HIV/AIDS

HEALTH SYSTEMS PLANNING & PROGRAMMING

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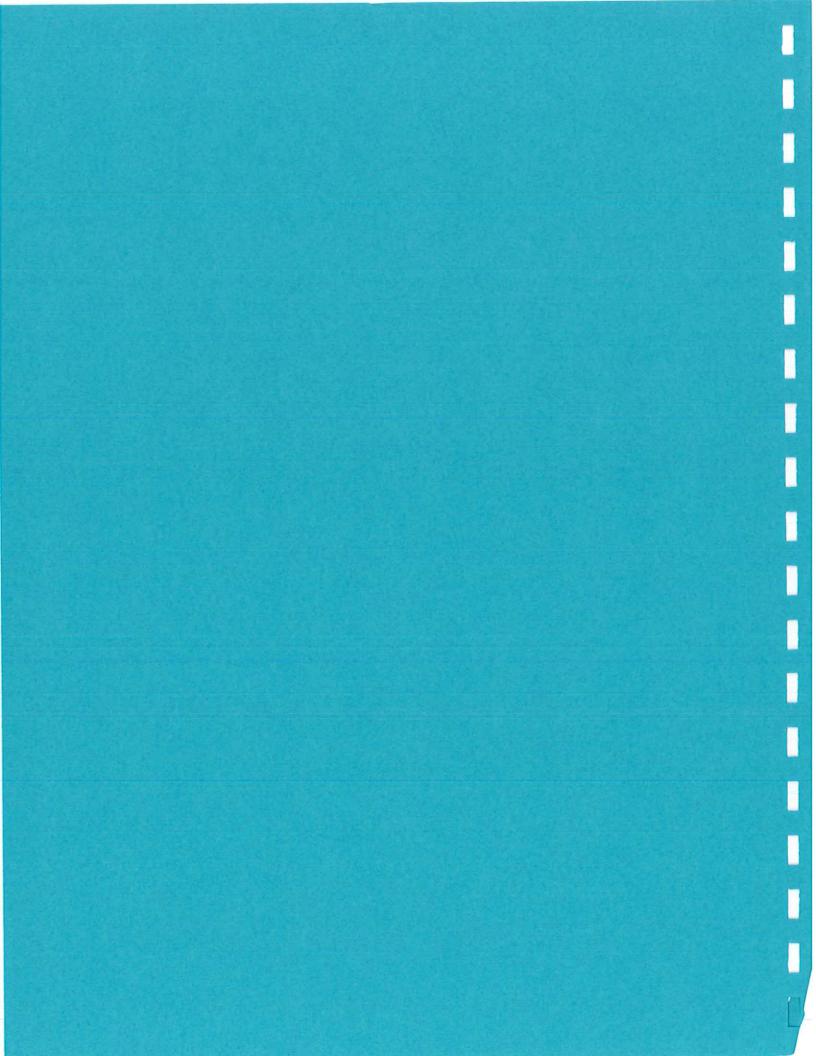


TABLE OF CONTENTS

Executive Summary			
SECTION I			
Health Care Needs			
Introduction	I.1		
Physical Domain of Health Care Need	I.1		
Mental and Emotional Domain of Health Care Need	I.3		
Social Domain of Health Care Need	I.3		
Episode Intensity and Duration	I.4		
Incidence and Prevalence	I.5		
Summary	I.9		
Dutilitary	1,7		
SECTION II			
Health Care Supply			
Introduction	II.1		
Diagnosis Phase	II.1		
Chronic Phase	II.2		
Terminal Phase	II.5		
Summary	II.7		
Summary	ш, /		
SECTION III			
Health Care Technology			
Introduction	Ш.1		
ELISA Test	III.1		
Home Collection HIV Test	III.3		
AZT	III.5		
Protease Inhibitors	III.7		
	III.7		
Summary	ш.8		
SECTION IV			
Health Care Financing and Cost			
Introduction	IV.1		
Financing HIV/AIDS Services in the U.S.	IV.1		
Cost to the Patient	IV.2		
Technology's Cost-Effectiveness	IV.4		
Summary	IV.6		
SECTION V			
	T 7 1		
References	V.1		

FIGURES

I.1	Percent of AIDS Cases by Exposure Category	I.10
I.2	Mode of HIV Transmission Among Women with AIDS	I.11
I.3	Percentage of AIDS Cases by Race/Ethnicity	I.12
I.4	Women with AIDS by State of Residence	I.13
II.1	Public Health Regions in Texas	II.8
II.2	Public Health Region 11	II.9
III.1	Design of ELISA Test	III.10
III.2	Steps in Early Stage of HIV Replication	III.11
Ш.3	Steps in Late Stage of HIV Replication	III.12
III.4	Cycle of HIV Production	III.13

TABLES

II.1	Health and Support Personnel and Health Facilities	II.10	
II.2	Health Personnel and Facilities in Public Health Region 11,		
	Texas, and U.S.	II.11	
II.3	Components of Five Hospice Models	II.12	
II.4	Direct and Indirect Team Components	II.13	
II.5	Supply of Hospice Team Members in U.S.	II.14	
III.1	Price Comparison of HIV Testing Options	III.14	
III.2	Recommended Therapy	III.15	
III.3	Comparison of Currently Available Protease Inhibitors	III.16	
ΓV.1	Federal Spending for HIV/AIDS	IV.7	
ΓV.2	Annual Expenditures for HIV/AIDS	IV.8	
IV.3	Price Comparison of HIV Testing Options	IV.9	
IV.4	Home Test Comparisons	IV.10	
IV.5	Cost of INVIRASE		

HEALTH SYSTEMS PLANNING FOR HIV / AIDS: EXECUTIVE SUMMARY

I. HEALTH CARE NEEDS

AIDS is a chronic illness that affects the patient at more than just the physical level. To better understand the health care needs of people with AIDS, three domains were considered and included physical, mental and emotional, and social. The health of the physical body declines when the immune system is damaged and weakened as the virus replicates within cells. The breakdown of the immune system leaves the body vulnerable to infections that may result in the patient's death. Stages of psychosocial adjustment for the AIDS patient include the initial crisis, transition phase, acceptance phase, and preparation for death. Quality of life can be improved through mental health services. Case management and a network of social support including friends and family can provide needed assistance to the AIDS patient.

The intensity and duration of the disease along with the incidence and prevalence reflect the need for health care services. A person can be infected with HIV for 8 to 15 years before developing AIDS. Once the person reaches the end-stage of the HIV infection, death usually occurs within 18 months to two years. It is estimated that worldwide 6,000 people are infected each day, and in the United States the estimate is 110 per day. Texas is ranked fourth in the U.S. with 39,871 AIDS cases. Blacks/African Americans and Hispanics accounted for 59 percent of the U.S. AIDS cases reported in 1995. The average age of women diagnosed with AIDS in 1995 was 33, and the average age for men was 38 years. Nationwide, AIDS cases are increasing most rapidly among women and minorities.

II. HEALTH CARE SUPPLY

Voluntary and community-based organizations as well as religious groups are helping to share the burden of caring for HIV/AIDS patients, particularly outside of hospitals. There is a segment of the U.S. population who must depend on the prison system while they are HIV positive or dying with AIDS. Texas, in 1993, was ranked third nationally with 1,212 HIV positive inmates. Hospice care may offer an alternative to the dying AIDS patient. There are 108 hospices in the state of Texas, with 18% of them located in Houston and Dallas. Currently, few AIDS patients appear to be using hospice care.

No matter what health facility is used by HIV/AIDS patients, health care personnel are a vital component. When comparing Texas supply/population ratios per AIDS patient to the United States ratios, Texas has fewer physicians, registered nurses, LPNs, pharmacists, psychologists, social workers, and health technicians than the U.S. Based on information and data presented here, it appears that the supply of health care services for HIV/AIDS patients in the state of Texas is not adequate to meet the growing need.

III. HEALTH CARE TECHNOLOGY

HIV testing procedures and drug treatments are important technologies for meeting the health care needs of people with HIV/AIDS. The ELISA test is the most frequently used diagnostic test for HIV. No definitive positive diagnosis can be made based on a single ELISA test. If the ELISA repeatedly gives reactive results, the specimen is then forwarded for a confirmatory test such as the Western Blot. A positive Western Blot would be regarded as being diagnostic of HIV infection.

Home collection HIV tests are providing an alternative to testing in a traditional clinic setting. CONFIDE is a testing kit approved by the FDA and available without a prescription. Blood samples collected in these tests are screened with the ELISA and Western Blot tests. The tests are conducted in licensed laboratory which operate in compliance with FDA guidelines.

Antiviral therapy directed against HIV is usually done in combination treatment regimens. AZT and protease inhibitors are part of that regimen. Use of the combination treatment can reduce viral load and increase CD4 counts. AZT works by inhibiting the in vitro replication of retroviruses, which include HIV. Certain protease inhibitors can reduce the amount of virus in a person infected with HIV by as much as 99 percent.

IV. HEALTH CARE FINANCING AND COST

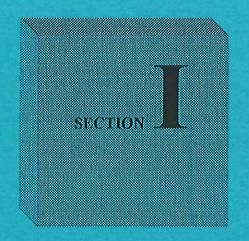
The cost factors of HIV/AIDS health care in the United States can reach staggering amounts. The estimated lifetime cost of treating one person with HIV from time of infection until death is approximately \$119,000. Hospital expenses associated with one episode of care for an HIV/AIDS patient with pneumonia is over \$7,000. A variety of sources provide the needed financing for HIV/AIDS care. About 35 to 40 percent of the total HIV-related expenditures come from federal agencies. In 1994, federal spending for HIV/AIDS was \$6,350 million. Other financial sources include private health insurance, out-of-pocked costs to patients, and individual state's share of Medicaid, public hospitals and other local expenditures.

HIV/AIDS patients experience psychological and social costs during the diagnosis, chronic and terminal phases of the disease. Persons with HIV/AIDS go through phases of psychosocial adjustment including the initial crisis, transition phase, acceptance of the disease, and preparation of death. Because of the stigma associated with AIDS, persons with the disease may experience a great deal of social isolation.

The cost of antiretroviral drug therapy can result in large financial costs. Combination drug therapies usually consists of three drugs, and a year's supply of each of these drugs will cost over \$3,000. Treatments with these powerful and expensive drugs should start when the presence of HIV is detected and continue through the chronic and terminal phases of the disease.

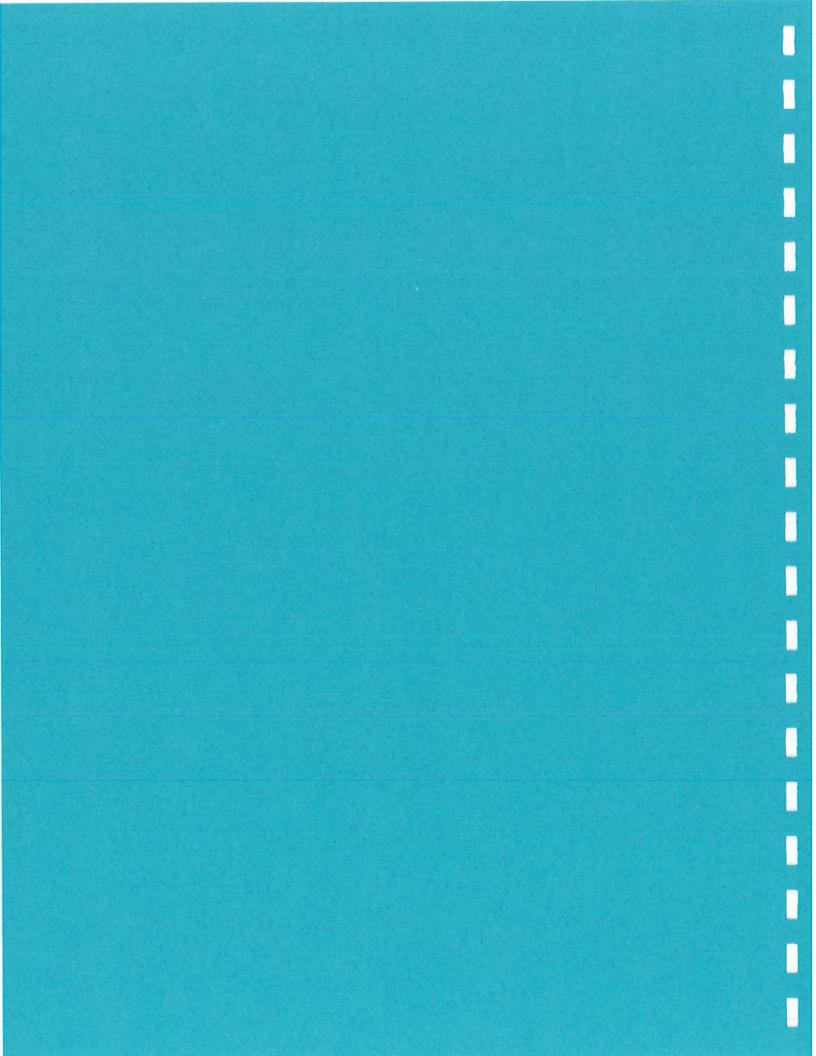
No drug is a cure for AIDS, and there are several hazards associated with using the drugs. These include toxicity, suppression of the bone marrow, muscle myopathy, nausea, vomiting, and diarrhea. Drugs such as AZT are only effective for a certain length of time. Then, its effectiveness ceases and may even produce symptoms similar to those produced by the virus.

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HEALTH CARE NEEDS

- A. Introduction
- B. Physical Domain
- C. Mental and Emotional Domain
- D. Social Domain
- E. Episode Intensity and Duration
- F. Incidence and Prevalence
- G. Summary



A. INTRODUCTION

The health care needs of HIV/AIDS patients are discussed in this section. The disease affects many areas of a patient's life. Therefore, various components of the physical, mental and emotional, and social domains are discussed.

On the physical level, the HIV infection is transmitted to an individual and the infected person experiences changes within cells. As the disease progresses, the immune system is compromised and the individual is susceptible to various life-threatening infections. These physical changes often contribute to mental and emotional changes for the person with HIV/AIDS. Case management and a social support system can help the patient identify health care needs and locate services that meet those needs.

