

Chapter 2

A Historical Overview of the Epidemiology of HIV/AIDS in the United States

Jamal Jones and Laura Salazar

2.1 Introduction

What began as an unknown, debilitating disease with a certain death sentence, has evolved. HIV infection can be prevented, but if infection does occur, due to the effectiveness and availability of over 20 antiretroviral drugs HIV is now viewed as a manageable, chronic illness. Much information on HIV treatment and prevention is available and accessible on the web and through various texts and other resources; however, 30 years into the epidemic, how and when the disease first surfaced may have been forgotten or, its origin may not be known, especially to those generations born after 1980. What first began as an anomalous infection afflicting a small subpopulation within the United States has progressed to a disease that affects nearly 1.2 million Americans today (CDC 2014a). This chapter provides an historical overview of the epidemiology of HIV/AIDS in the United States so that its history won't be forgotten, and for those new to the study of HIV/AIDS, they will become familiar with how the epidemic unfolded and mutated much like the virus. Each of the following sections will discuss key developments related to the epidemic such as the emergence of HIV testing and antiretroviral therapy, and how HIV/AIDS evolved from a disease designated to the gay community to one in which multiple populations face heightened risk for HIV infection. There may be some overlap between sections, as many of the developments in HIV surveillance, treatment, and prevention occurred concurrently; however, each section is discussed separately and in the context of the epidemic during certain points in time. The goal

J. Jones (✉) · L. Salazar
School of Public Health, Georgia State University, Atlanta, USA
e-mail: jjones158@student.gsu.edu

L. Salazar
e-mail: lsalazar1@gsu.edu

of this chapter is to provide the reader with a comprehensive overview so they may understand the reasons behind certain actions taken during the epidemic and learn from the missteps and achievements that occurred during its early stages.

2.2 Origin of the HIV Epidemic in the United States

The June 5, 1981 edition of Morbidity and Mortality Weekly Report (MMWR), which is published by the Centers for Disease Control and Prevention (CDC), described five cases of *Pneumocystis carinii* pneumonia (PCP), a rare lung infection that causes inflammation and fluid buildup in the lungs (CDC 1981a). Although contracting PCP is rare, its etiological cause is a very common fungus called *Pneumocystis jiroveci* that is spread through the air. Most people are exposed to it by age 3 or 4 without issue. However, in 1981, the treatment for PCP was a drug called pentamidine isethionate, which was not licensed in the United States. Physicians had to request the drug from the Parasitic Disease Drug Service, housed within the Parasitic Diseases Division of CDC's Center for Infectious Diseases. CDC staff noticed a substantial increase in requests for the drug to treat patients with PCP with no known cause of immune deficiency (Curran and Jaffe 2011).

The five cases were described as, drug-using, sexually-active homosexual men living in Los Angeles, California (CDC 1981a). The men described in these cases were previously healthy, had not known each other, nor did they have any known common contacts. It was documented that the occurrence of PCP among five previously healthy individuals was unusual because the illness almost exclusively affected immunosuppressed individuals and there was no clinically apparent underlying immunodeficiency in these cases. By the time the report was published, two of the five men had died. An editorial note in the MMWR report suggested that some characteristic of "homosexuality" may have been involved in the occurrence of PCP among these individuals. Following the initial MMWR report, a second MMWR report released 1 month later on July 3, 1981 described the occurrence of other life-threatening opportunistic infections (OIs) and a rare malignancy, Kaposi's Sarcoma (KS), in 26 homosexual men who had been treated during the previous 30 months in New York and Los Angeles (CDC 1981b). KS is a rare and aggressive cancer that in the United States primarily affected older men. Following the CDC's announcement, *The New York Times* reported that 41 homosexual men had been diagnosed with KS, eight of them dying less than 24 months after receiving the diagnosis (Altman 1981). These first reports in 1981 marked the beginning of what would later be known as the HIV/AIDS epidemic in the United States.

To respond to the growing concern of documented cases of PCP and KS among previously healthy homosexual males, the same year, the CDC under the leadership of its Director, Dr. William Foege, formed a Task Force directed by Dr. James Curran (Fig. 2.1) and consisted of CDC Epidemic Intelligence Service (EIS) officers and staff to begin surveillance and conduct epidemiologic



Fig. 2.1 James W. Curran, M.D., M.P.H., formerly, the Centers for Disease Control's Director of the Acquired Immunodeficiency Syndrome (AIDS) Activity Task Force, in the Division of HIV/AIDS, National Center for Infectious Diseases

investigations. However, before surveillance and further investigation could begin, a case definition had to be established to guide EIS officers and health departments to know what to look for. A case definition is critical to an investigation of an outbreak and allows for standardization of the cases during a current outbreak and also over time and geographic areas between outbreaks. Case definitions typically specify the criteria for people, place, time, and clinical features related to the outbreak. EIS officers were aware that both PCP and KS typically occurred in patients with severe suppression of the cellular immune system, but with treatment, neither was typically life-threatening. The original CDC case definition included the following: (1) biopsy-proven KS among persons <60 years of age or biopsy- or culture-proven life-threatening or fatal OIs, and (2) no known underlying illness (e.g., cancer or immune deficiency disease) or history of immunosuppressive therapy. This definition was soon adopted in the United States and all fifty states required reporting of any cases (Curran and Jaffe 2011).

In 1981, the Task Force contacted state and local health departments to assist with identifying potential cases fitting the case definition (Levine 2009). Towards the end of 1981, 5–6 cases were being diagnosed weekly (*The New York Times* 1981) and the surveillance task force, by years end, had identified 270 reported cases among gay men where 121 had died (AIDS.gov 2014). During this time, scientists had yet to identify or isolate the infectious agent or disease that was

causing the immunosuppression and resulting in the OIs and KS. Although a heterosexual woman fitting the case definition had been reported to the CDC in August of 1981, and a New York investigation of eleven men included seven drug users, five of whom were heterosexual (Levine 2009, p. 207), because most cases documented were among homosexual men, the disease was deemed by scientists as Gay-Related Immunodeficiency or GRID. While in the media, it was pejoratively being called the “gay plague.”

