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HIV and AIDS



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Germany

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Introduction

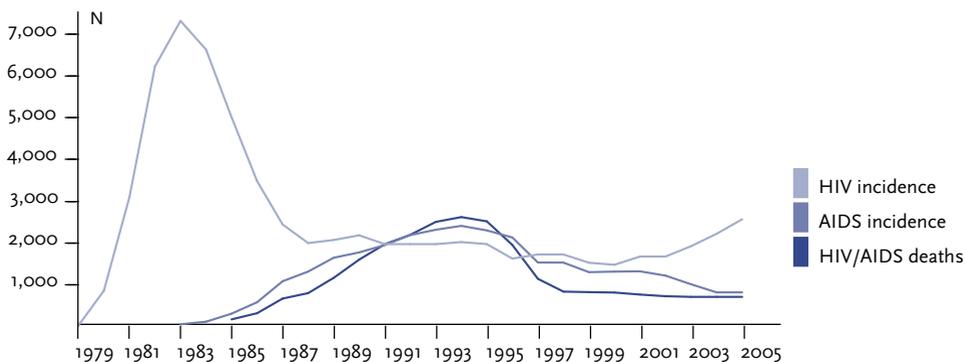
Over the last 20 years, the worldwide HIV/AIDS epidemic has emerged as one of the most significant health problems of modern time. The World Health Organization (WHO) estimates that by the end of 2005, nearly 40 million people will be infected with HIV worldwide, with a yearly rate of 5 million new infections and 3 million deaths [1]. Almost two-thirds of all HIV-infected people live in Sub-Saharan Africa, where in several countries as much as 20-40% of the population between the ages of 15 and 49 years old are infected. There, the epidemic poses a threat to economic, social and political stability, and represents a considerable restraint on development. In many other regions, the epidemic is still in its beginning stage, and if in the coming years no active measures for its containment are taken, the number of HIV-infected people worldwide will grow even more.

At the end of June 2001, the United Nations held a special general assembly on the topic of AIDS. The world community has recognized the HIV/AIDS epidemic as a global challenge that will only be countered through the collective efforts of both rich and poor countries. To this end, and in addition to other endeavours, a global fund has

been created to supply extra funding for the expansion of successful programs and new initiatives to combat not only HIV/AIDS, but also the other global epidemics of Tuberculosis and Malaria (The Global Fund to Fight AIDS, Tuberculosis and Malaria, GFATM). The German government is also obligated to international goals for the fight against HIV/AIDS; it has affirmed this with the adoption (in July, 2005) of its own “Strategy for the Combat of HIV/AIDS“ [2].

The situation in Germany is relatively favourable in comparison to that of other European and international regions. This can at least partly be credited to early adoption and effective implementation of prevention measures. The estimated number of new HIV infections in 2004 was 2.7 per 100,000 inhabitants [3]. HIV infections and AIDS illnesses, however, are very unevenly distributed in the population and lead to significant morbidity and mortality in particular regions and age groups. Although the possibility of treatment for HIV infection has significantly improved since 1996, in Germany currently approximately 750 people die yearly as a direct or indirect result of an HIV infection [2] (see Figure 1).

Figure 1
Model of the trends in HIV incidence, AIDS incidence and deaths of HIV-infected people in Germany from 1979-2005
 Source: Robert Koch Institute



HIV incidence: Estimated number of new HIV infections acquired in Germany or by German residents, who get infected abroad

AIDS incidence: Number of AIDS cases diagnosed in Germany

HIV/AIDS deaths: All cases of death among people infected with HIV, independent of the precise cause of death

HIV/AIDS is of significant relevance to health politics in Germany for many reasons: HIV infection affects predominantly 25-40 year-olds; a cure is not possible, but only a lifelong therapy, complicated by treatment-associated side effects and illnesses, high treatment costs, and the requirement for intense follow-up and psychosocial care.