The intensity and duration of the health care needs increase as the disease progresses from the time of exposure through the time when opportunistic infections are present. HIV/AIDS exists worldwide and affects men, women, children, heterosexuals and homosexuals from various age, race and ethnic groups. Therefore, the incidence and prevalence of HIV/AIDS are discussed.

B. PHYSICAL DOMAIN OF HEALTH CARE NEED

B.1. Infection

AIDS (Acquired Immune Deficiency Syndrome) is a "spectrum of conditions" that occurs as a result of the immune system being seriously damaged over the years by attacks from the human immunodeficiency virus (HIV) (HIVemir, 1997). AIDS reduces the body's ability to fight disease. It is caused by the HIV, which can be transmitted sexually, through blood exchange, from a pregnant woman to her fetus, and through a nursing mother's milk. As soon as a person becomes infected he/she are capable of transmitting the disease to others (AIDS Manual, 1997).

B.2. Cell Changes

Once an individual is infected with HIV, the virus attaches itself within the T₄ cells, commonly referred to as the Helper T Cells of the immune system (Thomas, 1993). This begins the destruction and progressive loss of immune functions. A retrovirus, HIV enters the cell and

infiltrates the cell's RNA, through which it transfers its own DNA to the cell's DNA by means of an enzyme. This enzyme is known as reverse transcriptase (Thomas, 1993). The change in DNA prevents the cell from functioning normally, resulting in the production of more HIV. In the very early period following infection, there may be signs of an acute, brief, nonspecific viral infection with fever, malaise, rash, arthralgias, and lymphadenopathy (Thomas, 1993).

B.3. <u>Immune System</u>

There are two types of cells in the immune system that are affected by the HIV virus (Schoub, 1994): (1) monocytes and macrophages, and (2) T-helper lymphocytes. Monocytes and macrophages function as a major reservoir for the HIV infection. The virus is able to replicate within these cells without destroying them. The T-helper lymphocytes act as regulator cells for the immune system and play a central role in controlling immune functions. The profound depletion of these cells as a result of the attack by the HIV virus is the hallmark of HIV-related disease (Schoub, 1994). Common results of severe immunosuppression are opportunistic infections leading to:

- Dramatic weight loss, with some people losing up to 50 percent of their weight in six months in severe cases.
- Chronic diarrhea ('wet AIDS') which may last for months.
- Chronically elevated body temperature or pyrexia ('hot AIDS') which may last for an
 extended period of time.
- Enlargement and swelling of lymph glands (lymphadenopathy) which is one of the first clinical signs of HIV infection.

B.4. Infections

The most common causes of death and the more prominent clinical signs of AIDS are due to the indirect effects of immunosuppression. The breakdown of the immune system leaves the body vulnerable to infections from a huge variety of micro-organisms and to the development of malignant tumors. Three types of infectious agents which may affect the body are (Schoub, 1994):

- Micro-organisms, particularly viruses, that can affect both healthy and immunosuppressed individuals but whose effects are more severe and last much longer for persons affected by HIV.
- 2) <u>Bacteria, fungi, and parasitic organisms</u> that are easily treated and cured in normal individuals but are especially problematic for immunosuppressed persons.
- Opportunistic infections which are responsible for the infectious diseases that are typical
 of immunosuppressed individuals in general and AIDS victims in particular. These

infections are called opportunistic or secondary because they are infections which the immune system would normally fight off (HIVemir, 1997). Examples are herpes simplex, shingles, candida albicans, Pneumocystis carnii, tuberculosis, and Kaposi sarcoma.

C. MENTAL AND EMOTIONAL DOMAIN OF HEALTH CARE NEED

There are a number of common psycho-social responses to the HIV/AIDS disease which induces denial, self-blame, fear, anxiety, anger, losing control, isolation, ambivalence, empowerment and hope (Andrews and Novick, 1995). Offering an array of mental health services to people with HIV/AIDS can improve the quality of their lives as they progress through the stages of adjustment (HIV/AIDS, 1996). Four stages of psycho-social adjustment which have been identified in clients with HIV infection include (Ostrow, 1984):

- 1) <u>Initial crisis</u>: When individual first learns of HIV-related diagnosis. Characterized by shock and denial. Great deal of patience required in dealing with client.
- 2) <u>Transition phase</u>: Psycho-social reactions may be extreme. Emotional stages range from self-devaluation, fear, depression, and helpless to escapism, and anger. Help with problem-solving, setting priorities, and developing peer-support system needed.
- 3) Acceptance phase: Some individuals don't make it to this phase. New crises may cause reactions similar to those in transition phase.
- 4) <u>Preparation for death</u>: Patients or persons in terminal stages of disease need to be able to express anything or nothing about their death. May involve reconciliation with family and friends.

D. SOCIAL DOMAIN OF HEALTH CARE NEED

D.1. Case Management

According to Land (1992), case management is needed to assist in the coordination of care. Persons with AIDS also need assistance with accessing public benefits, legal assistance, Social Security, and other important services. Necessities of life such as food and affordable

housing may be needed. Dependable transportation is needed when the person is no longer able to drive. Emotional support and counseling are needed by both clients and their loved ones (Land, 1992).

D.2. Social Support System

The disease affects lives of individuals with AIDS in different ways and to different degrees. It is important for people living with AIDS to do all that they can for themselves for as long as they are able. However, it is often difficult for someone who has AIDS is to keep up with regular daily activities such as shopping, paying bills, or cleaning house (American Red Cross, 1993).

Developing a good support system of friends and professionals can go a long way to keep someone with AIDS in good mental and physical health (Texas Department of Health, 1993). While it is valuable to have a social support system of friends and family, a person with AIDS should avoid close contact with people who have contagious illnesses until symptoms have disappeared (American Red Cross, 1993). This is because a person with AIDS has a difficult time resisting certain infections such as colds, the flu, or stomach flu (American Red Cross, 1993).

E. EPISODE INTENSITY AND DURATION

E.1. Intensity

The Walter Reed Classification System of an illness is used as a universal scale of measurement for HIV and AIDS (Thomas, 1993). The scale ranges for the time of exposure to the disease through the time when opportunistic infections are present.

Stage 0: Exposure

Stage 1: Infection. Flu-like syndrome characterized by fever, myalgia, malaise,

lymphadenopathy; identification of HIV antibodies in the blood (HIV+).

Stage 2: Chronic lymphadenopathy.

Stage 3: T₄ count less than 400.

<u>Stage 4</u>: Reduced delayed hypersensitivity response to common allergens.

<u>Stage 5</u>: Appearance of chronic viral of fungal infections of mucous membranes.

<u>Stage 6</u>: AIDS defined by presence of opportunistic infections present in sites other than skin or mucous membranes.

The clinical phase of AIDS can be defined as the point at which the individual passes the threshold of being HIV+ and is classified as having one or more of the opportunistic diseases. This would correspond with the sixth stage of the Reed Classification System, the presence of opportunistic infections. According to the Center for Disease Control, some of the most common of these infections include: Pneumocystis carinii pneumonia, HIV wasting syndrome, and Candidiasis of esophagus. A laboratory marker test of 200 T-Cells per cubic millimeter of peripheral blood is required to confirm diagnosis of AIDS (Rural Center for AIDS/STD Prevention). During this phase there may be some recovery from opportunistic infections as well as remissions of tumors, but both the infections and tumors usually return with increasing severity and frequency (Schoub, 1994).

Persons who have diseases in the following subgroups are said to have AIDS (HIVemir, 1997):

- Neurological diseases like dementia, myelopathy, or peripheral neuropathy.
- Secondary or opportunistic infections such as pneumocystis carinni pneumonia.
- Secondary cancers such as Kaposi are which are associated with HIV infection.

E.2. Duration

A person can have the HIV infection for 8 to 15 years before developing AIDS (Schoub, 1994). Infection can occur as soon as a person comes in contact with the virus, but the virus may not be detected in a laboratory test until three months after initial infection (American Red Cross, 1993). Once a person reaches this end-stage of the HIV infection, death usually occurs within about 18 months to two years (Schoub, 1994).

F. INCIDENCE AND PREVALENCE

F.1. Worldwide

The World Health Organization (WHO) has estimated that by the year 2000, 30-40 million persons will have been infected with HIV, and there will be a total of 10 million AIDS cases and more than 10 million AIDS orphans (CDC: Improving Nations Capacity, 1997). Through 1994, an estimated 18.5 million persons worldwide had been infected with HIV, including 1.5 million children. Through 1995, 6 million people had developed AIDS, and 4.5 million of these had died. An estimated 6,000 people are infected each day (CDC: Improving Nations Capacity, 1997).

F.2. United States

As a nation, the U.S. has made significant progress in slowing the spread of the HIV/AIDS epidemic. Annual increases in new AIDS cases have slowed from more than 85 percent in the mid-eighties, to a July 1996 rate of less than 5 percent due to early intervention and more effective medication treatment (CDC: HIV/AIDS Trends, 1996). That is still about 60,000 new AIDS cases a year. Moreover, CDC (HIV/AIDS Trends) estimate that at least 40,000 Americans are becoming infected with HIV each year.

F.3. Texas

The CDC semi-annual HIV/AIDS Surveillance Report (1996) ranked the states by their number of AIDS cases reported among the states' residents through December 1995. Texas ranked in the top four states. The states and their corresponding numbers of reported AIDS cases were:

- 1. New York (106,897)
- 2. California (98,157)
- 3. Florida (58,911)
- 4. Texas (39,871)

Metropolitan areas were also ranked by the number of reported AIDS cases. Texas was represented in this list by Houston. New York City ranked first with a reported 91,799 cases. Houston reported 14,293 AIDS cases and was ranked seventh (CDC: HIV/AIDS Surveillance Report, 1996).

F.4. Infection

HIV is spread through four body fluids: blood, semen, vaginal secretions, and breast milk. The most common ways to spread the virus are (1) by having vaginal, anal, or oral sex with someone who is infected with HIV, (2) by sharing needles or syringes with someone who is infected with HIV, and (3) from an infected mother to her baby during pregnancy or childbirth (American Red Cross, 1993). Earlier in the epidemic some people became infected from transplanted tissue or organs, or from infected blood, blood products, or plasma. This has been very rare since the late 1980s when blood centers began screening all donated blood and tissue for HIV (American Red Cross, 1993). Approximately 100 percent of hemophiliacs who were born before 1989 are HIV positive due to contaminated Factor VIII or IX

The rate of AIDS among some populations has slowed, and troubling trends have emerged in others. Nationwide, AIDS cases are now increasing most rapidly among women and minorities (CDC: HIV/AIDS Trends, 1996). Since 1992, heterosexual transmission has increased 63 percent (JAMA, 1997). Furthermore, there has not been a significant decline in new infections

among young people, and young and minority gay and bisexual men remain at high risk (CDC: HIV/AIDS Trends, 1996).

Figure I.1 shows the percent of AIDS cases by exposure category and year of report (1985-1995) in the United States (CDC: HIV/AIDS Surveillance Report, 1996). An encouraging trend is shown for homosexual/bisexual men during this ten-year period as the percent of cases dropped from nearly 70 percent to less than 50 percent. A discouraging trend is shown for the injecting drug user as their percent of cases goes up from approximately 20 percent to nearly 30 percent. The heterosexual percent of AIDS cases is also on the rise of 10 percent over 10 years. This may indicate several changes, (1) that gay men are practicing safer sex, (2) injecting drug users are sharing contaminated needles, and (3) heterosexuals are having unprotected sex with infected partners.

The rise in heterosexual transmission in the U.S. population may be due to the increasing percentage of women diagnosed in this category. Figure I.2 shows the mode of HIV transmission among women reported with AIDS in the U.S. (CDC: HIV/AIDS Surveillance Report, 1996). Heterosexual transmission accounted for 38 percent of the reported cases. Women who were injecting drug users also represented 38% of these cases. Since 1992, the most common route of infection for women has been through heterosexual transmission of the AIDS virus (CDC: Office of Women's Health, 1995). Before 1992, more AIDS cases among women were attributed to injection drug use than to heterosexual transmission. In 1993, CDC changed its definition of AIDS to include opportunistic diseases experienced by women but not by men. Before 1993, women were not considered to be at risk unless they were injecting drug users (CDC: Office of Women's Health, 1996).

F.5. Race/Ethnicity

Of the 513,486 AIDS cases among residents of the United States reported to CDC through December 1995, Blacks and Hispanics accounted for (CDC: HIV/AIDS Surveillance Report, 1996):

- 52% of the total
- 75% of the women
- 78% of the heterosexuals
- 81% of the children.

Blacks and Hispanics accounted for 59% of the AIDS cases reported in 1995 (CDC: HIV/AIDS Surveillance Report, 1996).

A ten-year (1985-1995) trend of AIDS cases by race/ethnicity is illustrated in Figure I.3. The percentage of White has dropped from over 60 percent to less than 50 percent. The Black

percentage has risen from approximately 25 percent in 1985 to about 40 percent in 1995. The Hispanic cases made a gradual increase to approximately 20% (CDC: HIV/AIDS Surveillance Report, 1996). This indicates a major shift in the race/ethnicity rates of AIDS cases. If this trend continues, the percentage of Whites reported with AIDS will soon be less than the percentage for of Blacks. This is especially alarming when compared to the U.S. population by race/ethnicity. The following is a comparison of U.S. AIDS cases reported in 1995 and an estimated 1995 U.S. population (CDC: HIV/AIDS Surveillance Report, 1996):

	<u>AIDS</u>	Population
	74,180	266,834,884
Anglo	40%	73%
African-American	40%	12%
Hispanic	19%	11%

African American and Hispanic women have been disproportionately affected by the AIDS epidemic. Although African American and Hispanic women make up 21 percent of all U.S. women, they constitute 77 percent of reported cases in 1994, with rates of 63 and 26 per 100,000, respectively, compared with 4 per 100,000 among White women (CDC: Office of Women's Health, 1995).