Early in 1982, to explore possible causes that were being hypothesized and that could explain why gay men were being affected, the CDC conducted a national case-control study. A case-control study is a classic epidemiological study design in which people who have the disease or outcome (cases) are matched to similar people who don’t have the disease or outcome (controls) on certain characteristics such as age, gender, and race/ethnicity. Then, interviews are conducted retrospectively with both cases and controls to determine potential exposures or risk factors that contribute to having the disease. Possible risk factors were infectious agents such as a new sexually transmitted disease or environmental exposures such as street drugs. Case patients were 50 gay men with PCP and/or KS, and the control subjects were 50 apparently, healthy gay men matched to the cases by age, race and city of residence. The results showed that the cases had more sexually transmitted infections and were more sexually active in terms of number of partners, thus supporting the sexually transmitted infectious agent hypothesis (Jaffe et al. 1983). But, because many gay men who were highly sexually active also used street drugs such as amyl nitrite, an inhalant sexual stimulant, combined with cocaine, the environmental exposure hypothesis was not entirely discarded.

Between June 1981 and May of 1982, 355 cases of KS and serious OIs, chief among these was PCP, had been reported to the CDC as fitting the case definition and were described in an updated report in CDC’s MMWR (CDC 1982a, b). Most of these illnesses occurred in previously healthy individuals between the ages of 15 and 60 years. These reports were consistent with previous reports of PCP and KS occurring in healthy individuals who would not ordinarily be susceptible to these illnesses. Most of the cases reported in MMWR were still occurring among gay men and a sexually transmitted infectious agent was still being theorized, but the agent had yet to be discovered and competing hypotheses were still being considered. It was in the spring of 1982 that more evidence was gathered to support the sexually transmitted infectious agent theory. Dr. David Auerbach, an EIS officer in Los Angeles collaborated with Dr. William Darrow, a sociologist and member of the Task Force. They conducted in-depth investigations into 13 of the first 19 reported cases in LA and Orange County. The results were startling: of the 13 men, 9 reported sexual contact with another man who was a reported “GRID” case within 5 years of having any symptoms (Auerbach et al. 1984). Given these results, Auerbach and Darrow expanded their investigation nationwide to an additional 90 cases, 40 of whom could be linked sexually to other case patients. This clustering of 40 cases provided strong evidence that GRID was caused by a sexually transmitted infectious agent.

Unfortunately, this ground-breaking epidemiological work would have unintended consequences. Auerbach and Darrow's sexual network analysis also identified one non-Californian man, who had sexual contact with 4 men from LA and 4 men from NYC, and who was considered from an epidemiological perspective as the index case within this cluster. This index case was later identified in Randy Shilts' 1987 book, *And the Band Played on: Politics, People and the AIDS Epidemic*, as French-Canadian flight attendant Gaetan Dugas. Dugas was erroneously deemed "patient zero" implying that he was the first HIV case in the United States and all other infections stemmed from him. Dugas died due to complications from KS in 1984. He was subsequently vilified and infamously blamed for the start of the HIV epidemic in the United States (McKay 2014), although later retrospective research disproved this notion and showed that HIV was brought to the United States much earlier and could never be attributed to only one person (Faria et al. 2014).

As the case reports continued to pour in, what would eventually be called AIDS began affecting populations outside of the gay community as occurrences of KS and serious OIs were not limited to gay men, as stated in the June 1982 MMWR report. Although 79 % of the cases were among homosexual or bisexual men, these illnesses were also documented in heterosexual men (12 % of reported cases) and women (4 % of reported cases), as well as men whose sexual orientation was unknown (6 % of reported cases). In fact, the proportion of heterosexuals succumbing to KS and serious OIs increased from 1 to 16 % by June 1982. In addition, of importance, the PCP heterosexual cases were more likely than the homosexual PCP cases to be Black or Hispanic (CDC 1982a, b).

During this time, twenty states reported cases of KS and serious OIs, yet reported cases appeared to be concentrated in just a handful of states: California, Florida, New Jersey, New York, and Texas accounted for more than 85 % of the reported cases. For example, the State of New York accounted for just over half of the homosexual male cases, almost half of the heterosexual male cases and 46 % of the female cases (CDC 1982a, b). A defining characteristic for reported groups affected (i.e. women, heterosexual men, and gay men) was the age at onset of symptoms. Individuals displaying symptoms of KS and serious OI were fairly young, as the median age at symptom onset was 26–36 years.

During the beginning of the epidemic, reported case-fatality ratios (the number of fatalities from a specific illness divided by the number of reported cases for the illness) for PCP cases were high among gay men. During the early stages of the epidemic, gay men constituted a large proportion of patients succumbing to symptoms and ultimately dying compared to their heterosexual counterparts. Though gay men accounted for a large number of fatalities stemming from PCP infection, the number of PCP diagnoses increased among the heterosexual population. The ratio of gay men to heterosexual men with PCP slightly decreased from 5–1 in 1980 to 4–1 in 1982, so one can see that as more and more heterosexuals began to account for prevalent cases the illness began to impact different populations who were at risk for infection. As it became evident that the disease was not limited to the homosexual population, by September of 1982, the CDC abandoned

the term GRID and designated the condition as Acquired Immune Deficiency Syndrome or AIDS.

In September 1982, a MMWR report stated that 593 AIDS cases had been reported, and on average, 1–2 new cases were reported each day (CDC 1982c). Most AIDS cases were still occurring among gay men (75 % of reported cases), however it was documented that 12 % of the cases occurring among gay men involved intravenous drug use (CDC 1982c). Intravenous drug use was also described in the majority of the known heterosexual cases (both male and female). Another subgroup, hemophilia patients, was also described as a subpopulation affected by AIDS. Specifically, the CDC reported that of the 14 AIDS cases that involved males under 60 years of age (who did not use drugs, did not report homosexual activity and who were not of Haitian nationality), two (14 %) had hemophilia A.

Hemophilia is a rare bleeding disorder in which the blood does not clot properly. The main treatment for this disorder is replacement therapy. Concentrates of clotting factor VIII (for hemophilia A) or clotting factor IX (for hemophilia B) are given intravenously. These infusions help replace the clotting factor that is missing or low. Clotting factor concentrates are derived from human blood plasma. To produce this coagulant, blood from hundreds of individual donors is pooled; thus, a single donation of infected blood could contaminate a large batch of Factor VIII with the potential to infect thousands. Dr. Dale Lawrence of the Task Force investigated the two hemophilia A cases and was able to determine that both had unexplained immunosuppression, no history of homosexual contact, or injection drug use (CDC 1982c).

