and numbers) within 90 days after the case report was completed and removed any reference to the individual's name.

States with these laws were likely to lose a portion of federal RWCA funding for the care and treatment of persons with HIV or AIDS if State Board of Health rules were not changed. This funding supports HIV case management, anti-HIV treatment regimens and HIV specific medical care at the state level.

Therefore, it was necessary for states with name-to-code systems to revise rules and laws to enable the department of health to re-ascertain the identities of previously reported cases of asymptomatic HIV infection and to report current HIV case data to the CDC in order to maintain HIV/AIDS care funding.

**The Ryan White CARE Act**

The federal Ryan White CARE Act provides health care for people with HIV disease. Enacted in 1990, it fills gaps in care faced by those with low incomes and little or no insurance. The HIV/AIDS Bureau (HAB) administers the program
through hundreds of grantees, who serve 571,000 people each year. In 2004, 2.3 million outpatient medical visits were funded by Ryan White.

The Ryan White CARE Act Title III HIV Capacity Development Grant Program is designed to assist public and nonprofit entities in their efforts to strengthen their organizational infrastructure and to enhance their capacity to develop, enhance, or expand access to high quality HIV primary health care services for people living with HIV or who are at risk of infection in underserved or rural communities and communities of color.

The Ryan White CARE Act is administered by the federal HIV/AIDS Bureau, Health Resources and Services Administration (HRSA), Department of Health and Human Services which was formed in August 1997 to consolidate all programs funded under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

The CARE Act was signed into law on August 15, 1990 to improve the quality and availability of care for people with HIV/AIDS and their families. Amended and reauthorized in May 1996 and November 2000, the Act is named after the Indiana teenager, Ryan White, who became an active public educator on HIV/AIDS after he contracted the syndrome. He died the same year the legislation was passed.

In serving people and families affected by HIV/AIDS, the Bureau has identified four factors that have significant implications for HIV/AIDS care, services and treatment:

1. The HIV/AIDS epidemic is growing among traditionally underserved and hard-to-reach populations.
2. The quality of emerging HIV/AIDS therapies can make a difference in the lives of people living with HIV.
3. Changes in the economics of health care are affecting the HIV/AIDS care network.
4. Policy and funding increasingly are determined by outcomes.

HIV care-related services such as case management, dental care, housing assistance, counseling, and food bank assistance may be supported in communities through Title II CARE funds. Community planning is based on the assessed needs of low income HIV-positive persons, community priorities, and available resources

Learning Activity 3:

You are a healthcare professional working in a clinic that provides anonymous HIV testing only. One of your patients has a confirmed positive HIV test. What is the requirement for reporting this? Write down your answer then turn to the last page for the answer.

Topic Summary: All states require reporting of AIDS cases to public health authorities. Positive HIV results obtained through anonymous testing are not reportable. Case report confirmation for individual patients can only be shared on a “need to know” basis. CDC has communicated that only HIV case data reported through a name-based system will be accepted in the national database. In an effort to avoid losing any Federal Ryan White CARE Act funding, states now require that all HIV case reports must be maintained in a name-based surveillance system.

Topic 4: Ethical Issues and Civil Rights

Topic Introduction: The ethics and law relevant to AIDS and HIV infection give rise to many issues that cut across several values. The issues around HIV/AIDS recreate controversies that have surrounded illnesses throughout history including leprosy and bubonic plague. The conflict today is often between the autonomy of the patient to behave freely, the autonomy of the patient to have care when needed, and the autonomy of the care provider to exercise judgment in
his/her practice. When you complete this topic, you should be aware of basic ethical principles, the aspects of clinical ethics as well as research ethics, end-of-life issues, ethical issues and the civil rights of those infected with HIV/AIDS.

**Ethical Concerns and Principles**

From its outset, the AIDS epidemic has raised many ethical challenges for public health officials, clinicians and the general public, reaching from macro-level policy to micro-level clinical decisions. Areas of particular concern are:

- global awareness and resource allocation to HIV/AIDS
- research and clinical trials on HIV medicines and vaccines
- testing and counseling
- equitable access to prevention and treatment services
- surveillance
- practical medical ethics

There are three widely recognized principles in American bioethics that apply to both clinical and research ethics: respect for persons, beneficence, and justice.

**Respect for persons** entails respecting the decisions of autonomous persons and protecting persons who lack decision-making capacity and therefore are not autonomous. It also imposes an obligation to treat persons with respect by maintaining confidences and keeping promises.

**Beneficence** imposes a positive obligation to act in the best interests of patients or research participants. It often is understood to require that the risks of research be minimized and that the risks be acceptable in light of the potential benefits of research.