F.6. Age

In 1993, heterosexual transmission of HIV accounted for 6,056 cases of AIDS reported among women, while it accounted for only 3,232 cases among men (CDC: Office of Women's Health, 1995). That year, the average age of women diagnosed with AIDS was 33, while the average age for men was 38 (CDC: Office of Women's Health, 1995).

Literature indicates that AIDS is the third greatest killer in women aged 25-44 (Hover et al., 1996). Heterosexual transmission of HIV has accounted for a greater proportion of AIDS cases among women 20-29 years old than among women over 30 (CDC: Office of Women's Health, 1995). This may be because of the long period between exposure to the virus and onset of symptoms. Cases of AIDS women in their twenties are thought to primarily affect people who were exposed to the virus as adolescents. The most common mode of transmission among adolescents has been through heterosexual contact (CDC: Office of Women's Health, 1995).

F.7. Geographic Location

The highest proportion of cases associated with heterosexual contact during 1993 was in the South (42 percent) and in the Northeast (31 percent). States with the largest number of heterosexually acquired cases in 1993 were Florida (1,772 cases), New York (1,336 cases), and New Jersey (855 cases) (CDC: Office of Women's Health, 1995). Figure I.4 presents a map of

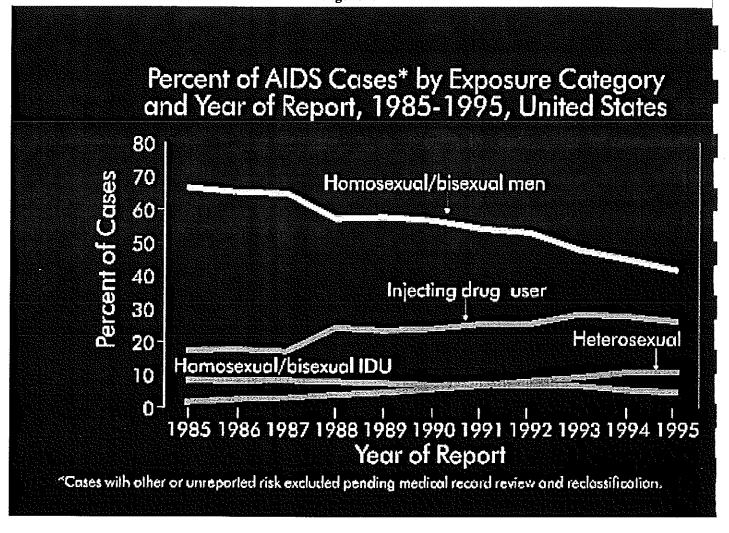
the U.S. and shows the number of women with AIDS by state of residence per 100,000 women as reported in 1995 (CDC: HIV/AIDS Surveillance Report, 1996). New York ranks highest with 40.5 per 100,000 women, Florida is second with 30.0 per 100,000, and Texas ranks 19th with 7.1 women per 100,000 women residents in the state.

G. SUMMARY

AIDS is a chronic illness that affects the patient at more than just the physical level. To better understand the health care needs of people with AIDS, three domains were considered and included physical, mental and emotional, and social. The health of the physical body declines when the immune system is damaged and weakened as the virus replicates within cells. The breakdown of the immune system leaves the body vulnerable to infections that may result in the patient's death. Stages of psycho-social adjustment for the AIDS patient include the initial crisis, transition phase, acceptance phase, and preparation for death. Quality of life can be improved through mental health services. Case management and a network of social support including friends and family can provide needed assistance to the AIDS patient.

The intensity and duration of the disease along with the incidence and prevalence reflect the need for health care services. A person can be infected with HIV for 8 to 15 years before developing AIDS. Once the person reaches the end-stage of the HIV infection, death usually occurs within 18 months to two years. It is estimated that worldwide 6,000 people are infected each day, and in the United States the estimate is 110 per day. Texas is ranked fourth in the U.S. with 39,871 AIDS cases. Blacks/African Americans and Hispanics accounted for 59 percent of the U.S. AIDS cases reported in 1995. The average age of women diagnosed with AIDS in 1995 was 33, and the average age for men was 38 years. Nationwide, AIDS cases are increasing most rapidly among women and minorities.

Figure I. 1

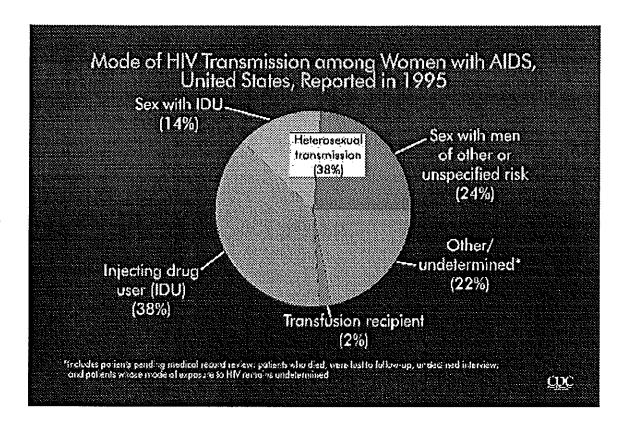


Source: Centers for Disease Control and Prevention

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Figure I. 2

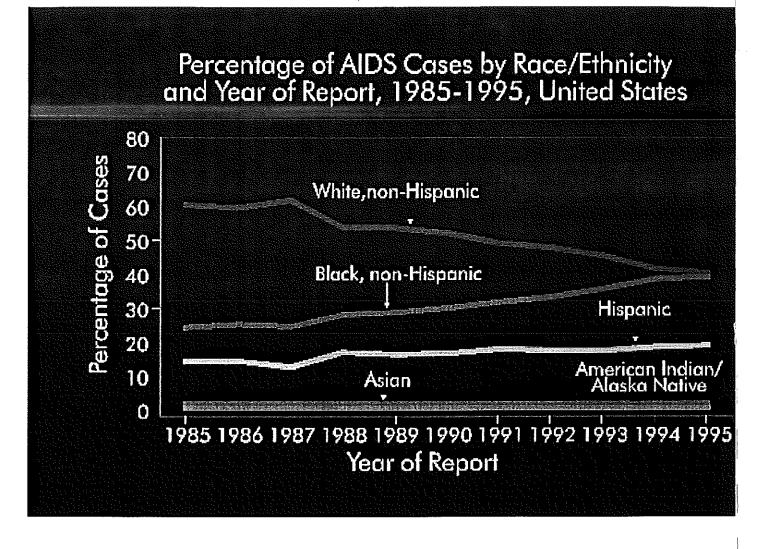


Source: Centers for Disease Control and Prevention

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Figure L 3

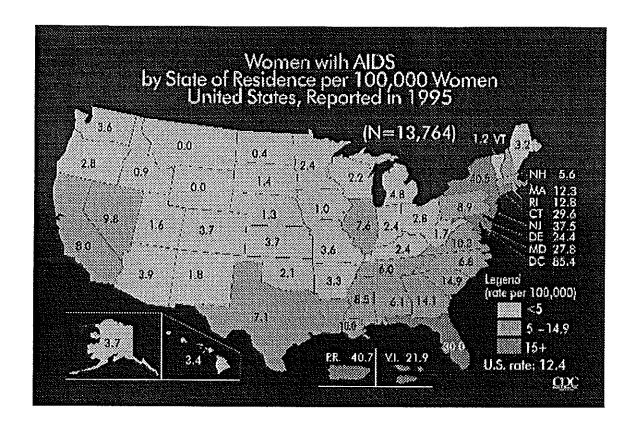


Source: Centers for Disease Control and Prevention

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Figure I. 4



Source: Centers for Disease Control and Prevention May 1997

http://www.cdc.gov/nchstp/hiv_aids/graphics/images/women/126_326.gif

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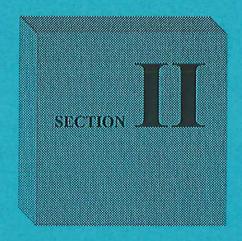
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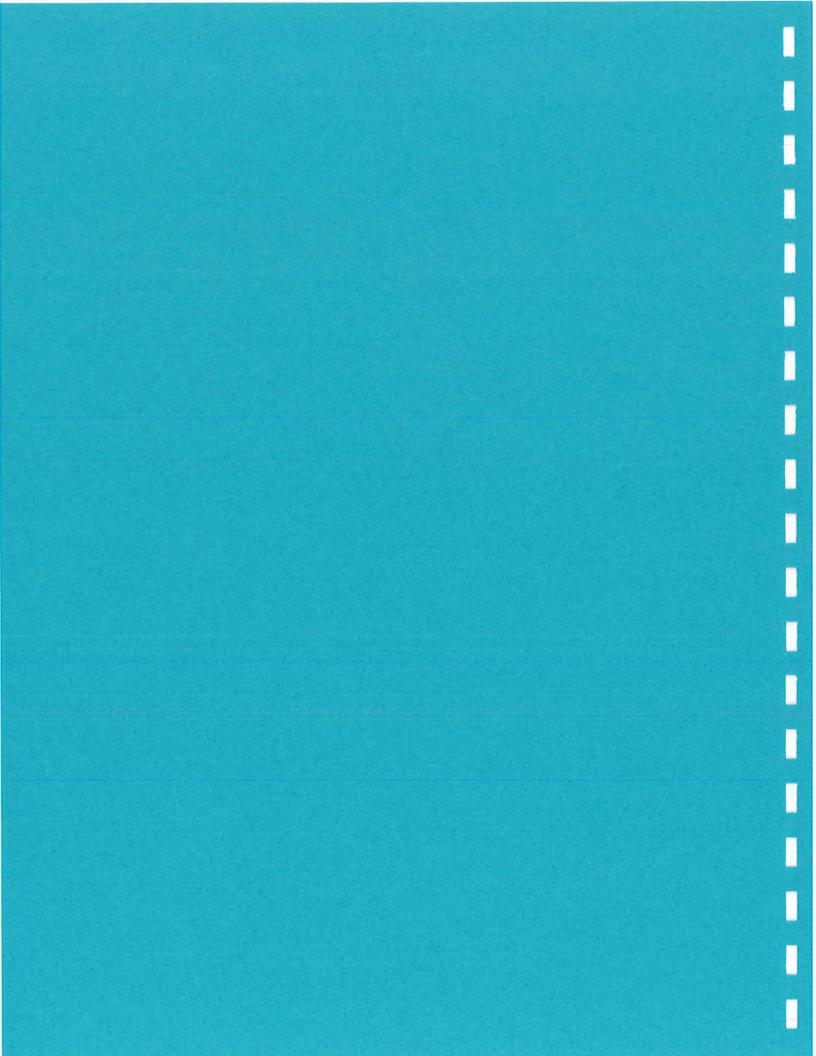
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HEALTH CARE SUPPLY

- A. Introduction
- **B.** Diagnosis Phase
- C. Chronic Phase
- D. Terminal Phase
- E. Summary



A. INTRODUCTION

The supply of health care services, including providers and facilities, utilized by people with HIV/AIDS is discussed in this section.

The diagnosis phase in this report is defined as occurring during the time period where individuals are considered at-risk for contracting HIV and undergo the HIV testing and diagnostic process. It is also extended to include the set-up of case management and monitoring of services. In reality, it may also include individuals who are HIV positive yet asymptomatic. The supply of services during the diagnosis phase includes the facilities where HIV testing is done, the health professionals who conduct the testing, and the social services that provide case management and referral information.

The chronic phase is defined as the time starting after an individual is diagnosed HIV positive or with AIDS. It is during this time that people experience exacerbations of the disease and opportunistic diseases. Health care services are aimed at controlling symptoms, utilizing drug therapy, and monitoring the patient's condition. A person in the chronic phase may receive services from voluntary and community-based organization, religious groups, correction systems, hospitals, and a variety of health professionals.

The terminal phase is when death for the person with AIDS has become immanent. During this phase, services are directed at symptom management, pain control, and counseling. Hospice programs exist in various models to provide medical and nursing care for people dying with AIDS.

B. DIAGNOSIS PHASE

B.1. Services

The general categories of services needed in the diagnosis phase include testing, counseling, medical assessment and treatment, and social services. These services are designed to provide support and direction for the individuals diagnosed as HIV positive.

B.2. Facilities

Facilities providing HIV testing and other direct services for the general population and the at-risk population include clinics and doctor's offices, hospitals, prisons, blood donation centers, substance abuse treatment centers, county health departments, and community-based agencies specifically designed for HIV/AIDS testing and case management.

B.3. Providers

Physicians who provide services to the HIV/AIDS at-risk population and who may initiate the diagnosis phase include family practitioners, internists, general practitioners, oncologists, psychiatrists, and pediatricians. Additionally, women receive medical services and HIV testing from obstetricians and gynecologists. Other health professionals in contact with the at-risk population include dentists, nurses, physician assistants and dietitians.

Social service providers can be from government or private sectors. This group of providers supplies counseling, education and case management services. The Center for Disease Control (CDC) Information Clearinghouse can assist the at-risk/diagnosis phase population in their search for appropriate service providers.

C. CHRONIC PHASE

C.1. Voluntary and Community-Based Organizations

Government's slow response to the HIV/AIDS epidemic was filled very early on by an outpouring of volunteer activity. Throughout the country, volunteering movements have carried a surprisingly large share of the burden of caring for AIDS patients, particularly outside hospitals (Jonsen, 1993). In addition, advocacy for appropriate social policies that would both contain the epidemic and protect the rights of affected individuals came from community-based organizations (Jonsen, 1993).

C.2. Religious Groups

Many churches have engaged in extensive programs for the case and support of persons with AIDS and have, within their doctrinal limits, become active educators about the epidemic with regard to both discrimination and prevention (Jonsen, 1993).