Further, the December 10, 1982 MMWR report described four additional cases of patients with hemophilia A, who were heterosexual, in which serious OIs developed as evidenced by a compromised immune system. Like previously described cases of hemophiliacs, there was no evidence to suggest that these patients could have been immune compromised as a result of homosexual contact, illicit drug use, or contact with Haitian immigrants (who were a suspected risk group during this time) (CDC 1982d; Jaffe et al. 1983). Another hemophilia case was identified as being “highly suspected” to have AIDS but did not meet the surveillance definition. A common characteristic among these cases was that each patient had received Factor VIII concentrates in addition to having compromised immune systems (CDC 1982d). Thus, there was evidence to suggest that what was causing AIDS could be an infectious agent transmitted by blood, through homosexual and heterosexual contact, as well as injection drug use practices.

Perhaps the most widely known reported hemophilia case was a young boy, Ryan White, who in 1984, at age 13, was diagnosed with AIDS. Over the next 6 years, Ryan became a national advocate fighting for the right to attend school, becoming a spokesperson who sought to educate the public about AIDS and reduce the stigma. In 1990, Ryan succumbed to a severe respiratory infection and died. Months later, Congress passed the AIDS bill that bears his name—the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act. The legislation has been reauthorized four times since—in 1996, 2000, 2006, and 2009—and is

now called the Ryan White HIV/AIDS Program—the largest federal program in the United States focused on HIV/AIDS care.

In addition to the hemophilia A cases, the September 1982 MMWR report also documented that Haitians residing in the United States represented a small proportion of all cases (only 6 %), however, this subgroup comprised half of the cases in which both homosexual activity and intravenous drug abuse were denied. Investigations into these cases showed that 34 were Haitian men, who had migrated to the United States and reported to be heterosexual with no known risk factors.

The CDC (1982c) broadened its scope to identify groups most at risk for AIDS, stating:

Reported AIDS cases may be separated into groups based on these risk factors: homosexual or bisexual males – 75 %, intravenous drug abusers with no history of male homosexual activity – 13 %, Haitians with neither a history of homosexuality nor a history of intravenous drug abuse – 6 %, persons with hemophilia A who were not Haitians, homosexuals, or intravenous drug abusers – 0.3 %, and persons in none of the other groups – 5 % (pp. 507–508).

The fact that being of Haitian nationality was classified as a risk factor for AIDS was met with serious backlash and protests as the stigma of AIDS seriously compounded life for Haitian migrants living in the United States. Many had fled Haiti to avoid severe poverty and political persecution, but were now being fired from their jobs or evicted from their homes (Farmer 1992).

2.3 Evolution of the AIDS Case Definition and the Discovery of the HIV-1 Virus

2.3.1 The 1982 Case Definition of AIDS

At the onset of the HIV Epidemic, the CDC Task Force and Department of Health and Human Services initiated surveillance activities to monitor cases fitting the case definition. Almost immediately the CDC received case reports directly from health care providers and State and local health departments documenting AIDS cases in which PCP and KS co-morbidity were present. The initial case definition was, “a disease, at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease” and required the diagnosis of one of eleven opportunistic infections or one of at least two cancers. The 1982 case definition for AIDS was intended for surveillance purposes with goals of monitoring trends in the number of AIDS cases as well as monitoring the scope of severe morbidity due to infection with the human immunodeficiency virus. Since 1982, the CDC’s case definition for AIDS has been revised multiple times: in 1985, 1987, 1993, 1999, 2008, and most recently in 2014. Each revision had an impact on how HIV was reported and how the populations most at risk were identified.

2.3.2 *The 1985 Case Definition of AIDS*

After the publication of the CDC's initial case definition for AIDS in 1982, two research teams independently identified a novel retrovirus present in individuals most at risk for AIDS. One research team, led by Luc Montagnier of the Pasteur Institute in Paris, termed the newly discovered virus as lymphadenopathy-associated virus (LAV) as it was isolated from a patient presenting with lymphadenopathy and asthenia (Barré-Sinoussi et al. 1983). The report published by Montagnier and his colleagues suggested LAV was immunologically different from other classes of human T-Lymphotropic viruses (HTLV). The other research team, led by Robert Gallo of the National Cancer Institute, termed the virus human T-cell lymphotropic virus-III (HTLV-III) due to its shape and similarity to previously isolated HTLVs (Popovic et al. 1984). However, both teams had discovered the same virus, which was deemed as the cause of AIDS. It was renamed the human immunodeficiency virus in 1986. Laboratory tests were then developed to detect the presence of HIV antibodies—proteins produced by the body's immune system to protect against foreign substances called antigens—and these tests were used as diagnostic indicators for HIV manifestation. Thus HIV testing and confirmed positive results for the presence of HIV antibodies were incorporated in the revised case definition for AIDS. The CDC (1985) changed its AIDS surveillance definition in 1985 to define it as:

In the absence of the opportunistic diseases required by the current[1982] case definition, any of the following diseases will be considered indicative of AIDS if the patient has a positive serologic or virologic test for HTLV-III/LAV [human T-cell lymphotropic virus, type III/lymphadenopathy-associated virus] (pp. 373–375).

The CDC's 1985 case definition specified that a positive test for HTLV-III/LAV, cases of disseminated histoplasmosis, isosporiasis causing chronic diarrhea, bronchial or pulmonary candidiasis, non-Hodgkin's lymphoma, and Kaposi's sarcoma in persons 60 years of age or over were to be included in the surveillance case definition of AIDS (CDC 1985). Following the expanded case definition, there were 16,458 reported AIDS cases in the United States between June 1981 and January 1986 with over half of the adult (51 %) and child populations (59 %) infected with HIV/AIDS dying from the disease during this time. A quarter (25 %) of the reported cases occurred among African Americans and 14 % occurred among Hispanics, although African Americans and Hispanics constituted only 12 and 6 % of the U.S. population respectively during that time (CDC 1986a). By the end of 1986, black/non-Hispanic and Hispanic women accounted for large proportions (52 and 20 %, respectively) of women living with AIDS, while black/non-Hispanic and Hispanic men accounted for 22 and 14 % respectively of men with living with AIDS (CDC 1986b). All 50 States in the Union, the District of Columbia, and four U.S. Territories had now reported at least one AIDS case to the CDC.