**Justice** requires that people be treated fairly. It is often understood to require that benefits and burdens be distributed fairly within society.

Although the ethical principles are useful guidelines that help to focus discussion, they cannot be mechanically or rigidly applied. Nor are they absolute – exceptions to the principles may be appropriate in particular cases. Furthermore, they often conflict. Accordingly, these ethical principles must be interpreted in the context of specific cases. Although appeal to these three principles is the dominant approach in American bioethics, other approaches have been suggested and vary dramatically according to different trains of philosophic thought:

- The utilitarian perspective embodies the idea that acts should be evaluated according to their consequences.
- The deontological approach stresses that research ethics should be guided by generalizable rules or obligations.
- The casuistry approach uses paradigmatic cases to guide decision-making.
- The ethic of caring judges acts based on their effect on relationships.
- Communitarians evaluate acts based on their consequences for the community.
- Virtue ethics focuses on the motivation or character of the actor, rather than the act itself.

The application of these principles to cases outside the United States has been the subject of considerable debate. In particular, the emphasis on individual autonomy has been criticized as representing an Anglo-American perspective that may not be shared by other cultures that may place greater importance on community. Nevertheless, widely accepted...
international ethical guidelines do embrace the fundamental principles of autonomy, beneficence, and justice. These principles therefore provide an appropriate ethical framework both inside and outside the United States.

Clinical Ethics

Aspects of clinical ethics include confidentiality, informed consent for HIV testing, and exceptions to informed consent which have previously been discussed. Also included are pre-natal HIV testing and end-of-life issues.

Prenatal HIV Testing

Mother-to-child transmission of HIV has been a priority area for earlier detection because transmission is significantly reduced if pregnant women identified as seropositive take antiretroviral therapy. In 1999, an Institute of Medicine (IOM) panel on reducing perinatal HIV transmission concluded that pre-test counseling and written informed consent requirements for HIV testing were barriers to prenatal HIV testing.

To take advantage of the proven effectiveness of antiretroviral therapy for preventing perinatal HIV transmission, the panel proposed significant changes in HIV testing policies for pregnant women in the United States. It recommended that all pregnant women be tested for HIV as a routine part of prenatal care. Under its recommendations, women would be informed that an HIV test would be conducted, along with other prenatal blood tests, but would not be required to consent specifically to the HIV test. The American College of Obstetrics and Gynecology and the American Academy of Pediatrics have supported routine universal prenatal HIV testing.

Whether the IOM recommendations are adopted remains to be seen. In October 2000, the U.S. Public Health Service (USPHS) issued draft revised guidelines for prenatal HIV testing that stop short of the IOM recommendations. The USPHS recommended that health care providers recommend HIV testing to all of their pregnant patients, but embraced the requirements for specific written informed consent required by many states. It did note that verbal consent may be used, where permitted by state law, if written consent is deemed a barrier to testing.

The proposals to make HIV testing a routine part of prenatal care raise several concerns:

- First, it is unknown whether such testing would be acceptable to pregnant women.
- Second, there is a danger that, if HIV testing becomes routine, it will become so habitual or mechanical that pregnant women may not realize that they have the option to decline testing. Thus, the decision to be tested may not really be an autonomous one.
- Third, caregivers and patients may forget that HIV testing entails much greater psychosocial risks than other blood tests and that pre-natal HIV testing differs from HIV testing in other settings. Additional procedures or protections may be necessary to safeguard pregnant women's autonomous choices.
- Fourth, by foregoing opportunities for education and counseling, routine testing may undermine prevention efforts.
- Finally, routine HIV testing in the prenatal context may affect adherence to the norms of pre-test counseling and informed consent for HIV testing in other contexts.

The ethical concerns surrounding prenatal HIV testing are different in developing countries. To date, the cost of antiretroviral prophylaxis has been prohibitive and therefore, for the most part, pregnant women do not receive it. Although knowing their HIV status may be helpful in guiding decisions concerning breastfeeding, in many circumstances, bottle-feeding is not a feasible option because of cost and lack of access to clean water. Accordingly, determining HIV
status may be of limited benefit. Moreover, such determination could subject women to risk of physical harm or loss of housing and support. The benefits of testing will increase as prenatal antiretroviral prophylaxis, along with support services, becomes increasingly available.

**End-of-Life Issues**

Healthcare professionals play an important role in assisting patients to understand their treatment options so they can make fully informed decisions. Education and support are critical to the process, especially when a person makes the decision to stop treatment. Some patients explore issues related to dependency on others, making life decisions within a limited timeframe, and preparing for the management of pain. All of these issues focus on the progression of disease and the corresponding losses that may ensue.