C.3. Correction Systems

HIV/AIDS persons are found in the prison system, as evidenced by figures in the Bureau of Justice Statistics for 1993. The Bureau of Justice Statistics (BJS) began reporting information about HIV/AIDS in the prison populations in 1991 (U.S. Department of Justice, 1995). In its first report, BJS reported 17,551 inmates (2.2% of the prison population) were HIV cases. By year end in 1993, 21,538 of the 880,101 inmates held in U.S. prisons (2.4% of Federal and State prison inmates) were known to be infected with HIV (U.S. Dept. of Justice, 1995). Of the total prison population, 3,765 inmates, or 0.4%, had AIDS. State prisons reported that 2.6% of inmates were HIV positive while Federal prisons reported 1.2%. Texas, in 1993, had the third largest number of HIV positive inmates (1,212) following New York (8,000) and Florida (1,780). During that year, Harris County, Texas had 181 inmates with HIV and Dallas County, Texas had 165 HIV inmates. In total, 736 men and 25 women died from AIDS in State prisons during 1993. Males were almost twice as likely to die of AIDS as females; 98 per 100,000 male inmates died of AIDS during 1993 compared to 54 per 100,000 female inmates (U.S. Department of Justice, 1995).

C.4. Health Professionals

Concern is growing that the burden of the AIDS epidemic may dissuade young physicians from practicing in a geographic location where the burden of caring for patients with HIV disease is perceived to be high (Jonsen, 1993). According to a study which looked at HIV service delivery for rural areas of South and West Texas, the HIV/AIDS population in the rural communities had a very small number of physicians and even fewer willing to see persons with HIV/AIDS (Cattoi et al., 1992).

Since all providers are not willing to attend to persons with HIV/AIDS, more providers perhaps increase the chance of finding a physician who will accept an AIDS patient. For this reason, comparing the supply/population ratios for different areas or locations is a good way to determine where there are shortages of health personnel or service. This method of comparison is used in Tables II.1 and II.2. For 1990, the different supply ratios listed in Tables II.1 and II.2 include the United States, the state of Texas, and the counties in Public Health Region 11 (PHR 11) for Texas.

Public Health Region 11 is selected as a comparison area because it represents a rural and poor population in Texas. The Texas map in Figure II.1 depicts the location of PHR 11 at the lower tip of Texas, just north of the Mexico border. The nineteen counties in PHR 11 include: Aransas, Bee, Brooks, Cameron, Duval, Hidalgo, Jim Hogg, Jim Wells, Kenedy, Kleberg, Live Oak, McMullen, Nueces, Rufugio, San Patricio, Starr, Webb, Willacy, Zapata (Table II.1).

Additional demography information (Figure II.2) indicates the largest race/ethnic group in PHR 11 is Hispanic at 76.6 percent of the region's total population for 1995. During that same time period, PHR 11 had 21.1 percent Anglo population and 1.5 percent Black (Texas State Data Center, 1996). Texas as a whole has a quite different population distribution by race/ethnicity. In 1995, Texas had 28.2 percent Hispanic, 57.7 percent Anglo, and 11.5 percent Black populations (Texas State Data Center, 1996). In 1996, the AIDS prevalence rate per 100,000 for PHR 11 is 31.5 compared to Texas at 36.1 and the U.S. at 39.6. During that same year, the AIDS incidence rates per 100,000 for PHR 11, Texas and U.S. are 9.4, 20.5, and 27.1 (Texas Department of Health, 1996; CDC, 1996).

The 1990 supply/population ratios of health care providers and facilities for PHR 11, Texas and the U.S. are compared in Table II.1. With the data from Table II.1, calculations are made to indicate differences between rations for PHR 11, Texas, and the United States. The greatest discrepancy involves the ratios of registered nurses. The number needed in PHR 11 to match the U.S. ratio per 100,000 is 10,235, and the number needed to match the Texas ratio per 100,000 is 2,879 (U.S. Bureau of Census, 1990). This is alarming information because the care of AIDS patients in the terminal stages of the disease falls very heavily on hospital-based nurses (Jonsen, 1993). A shortage of nurses has been identified as a major obstacle to improving care of AIDS patients (Jonsen, 1993).

Table II.2 compares 1990 rates per 100,000 for health personnel and facilities in PHR 11, Texas and the U.S. For the vast majority of the categories, the U.S. rate is greater than for Texas or PHR 11. Highlights of the rate differences include:

Health Care Personnel

- Texas has lower supply/population ratios than the U.S. for all health personnel except LVNs.
- PHR 11 has lower supply/population ratios than the U.S. and Texas for all health personnel except LPNs.
- Compared to the U.S., PHR 11 has fewer health personnel per AIDS patient for physicians and RNs.

Health Care Facilities

- Texas nursing home rate is greater than the U.S. rate.
- Clinic rate in 1996 for PHR 11 is greater than the Texas rate.
- For PHR 11, 8 of the 19 counties have no hospital.
- Both PHR 11 and Texas have fewer hospital beds per 100,000 persons than the U.S.

- Six of the 19 counties (Duval, Jim Hogg, Kenedy, Live Oak, Willacy, and Zapata) in PHR11 have no hospital or physician.
- Three of the counties in PHR 11 (Jim Hogg, Kenedy, and Zapata) have no physician, hospital, or nursing home beds.

Based on these ratios, it appears that the supply of AIDS services in PHR 11 is inadequate.

C.5. Proportion of Total Supply (providers and facilities) Used by AIDS Patients

A report prepared by the Agency for Health Care Policy and Research (Mohr, 1994) listed the percentage of persons with HIV/AIDS in the U.S. who used the following services and facilities:

- Nursing homes: less than 2% of persons with HIV.
- Hospitals: 11% of persons who were HIV-symptomatic; 30% of persons with AIDS.
- Ambulatory care: 3.5 visits for asymptomatic persons; 4.2 for HIV-symptomatic; 5.3 for persons with AIDS.
- Psychological counseling: 29% of HIV-symptomatic persons and persons with AIDS.
- Dental services: 20% for HIV-symptomatic persons.

Even if we consider that not all prevalent AIDS patients need these services at a given point in time, there still remains a gross discrepancy in under-utilization by AIDS patients. This may indicate barriers of access to needed health care services for AIDS patients.

D. TERMINAL PHASE

D.1. Hospice Care

Since the early 1970s, hospice care in the U.S. has evolved from being a philosophy of care for dying patients and their families to a recognized form of health care provision. The objectives of hospice care are to maximize patient and family autonomy during the last weeks of life and to allow terminally ill patients to die at home, among family, with as much dignity as possible and relatively free of pain.

D.2. Hospice Models

There are five key hospice models, (1) hospital-based, (2) scattered-bed, (3) home care, (4) free-standing, and (5) community-based (McDonnell, 1986). Salient features of each model are compared, and Table II.3 presents some characteristics common to each model and

demonstrates how the models vary. Compared to the other four models, the hospital-based model offers the largest percentage of service in pain control, volunteer services and pastoral care. The free-standing and community-based models have inter-disciplinary teams (McDonnell, 1986).

D.3. <u>Hospice Service Providers</u>

Hospices in the U.S. employ approximately 25,000 paid professionals and 96,000 volunteers (Hospice Fact Sheet, 1997). These volunteers undergo a minimum of 22 hours of training and usually provide service for three years (Hospice Fact Sheet, 1997). Service providers are both directly and indirectly associated with the patient in hospice care. Table II.4 lists direct and indirect team components of care. Administrative duties provide indirect service while the primary care to the patients is a direct service (McDonnell, 1986). Table II.5 lists hospice team members and their supply in the U.S. The majority of hospice care providers are registered nurses (45,400), while physicians number 5,300 (National Home and Hospice Care Survey, 1994).

D.4. Patient Mix

Although the hospice patient mix may change as the hospice industry continues to grow due to an increase in terminal AIDS patients, hospice patients traditionally have been predominately white, elderly, with terminal cancers (HCFA, 1994). Based on 1993 national hospice data, 73 percent of patients were 65 years or older and 71 percent suffered some form of neoplasm (HCFA, 1994). According to the Medical Center Hospice (1997) in Houston, Texas, approximately 4 percent of their clients are terminal AIDS patients, and over 90% of their patients have a form of cancer. Hospice guidelines frequently require that a family member or friend be present at all times for the terminal patient. For many patients with AIDS, there is no one available for this constant supervision so they would not qualify for Hospice services.

D.5. Geographical Distribution

Approximately 30% of hospices are independent community-based organizations; 28% are divisions of hospitals; 22% are divisions of home health agencies; 5% are divisions of hospice corporations; 1% are divisions of nursing homes; and 14% are "other" or not identified (Hospice Fact Sheet, 1997). The 1994 establishment of 10,900 home care agencies (both home care and hospice) represents a 30% increase from 1992 (Hospice Hotlinks (HH), 1997).

As of June 30, 1996, the National Health Organization (NHO) had knowledge of approximately 2,800 operational or planned hospice programs throughout all 50 states (Hospice Fact Sheet (HFS), 1997). In the state of Texas during 1997, there are a total of 108 hospices recognized by the NHO, and approximately 10 percent of these are located in Houston, and 8 percent are in Dallas (Hospice Web:Texas, 1997). In 1986, the number of hospices was only 269

(HFS, 1997). The 1990s annual growth of hospices has average around 8 percent and in the past five years, growth has averaged nearly 17 percent (HFS, 1997).

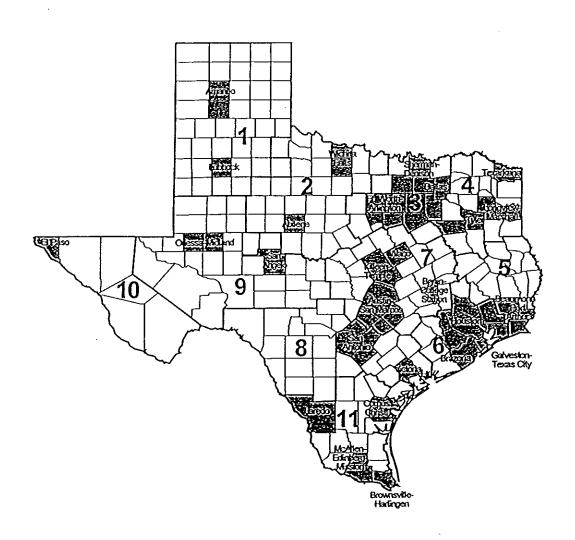
NHO estimates that 390,000 patients were served by hospice in the U.S. in 1995. In the 1990s, annual growth in the number of hospice patients nationwide averaged 13 percent. In 1995, approximately one out of every seven deaths (14.8%) in America were tended to by a hospice program (HFS, 1997). In 1994, over 300,000 persons chose hospice care in the U.S. This is more than twice as many as in 1985, and over 90 percent of hospice care is provided in the patients home (HH, 1997).

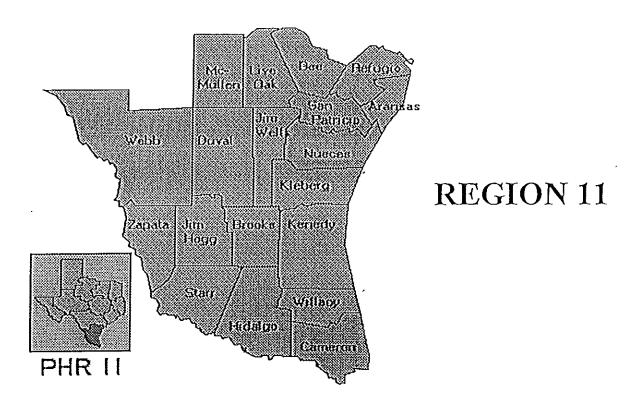
E. SUMMARY

Voluntary and community-based organizations as well as religious groups are helping to share the burden of caring for HIV/AIDS patients, particularly outside of hospitals. There is a segment of the U.S. population who must depend on the prison system while they are HIV positive or dying with AIDS. Texas, in 1993, was ranked third nationally with 1,212 HIV positive inmates. Hospice care may offer an alternative to the dying AIDS patient. There are 108 hospices in the state of Texas, with 18% of them located in Houston and Dallas. Currently, few AIDS patients appear to be using hospice care.

No matter what health facility is used by HIV/AIDS patients, health care personnel are a vital component. When comparing Texas supply/population ratios per AIDS patient to the United States ratios, Texas has fewer physicians, registered nurses, LPNs, pharmacists, psychologists, social workers, and health technicians than the U.S. Based on information and data presented here, it appears that the supply of health care services for HIV/AIDS patients in the state of Texas is not adequate to meet the growing need.

FIGURE II. 1 PUBLIC HEALTH REAGIONS IN TEXAS







1995 Projected Population => 1,536,480 Population

Population Rank Among Texas' 11 Regions => 5

Population per square mile => 72.2

Population Distribution by Age and Race/Ethnicity:

Age	Anglo	Black	Hispanic	Other	Percent
0 - 4 5- 14 15-24 25-34 35-44 45-54	17,848 38,010 36,092 39,064 47,790 38,671 32,341	1,564 3,100 4,046 4,917 3,651 1,684 1,179	141,724 218,893 235,549 173,147 153,482 103,581 67,341	812 1,638 2,101 1,752 2,128 1,620 832	10.5 % 17.0 % 18.1 % 14.2 % 13.5 % 9.5 % 6.6 %
65-74 75+	42,568 31,529	1,304 986	53,643 31,065	575 253	6.4 %
	323,913	22,431	1,178,425	11,711	100.0 %
Region State	21.1 % 57.7 %	1.5 % 11.5 %	76.6 % 28.2 %	0.8 % 2.6 %	

Source: Texas State Data Center. (1996). Projections of the Population of Texas and Counties in Texas by Age, Sex, and Race/Ethnicity for 1990-2030. Texas Agriculture Experiment Station, Texas A&M University System.