2.3.3 The 1987 Case Definition of AIDS

In August of 1987, the CDC revised the case definition of AIDS to reflect increases in the understanding of HIV infection (CDC 1987). The 1987 case definition for AIDS included 23 AIDS defining conditions including: bronchial, tracheal, or pulmonary candidiasis; esophageal candidiasis; HIV encephalopathy; HIV wasting syndrome; and a broader range of malignancies (CDC 1987). The CDC aimed (1) to simplify AIDS reporting; (2) to make the definition consistent with standards of medical care for HIV-infected persons during that time; and, (3) more accurately record the number of persons with severe HIV-related immunosuppression (CDC 1987). The 1987 definition allowed for a presumptive AIDS diagnosis based upon the presence of clinical signs and symptoms of opportunistic illnesses, such as PCP and KS, and other AIDS indicator diseases in the absence of a confirmed laboratory HIV-positive test. That is, clinicians could diagnose a person with AIDS if he/she presented with signs and symptoms of one of the indicator diseases (e.g. Kaposi's sarcoma, PCP), even if the person did not have a confirmed HIV-positive test. The case definition of AIDS was also accompanied or qualified according to laboratory evidence of HIV infection: unknown or inconclusive HIV test, positive HIV test, and negative HIV test. Twenty-nine percent of the 40,836 AIDS cases reported between September 1987 and December 1988 met the newly established criteria of the CDC's 1987 revised case definition and most likely involved people who were presumptively diagnosed with AIDS or presented with wasting syndrome or one of the other nonmalignant HIV-associated conditions (such as a neurologic manifestation). These cases would not have been reported as AIDS cases under earlier definitions.

As a result of the revised case definition, increased proportions of AIDS cases in women, injection drug users, and minorities were reported to the CDC. Among the cases meeting the criteria of the 1987 definition, 15 % were women, as compared with 9 % of cases meeting the pre-1987 definition. A sizeable percentage (35 %) of the cases were heterosexual injection drug users, as compared with 18 % meeting the pre-1987 definition. About 34 % of the cases meeting the 1987 definition were African American compared to 26 % based on the pre-1987 percentage of this population living with HIV/AIDS. Roughly 21 % of the cases were Hispanic compared to the pre-1987 percentages of 14 % for Hispanics (CDC 1989).

2.3.4 The 1993 Case Definition of AIDS

The CDC proposed a revision to the surveillance case definition and the disease classification system to differentiate asymptomatic HIV infection from symptomatic infection and the more severe AIDS illness (CDC 1991). By changing the definition, the CDC sought to simplify the classification of HIV infection to reflect standards of medical care for HIV-infected persons in the early 1990s, and

categorize HIV-related morbidity more accurately (CDC 1992a). It is important to note that at this point in time of the epidemic AIDS was the leading cause of death among persons 25–34 years of age and eighth among all causes of death.

Studies examining the natural history of HIV infection documented a gamut of disease manifestations, ranging from asymptomatic infection to life-threatening conditions characterized by severe immunodeficiency, serious opportunistic infections, and cancers (CDC 1992a). Studies began to show that lower than expected counts of CD4 or T lymphocyte (T-cell) cells, which are white blood cells that play a major role in fighting infection, predicted more advanced immunosuppression and severe illness. These measures were used to guide clinical and therapeutic management of people living with HIV (Fernandez-Cruz et al. 1990). Antimicrobial prophylaxis and antiretroviral therapies developed during the 1980s (to be discussed in later sections) were shown to be effective within certain levels of immune dysfunction (CDC 1992b; Easterbrook et al. 1991; Fischl et al. 1990; Lagakos et al. 1991; National Institutes of Health 1990; Volberding et al. 1990). The revised classification system for HIV emphasized the clinical importance of CD4 or T-cell count as it relates to HIV-related medical conditions for those infected as these cells were now included as a marker for HIV-related immunosuppression.

Under the revised classification system, the human immunodeficiency virus was designated as the retrovirus that causes AIDS. The CDC documented that the HIV virus targeted the CD4 (T-Cell) because of its affinity for the CD4 cell surface marker. It was also documented that CD4 cells coordinate numerous, important immune functions and that any compromise to these functions results in “progressive impairment of the immune response.” The 1993 revision to the AIDS case definition established mutually exclusive subgroups for which the spectrum of clinical conditions were included with the T-cell count. That is, diagnosis of HIV or the more severe disease of AIDS would now be categorized based upon separate groups related to the individual’s T-cell count and any opportunistic co-infection or HIV-related illness. Thus the 1993-revised case definition for HIV/AIDS was expanded to include all HIV-infected persons who have less than 200 CD4 or a CD4 percentage of total lymphocytes of less than 14. Any person meeting this condition would be considered to have AIDS. The CDC recommended that “antiretroviral therapy should be considered for all persons with CD4 T-lymphocyte counts of less than 500/ μ L, and prophylaxis against *Pneumocystis carinii* pneumonia (PCP), the most common serious opportunistic infection diagnosed in men and women with AIDS, is recommended for all persons with CD4 T-lymphocyte counts of less than 200/ μ and for persons who have had prior episodes of PCP” (CDC 1992a, para. 3). As a result of these recommendations, CD4 T-lymphocyte determinations became an integral part of medical management of HIV-infected persons in the United States.

The revised CDC classification system for HIV-infected adolescents and adults categorized persons on the basis of clinical conditions associated with HIV infection and CD4 T-lymphocyte counts. The system during this time was based on three

ranges of T-cell counts and three clinical categories and was represented by a matrix of nine mutually exclusive categories. This system replaced the classification system established in 1986, which included only clinical disease criteria and was developed before the widespread use of CD4 T-cell testing.

2.3.5 Impact of 1993 Case Definition on Women and Overall Epidemiology in the U.S.

Although it was 12 years into the epidemic and there had been many heterosexual or injection drug use female AIDS cases, the CDC claimed there was insufficient evidence to include gynecological conditions in previous versions of the case definition. There were few studies implemented that used large scale observational research designs to describe HIV at the onset of the epidemic and to accurately define all the populations most at risk for HIV acquisition. Because most of the early reports of HIV/AIDS involved cases in which homosexual activity among men was described, women were overlooked as a population at risk. However, as described in previous sections of this chapter, there were many documented reports of women infected with HIV as early as 1982. Prior to 1993, medical conditions specific to women had not been included in the formal case definition for HIV as it was still considered to be a primarily gay-related illness. The expansion included three clinical conditions: pulmonary tuberculosis, recurrent pneumonia, and invasive cervical cancer—and it retained the 23 clinical conditions already used in the 1987 case definition of AIDS. This marked the first time a female-specific condition was included in the case definition for HIV and officially recognized women as a population at risk for HIV infection.