Most hospitals, nursing homes, home health agencies, and HMO's routinely provide information on **advance directives** at the time of admission. They are required to do so under a federal law called the **Patient Self-Determination Act (PSDA)**.

With the Patient Self-Determination Act, patients can specify if they want to accept or refuse specific medical care. They can also identify a legal representative for urgent healthcare decision purposes. Then if they become unable to make decisions due to illness, the patients' wishes have been clearly documented at an earlier point of time.

The requirements of the Patient Self-Determination Act are deceptively simple. In spite of their apparent simplicity they carry profound implications for the way healthcare is practiced. The law mandates that, in those healthcare institutions which receive Medicare or Medicaid funding, patients must be informed in writing upon admission of:

1. their right to accept or refuse treatment
2. their rights under existing state laws regarding advance directives
3. any policies which the institution has regarding the withholding or withdrawal of life-sustaining treatments

The institutions are also required to engage in on-going educational activities for both their employees and the general public regarding the right to accept or refuse treatment and regarding the opportunity for drafting or signing advance directives.

The Patient Self-Determination Act is based on the principles of informed consent. The law lays the foundation for the exercise of the patient's decision-making authority which will affect the course of treatment for all patients whether or not they possess decisional capacity. By extending the law to all healthcare institutions including hospitals, extended care facilities, hospices, HMOs, and home healthcare agencies funded by Medicare or Medicaid, virtually all individuals seeking healthcare will be covered. The only exceptions might be those few institutions where services are paid for directly by patients independent of government funding.

The law does not give any new rights to patients except the right to be informed of the stipulated matters at the time of admission to certain healthcare facilities. It generally reaffirms rights which patients already possess, such as the right to refuse treatment. Unfortunately, patients have not always been aware of these rights and for this reason they have all too often become victims of the decisions of others. The right of patients to receive adequate information about matters which will help them exercise their self-determination in healthcare practices is underscored by the new duty imposed upon healthcare facilities to provide specific information to them.
The Patient Self-Determination Act seeks to empower patients by insuring that they receive the proper information so that they can consider the role of advance directives in their healthcare plans and make the appropriate decisions about them in view of their values and goals.

**Advance directives** are documents signed by a competent person giving direction to health care providers about treatment choices in certain circumstances. There are two types of advance directives:

1. **A durable power of attorney** for health care allows persons to name a "patient advocate" to act for them and carry out their wishes when they are unable to do so.
2. **A living will** allows persons to state their wishes about life-sustaining medical care in writing, but does not name a patient advocate.

Advance directives are legal documents that are to be used in the event that the patient becomes mentally or physically incapacitated. Issues outlined in the documents may address resuscitation, feeding, or other medical care. As these are legal documents, they should be reviewed periodically to accurately reflect the patient’s desires.

A **health care proxy** is an agent, at least 18 years old, appointed to make a patient’s medical decisions if the patient is unable to do so. Generally, people assign someone they know well and trust to represent their preferences when they can no longer do so. Patients should be sure to ask this person for agreement to act as their agent. An agent may have to exercise judgment in the event of a medical decision for which the patient's wishes are not known.

The **durable power of attorney for health care** is the legal document that names a patient's health care proxy. This transfer of authority for decision-making is extremely important when a significant other would not be recognized legally as having authority to make decisions. A durable power of attorney goes into effect only when a person is unable to make his/her own decisions. Once written, it should be signed, dated, witnessed, notarized, copied, distributed, and incorporated into the patient's medical record.

Unlike a durable power of attorney for health care, the **living will** provides a designated person with specific instructions related to prolonging life. Living wills apply only to medical decisions and are the most common advance directive. A living will is a set of instructions documenting a person's wishes about medical care intended to sustain life. It is used if a patient becomes terminally ill, incapacitated, or unable to communicate or make decisions. Everyone has the right to accept or refuse medical care. A living will protects the patient's rights and removes the burden for making decisions from family, friends, and physicians. There are many types of life-sustaining care that should be taken into consideration when drafting a living will. These include:

- the use of life-sustaining equipment (dialysis machines, ventilators, and respirators)
- "do not resuscitate" orders; that is, instructions not to use CPR if breathing or heartbeat stops
- artificial hydration and nutrition (tube feeding)
- withholding of food and fluids
- palliative/comfort care
- organ and tissue donation

It is also important to understand that a decision not to receive "aggressive medical treatment" is not the same as withholding all medical care. A patient can still receive antibiotics, nutrition, pain medication, and other interventions when the goal of treatment becomes comfort rather than cure. This is called palliative care, and its primary focus is helping the patient remain as comfortable as possible. Patients can change their minds and ask to resume more aggressive treatment. Any changes in the type of treatment a patient wants to receive should be reflected in the patient's living will.