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Note: Hospital and nursing home data are for 1994) for 1994									-	-	2
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Source: Occupation data, U.S. Bureau of the Census, 1990 Equal	the Census, 1:	990 Equal En	nployment Op	portunity file:	Employment Opportunity file; hospital and nursing home data 1893 Applies Supervision	ing home data	1993 Annin	Our and and				
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TABLE II. 2

HEALTH PERSONNEL AND FACILITIES IN PUBLIC HEALTH REGION 11, TEXAS, AND U.S. (1990)

TYN A WILL BED COSINEY	ТҮРЕ	PHR 11	TEXAS	U.S.
HEALTH PERSONNEL	SERVICE	(number)	(number)	(number)
(Rates per 100,000)	SERVICE	(number)	(Humber)	(
Physicians	Direct	1,518	33,506	586,715
Physicians Rate	Direct	112	197	236
Dentists	Direct	402	9,016	155,529
	Datet	30	53	63
Rate	Direct	5,034	99,576	1,885,129
Registered Nurses	Direct	373	586	758
Rate	Direct	2,466	30,598	429,473
LPNs	Direct	183	180	173
Rate	Direct	85	1,653	25,569
Physician Assts.	Direct	6	10	10
Rate	Direct	402	9,016	155,529
Dentists	Direct	30	53	63
Rate	Tudinat	664	11,744	181,798
Pharmacists	Indirect	49	69	73
Rate		49	09	
SOCIAL SERVICES				
Psychologists Psychologists	Direct	313	8,979	191,962
Rate		23	53	77
Social Workers	Direct	2,567	31,305	658,919
Rate	Breet	190	184	265
Rate				
SUPPORT PERSONNEL				
Health technicians	Indirect	3,181	59,628	999,624
Rate		236	351	402
HEALTH FACILITIES				
Hospital beds,		4,230	58,521	902,000
staffed, community (1994)				
Rate		3.1	3.1	3.6
Nursing home beds (1994)		7,028	121,834	1,558,000
Rate		43.4	64.6	46.4
Clinics (1996)		50	438	NA
Rate		3.3	2.4	NA
Health Departments		6	65	NA
Source: Occupation data II S Bu			ment Opportunity	file: hospital

Source: Occupation data, U.S. Bureau of the Census, 1990 Equal Employment Opportunity file; hospital and nursing home data, 1993 Annual Survey of Hospitals, Bureau of State Health Data and Policy Analysis, Texas Department of Health, Occupancy Report for Nursing Facilities, 1993, Bureau of Long Term Care, Texas Department of Human Services; American Hospital Association, Hospital Statistics, 1995-96.

TABLE II. 3

COMPONENTS OF FIVE HOSPICE MODELS

Hospice Model	24 Hour Service	Pain Control	Volunteer Services	Pastoral Care	Inter- discipline team
Hospital based	100%	70%	100%	65%	50%
Scattered bed	100%	60%	30%	15%	70%
Home care	100%	15%	8%	0	30%
Free standing	100%	17%	30%	15%	100%
Community based	100%	10%	35%	30%	100%

Hospice Model	Coordinator	Bereavement	Family as Unit of Care	Administrator
Hospital based	100%	100%	100%	100%
Scattered bed	100%	100%	100%	0
Home care	100%	75%	100%	0
Free standing	100%	80%	100%	100%
Community based	100%	80%	100%	100%

Source: McDonnell, Alice. (1986). Quality Hospice Care: Administration, Organization, and Models. National Health Publishing.

TABLE II. 4

	DIRECT AND INDIRECT TEAM COMPONENTS				
Indirect Patient Care	Direct Patient Care				
Executive Director	Primary Physician				
R.N. Director Patient/Family Services	R.N.				
R.N. Patient Care Coordinator	L.V.N.				
Home Health Services Clinical Supervisor	Medical Social Worker				
Medical Director	Health Aide				
Director of Social Services	Physical Therapist Occupational Therapist				
Director of Volunteers	Psychologist				
Director of Bereavement	Nutritionist				
Director of Education	Speech Therapist				
Director of Evaluation	Clergy				
Parent Organization	Pharmacist				
Pharmacy	Home-maker				
	Volunteer				

Source: McDonnell, Alice. (1986). *Quality Hospice Care: Administration, Organization, and Models.* National Health Publishing.

TABLE II. 5

SUPPLY OF HOSPICE TEAM MEMBERS IN UNITED STATES (1993)

Team Member	Professionals Employed by Hospices
Physician	5,300
R.N.	45,400
L.V.N.	6,200
Medical Social Worker	33,800
Health Aide	21,100
Physical Therapist	1,700
Occupational Therapist	700
Health Educator	1,900
Nutritionist	1,600
Volunteer	15,200
Home-maker	2,900
110mo-maroi	2,500

Source:

McDonnell, Alice. (1986). Quality Hospice Care: Administration, Organization, and Models. National Health Publishing.

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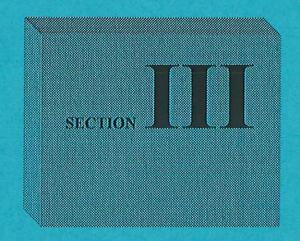
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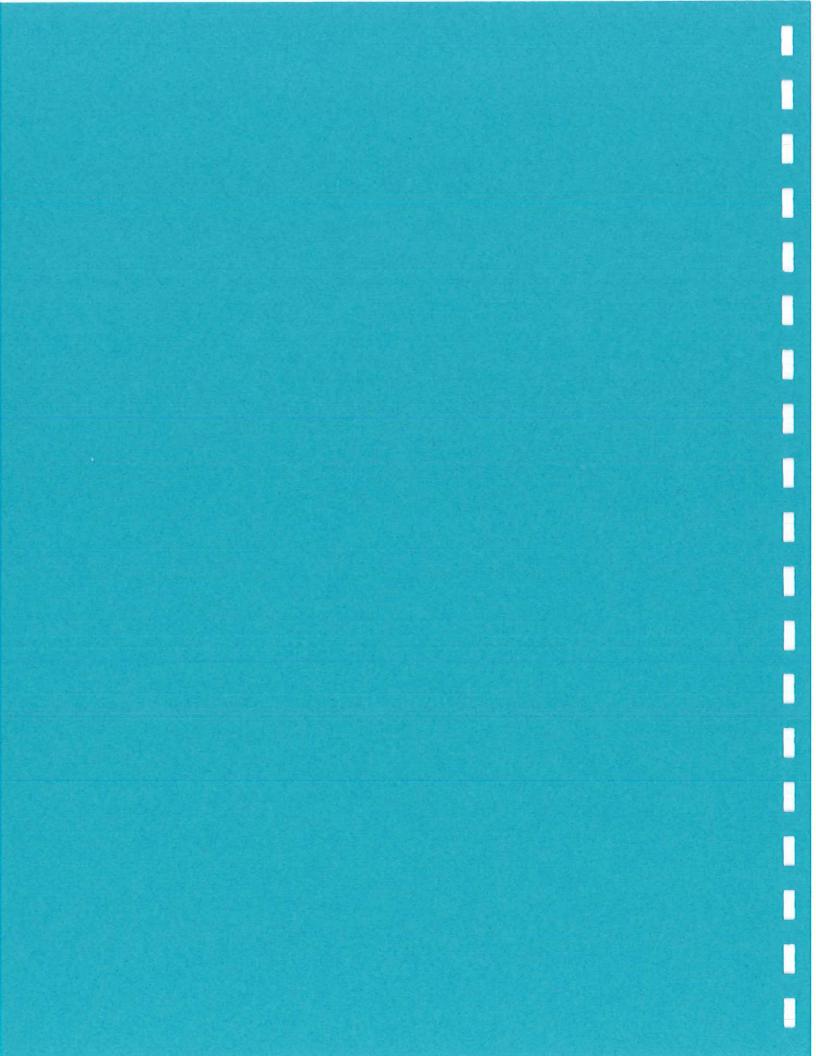
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HEALTH CARE TECHNOLOGY

- A. Introduction
- B. ELISA Test
- C. Home Collection HIV Test
- D. AZT
- E. Protease Inhibitors
- F. Summary



A. INTRODUCTION

The focus of this section is the technology used to diagnose and treat HIV/AIDS. An overview of the technology development and description of how the technology works is included. Special considerations and expected outcomes for the use of each diagnostic test or treatment are also provided. For the testing of HIV infection, both the ELISA test and home collection testing kits are discussed. Drugs included in the discussion are AZT and protease inhibitors. It is recognized that combination drug treatment regimens are used in the treatment of HIV/AIDS. However, AZT and protease inhibitors are discussed separately.

B. ELISA TEST

B.1. <u>Development</u>

Following Montagnier's discovery of HIV in 1983 (Schoub, 1994) and Gallo's demonstration in 1984 of the propagation of HIV in cell culture (Schoub, 1994), efforts began to develop a diagnostic test for AIDS. The first kits for antibody testing became available in April 1985 and later that year commercially provided HIV diagnostic tests were licensed by the FDA in the United States (Schoub, 1994). The initial routine HIV test is the Enzyme-Linked ImmunoSorbent Assay (ELISA) test, which is the most commonly used serological test in virology (Schoub, 1994).

B.2. How the ELISA Test Works

Schoub, in his Guide to Understanding the Virus and Its Consequences (1994), clearly explains the test process. In the ELISA test, the known specific antigen is stuck onto a plastic surface in a specially designed plastic plate or on spherical plastic beads. The patient's serum is then added, and if a specific antibody is present it will stick to the antigen. Another antibody, called an indicator antibody, which is produced in an animal and directed against the human immunoglobulin molecule (which the antibody comprises), is added. This latter antibody then detects whether the patient's antibody has adhered to the antigen stuck to the plastic plate or plastic bead. The indicator antibody has an enzyme attached to it (hence the term linked

immunoassay) which will convert a colorless material which is added to the system into a yellow or brown colored dye (refer to Figure III.1). Thus, a positive or negative reaction in the plastic plate or in the test tube housing the plastic bead can be read by the naked eye (Schoub, 1994). If the test result is negative, the individual may be reassured and generally no further testing is needed because of the high sensitivity of the ELISA test. A positive ELISA is usually referred to as being reactive rather than positive as no definitive positive diagnosis can be made on a single ELISA test. Following a reactive result, the test is then repeated using an ELISA from a different manufacturer. If it is repeatedly reactive, the specimen is then forwarded for a confirmatory test, usually the Western Blot. A positive Western Blot would be regarded as being diagnostic of HIV infection (Schoub, 1994).

B.3. Expected Outcomes

Cohen (1990) summarizes three of the benefits resulting from HIV testing. First, there is a benefit to the individual being tested. With early detection of the infection, the individual can begin needed treatment. Second, HIV testing can help with infection control. For example, public health policy-making decisions can be based on the epidemiological characterization of the disease. Third, there is the benefit of reducing exposure to other individuals. If individuals are aware of their HIV infection, they can be counseled about ways to minimize the risks of spreading HIV or being re-infected through sex and needle sharing.

B.4. Special Considerations

B.4.1 Providers

Testing for evidence of HIV infection should be accompanied by pre- and post-test counseling. Special expertise and training are required to counsel persons effectively. Because results of tests for HIV infection have profound consequences and raise many questions, individuals give informed consent for the testing procedure and understand the choices implied by the test results (Cohen, 1990).

B.4.2 Facilities

One of the major reasons why the ELISA has become so popular is that it lends itself to automation and bulk-handling of specimens. Thus, in high volume modern laboratories, for example in bloodbank screening, large numbers of specimens can be tested in short periods of time by automated equipment, often using robotics, to dilute serum, add reagents, incubate and read the colorimeter (Schoub, 1994).

B.4.3 Preparation

Because an infected individual does not develop antibodies immediately (in most HIV infections, antibodies appear within three to six months after infection), a negative result cannot

rule out more recent HIV infection. If recent exposure is suspected, the test must be repeated in six months (Cohen, 1990).

A positive HIV antibody test in a person without apparent risks or in a low-prevalence population should be followed by rigorous retesting of new serum specimens in a laboratory known for its quality control proficiency (Cohen, 1990).

B.5. Hazards

The risk that HIV test results will become known must be recognized by individuals who are considering being tested. Persons infected with HIV confront not only fear and pain from knowing they are infected, but also serious social, financial and emotional problems resulting from unfortunate social and institutional attitudes toward HIV infection. Eviction, job loss, the inability to buy or maintain health insurance, and abandonment by friends and loved ones are examples of some of the unfortunate consequences of being labeled as infected with the AIDS virus. These are not rare events, and they may occur whenever confidentiality is violated or whenever test results are requested by or released to employers, insurance companies, or others (Cohen, 1990).

C. HOME COLLECTION HIV TEST

C.1. <u>Development</u>

CONFIDE was the first home collection HIV tests to be approved by the Food and Drug Administration (FDA). The CONFIDE testing kit was produced and marketed by Direct Access Diagnostics, a subsidiary of Johnson & Johnson (Confide, 1997). On May 13, 1996, the FDA approved this HIV home test to be sold without a prescription (CNN Interactive, 1997). CONFIDE's FDA approval was followed by the approval of Home Access Health Corporation's test, HOME ACCESS, on July 22, 1996 (Home Access, 1997), which is no longer on the market.

C.2. How the Test Works

The home testing kits include everything needed to conduct a blood sample, meet mailing requirements and find out anonymously whether or not the sample shows an HIV infection.

CONFIDE (1997) explains the three step testing process as:

(1) Take a blood sample from a fingertip and apply it to a special Test Card that has a unique identification number. This number is used to get the test result.

- (2) Mail the Test Card to CONFIDE's laboratory where the sample is tested using the same accurate screening and methods as doctors and hospitals.
- (3) Call the CONFIDE Result Center's toll-free telephone number seven days later to receive the test result, counseling, and referrals to local sources of medical evaluation and support services.

With an HIV blood test, the laboratory tests for the presence of HIV antibodies (Confide, 1997). Blood samples are screened with the Enzyme-Linked ImmunoSorbent Assay (ELISA) test. If a sample tests positive, it is re-tested twice with ELISA. If either or both of these repeat tests is positive, the result is confirmed using either the Western Blot or Immunofluorescence Assay (IFA) tests. HIV test samples are tested in a licensed laboratory which operates in compliance with U.S. Food and Drug Administration guidelines and Clinical Laboratory Improvement Amendment of 1988 regulation (Confide, 1997). The test has three components: (1) an over-the-counter home blood collection, (2) HIV antibody testing at a certified laboratory, and (3) a test result center that provides the results and counseling (CNN Interactive, 1997).