Clinical picture and course of HIV infection

The Human Immunodeficiency Virus (HIV) belongs to a group of viruses known as retroviruses. Infection with HIV leads to life-threatening illnesses predominantly as a result of the severe impairment of cellular immunity. The main cellular target of the HI-virus is the T-helper cell, which play a decisive role in the coordination of the immune response. When the virus enters the body, it is faced with an immune response, which cannot, however, completely eliminate the virus. The HI-virus replicates and the genetic information of the virus is assembled in the nucleus of infected cells. As a result, the host cell is reprogrammed and produces new copies of the virus. The genetic information of the HI-virus is passed on via cell division and consequently remains in the body of infected people for life, making a cure as of yet impossible. With the advancement of the disease the functional capability of the T-helper cells is reduced, resulting in the progressive deterioration of the capacity of the immune system to fulfil its protective function. This corresponds with a dramatic worsening of the health status of the infected person and, untreated, leads to death.

Acute HIV illness

Almost half of those people who are newly infected with HIV will develop an acute HIV-illness within days to a few weeks after infection. The most common clinical symptoms of this acute illness are: fever, swelling of the lymph nodes, general malaise, inflammation of the pharynx (pharyngitis), a volatile rash (exanthema), diarrhoea, headache, and aching limbs. During acute illness, the concentration of HIV in the plasma is generally very

high, and the T-helper cell count in the blood noticeably lowered. The above-mentioned symptoms disappear spontaneously after three to four weeks, at which time the virus concentration drops and the T-helper cell count re-increases.

Asymptomatic Phase

After this acute phase, the majority of patients are free of HIV-associated symptoms for individually varying periods of time from some months to many years, although during this time virus replication continues and the number of T-helper cells circulating in the blood gradually declines. The time between infection with HIV and the appearance of AIDS-defining illnesses varies among individuals and without therapeutic intervention averages around ten years. The transition from the asymptomatic phase to the AIDS-phase (Acquired Immunodeficiency Syndrome) can occur abruptly, however in the majority of patients it appears as a gradual worsening of the health status.

Symptomatic Phase

Diminished capabilities, unintentional weight loss, flash fevers without recognizable cause, diarrhoea without detectable intestinal pathogens, and dry skin are the most commonly reported symptoms in this phase. The most visible disease phenomena occur to the skin and mucous membranes. Oral infections with the fungus *Candida albicans* are also often observed.

The classification of the phases of HIV disease developed by the American Centers for Disease Control (CDC) has been in standard use since 1993. The classification comprises three clinical (A, B, C) and three laboratory (I, II, III) categories with which the phases of the disease can be characterized (see Table 1). The classification-scheme is unidirectional – going only in one direction; reverse movement through the categories does not occur, and the attained classification remains valid even if, for example, the T-helper cell count is later increased as a result of therapeutic intervention.

Table 1
Clinical and laboratory categories of the CDC classification system
of the phases of HIV disease

Source: Centers for Disease Control and Prevention [4]

Clinical categories of the CDC classification		
A	B	C
Asymptomatic HIV infection	Illnesses indicating a disturbance of cellular immunity, e.g.: – Oral candidiasis	AIDS-defining illness, e.g.: – Pneumocystis Pneumonia – Cerebral Toxoplasmosis
Laboratory categories of the CDC classification		
I	II	III
Number of helper cells/ μ l ≥ 500	Number of helper cells/ μ l 200-499	Number of helper cells/ μ l <200

Clinical picture of AIDS

According to the European case-definition, AIDS refers to a defined group of illnesses that are characteristic of a progressive phase of the chronic HIV infection. The gradual destruction of the immune system results in particular life-threatening opportunistic infections and malignant tumours. Opportunistic infections refer to both newly acquired and/or reactivated infectious diseases resulting from pathogens that are widespread in the natural environment and that pose no danger for the intact immune system. Among the most frequent of these infections are: Pneumocystis Pneumonia (PcP) (pneumonia via the pathogen *Pneumocystis jirovecii*, previously: *carinii*), oesophageal candidiasis (inflammation of the esophagus via the fungus *Candida albicans*), and cerebral toxoplasmosis (abscesses in the brain caused by *Toxoplasma gondii*). Malignant tumours include Kaposi's sarcoma (proliferations of blood-vessel cells on the skin and inner organs), B-cell Lymphoma (malignant proliferation of the B-cells of the lymph nodes, of the defence cells of the specific immune system), as well as Human Papilloma Virus (HPV) associated cervical and anal carcinomas (malignant carcinoma of the cervix, or the outside of the anus or anal canal).