Once a living will has been drawn up, patients may want to talk about their decisions with the people who matter most to them, explaining the values underlying their decisions. Most states require that the document be witnessed. Then it is
advisable to make copies of the document, place the original in a safe, accessible place, and give copies to the patient’s doctor, hospital, and next of kin. Patients may also want to consider keeping a card in their wallet declaring that they have a living will and where it can be found.

Patients may also want to appoint someone to manage their financial affairs, if they cannot. This is called a **durable power of attorney for finances**, and is a separate legal document from the durable power of attorney for health care. Patients may choose the same person or someone different from their health care proxy to act as their agent in financial matters.

**Research Ethics**

Research with human participants raises ethical concerns because people accept risks and inconvenience primarily to advance scientific knowledge and to benefit others. Although some research offers the prospect of direct benefit to research participants, most research does not.

**Research Design**

It is unethical to expose subjects to the risks of participating in a research study unless the design is sufficiently rigorous that the results will be valid and generalizable. To meet the ethical obligations for research, the study size must be adequate and appropriate study endpoints must be chosen. Clinical trials usually require preliminary laboratory and animal research.

**Informed Consent**

The expectations of potential research participants may complicate obtaining informed consent in the research context. Although the goal of research is to test a hypothesis and develop generalizable knowledge, many participants enter research studies to benefit personally. The language that investigators use (e.g., “experiment” vs. “research”) may have significantly different meanings for participants and affect their understanding of their participation. Many participants also do not understand randomization and expect that decisions about which intervention they receive will be based on their individual clinical needs. Some may not even be aware that they are participating in research. Some of these misconceptions may arise because patients apply their own experience with healthcare providers, who have an ethical obligation to place patients’ interests first, to the research setting, which must take responsibility for the scientific and logistical aspects of the research as well as the interests of the individual participant. Because of such hopes and misconceptions, patients may misinterpret the information given to them about the study.

The role of healthcare providers in research may contribute to participants’ misunderstanding. Healthcare providers exert considerable power in their relationships with patients, and patients are inclined to follow their health care providers’ advice. Patients often understand offers to participate in research as recommendations for their care. Patients also may agree to participate in research if their health care providers ask because they want to please their providers or fear that the quality of their care will be negatively affected if they refuse. In addition, patients’ trust in their health care providers, medical institutions, and the research enterprise may lead them to agree to participate in research without critically reviewing information about the trial. Healthcare providers themselves frequently overestimate the benefits of experimental interventions and participation in clinical trials. When health care providers also are investigators, special care must be taken to:

- ensure that the patient/participant understands the health care provider's/investigator's divided interests
- where possible, separate these roles

Healthcare providers can help address these potential problems by:
- clarifying that participation in a clinical trial is voluntary and will not influence a patient's care
- making clear whether they are recommending the patient participate in a trial or merely offering the opportunity
- checking that patients have understood the key aspects of the trial and correcting any misunderstandings

If the healthcare provider is also the investigator, another member of the research team, if possible, should handle consent discussions and follow-up visits that are part of the study.

**Vulnerable Participants**

Some people may be at greater risk from research and are considered vulnerable. Traditionally, vulnerability in research has been defined by categories. For example, the U.S. federal regulations identify children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons as vulnerable populations. The May 2001 report from the U.S. National Bioethics Advisory Commission (NBAC) on research with human participants recommended that vulnerability should be based on characteristics of individuals, rather than on group membership. NBAC proposed six categories of vulnerability: cognitive, institutional, deferential, medical, economic, and social. Both the U.S. federal and NBAC approaches conclude that vulnerable people require special protection from research risks. Such vulnerability must be taken into account in research design.

Vulnerability is particularly important in the context of HIV-related research. Those infected with HIV may be medically vulnerable because of their infection. In addition, homosexuals, injection drug users, minorities, and women, who, for various reasons, may be at higher risk of HIV infection, are more likely to be socially and economically vulnerable because of historical attitudes and discrimination. Accordingly, investigators conducting HIV-related research must pay particular attention to vulnerability and take steps to protect potentially vulnerable research participants.