Upon expanding the HIV/AIDS case definition, the CDC predicted that the number of reported cases would increase by approximately 75 % (CDC 1992a). Officials determined that the early effects of the expanded surveillance would be greater than long-term effects because prevalent and incident cases of immunosuppression would be counted following implementation of the expanded surveillance case definition. In subsequent years, the effect on the number of reported cases was expected to be much smaller. It was believed that the immediate increase in the number of cases reported would be most attributable to the addition of severe immunosuppression to the definition. A smaller impact was expected from the addition of pulmonary TB, recurrent pneumonia, and invasive cervical cancer because many persons with these diseases would also have CD4 T-lymphocyte counts of less than 200 cells/ μ . Officials estimated that if the AIDS surveillance definition for case reporting was unchanged, only 50,000–60,000 reported AIDS cases would have been expected in 1993. The expanded case definition had a far greater impact than anticipated.

The expanded case definition had a dramatic effect on the number of reported HIV/AIDS cases as the number of cases within certain subpopulations were more than double the reported number of cases in the previous year. Following the expanded definition, in 1993, 103,500 AIDS cases were reported in the United States among the population aged at least 13 years (CDC 1994a). This was a 111 % increase over the 49,016 reported in 1992. Of the reported AIDS cases in 1993, 54 % were reported based on conditions added to the 1993 case definition with most of these cases having severe human immunodeficiency virus (HIV)-related immunosuppression only. Other conditions related to the 1993 expanded case definition criteria such as pulmonary tuberculosis (TB), recurrent pneumonia, and invasive cervical cancer made up substantially less proportions of reported AIDS cases. The increase in reported AIDS cases during this time was greater among females (6,571 in 1992 to 16,514 in 1993, or a 151 % increase) than among males (42,445 in 1992 to 86,986 in 1993 or a 105 % increase) and the largest increases occurred among adolescents and young adults (177 in 1992 to 555 in 1993 for persons aged 13–19 years, a 214 % increase and 1,600 in 1992 to 3,722 in 1993 for persons aged 20–24 years, a 133 % increase). Among adolescents and young adults reporting AIDS based on the expanded criteria, a greater proportion of cases were reported among women (35 and 29 %, respectively) and were attributed to heterosexual transmission (22 and 18 %, respectively). Though there was a 102 % increase in the reported number of white/non-Hispanics living with HIV/AIDS (47,003 in 1993 vs. 23,305 in 1992) attributed to the expanded case definition, racial/ethnic minorities also represented increases that were greater than the percent increase for white/non-Hispanics. The number of black/non-Hispanics accounting for reported AIDS cases in 1993 was 36,951 which was a 123 % increase from 16,582 cases reported in 1992. The number of reported Hispanics living with HIV/AIDS was 18,318 in 1993, up from 8,541 reported in 1992 (a 114 % increase). By the time 1996 arrived, this trajectory of increased reports among minority race/ethnicities reached a major turning point. For the first time, there were more reported AIDS cases among African Americans (41 %) than among whites (38 %). With the 1993 AIDS case definition, there was also a substantial increase in HIV/AIDS reported cases among injection drug users (28,687 in 1993 vs. 12,163 in 1992) as well as among hemophiliacs (1,041 in 1993 vs. 360 in 1992).

2.3.6 1999 and 2008 Case Definitions for HIV/AIDS

In 1999, the CDC published another revision to the case definition for AIDS to combine the reporting criteria for HIV and AIDS into a single case definition to reflect advances in laboratory techniques that were unavailable in 1993 (CDC 1999). The case definition also made specific provisions for children under the age of 13 for surveillance purposes. Under the revised system of reporting:

...children aged 18 months to <13 years, laboratory-confirmed evidence of HIV infection is now required to meet the surveillance case definition for HIV infection and AIDS. Diagnostic confirmation of an AIDS-defining condition alone, without laboratory-confirmed evidence of HIV infection, is no longer sufficient to classify a child as HIV infected for surveillance purposes. No changes have been made to the 24 AIDS-defining conditions or the HIV infection classification system for children aged <13 years (CDC 1999, p. 7).

By the end of the year 2000, there were approximately 337,731 people in the United States living with AIDS (CDC 2002). Of those living with AIDS, about 139,522 cases (41 %) were black, 127,838 cases (38 %) were white/non-Hispanic, and 65,991 cases (20 %) were Hispanic. The Southern region of the U.S. accounted for 129,333 (38 %) of AIDS cases, the most of any other region, followed by the Northeast which accounted for 99,482 cases (29 %), the West which accounted for 66,085 cases (20 %) and the Midwest, accounting for 32,909 cases (10 %). Other U.S. Territories accounted for 3 % of cases during this time. Not only were more risk groups added as a result of the changing case definition, but the geographic region in which cases were concentrated had also shifted to other parts of the United States. HIV/AIDS had become a major burden in the Deep South, such that HIV clusters developed in this region. The majority of male cases among the estimated 264,149 adult and adolescents (i.e., person aged >13 years) living with AIDS, were men who have sex with men (MSM), who accounted for approximately 151,325 cases (57 %). About 24 % (64,522) of adult and adolescent male cases were IDUs, and 20,528 cases (8 %) were MSM who reported IDU. Only 23,333 (9 %) of adult and adolescent male cases were exposed through heterosexual contact. Most of the 69,775 adult and adolescent women living with AIDS were exposed through heterosexual contact (40,051 cases or 57 %), and 27,475 (39 %) were IDUs. There were approximately 3,807 children aged <13 years living with AIDS, the majority of whom (90 %) were infected via perinatal (mother to child) transmission of HIV.

By 2008, all states had implemented confidential, name-based HIV infection reporting, and the case definition of HIV was revised extending the definition to apply to HIV-1 or HIV-2 and to AIDS-defining conditions for adults and children >13 years of age that require laboratory evidence of HIV (CDC 2008). The 2008 HIV infection case definition for adults and adolescents (aged >13 years) replaced previous HIV infection and AIDS case definitions as well as the HIV infection classification system from previous iterations. The definition applied to all HIV variants (e.g., HIV-1 or HIV-2) and excludes confirmation of HIV infection through diagnosis of AIDS-defining conditions alone. For surveillance purposes, the CDC categorized a reportable case of HIV infection among adults and adolescents aged >13 years by increasing severity as follows:

Stage 1 HIV Infection

No AIDS-defining condition and either T-cell count of >500 cells/ μ L or T-cell percentage of total lymphocytes of >29 or as stage unknown.

Stage 2 HIV Infection

No AIDS-defining condition and either T-cell count of 200–499 cells/ μ L or T-cell percentage of total lymphocytes of 14–28.