Effects to the central nervous system (HIV-encephalopathy) can lead to mental, vegetative, and motor failures. Wasting syndrome, and HIV-dependent weight loss of more than 10% of one's body weight, associated with chronic diarrhoea or weakness and fever (HIV cachexia), can be life threatening, particularly in conjunction with other diseases.

Without therapeutic intervention, HIV disease leads to death. Findings of large cohort studies indicate that without treatment, within 14 years of the infection, 69% of patients advance to the end-stage of the disease (AIDS) or are already deceased [5].

Modes of transmission and risk factors

Every person infected with HIV is potentially capable of transmitting the virus during one's whole life. Infectivity is particularly high in the first weeks after infection, before the body's defence system has responded. With the decline of the virus concentration in the blood, the infectivity subsides distinctly, however it rises again as the immune-deficiency advances and clinical symptoms appear.

Infection with HIV occurs via bodily fluids containing high concentrations of virus like blood, semen and vaginal fluid. Transmission via breastfeeding is also possible.

The major transmission modes of HIV-infection are:

- ▶ Contact of virus-containing bodily fluids with mucous membranes during unprotected sex
- ▶ Insertion of pathogen-containing blood or blood-products into the bloodstream
- ▶ Mother-to-child transmission

No infection risk is posed by everyday contact with HIV-infected people. This holds for social contact while living in the same household, in the workplace, in school or kindergarten. There is no danger from handshaking, the shared use of dishes, cutlery or glassware, from coughing or sneezing, or from the shared use of a swimming pool or sauna. Transmission via animals (mosquitoes, dogs, cats) is not possible.

Sexual transmission

Corresponding to the modes of transmission, people with HIV-infected sexual partners and people with frequently changing sexual partners have a distinctly elevated risk of becoming infected with HIV if they do not protect themselves (safer sex). Accordingly, anal intercourse poses a higher risk than vaginal intercourse, and both in turn pose a distinctly higher risk than oral-genital contact. Moreover, with mucous membrane contact, local abrasions can lead to a higher HIV-concentration in the region of contact. This means that, for example, secondary infections with other sexually transmitted pathogens can act as cofactors, elevating the possibility of sexual transmission of HIV. At the beginning of the HIV/AIDS epidemic, men who have sex with men (MSM) were considered as the particularly at-risk group for sexual transmission. All people, however – thus also heterosexuals – are threatened with an HIV infection if they have unprotected sexual contact without knowing the HIV status of their sexual partner. In Germany as well as worldwide, HIV is most often transmitted via sexual contact.

Transmission via contaminated blood/blood products

Infections via blood transfusions/blood products

In the past, blood, as an infectious bodily fluid, played an important role in the transmission of HIV. HIV infections via blood transfusions occurred primarily in patients who required large volumes of blood to be transfused as a result of illness or trauma. Before the introduction of donor testing in 1985 and the virus-inactivation of plasma

products, a risk of HIV infection existed in Germany as a result of the handling of blood or blood products (see for this purpose also prevention of transmission via contaminated blood/blood products). Caution with regard to blood transfusions is still required in countries in which such monitoring is inconsistently or not at all implemented.

Infections in the medical profession

Risk of infection is also posed by failure to comply with required standards of hygiene or from accidents involving medical and paramedical insertion of syringes and instruments. Needle-stick injuries therefore represent a risk for the occupational transmission of HIV. The risk of HIV-infection through a needle-stick injury is, however, distinctly less than, for example, the risk of transmission of Hepatitis B. The recommendations for post-exposure prophylaxis (PEP) for HIV [6] include, in addition to immediate decontamination measures, provisions for pharmaceutical prophylaxis and should therefore impede the reproduction of the virus and thus the establishment of a chronic infection. The earlier the prophylaxis is begun, the more effective it is.

Infections through intravenous drug use

Risks of HIV transmission by intravenous drug use are the result of various forms of the shared use of injection equipment, particularly of syringes and needles. Amongst other things, these risks are affected by the number of people using the same equipment.

Mother-to-child transmission

HIV infection in pregnant women presents a considerable risk of transmission of the virus to the newborn if no risk-minimizing measures are taken. Children can be infected by the mother in the womb, during childbirth and through breastfeeding.