C.3. Expected Outcomes

According to CONFIDE and HOME ACCESS, both HIV test kits use the same testing methodology as hospitals, blood banks and physicians. The HIV home collection tests provide an alternative choice for people who will not or cannot go to a doctor's office or clinic to be tested. In a 1992 National Health Interview Survey (Shelton, 1997), 8 percent of Americans said they expect to be tested for HIV within the year for reasons other than blood donation, insurance purposes or military service. One third of those interviewed said they would rather use a home collection kit than visit a physician or clinic.

The expected benefits of home collection tests include the anonymity and comfort of the consumer taking the test. Also, the availability of the tests may increase early testing and diagnosis of those at risk. It is hoped that those with a positive result will seek out the health services that they need as well as notify contacts about possible risk.

C.4. Special Considerations

C.4.1 Provider

Home testing is changing the role of health professionals in the HIV testing process. Because informed consent is required, HIV testing has always been consumer based. It is expected that consumers will make choices different from those that health professionals may recommend. It places the health professional in the role of assisting the consumer in making well-informed decisions using the best available evidence (CDC: HIV/AIDS Prevention Newsletter, 1996).

C.4.2 Patient

Confidentiality is a primary concern to many potential consumers interested in using the HIV home test (CDC: HIV/AIDS Prevention Newsletter, 1996). Both CONFIDE and HOME ACCESS have procedures in place to insure anonymity. CONFIDE's test card has a unique 14-digit personal identification number (Confide, 1997). For HOME ACCESS, the consumer calls and registers the anonymous HOME ACCESS code number and completes a pre-test counseling procedure (Home Access, 1997).

Pre-test and post-test counseling and referral services are made available to consumers of either CONFIDE or HOME ACCESS. The counselors are professionals with college degrees and additional extensive training in HIV/AIDS and related fields (Home Access, 1997; Confide, 1997).

C.5. Disadvantages

The home testing kit is more expensive than going to the local health department. Cost ranges from \$30 to \$50. See Table III.1 for comparison of prices. The consumer has some responsibility for confidentiality when purchasing the kit at a store or pharmacy, purchasing through the Internet or telephone with a credit card and mailing address, and disposing of the kit packaging.

D. AZT

D.1. Combination HIV Therapy

AZT is used in combination HIV therapy. Other drugs used in a triple drug regimen may include saquinavir and zalcitabine. Use of the combination treatment can reduce viral load and increase CD4 counts (Medical Sciences Bulletin, 1997).

D.2. Development

Zidovudine, formerly known as AZT or azidothymidine, is a drug active against the HIV virus. It is a natural nucleoside analog with a thymidine base attached to a ribose sugar (Schoub, 1994). The brand name for zidovudine is RETROVIR. Most of the research and development efforts for AZT took place from the early to late 1980s (O'Reilly, 1990). In the early 1980s, Janet Rideout, an organic chemist at Burroughs Wellcome had begun studying AZT and found it to be very effective against certain bacteria. Sam Broder, senior researcher at the National

Cancer Institute (NCI), requested Burroughs send him promising drugs for AIDS research. AZT was among the drugs submitted to NCI, and it was found to be by far the most effective against AIDS. The company obtained an exclusive patent on the drug and a supply of thymidine. NCI injected AZT into humans for the first time in 1985. In 1987, Burroughs Wellcome received government approval for AZT (O'Reilly, 1990).

D.3. How AZT Works

Zidovudine works by inhibiting the in vitro replication of retroviruses which include HIV (Schoub, 1994). The zidovudine triphosphate inhibits viral replication by interfering with the HIV viral RNA dependent DNA polymerase. It also inhibits cellular DNA polymerase. In vitro, the reverse transcriptase enzyme of the virus is tricked into incorporating zidovudine into growing chains of DNA, which results in the termination of the chain (Schoub, 1994). See Figures III.2 and III.3 for an illustration of the steps in early and late stages of HIV replication and the points where anti-HIV agents enter.

D.4. Expected Outcomes

Schoub (1994) explains several outcomes for using AZT. First, a reduction in the severity and frequency of opportunistic infections occur. Second, there is a delay in the progression of disease in asymptomatic HIV-infected patients. Third, patients experience an overall improvement in the quality of life. However, HIV rapidly becomes resistant to AZT.

D.5. Special Considerations

AZT is not a cure for AIDS. Patients may continue to develop illnesses, including opportunistic infections, associated with HIV during therapy. Patients, especially those in advanced stages of the disease, need to have their blood count followed closely while they are on the medication (Schoub, 1994).

Pregnant women should be advised that transmission of the virus to their child may still occur in spite of treatment. The long-term effects on in utero and infant exposure to AZT are not known. To avoid transmission of the virus to a child who is not yet infected, pregnant women who are HIV-infected should not breast feed (Schoub, 1994).

D.6. Hazards or Disadvantages

Toxicity is a hazard for the patient taking AZT (Schoub, 1994). There is a greater risk of toxicity for patients who started the treatment later in the course of their infection or who have more advanced disease. Toxicity may force the patient to discontinue therapy (Schoub, 1994).

Nausea, vomiting and diarrhea are common side effects to AZT (Schoub, 1994). Suppression of the bone marrow results from the drug inhibiting the replication of the cells of the

bloodstream which are located in the bone marrow (Schoub, 1994). Over half of the persons on long-term therapy will need blood transfusions to replenish their blood cells (Schoub, 1994).

E. PROTEASE INHIBITORS

E.1. <u>Development</u>

In November 1995, the Antiviral Drugs Advisory Committee of the FDA recommended approval for saquinavir, the first in a class of orally active anti-retroviral AIDS therapies, the protease inhibitors. Saquinavir was developed using computer-based drug modeling techniques and is a highly specific inhibitor of HIV-1 and HIV-2 protease with antiviral activity at concentrations 1000-fold lower than those causing cytotoxicity (Markowitz, 1997). In vitro studies indicated its activity was synergistic or additive to that of zidovudine (AZT) because it acts at a different point in the cell. INVIRASE, the trade name for saquinavir, was approved by the FDA on December 7, 1995 (Hoffman-LaRoche, 1997).

E.2. How Protease Inhibitors Work

Certain protease inhibitors can reduce the amount of virus in a person infected with HIV by as much as 99 percent (Markowitz, 1997). *Cycles of HIV Production* (1997) illustrates how new copies of HIV are made inside infected cells (refer to Figure III.4). HIV depends on several enzymes that it brings into the cell or makes inside the cell. All of these enzymes have specific jobs in the HIV replication process. Protease is one of HIV's enzymes, and it is required to continue the process of HIV infection. Its job comes near the end of the HIV replication process. By then, HIV has already entered the cell's nucleus and has made long chains of proteins and enzymes that will form many new copies of HIV. The HIV protease enzyme is like a "chemical scissors" because it cuts the long chain into shorter pieces.

Protease inhibitors are drugs that resemble pieces of the protein chain that protease normally cuts. HIV protease inhibitors prevent protease from cutting long chains of proteins and enzymes into the shorter pieces that HIV needs to make new copies of itself. New copies of HIV are still made and still push through the wall of the infected cell even if the long chains are not cut into the correct smaller pieces. But these new copies of HIV are not completely formed, so they cannot go on to infect other cells. Protease inhibitors can greatly reduce the number of new infectious copies of HIV made inside the cells. Figure III.4 presents a graphical representation of

the point at which the replication of HIV virus protease inhibitors interfere. Table III.2 depicts disease status of the patient and recommended implementation of protease inhibitor therapy.

E.3. Expected Outcomes

Early clinical studies completed in Europe and the U.S. showed that INVIRASE is well tolerated in combination with zalcitabine and AZT, and revealed improvements in the number of circulating CD4 lymphocytes and reduction of viral load (Hoffman-LaRoche, 1997). Over 16 weeks of treatment during trial tests, CD4 counts increased on average 30 to 40 cells above entry levels in patients on saquinavir in combination with zilcitabine or AZT, or with AZT plus zilcitabine (Hoffman-LaRoche). A comparison of currently available protease inhibitors and their recommended dosages is made in Table III.3.

E.4. Special Considerations

With the development of new drugs to combat HIV and AIDS coming at such a fast pace, the authority no longer lies with the physician but rather with the pharmacist. Physicians are having an increasingly difficult time keeping up with studies being conducted on various drug therapies and often seek consultations with local pharmacists and/or HIV/AIDS counselors in the area.

E.5 Hazards

The hazards of primary concern center around the patient. In clinical studies of male patients, INVIRASE was well tolerated by most and reported adverse events were mostly of mild intensity (Medical Sciences Bulletin, 1997). Most frequently reported adverse events include diarrhea (3.8 percent), abdominal discomfort (1.3 percent) and nausea (1.9 percent) (Medical Sciences Bulletin). The effects on females with HIV/AIDS need to be investigated further.

F. SUMMARY

HIV testing procedures and drug treatments are important technologies for meeting the health care needs of people with HIV/AIDS. The four technologies discussed include (1) ELISA test, (2) home collection HIV tests, (3) AZT and (4) protease inhibitors. Information about technology development and descriptions of how the technologies work are provided for each. In addition, special considerations and expected outcomes are included for each technology.

The ELISA test is the most frequently used test for diagnosing possible HIV exposure.

No definitive positive diagnosis can be made based on a single ELISA test. If the ELISA repeatedly gives reactive results, the specimen is then forwarded for a confirmatory test such as

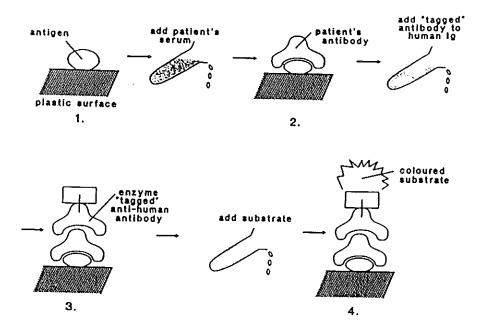
the Western Blot. A positive Western Blot would be regarded as being diagnostic of HIV infection.

Home collection HIV tests are providing an alternative to testing in a traditional clinic setting. CONFIDE is a testing kit approved by the FDA and available without a prescription. Blood samples collected in these tests are screened with the ELISA and Western Blot tests. The tests are conducted in licensed laboratory which operate in compliance with FDA guidelines.

Antiviral therapy directed against HIV is usually done in combination treatment regimens. AZT and protease inhibitors are part of that regimen. Use of the combination treatment can reduce viral load and increase CD4 counts. AZT works by inhibiting the in vitro replication of retroviruses, which include HIV. Certain protease inhibitors can reduce the amount of virus in a person infected with HIV by as much as 99 percent.

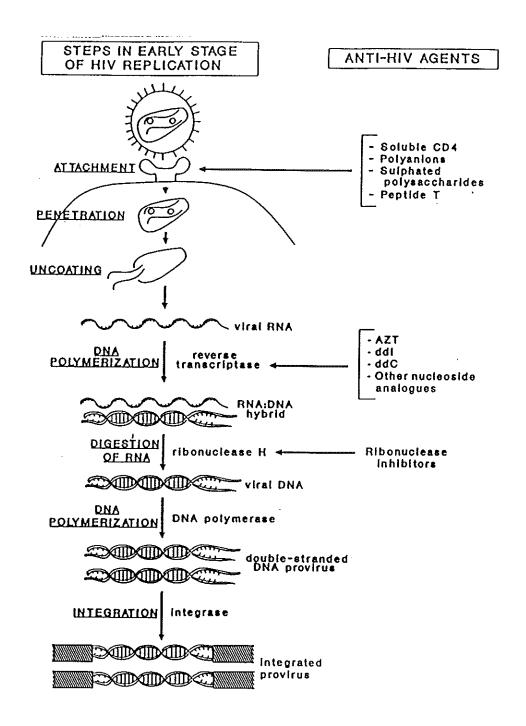
Figure III. 1

Design of ELISA Test to Detect a Specific Antibody in Patient's Serum



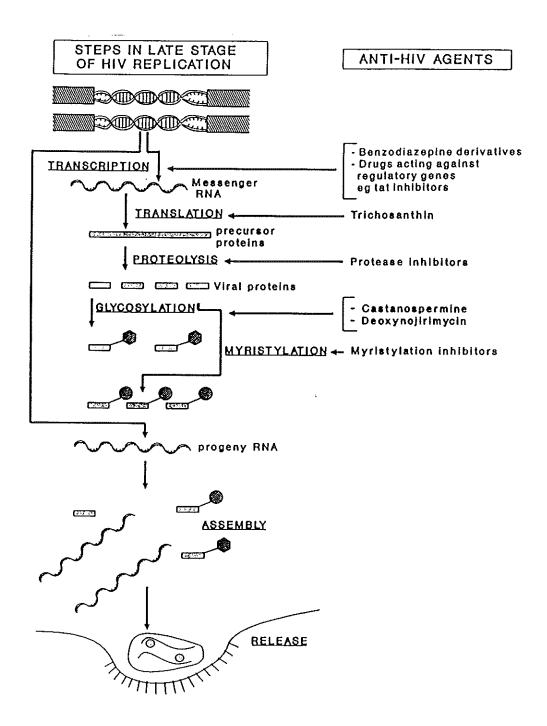
Source: Schoub, B.D. (1994). AIDS & HIV in Perspective: A Guide to Understanding the Virus and its Consequences. Cambridge: Cambridge University Press. P.132.

Figure III. 2

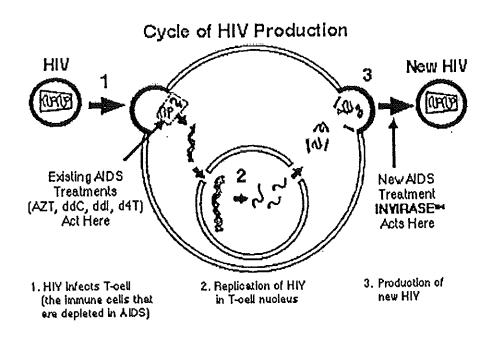


Source: Schoub, B.D. (1994). AIDS & HIV in Perspective: A Guide to Understanding the Virus and its Consequences. Cambridge: Cambridge University Press. P.164.