**Conflicts of Interest**

Some conflicting interests are inherent in research. For example, healthcare providers gain prestige, grants, and promotions through their research and publication of their work. Accordingly, they have a personal interest in recruiting and maintaining participants in their studies. Although this interest may sometimes conflict with the best interests of participants, it is an accepted element of research, in part, because it is open and acknowledged. However, some conflicting interests, particularly financial ones, create ethical problems because they may influence the myriad of decisions researchers make over the course of a study. For example, such interests may lead researchers to overestimate the benefits of a study, underestimate the risks, fail to objectively review existing evidence, and, if necessary, halt an ongoing study.

Some steps can be taken to minimize conflicting interests. These include:

- openly discussing research plans with colleagues and ensuring peer review of research protocols
- blinding investigators and participants to which intervention participants are receiving
- using an independent data safety monitoring board to interpret interim data and assess reports of adverse events

Disclosing conflicting interests may also be necessary. In California, for example, such disclosure is legally mandated by a 1990 California Supreme Court decision in *Moore v. Regents of University of California*, which declared that healthcare providers need to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the health care provider's professional judgment." The courts of other states have not confronted the issue posed by *Moore*. However, there are strong reasons, both ethical and legal, for requiring such disclosures. They allow people to make informed decisions about participating in a clinical trial and to evaluate study results in which investigators have a financial stake. Some conflicts of interest are so problematic that they should be prohibited, not merely disclosed. In
particular, all researchers in clinical trials, and their immediate families, should be prohibited from holding stock options or management positions in the company making the product or technology tested its competitors, or the sponsor of the study.

Special Issues in Vaccine Research

Some of the requirements for ethical research design present difficulties in HIV vaccine research because:

a) a good animal model does not exist,
b) HIV is highly variable and undergoes rapid mutation, and
c) there is currently little information about how to build protection against HIV. However, because of the enormous disease burdens of HIV, it is ethically appropriate to begin trials without fully understanding the correlates of viral immunity provided the other requirements are met.

Vaccine trial participants may mistakenly believe that they will receive protection from the vaccine and, therefore, may increase their risky behaviors. Although researchers need outcomes (i.e., seroconversions) to evaluate the efficacy of the vaccine candidate, they also have an obligation to protect research participants. Accordingly, researchers must provide high-quality risk reduction counseling and emphasize the uncertainty about the effectiveness of the vaccine candidate to all participants, while hoping that such counseling is not fully effective in reducing risk. Because of this conflict between researchers' obligations to carry out sound research and their obligations to protect their subjects, it may be necessary to have separate counseling and vaccine staff.

HIV vaccine trials pose unique risks to participants. Participants may be prevented from participating in future vaccine trials, and vaccines developed later may be less effective for them. In addition, because participants may react positively to certain HIV antibody tests, they may also face limits on international travel and on eligibility for certain governmental jobs (in the U.S., for example, Peace Corp, Foreign Service, Job Corps, and the military) even if their seroconversion does not represent true infection. Subjects may also face stigmatization from family or friends to whom they disclose information. Participation in some trials (e.g., Phase III trials) may identify the subject as someone at high risk of contracting HIV, an identification that may entail numerous difficulties. Although researchers always have an obligation to protect the confidentiality of the information they collect, this duty is particularly important in HIV vaccine trials because of the high stakes if confidentiality is breached.

In May 2000, the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued a guidance document regarding HIV preventive vaccine research. The document contains 18 specific guidance points regarding the conduct of this research. Among the key points are:

- Early phase clinical trials should take place in sponsor (developed) countries, unless there are specific scientific and public health reasons to justify conducting such trials in a host (developing) country (Point 8).
- Placebo-controlled vaccine trials are ethically acceptable as long as there is no known effective HIV preventive vaccine (Point 11).
- All vaccine trial participants should have access to appropriate risk-reduction counseling and access to prevention methods (Point 14).
- An appropriate monitoring system must be in place (Point 15).
- Participants in HIV preventive vaccine trials should be provided with care and treatment for HIV/AIDS and its associated complications, with the ideal being to provide the best proven therapy, and the minimum to provide the highest level of care attainable in the host country in light of:
  - the level of care and treatment available in the sponsor country
• highest level of care available in the host country
• availability of infrastructure to provide care and treatment in the context of research
• potential duration and sustainability of care and treatment for the trial participant (Point 16)

**International Research**

There has been considerable dispute over whether researchers are obligated to provide state-of-the-art care, and, particularly, for international studies, which standard of care should govern. The debate was driven, in part, by language in the World Medical Association's Declaration of Helsinki (first adopted in 1964), which set forth ethical principles for medical research involving human subjects and stated that "In any medical study, every patient, including those of a control group, if any, should be assured the best proven diagnostic and therapeutic methods". Relying on this language, some have argued that placebo-controlled trials in developing countries are unethical when a proven effective treatment exists, even if the treatment is not available in the country because of cost or other reasons. Others have argued that such placebo-controlled trials may be appropriate because they provide information that responds to local needs. A developing country needs to know whether a simpler, cheaper therapeutic regimen is superior to what is currently available in the country (generally no therapy). It may not be relevant to the developing country whether a simpler, cheaper treatment is as effective as the best proven treatment, which the country cannot afford. Participation of local government, investigators, and community members helps ensure that the research is ethical and that the standard of care is the highest standard "practically attainable" in that country.