Stage 3 HIV Infection (AIDS)

A T-cell count of <200 cells/ μ L or T-cell percentage of total lymphocytes of <14 or documentation of an AIDS-defining condition. Documentation of an AIDS-defining condition supersedes a T-cell count of >200 cells/ μ L and a T-cell percentage of total lymphocytes of >14.

Stage Unknown HIV Infection

No information available on T-cell count or percentage and no information available on AIDS-defining conditions.

In 2011, there were 50,007 reported HIV diagnoses among adults and adolescents, following the revised case definition (CDC 2013a). Among those diagnosed with HIV/AIDS in 2011, most were among MSM who accounted for 61.8 % of diagnoses. Of the 30,896 cases attributed to MSM, 38.2 % were estimated among black/African Americans, 33.6 % were among whites, and 23.5 % were among Hispanic/Latinos. The greatest number of new HIV infections occurred in young black/African American MSM aged 13–24 years, who accounted for 45 % of new HIV infections among black MSM and 55 % of new HIV infections among young MSM overall. Women accounted for 21.6 % of new HIV infections in 2011, most of which occurred through heterosexual contact.

Racial and ethnic disparities in HIV/AIDS still persisted in 2011 and continue to persist where Blacks/African Americans accounted for 46 % of new HIV infections. More than 260,800 black/non-Hispanics living with AIDS have died since the epidemic began. Hispanics have also faced a burden of HIV infection. In 2011, the Hispanic population accounted for 22 % of new HIV infections and more than 96,200 Hispanics/Latinos with an AIDS diagnosis have died since the beginning of the epidemic. Figure 2.2 shows this disproportion burden African Americans and Hispanic/Latinos experience in terms of new HIV infections in 2011. As shown, for both males and females, African Americans and Hispanic/Latinos have the highest and second highest rates respectively of HIV infection in the United States.

2.3.7 2014 Case Definitions for HIV/AIDS

Beginning in 2013, the CDC began referring to AIDS as HIV infection, stage 3 (AIDS) in all HIV surveillance reports. There was a need to revise the case definition based upon changes in diagnostic criteria. There was also a need to change the definition based upon early recognition of HIV, distinguishing HIV-1 from HIV-2 infection, consolidate the staging systems for adults/adolescents and child cases, simplify the criteria for opportunistic infections indicative of AIDS, and revise the criteria for reporting HIV/AIDS diagnoses in the absence of laboratory evidence (CDC 2014b). The new surveillance case definition now includes a

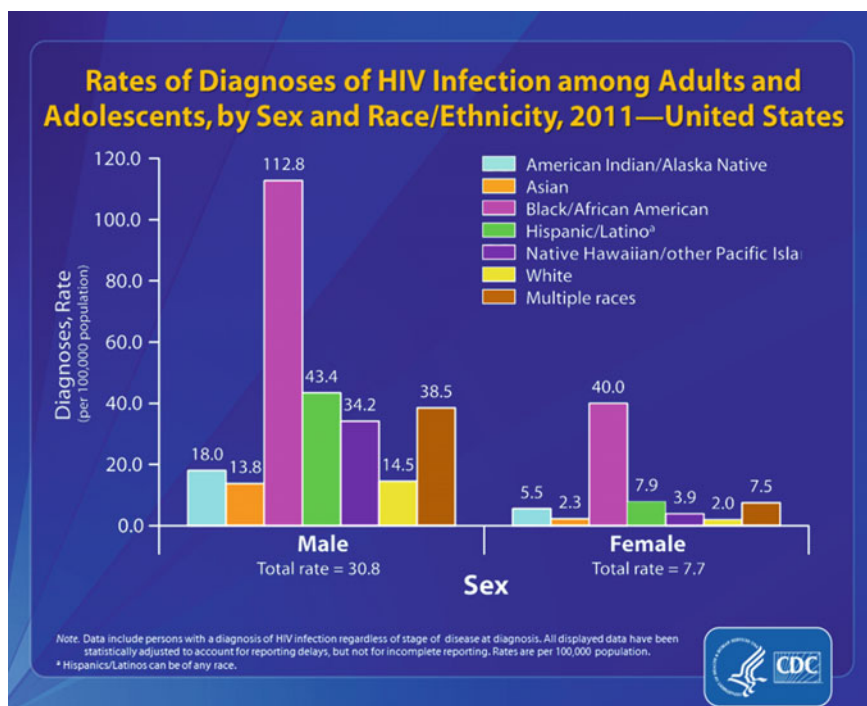


Fig. 2.2 2011 Incidence Rates of HIV among Adults and Adolescents by race and sex in the United States (*Source* Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, Sexual Transmitted Diseases and Tuberculosis Prevention, Centers for Disease Control and Prevention)

“stage 0” based upon a series of positive and negative tests that may indicate early HIV-infection. It takes advantage of new testing algorithms that are more sensitive to early HIV infection. The new case definition also does not distinguish between presumptive and definitive HIV infection to avoid complexity for surveillance purposes. Although 2011 represents the most recent surveillance data available, for specific details regarding the 2014 case definition for HIV/AIDS, the reader is encouraged to consult the CDC’s MMWR report which can be found at the following website: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_e. A summary of the changes can be found below:

- Specific criteria added for defining HIV-2 case, not included in the 2008 case definition. The new definition incorporates criteria for HIV-2 infection used in surveillance for HIV-2 infection.
- Eliminates the requirement to indicate if AIDS-defining conditions, indicative of stage 3 (AIDS), were diagnosed by “definitive” or “presumptive” methods.
- Classifies stages 1–3 of HIV infection on the basis of the CD4 count unless persons have had a stage-3–AIDS defining opportunistic illness. The CD4+

T-lymphocyte percentage is used only when the corresponding CD4 count is unknown.

- Removes the requirement that a “physician-documented” diagnosis must be based on laboratory evidence.
- Combines the adult and pediatric criteria for a confirmed case of HIV infection and specifies different criteria for staging HIV infection among three age groups (<1 year, 1–5 years, and ≥ 6 years).
- Eliminates the distinction between definitive and presumptive diagnoses of HIV infection in children aged <18 months.
- Removes lymphoid interstitial pneumonia (pulmonary lymphoid hyperplasia) from the list of opportunistic illnesses indicative of stage 3 in children. This illness is associated with moderate rather than severe immunodeficiency.
- Evidence of HIV infection in a child’s biologic mother is no longer needed to define a case of HIV infection in a child aged <18 months when laboratory testing of the child independently confirms HIV infection.
- Extends the use of CD4 counts and percentages for determining the stage of HIV infection to children as well as adults and adolescents. CD4 counts are now used to determine the stage in children aged 6–12 years the same way as in adults and adolescents (CDC 2014b, p. 2).