Figure III. 3



Source: Schoub, B.D. (1994). AIDS & HIV in Perspective: A Guide to Understanding the Virus and its Consequences. Cambridge: Cambridge University Press. P.166.



Source: Pharmaceutical Information Network. Cycles of HIV Production. (May 1997). http://pharminfo.com/images/HIV_cyc.gif

Table III. 1

Price Comparison of HIV Testing Options

TYPE OF TEST	LOCATION	COST*	RESULTS
CONFIDE Home Collection Kit	Clinics	\$30 - \$35	7 days
	Pharmacies	\$40	
	Direct Mail	\$49	
HIV Test in Provider Setting	Brazos County Health Dept.	\$0 - \$12	14 days
	AIDS Services of Brazos Valley	FREE	14 days
	Private Physician's Office	ELISA \$40 Western Blot \$120	14 days

^{*} Cost is approximate retail, April, 1997; Brazos County, TX.

Table III. 2

Recommended Therapy

Status	Recommendation*
Symptomatic HIV disease (includes symptoms such as recurrent mucosal candidiasis, oral hairy leukoplakia, and chronic and unexplained fever, night sweats, and weight loss).	Therapy recommended for all patients.
Asymptomatic CD4+ cell count <0.500 x 10 ⁹ /L. **	Therapy recommended. Some doctors would defer therapy in a subset of patients with stable CD4+ cell counts between 0.350 and 0.500 X 10 ⁹ /L and plasma HIV RNA levels consistently below 5,000-10,000 copies/mL.
Asymptomatic, CD4+ cell count <0.500 x 10 ⁹ /L. **	Therapy recommended for patients with 30,000-50,000 HIV RNA copies/mL or rapidly declining CD4+ cell counts.
	Therapy should be considered for patients with >5,000-10,000 HIV RNA copies/mL.

^{*} Source: HIV/AIDS Treatment Information Service. Questions and Answers About Protease Inhibitors. (May 1997). http://www.hivatis.org/atisqa.htm

^{**} As of September 1997, treatment is recommended to begin as soon as the person tests positive. (CDC, *Treatment Recommendation*. (September 1997).

Table III. 3

	Invirase(tm) Roche saquinavir	Norvir(tm) Abbott ritonavir	Crixivan® Merck indinavir
Dosage	600mg tid	600mg bid	800mg q8h
Dosage Strength/ Dosage Form	200mg capsule	100mg capsule 600mg/7.5ml oral solution	200mg capsule 400mg capsule
Number of Capsules per Full Dose	3 capsules (9/day full dose)	6 capsules (12/day full dose)	2 (400mg) capsules (6/day full dose)
Volume per Full Dose	n/a	7.5ml (15ml/day full dose)	n/a
Relation to Food	Take on a full stomach, within 2 hours of a high calorie, high fat meal if possible. (e.g., 48 g protein, 60 g carbohydrate, 57g fat; 1006 kcal) (Administration of saquinavir on an empty stomach dramatically reduces the drug's absorption.)	Take with food if possible. The taste of the oral solution may be improved by mixing with chocolate milk, Ensure or Advera. If the solution is mixed to improve the taste, it must be taken within 1 hour of mixing.	Take on an empty stomach with water 1 hour before or 2 hours after a meal. May be administered with other liquids such as skim milk, juice, coffee, or tea or with a light meal. (Ingestion of Crixivan with a meal high in calories, fat, and protein reduces the drug's absorption.) At least 1.5 liters of liquids should be taken during the course of 24 hours to ensure adequate hydration and minimize potential side effect of nephrolithiasis.

Source: *Protease Inhibitors & You.* (May 1997). http://www.hivatis.org/protease/protintr.htrr

Table III. 3 (continued)

11	· · · · · · · · · · · · · · · · · · ·	7	
Dosage Initiation/ Adjustments (Also see drug interactions)	In combination therapy, dose adjustment of the nucleoside analogue should be based on the drug's toxicity profile. Lower doses of saquinavir are not recommended due to poor bioavailability.	Dose escalation may provide relief of nausea when initiating therapy.(1) Begin at no less than 300 mg bid and increase by 100 mg bid increments up to 600 mg bid.	Reduce the dose to 600mg q 8 h in mild-to-moderate hepatic insufficiency due to cirrhosis. Patients who experience nephrolithiasis may interrupt or discontinue therapy (e.g., 1-3 days) during the acute episode.
Storage Requirements	Room Temperature Tightly Closed Bottle	Store capsules in the refrigerator at all times and protect from light. Store oral solution in the refrigerator until dispensed. Refrigeration by the patient of the oral solution is recommended but not required if used within 30 days. Store in original container. Avoid exposure to excessive heat.	Room Temperature Tightly Closed Bottle. Capsules are sensitive to moisture and should be dispensed and stored in the original container. The desiccant should remain in the original bottle.
Combination or Monotherapy	Combination Use Only	Combination and Monotherapy Use	Combination and Monotherapy Use
Route of Metabolism	Cytochrome P450, specifically CYP3A4 isoenzyme. Undergoes extensive first-pass metabolism.	Cytochrome P450 3A (CYP3A)	Cytochrome P-450 3A4 (CYP344)

Table III. 3 (continued)

Adverse Effects (Most frequently reported- check with your physician for complete information)	diarrhea, abdominal discomfort and nausea	asthenia, diarrhea, nausea, vomiting, circumoral paresthesia, taste perversion, peripheral paresthesia	nephrolithiasis, asymptomatic hyperbilirubinemia, nausea, abdominal pain
FDA Status (as of 6/96)	Accelerated Approval	Accelerated and Traditional Approval(2)	Accelerated Approval

Source: *Protease Inhibitors & You.* (May 1997). http://www.hivatis.org/protease/protintr.htrr

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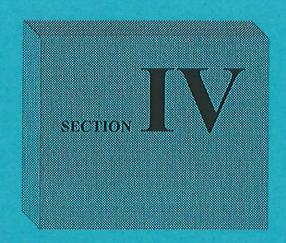
Pharmaceutical Information Network. Cycles of HIV Production. (May 1997). http://pharminfo.com/images/HIV_cyc.gif

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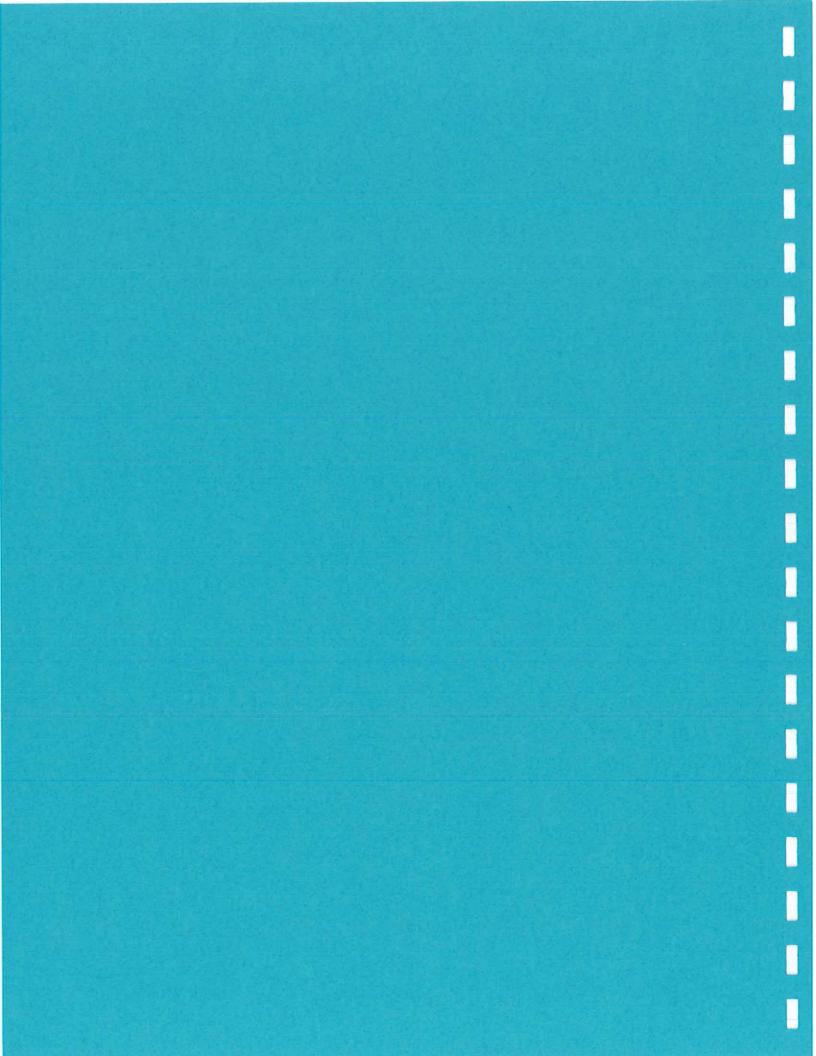
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HEALTH CARE FINANCING AND COST

- A. Introduction
- B. Financing HIV/AIDS Services in the U.S.
- C. Cost to the Patient
- D. Technology's Cost-Effectiveness
- E. Summary



A. INTRODUCTION

Financing and cost factors of HIV/AIDS in the United States will be reviewed in this section. Questions addressed include: (1) What does it cost to provide health care for an HIV/AIDS patient and who are the sources for financing that care? (2) What costs are incurred by the patient? and (3) What is the cost-effectiveness of technology?

B. FINANCING HIV/AIDS HEALTH SERVICES IN THE U.S.

B.1. Lifetime Cost

In addition to its toll on human lives, the AIDS epidemic carries a heavy price tag. The estimated lifetime cost of treating one person with HIV from time of infection until death is approximately \$119,000 (Fast Facts, 1997). According to the St. Anthony DRG Handbook (1996), the 1995 hospital expenses for one episode of care for an HIV/AIDS patient with pneumonia (a major complication) is \$7,142. Patients in the chronic phase experience financial, psychological and social costs.

B.2. Sources of Financing

There are a variety of sources for financing HIV/AIDS care. Federal expenditures on HIV-related activities are estimated to represent only about 35 to 40 percent of total HIV-related expenditures (National Center for Health Statistics (NCHS, 1995). In 1994, federal spending for HIV/AIDS was \$6,350 million (NCHS, 1995). Federal agencies such as Public Health Services, Social Security Administration, Veterans Affairs and the Administration of Medicaid and Medicare programs used this federal spending for research, education and prevention, medical care, and cash assistance during 1994 (NCHS, 1995). The activity responsible for the largest amount of federal spending for HIV/AIDS was medical care at \$2,527 million. Approximately half that amount was spent on research, \$1,361 million; followed by cash assistance at \$866 million; then education and prevention at \$576 million (NCHS, 1995) (refer to Table IV.1). As listed in Table IV.2, the 1994 annual expenditures for HIV/AIDS according to various sources included \$5,400 million from the Department of Health and Human Services to \$4 million from the Indian Health Service (NCHS, 1995). Other financial sources included coverage by private

health insurance, out-of-pocket costs to patients, and individual state's share of Medicaid, public hospitals and other local expenditures (NCHS, 1995).

The federal government's share of Medicaid spending for HIV related activities in 1994 was \$1,490 million (Health Care Financing Administration (HCFA), 1997). That is only 1.12% of Medicaid's budget. Considering a rate of 202 per 100,000 United States residents infected with AIDS and the cost of health care for those infected with HIV/AIDS, this allocation of funds for HIV/AIDS related activities seems too low to meet the health care needs.

B.3. Drug Reimbursement Program

One federal development has been the creation of the Public Health Service's AIDS Drug Reimbursement Program, a pool of money earmarked for assisting patients who are neither insured nor affluent enough to pay for expensive HIV/related drugs (Jonsen, 1993). This fund, initiated soon after the licensing of the drug AZT, was created from funds already earmarked for AIDS research and care in agencies of the Public Health Services (Jonsen, 1993).

B.4. HIV/AIDS Spending Compared to Other Diseases

Comparisons can be made between federal spending on HIV/AIDS, heart disease, cancer and end-stage renal disease. Calculations based on 1989 federal spending for HIV/AIDS was \$1.31 billion while the infection was responsible for 34,388 deaths (Schoub, 1994). Federal spending during the same time period was \$1.01 billion for heart disease which caused 777,626 deaths, and \$1.54 billion was spent on cancer which caused 494,422 deaths (Schoub, 1994). A 1994 per capita comparison of Medicare expenditures for persons with HIV/AIDS and end-stage renal disease (ESRD) indicated \$3,526 spent on HIV/AIDS and \$12,844 on ESRD (Medicare and Medicaid Statistical Supplement, 1996).

C. COST TO THE PATIENT

C.1. Cost to the Patient for Diagnosis

C.1.1 Medical Costs

Diagnosis of HIV/AIDS requires the consumer or patient take a blood test, either in a clinic setting or at home. The actual charge of the HIV test ranges from no charge to about \$120. A price comparison of HIV testing options is shown in Table IV.3. Free testing may be done by local health departments such as the Brazos County Health Department, or by non-profit agencies such as AIDS Services of Brazos Valley. The higher range charges are for testing kits purchased

directly by the consumer. Costs beyond the actual test charge include transportation costs to testing and counseling appointments. In the case of direct mail purchases, the expense of postage and handling are extra.

C.1.2 Opportunity Costs

There is the cost of time involved for HIV testing. Loss of time at work may be needed to take the test and this results in income loss. The psychological cost should not be overlooked. Stress and fear of being HIV positive are psychological factors that people face during the diagnosis phase of HIV which includes a 3 to 14 day waiting period for test results.

C.2. Cost to the Patient During the Chronic Phase

C.2.1 Financial Costs

Unemployment results in a financial loss for HIV/AIDS patients. In 1991, about 51 percent of asymptomatic persons, 58 percent of HIV-symptomatic persons, and 83 percent of persons with AIDS were unemployed (Mohr, 1994).