The World Medical Association revised the Declaration of Helsinki in 2000. After considerable debate about the role of placebo-controlled trials, the final version reads: "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic methods exists." The "highest attainable and sustainable" standard was explicitly rejected. Although the Declaration of Helsinki serves an important symbolic role, it has no enforcement mechanism and may conflict with national laws and regulations.

Another issue in international research is making therapies available to developing countries once they are shown to be effective there. Researchers, research sponsors, and international organizations are trying to negotiate with drug manufacturers and host country governments to make therapies available at affordable prices. This may entail discounted prices, licensing agreements to manufacture the drug in a developing country, or other strategies. However, the appropriateness of providing antiretroviral therapies in developing countries, particularly Africa, has been the subject of debate. Some have argued that the severity of the AIDS epidemic in the developing world requires that antiretroviral therapies be provided to those affected by it. Others have argued that the lack of health care infrastructure makes provision of these drugs inappropriate at this time.

**Provision of Care**

Questions have arisen about the obligation of healthcare professionals to provide service for all patients who seek care. With the AIDS epidemic, these issues are brought to the surface. Many studies have reported providers being reluctant to treat HIV-infected patients because they lacked the clinical expertise, expressed fear of contagion, or were concerned about the impact that treating AIDS patients would have on their practice. Other studies have concluded that, even among professionals who care for HIV-infected patients, many disapprove of or dislike their patients. Regardless of their feelings, healthcare professionals have an obligation to care for HIV-infected patients.

Some professionals, reluctant to care for HIV/AIDS patients, may find that the law enforces the duty to care for all patients. Nurses, for example, may refuse to compromise their own safety and ethical standards, but they have a professional responsibility to ensure that the nursing needs of patients are met on an emergency basis. Whether the nurse has a duty to care for all patients combines the nurse’s ability, the requirements of...
the patient, and the degree of risk. Nurses may consider the risk of nursing some patients in the light of whether there is a risk to themselves, their families, and their personal ethics.

If the risk is minimal or low, the legal duty of the nurse is high. The more actual risk, the less the legal duty becomes. Today, fearing infection, some are reluctant to care for patients with HIV/AIDS. Law enforces a minimal ethical duty owed toward all patients, including those infected with HIV/AIDS. Some statutes, in forbidding discrimination by nurses, may impinge on the nurse’s ability to decline to care for certain patients. In addition, nurses may be obligated to give care under their employment relationship, under the code of ethics, and enforcement of such ethics by state boards of nursing.

The American Nurses’ Association Committee on Ethics issued the “Statement Regarding Risk vs. Responsibility in Providing Nursing Care” that addresses the professional responsibility of caring for individuals affected by infectious diseases while recognizing and respecting the rights of individual nurses (American Nurses’ Association ‘ANA”, 1986). The manuscript defines the circumstances in which a nurse may refuse to care for a patient. These include situations that:

1. violate the patient’s rights or wishes, or
2. involve a nurse who has a moral objection to a certain intervention

It is unethical for a physician to deny treatment to HIV-infected individuals because they are HIV-seropositive or because they are unwilling to undergo HIV testing, except in the instance where knowledge of the patient’s HIV status is vital to the appropriate treatment of the patient. When a patient refuses to be tested after being informed of the physician’s medical opinion, the physician may transfer the patient to another physician who is willing to manage the patient’s care in accordance with the patient’s preferences about testing.

Several states have enacted a number of laws to help protect healthcare workers who are at risk of contracting HIV and other bloodborne diseases while performing the duties of their jobs. These laws most often focus on one or more of the following outcomes:

- providing safeguards for workers to protect them from exposure
- making it easier for workers to learn of possible exposure
- requiring employees to notify employers of exposure
- requiring a source person to be tested under certain circumstances
- providing exposed employees with greater opportunities for treatment and support services

A healthcare provider who knows that he/she is seropositive should not engage in any activity that creates a significant risk of transmission of the disease to others. Transmission of HIV to patients while in healthcare settings is rare. The CDC recognizes that the risk of transmission from a healthcare provider to a patient during an invasive procedure is small. Preventing transmission requires strict adherence to universal precautions rather than practice restrictions. Under these recommendations, providers are not required to disclose their HIV status to patients. Instead, providers are encouraged to submit to local panels for an evaluation of the ability to comply with infection control guidelines and avoid exposing patients to risk. However, the option is open for local panels to require disclosure in circumstances where the procedure may pose even a small risk to the patient.