2.4 Overview of HIV Testing and the Fight Against AIDS

Isolation and identification of the HIV virus was pivotal in addressing AIDS early on in the epidemic. As discussed earlier in the chapter, the teams of Robert Gallo and Luc Montagnier independently isolated and identified the HIV virus in early 1983. In 1984, then Secretary of Health and Human Services, Margaret M. Heckler, announced the discovery that the HIV virus was the cause of AIDS and federal researchers revealed they had developed a test that could identify antibodies specific to HIV in the blood (Altman 1984). Upon that announcement, federal researchers applied for patents to develop commercial tests for HIV. In March of 1985, the Food and Drug Administration (FDA) granted the first commercial license for screening tests which could detect HIV antibodies in the blood that indicate viral infection via enzyme linked immunosorbant assay (ELISA); this was originally intended to screen blood products for treatment among hemophiliacs. This initial test was implemented in blood banks, plasma collection centers, health departments, and clinical-care settings to deter HIV acquisition in hemophiliacs receiving blood transfusions. Since the licensure of the first commercially available screening test, more than 40 different ELISA test kits have become available, but only about 10 are licensed by the FDA for use in the United States. Other HIV testing methods have been developed and are now regularly used to test for various aspects of the virus including: antibody screening tests (immunoassay), the most common form of the HIV testing that can be conducted in the lab or in one’s home (via rapid testing);

polymerase chain reaction (PCR) tests, which are used to test for the genetic material belonging to the virus; antigen tests, which tests for specific HIV viral proteins; and, RNA tests, which are used to detect the virus directly (instead of the antibodies to HIV) and can detect HIV approximately 10 days after one becomes infected. Advances in HIV rapid testing are highlighted in the next section.

2.4.1 Development of HIV Rapid Testing

Prior to the development of rapid HIV testing, testing for HIV involved ELISA, a long process which initially required blood to be drawn in order to detect HIV antibodies. This process involves using fluorescent enzyme probes linked with antigens that are used to detect antibodies present in the blood serum. The process usually requires a person to wait several weeks in order to receive test results. With the advent of quicker and cheaper tests, results could be provided during the clinical visit and infected patients could be counseled and placed on therapy before HIV progressed into the more severe manifestation of AIDS. Persons with a confirmed positive test could take the steps necessary to prevent the transmission of the illness to a sexual partner, a child, or another injection drug user. This dramatically changed the epidemiology of HIV as incident cases slowly decreased and more people could be tested than before.

In 1989, a rapid immunoassay, the Recombigen HIV-1 Latex Agglutination assay, was licensed to Cambridge Biotech Corp. Several years later, in 1992, a second rapid HIV assay, the SUDS HIV-1 Test, was licensed to Abbot Murex Diagnostics, Inc. (Poffenberger 2000). These tests were originally licensed as screening tests (including use in blood banks under restricted conditions) for the rapid detection of antibodies to HIV-1 in plasma or serum. The licensure of these tests offered a greater advantage for clinicians and researchers conducting screening and testing in resource poor settings as these tests provide a result that indicates the presence or absence of antibodies to HIV within 20 min (usually less than 10 min). Although the tests were designed to be rapidly performed and interpreted by a trained individual on-the-spot (at the site the sample is taken), the kits in which the tests were provided included all reagents, no need of specialized equipment, and in some cases no requirement of refrigeration (Poffenberger 2000). The result of the test is based on visual detection of an HIV specific spot or line (usually pink or blue in color). Unlike laboratory testing, individuals could receive results on the detection of HIV antibodies within minutes instead of waiting several weeks using laboratory-testing techniques. The Recombigen HIV-1 Latex Agglutination assay and SUDS HIV-1 Test were the only commercially available tests on the market in the U.S. during this time, in contrast to countries in Europe and nations in Africa where several rapid HIV assays were available in the market (Poffenberger 2000).

2.4.2 Reduction of Mother-to-Child Transmission

During the early stages of the epidemic, women were not treated as a risk group for HIV/AIDS. The CDC estimated that mother-to-child HIV transmissions peaked in 1991 when 1,650 cases were reported. However, more studies began to show that routine testing was a cost-effective and crucial method for identifying and treating people with HIV who were previously unaware of their status. During the early 1990s, testing policies of pregnant women were geared toward voluntary testing as a mechanism to increase education, prevention, and medical follow-up services for women with a confirmed positive test. It soon became clear that women who tested positive and received AZT therapy during the early stages of pregnancy were less likely to transmit the virus vertically to their unborn fetus (CDC 1994b). More health departments and professional medical societies began to move in favor of mandatory screening policies for pregnant women (Bozzette 2005; Paltiel et al. 2005; Sanders et al. 2005). With more hospitals requiring mandatory HIV screening for pregnant women, by 2005, the reported number of mother-to-child transmissions declined to a range of 100–200 transmissions (CDC 2007). Screening of pregnant women is seen as a success in the U.S. HIV epidemic because fewer children are born with HIV and it has helped to quell the incidence of the disease in the United States.

2.4.3 Ten-Year Trends in HIV Testing

With numerous developments made in HIV testing, testing for the virus is emphasized in the National HIV/AIDS Strategy (NHAS) and the Division of HIV/AIDS Prevention (DHAP) Strategic Plan and is seen as an important prevention measure against the spread of new infections. Ten-year HIV testing trends have shown significant increases in reported HIV testing among all adults (36.6 % in 2000 to 45.0 % in 2010) including: all race/ethnicity groups, adults aged 25–64 years, males and females, and adults who did and did not report a risk for HIV (based upon NHIS reporting) (CDC 2013b). However, NHANES reporting of HIV testing has not shown significant increases between 2000 (42.5 %) and 2010 (43.1 %) among adults who have reported ever receiving an HIV test (CDC 2013b). Increases in the percentage of adults who reported an HIV test in the past 12 months has also been observed, from 80.7 % in 2000 to 84.0 % in 2010 (CDC 2013b). Many adults have received HIV tests in a health care setting as HIV testing in this context has increased from 78.2 % in 2000 to 83 % among adults who had ever been tested for HIV (CDC 2013b). Gains in HIV testing have been met with some challenges. Significant increases in HIV testing among adolescents (11.6 % in 2005 and 13.2 % in 2011) and pregnant women (59.3 % in 2000 and 53.7 % in 2010) have not been observed, two groups vulnerable to HIV transmission (CDC 2013b).