In a report from the Fifth European Conference on Clinical Aspects and Treatment of HIV Infection, it is suggested that the ideal antiretroviral treatment should start when the presence of HIV is detected, and a combination of drugs should be used (Churchill, 1996). It is believed that it may be easier to suppress the virus with powerful drugs at this stage rather than later in the infection (Churchill, 1996). Combination drug therapies can quickly become a financial burden. Usually, the therapy consists of three drugs and may include saquinavir, zalcitabine and AZT (Churchill, 1996). A year's supply of AZT could cost from \$2,800 to \$3,300 and saquinavir costs over \$5,000 a year (based on prices obtained from pharmacies in the Bryan/College Station area (May 1997) and drug dosage as recommended in the 1996 edition of the Physicians Desk Reference).

C.2.2 Psychological and Social Costs

Persons with HIV/AIDS go through phases of psychosocial adjustment similar to those experienced by persons who are dying (Ostrow, 1984) and include: (1) initial crisis when the individual first learns of the HIV-related diagnosis, (2) transition phase where the emotional states range from self-devaluation, fear, depression, helplessness, escapism, and anger, (3) acceptance of the disease and (4) preparation for death. The caregivers of AIDS patients suffer from stigmatization, mental conflict, life disruption, alienation, and physical and mental exhaustion (Maloney, 1988). Because of the stigma associated with AIDS, persons with the disease may experience a great deal of social isolation. These costs cannot be measured in dollars, but they do represent a high price.

C.3. Cost to the Patient During the Terminal Phase

C.3.1 Financial Cost

Specific medications will vary for each individual but may cost tens of thousands of dollars annually. This figure would remain approximately true during the terminal stage because those patients would still be prescribed the protease inhibitor in combination with other drugs (Hoffman-LaRoche, 1997).

Opportunistic infections, such as pneumonia, can result in major financial expenses. For instance in 1995, one episode of care for an HIV/AIDS patient with pneumonia was \$7,142 (St. Anthony DRG Handbook, 1996). This is in addition to the home care or hospice care that becomes essential for someone in the terminal stage of AIDS. According to Hospice Austin (1997), comprehensive hospice coverage is available through Medicare, Medicaid, and most insurance providers. Private pay is offered on a sliding scale, and Hospice Austin accepts patients regardless of their ability to pay for services.

C.3.2 Psychological and Social Costs

Family members of the dying patient commonly suffer a variety of mental, emotional, and social constraints as a result of the disease. While the patient requires constant care, the family is in need of support both emotionally and financially, especially if the patient had provided the primary source of income (Maloney, 1988).

D. TECHNOLOGY'S COST-EFFECTIVENESS

D.1. Blood Screening

D.1.1 ELISA Test

Donor blood samples are screened with the Enzyme-Linked ImmunoSorbent Assay (ELISA) test. An individual suspecting exposure to HIV/AIDS is also screened using the ELISA test. If his/her test is positive, it is re-tested twice with ELISA. If either or both of these repeat tests is positive, the result is confirmed using either the Western Blot or ImmunoFluorenscence Assay (IFA) test. The cost of HIV testing in a clinic setting ranges from no charge to \$120 for the patient (refer to Table IV.3). HIV test samples are tested in a licensed laboratory which operates in compliance with U.S. Food and Drug Administration guidelines and Clinical Laboratory Improvement Amendment of 1988 regulations (Confide, 1997).

D.1.2 HIV Home Testing Kits

Home testing kits for HIV do not replace the traditional HIV test available from health care providers. It is a viable option for achieving a widespread screening test. The cost, \$30 to \$50, for a kit is higher than the cost of HIV testing in a clinic setting (refer to Table IV.3). Compared to other home tests available such as the cholesterol test, pregnancy test and others that are available without a prescription, the HIV home collection kits are considerably more expensive. For example, an HIV home collection kit is 278% more expensive than a cholesterol test (refer to Table IV.4).

D.1.3 Public Benefits of HIV Testing

The public benefits of widespread testing for HIV infection include epidemiology monitoring of the epidemic. In other words, information obtained from individuals tested for HIV can be used to help design prevention and treatment strategies (Cohen, 1990). HIV screening of blood and organ donors helps ensure safety of blood products, and testing of the blood supply has reduced the risk of transfusion-associated HIV infection to a very low level (Cohen, 1990).

D.2. AZT (RETROVIR)

RETROVIR can be bought in bottles of 100 in two strengths, 100 mg and 300 mg. In the Bryan/College Station area, the 100-mg capsules cost about \$1.50 per pill and the 300-mg capsules about \$4.55 each. The recommended dosage is 6 capsules a day for adults with symptomatic infections and 5 capsules a day for asymptomatic adults (Physicians Desk Reference, 1996). The annual cost for the drug runs from about \$2,800 to \$3,300, depending on strength and dosage of the medication.

AZT is not a cure for AIDS. There are several hazards associated with using the drug. These include toxicity, suppression of the bone marrow, muscle myopathy, nausea, vomiting, and diarrhea (Schoub, 1994). AZT is only effective up to a certain point. After taking the drug for a certain length of time, its effectiveness ceases and may even produce symptoms similar to those produced by the virus. It works best in combination with other drugs (Schoub, 1994).

D.3. Protease Inhibitors

The manufacturing cost of the individual protease inhibitors vary, but LaRoche Laboratories, which produces and markets INVIRASE, estimates a daily dose of 600 mg taken three times a day costing the patient approximately \$15.89 per day (Hoffman-LaRoche, 1997). According to Bryan/College Station, Texas pharmacies, a unit of this medication is defined as the amount required for 30 days. In the case of INVIRASE this factors out to 270 pills (3 pills taken 3 times a day) at a cost to the patient of \$476.70 per month. Table IV.5 compares the costs a

HIV/AIDS patient on INVIRASE would encounter in the Bryan/College Station area pharmacies.

The protease inhibitors in conjunction with AZT have proven to be remarkable at restoring the patient's T₄ cells. However, it is too soon to determine if the combination treatment regimen is capable of eliminating the virus from the body or if the HIV has simply mutated itself into yet another undetectable form (Hoffman-LaRoche, 1997). Common hazards a patient would encounter as a result of INVIRASE include diarrhea, abdominal discomfort and nausea (Hoffman-LaRoche, 1997).

E. SUMMARY

The cost factors of HIV/AIDS health care in the United States can reach staggering amounts. The estimated lifetime cost of treating one person with HIV from time of infection until death is approximately \$119,000. Hospital expenses associated with one episode of care for an HIV/AIDS patient with pneumonia is over \$7,000. A variety of sources provide the needed financing for HIV/AIDS care. About 35 to 40 percent of the total HIV-related expenditures come from federal agencies. In 1994, federal spending for HIV/AIDS was \$6,350 million. Other financial sources include private health insurance, out-of-pocked costs to patients, and individual state's share of Medicaid, public hospitals and other local expenditures.

HIV/AIDS patients experience psychological and social costs during the diagnosis, chronic and terminal phases of the disease. Persons with HIV/AIDS go through phases of psychosocial adjustment including the initial crisis, transition phase, acceptance of the disease, and preparation of death. Because of the stigma associated with AIDS, persons with the disease may experience a great deal of social isolation.

The cost of antiretroviral drug therapy can result in large financial costs. Combination drug therapies usually consists of three drugs, and a one-year supply of each of these drugs will cost over \$3,000. Treatments with these powerful and expensive drugs should start when the presence of HIV is detected and continue through the chronic and terminal phases of the disease.

No drug is a cure for AIDS, and there are several hazards associated with using the drugs. These include toxicity, suppression of the bone marrow, muscle myopathy, nausea, vomiting, and diarrhea. Drugs such as AZT are only effective for a certain length of time. Then, its effectiveness ceases and may even produce symptoms similar to those produced by the virus.

Table IV. 1
Federal Spending for HIV/AIDS, 1994
(dollar amount in millions)

RESEARCH	\$1,361
Public Health Service	1,284
Department of Veterans Affairs	7
Department of Defense	70
EDUCATION AND PREVENTION	\$576
Public Health Service	395
Department of Veterans Affairs	31
Department of Defense	27
Agency for International Development	117
Other	3
MEDICAL CARE	\$2,527
Medicaid	1,290
Medicare	385
Public Health Service	397
Department of Veterans Affairs	287
Department of Defense	62
Office of Personnel Management	98
Other	8
CASH ASSISTANCE	\$866
Social Security Administration:	
Disability Insurance	505
Supplemental Security Income	165
HUD	196

Source: National Center for Health Statistics (1995). *Health, United States, 1994.* Hyattsville, Maryland: Public Health Service. P.239.

Table IV. 2

Annual Expenditures for HIV/AIDS by Agencies, 1993 and 1994)

(dollar amount in millions)

AGENCY	1993	1994
Department of Health and Human Services	\$4,426	\$5,400
Public Health Service Total	2,078	2,572
National Institute of Health	1,073	1,301
Centers for Disease Control and Prevention	498	543
Federal Drug Administration	73	72
Health Resources and Services	390	608
Agency for Health Care Policy and Research	10	11
Office of Assistant Secretary for Health	5	5
Indian Health Service	3	4
Health Care Financing	1,675	1,990
Social Security Administration	670	835
Department of Veterans Affairs	325	331
Department of Defense	159	129
Agency for International Development	117	117
HUD	196	253
Office of Personnel Management	98	108
Total Federal Spending	5,332	6,350

Source: National Center for Health Statistics. (1995). *Health, United States, 1994*. Hyattsville, Maryland: Public Health Service. P.239.

Table IV. 3

Price Comparison of HIV Testing Options

TYPE OF TEST	LOCATION	COST*	RESULTS
CONFIDE Home Collection Kit	Clinics	\$30 - \$35	7 days
	Pharmacies	\$40	
	Direct Mail	\$49	
HIV Test in Provider Setting	Brazos County Health Dept.	\$0 - \$12	14 days
	AIDS Services of Brazos Valley	FREE	14 days
	Private Physician's Office	ELISA \$40 Western Blot \$120	14 days

^{*} Cost is approximate retail, April, 1997; Brazos County, TX.

Table IV. 4
Home Test Comparisons

COST*	
\$39.00	<u></u>
\$17.00	
\$27.50	
\$14.00	
\$12.00	
	\$39.00 \$17.00 \$27.50 \$14.00

^{*} Cost is approximate retail, April, 1997; Brazos County, TX.

Table IV. 5

Cost of INVIRASE in Bryan/College Station, Texas

Location	Cost Per Day*	Cost Per Month**	Cost Per Year
Hoffman-LaRoche (wholesale)	\$15.89	\$476.70	\$5,720.40
Eckerd Drugs	\$19.07	\$572.09	\$6,865.08
Randall's	\$18.32	\$549.58	\$6,594.97
Walmart	\$18.99	\$569.72	\$6,836.64

Source: Hoffman-LaRoche. *Invirase Press Release #4.* (May 1997). http://pharminfo.com/drugpr/inverase_pr4.httr

> Eckerd Drugs. College Station, TX. Randall's Supermarket. College Station, TX. Wal-Mart Superstore. Bryan, TX

^{*}Cost per day is based on the recommended dosage of three 200mg capsules 3 times per day.

^{**}Monthly costs are based on 270 capsules consumed within a 30-day period.

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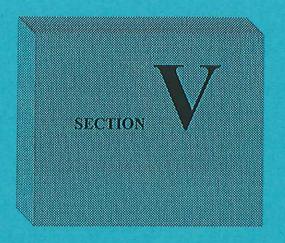
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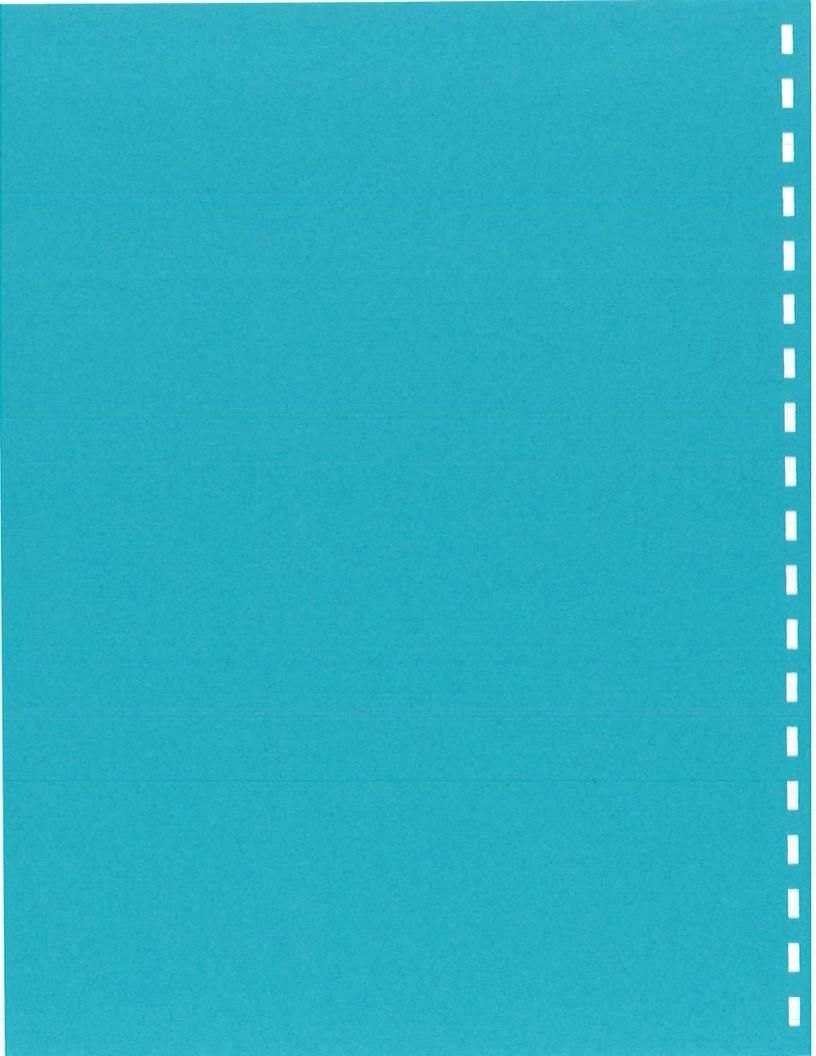
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