The fear of HIV by the public has created many problems for those infected with HIV – both patients and practitioners. Instances exist of confidences being violated, jobs lost, and privileges to practice denied, all because of HIV-positive status. Inclusion of HIV-infected people under the Americans with Disabilities Act may protect them from some of these circumstances.

The National Rehabilitation Act of 1973 was established to prohibit discrimination against individuals with a handicap. The Americans with Disabilities Act (ADA) of 1990, which took effect July 26, 1992, broadened the scope of the
Rehabilitation Act and prohibits private employers, state and local governments, employment agencies and labor unions from discriminating against qualified individuals with disabilities in job application procedures, hiring, firing, advancement, compensation, job training, and other terms, conditions and privileges of employment. An individual with a disability is a person who:

- has a physical or mental impairment that substantially limits one or more major life activities;
- has a record of such an impairment; or
- is regarded as having such an impairment (includes individuals who do not have an impairment but are discriminated against because of a former impairment or are perceived as having an impairment)

HIV-infected healthcare providers are protected under these acts. However, because of their work in healthcare settings, issues involving public safety have been raised and several cases have been reported where infected healthcare providers were removed from their duties because a perceived risk of transmission existed.

**Disabilities and Discrimination**

HIV infection and AIDS are medical conditions that are considered disabilities under the federal Americans with Disability Act. These laws mean that it is illegal to discriminate against someone who is HIV-infected or who has AIDS. It is also illegal to discriminate against someone who is ‘believed’ to be infected, even though that person is not, in fact, infected. The areas covered in these laws are:

- employment
- rental, purchase or sale of apartment, house or real estate
- places of public accommodation (restaurants, theaters, etc.)
- health care, legal services, home repairs, and other personal services available to the general public
- applying for a loan or credit card, or other credit transaction
- certain insurance transactions

Laws also protect HIV-infected and AIDS-diagnosed people from employment discrimination. Employers may not discriminate against infected persons in:

- terminations
- rate of pay
- job assignments
- benefits

Employers are required to provide and maintain a working environment free of discrimination. They must assure that no harassment, intimidation or personnel distinction is made in terms and conditions of employment. If a worksite situation develops that poses the threat of discrimination, employees must be given education and supervision to end harassment, the use of slurs and/or intimidation.

Employers are responsible for providing reasonable worksite accommodations which will enable a qualified, disabled employee or job applicant to perform the essential tasks of a particular job. Reasonable accommodation means relatively inexpensive and minimal modifications, such as:

- providing special equipment
- altering the work environment
- allowing flex-time
- providing frequent rest breaks
- allowing the person to work at home (telecommute)
• restructuring the job

When a person goes for a job interview or is hired, the employer:

- cannot ask questions directed at the perception or presence of HIV infection or AIDS, unless based on a “bona fide” occupational qualification, which at this time, according to CDC, does not exist

- cannot require a blood test to determine HIV infection unless HIV status limits the ability to perform the work (i.e., overseas assignment in a country that requires HIV certification)

- cannot require a physical exam directed to identify HIV infection, except for exams necessary to evaluate the need for, or nature of, reasonable accommodation or specific job-related conditions

- cannot ask question about lifestyle, living arrangements, or sexual orientation

*Exceptions to this are job applicants for the U.S. Military, the Peace Corps, the Job Corps, and persons applying for U.S. citizenship.*

Persons with HIV infection and/or AIDS who feel discriminated against on the basis of their disease may file a complaint with the Office for Civil Rights (OCR) of the U.S. Department of Health and Human Services or their state’s Human Rights Commission. OCR will investigate anonymous reports.

**HIV/AIDS in the Workplace**

HIV and AIDS affect every segment of society: the home, religious institutions, and the workplace. One in 6 large U.S. work sites (more than 50 employees) and 1 in 16 small U.S. work sites (less than 50 employees) have experienced an employee with HIV infection or AIDS. As with any catastrophic illness, HIV/AIDS can affect an employer in many ways:

- Americans with Disabilities Act compliance
- legal considerations
- insurance and health care costs
- confidentiality and privacy
- work disruption
- discrimination concerns
- consumer concerns
- disability requirements
- employee morale
- job accommodation
- community service

The CDC’s Business Responds to AIDS Program (BRTA) is designed to help businesses across the country develop and implement comprehensive workplace-based HIV and AIDS prevention education programs. CDC has developed materials and technical assistance to assist business and unions in forming comprehensive HIV/AIDS workplace programs.