2.4.4 FDA Approval of the First Over-the-Counter Home-Based Rapid HIV Test

On July 3, 2012 the U.S. Food and Drug Administration approved the OraQuick In-Home HIV Test, the first over-the-counter home-use rapid HIV test kit to detect the presence of antibodies to HIV types 1 and 2 (HIV-1 and HIV-2) (Food and Drug Administration 2014a; OraSure Technologies 2014). Prior to approving the home-based rapid HIV test, the FDA approved the Home Access HIV-1 Test System in 1996 (2014b). However, this over the counter HIV test requires a finger prick to collect a blood specimen, sending the specimen to a laboratory and then waiting for the laboratory to confirm the results. This HIV testing kit was not as successful commercially as the OraQuick In-Home HIV test. The OraQuick In-Home HIV test, an immunoassay manufactured by OraSure Technologies, is designed to allow individuals to collect an oral fluid sample (OraSure Technologies 2014). By swabbing the gums inside of their mouths, individuals can collect oral fluid and then place the sample swab into a developer vial, and obtain HIV antibody test results in about 40 min. This marked the first time people could purchase an HIV testing kit from their local pharmacy and test for HIV without sending a sample to a lab or verifying results in the presence of a trained professional.

Excitement surrounding the test was due to its potential to identify vast numbers of previously undiagnosed HIV infections, especially among those who were unlikely to use standard screening methods. Another important aspect of the OraQuick HIV rapid testing kit is its high degree of sensitivity and specificity. According to the manufacturer, clinical studies for self-testing have shown the test has a sensitivity of 92 %, the percentage of results that will be positive when HIV is present (one false negative result would be expected out of every 12 tests in HIV-infected individuals) and a specificity of 99.98 % (one false positive would be expected out of every 5,000 tests in uninfected individuals). Advancements in HIV testing, such as the development of HIV rapid tests, helped to influence the progress of surveillance and prevention strategies aimed at combating the epidemic.

2.5 Development and Impact of Antiretroviral Medication

One of the biggest developments in the fight against HIV/AIDS was the development of antiretroviral drugs. For the first time, infected individuals could take medication that would slow the replication of the AIDS virus. On March 19, 1987, the FDA approved the first antiretroviral drug, zidovudine (AZT) (AIDS.gov 2014). Although there were severe side effects associated with the drug, it was seen as a crucial step in limiting the spread of HIV. Congress approved \$30 million in emergency funding to states for AZT, which laid the groundwork for what would eventually become the AIDS Drug Assistance Program (ADAP), authorized by the Ryan White CARE Act in 1990. With the benefits of antiretroviral therapy unfolding, on August 18, 1987, the

FDA sanctioned the first human testing of a candidate vaccine against HIV. There was more drive than ever in the scientific community to find a cure for HIV/AIDS. Several years later, in October of 1990, the U.S. Food and Drug Administration (FDA) approved use of AZT for pediatric AIDS (AIDS.gov 2014). Following the success of AZT, new therapies were developed to fight HIV viral replication among infected individuals. The advent of highly active antiretroviral therapy (HAART), which involved a combination of three antiretroviral drugs, made it possible for people to live meaningful lives for those infected with HIV. In 1996, for the first time in the history of the epidemic, the number of new AIDS cases diagnosed in the U.S. declined (AIDS.gov 2014). AIDS was no longer leading cause of death for all Americans ages 25–44. However, HIV/AIDS remains a significant health disparity in the African American community and is a leading cause of death for African American men and women in this age group.

2.6 Summary

Since the beginning of the HIV/AIDS epidemic, numerous gains have been made in understanding the virus and modes of transmission as well as prevention of HIV/AIDS in vulnerable populations. The evolving case definition changed who was identified as being most at risk for HIV acquisition, which documented that what began as a white gay men's disease progressed dramatically over the years to one that affects Black/African Americans and Hispanic/Latinos disproportionately. Advances in HIV testing and screening have prevented transmission through blood transfusions, thus hemophiliacs no longer face fear of contracting HIV. Campaigns surrounding HIV testing have raised awareness about HIV and what people can do to prevent transmission. HAART therapy has made it possible for mothers infected with HIV to bear children who are free of infection and those living with HIV now live much longer lives. In addition, researchers have tested HAART therapy as a form of prevention (deemed pre-exposure prophylaxis or PrEP) among groups most at risk. Studies have shown that PrEP equates with promising rates of effectiveness. Biomedical approaches hold great potential, but because sexual contact is the most common mode of transmission, numerous behavioral interventions to reduce risk sexual behavior have been implemented and have been found to be effective. Yet, scale up of behavioral interventions is difficult unless we find a way to reach large numbers of persons most at risk.

The incidence of HIV has reduced dramatically since its peak in the 1990s due to testing, treatment, and prevention; however, even with the progress that has been made, incidence has been stable at approximately 50,000 annually. Although this suggests that prevention efforts may be working given the rising prevalence each year, clearly, there is still much work to do. Of concern are the high transmission rates among MSM as well as adolescents and young adults. HIV/AIDS remains a significant health disparity among blacks and Hispanics with new subgroups being identified. The transgender population is a subpopulation that was not initially

described in the early reports, however, this population faces a significant risk for HIV acquisition and more efforts in terms of research and policy are needed to reduce the burden of HIV in this hidden population.

To overcome the HIV/AIDS disparities facing subpopulations in the U.S., innovative efforts are needed that will involve a combination of experts in academia, public health practitioners, medical providers, community stakeholders, and policy makers at every level of government, to develop practical, cost-effective strategies and policies that affect social determinants, target risk factors that contribute to HIV transmission, and reduce stigma so that more people will get tested and treated. Specifically, much work needs to be done to address poverty and lack of access to affordable HIV medication. Practitioners and other persons in the field of HIV prevention must work with communities to reduce stigma associated with HIV and homosexuality, especially in communities of color. Education on correct and consistent condom use should target youth in various settings. The academic and scientific community must work with policy makers to enact laws that are not biased against the transgender community and do not criminalize behaviors associated with their survival. It will also take motivated individuals to educate themselves on HIV risk and practice health behaviors that minimize risk. Through collaborative efforts, HIV can be eradicated in the United States.

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