Business Responds to AIDS is a cooperative effort between the CDC and the business sector. It is a multifaceted program that offers solid information on HIV/AIDS for large and small businesses and an extensive resource service. *The most important tool in preventing HIV/AIDS is information.* Working together, business and labor can be the source for credible and accurate information that can prevent the spread of this disease. Simply, educating people about HIV/AIDS can save lives and the workplace is a great place to start.

CDC has available a Manager’s Kit which contains everything needed to create a comprehensive and effective HIV/AIDS program in the workplace. It contains step-by-step instructions that can be helpful to all levels of large and small businesses. This Kit contains information on:

- policy development
- educating employees and their families
- manager training
- community service
Developing a workplace policy on HIV/AIDS requires input and commitment from many people within a business, but
the benefits are invaluable. Remember that some information is better than none at all, so if the time and resources
aren’t available to apply the complete program, businesses should do what they can to disseminate some of the
information.

Learning Activity 4:

As the admission coordinator for your facility, it is your responsibility to inform new patients about advance directives.
What do you tell them?

Define advance directives; state the types and the purpose of each. Write down your answers then turn to the last page
for the answer.

Topic Summary: The AIDS epidemic has raised many ethical challenges for public health officials. There are three widely
recognized principles that apply to both clinical and research ethics: respect for persons, beneficence, and justice.
Aspects of clinical ethics include confidentiality, informed consent for HIV testing, exceptions to informed consent, pre-
natal HIV testing and end-of-life issues.

With the Patient Self-Determination Act, patients can specify if they want to accept or refuse specific medical care in the
form of advance directives. They can also identify a legal representative for urgent healthcare decision purposes. HIV
infection and AIDS are medical conditions that are considered disabilities. It is illegal to discriminate against someone
who is HIV-infected or who has AIDS or someone who is ‘believed’ to be infected. Employers are required to provide and
maintain a discrimination-free work environment. The most important tool in preventing HIV/AIDS is information.
Educating people about HIV/AIDS can save lives and the workplace is a great place to start.

Resources

AIDS Law Project: South Africa
http://www.alp.org.za/

American Medical Association: Professional Resources: Medical Ethics

Centers for Disease Control and Prevention: Business Responds to AIDS/Labor Responds to AIDS: HIV & The Law
http://www.brta-lrta.org/law/law.htm

HIV InSite: HIV/AIDS Law
http://hivinsite.ucsf.edu/InSite?page=li-02-01

http://hab.hrsa.gov/law.htm

World Health Organization: Ethical issues raised by the HIV/AIDS epidemic
www.who.int/ethics/topics/hiv_aids/en/index.html

YUANDAIDS - The HIV/AIDS Portal for Asia Pacific: Human Rights, Law, and Ethics
http://www.youandaids.org/Themes/HumanRights.asp
References


Author Biography

Sharon Molinari, RN, HCS-D, COS-C, is a registered nurse, licensed in Florida and Nevada. She moved to Florida in 1989 from upstate New York where she started her career as an Emergency Room nurse, and then worked in Occupational Health as an Employee Health nurse. Since moving to FL, she has had multiple roles in Home Health including case manager, patient care liaison, clinical manager, branch manager, reimbursement manager, education/compliance manager and director of nurses.

Ms. Molinari has earned certification as a Homecare Coding Specialist - Diagnosis (HCS-D) and a Certificate for OASIS Specialist - Clinical (COS-C). She recently moved to Nevada to be closer to her family and is currently a home health consultant.

Answer to Learning Activity 1:

No, this information is confidential and you may not disclose it to anyone unless your client gives consent and signs a release of information form.

Answer to Learning Activity 2:

HIV testing should be voluntary, informed, and consented.

Answer to Learning Activity 3:

Reporting is not required, if an agency provides anonymous testing only.

Answer to Learning Activity 4:

Advance directives are documents signed by a competent person giving direction to health care providers about treatment choices in certain circumstances. There are two types of advance directives:

1. A durable power of attorney for health care allows persons to name a "patient advocate" to act for them and carry out their wishes when they are unable to do so.

2. A living will allows persons to state their wishes about life-sustaining medical care in writing, but does not name a patient advocate.