Prevalence

Reporting procedures and epidemiological surveillance

The first cases of what would later be referred to as AIDS-illnesses were reported in 1981 in the USA. The first AIDS cases in Germany were reported in 1982 in Frankfurt am Main, Munich, and Berlin. In the following years, the number of newly diagnosed patients rose rapidly, necessitating an assessment of the situation and its progression in Germany. The surveillance of the HIV/AIDS epidemic in Germany is based primarily upon an AIDS case registry and the compulsory reporting of diagnosed cases of HIV infection by the diagnosing laboratories.

AIDS case registry

In Germany, since 1982, voluntary and anonymous case-reports of AIDS illnesses and deaths provided by treating physicians have been compiled and analyzed in a central case registry. The basis of the registration is the applicable AIDS case definition of epidemiological surveillance in Europe. The AIDS case registry provides data for the estimation of the magnitude of the AIDS epidemic. Conclusions about the size and course of the underlying HIV epidemic can be made for the first years of the epidemic by using reverse-projection models based on observed AIDS cases. Since the introduction of highly effective antiretroviral combination therapies in the middle of the 1990s, the AIDS case statistics no longer reflect the natural course of HIV infection. Therefore, the importance of the registration of diagnosed HIV infections (see obligatory reporting by the HIV laboratories) for the estimation of the course and dynamics of the HIV epidemic has risen considerably.

Obligatory reporting by the HIV laboratories

As of 1987, all confirmed HIV-positive diagnoses have been anonymously reported to the AIDS centre of the federal public health institute, and later to the Robert Koch Institute (RKI), as mandated by the Laboratory Report Regulation (LabVO). Because entries in the registry were anonymous and

unlinked, problems of interpretation arose in that multiple registrations of the same case could not be reliably identified. In 1993 the laboratory report was complemented by a voluntary report by the diagnosing physician, allowing for some distinction between confirmed new diagnoses, double reports, and reports with unclear status. For lack of a more direct measurement possibility, the number of new infections is approximated as the sum of confirmed new diagnoses and an estimated proportion of new diagnoses among the reports with unclear status. Since the Infection Protection Law (IfSG) came into force in 2001 [7], all reports on HIV diagnoses remained anonymous, but must include a case-linked code to enable the identification of multiple reports in accordance with Section 7, paragraph 3 of the IfSG. Reporting to the RKI must be conducted directly through the diagnosing laboratory. The doctor who submitted the specimen for testing is legally bound to complete the laboratory report, including demographic, clinical, and medical history information.

Both survey instruments were supplemented by the findings of an anonymous, unlinked testing (AUT) programme of newborns (1993-1999) – an anonymous screening of HIV antibodies in all newborns in Berlin, Lower Saxony and Bavaria (1994/95). Screening refers to the testing of affected people who are unaware of their infection according to defined criteria (e.g. tests, laboratory values).

Currently, within the scope of the “Clinical Surveillance of the HIV Illness“ (KlinSurv HIV), routine data from health care providers is collected regarding the clinical course of the disease, laboratory parameters, and the treatment of the illness in HIV patients in Germany. Simultaneously, the routine testing of all blood donors produces data on the incidence of HIV in all first time and repeat donors in Germany, which are reported quarterly to the RKI and analyzed (blood donor screening).

Since 1991, in the newly established German federal states and in East Berlin, an HIV sentinel study has been set up to help complete the data obtained by the AIDS centre. Anonymized data on newly-diagnosed HIV-positive persons were collected monthly in clinics for sexually transmitted diseases and HIV/AIDS outreach clinics in large cities and were forwarded to the study-headquarter at the RKI. Other diagnosed sexually transmitted diseases were also included in this study as

of 1995. In 2002, this sentinel study with additional data regarding HIV infections and sexually transmitted diseases was expanded and carried out nationally with a modified survey instrument, in line with the scope of the STD sentinel system [8]. As part of this system, practicing physicians, STD- and HIV-outreach clinics of the public health departments, as well as local clinics report all incident STD cases to the RKI.

Current data regarding the HIV and AIDS epidemic in Germany is regularly made available by the RKI on its website (www.rki.de).

The course of the HIV epidemic in Germany

As of the end of 2004, the total number of people living with HIV (less those already deceased) is estimated at around 46,500, of which 83% are men, 17% women, and less than one percent children. Of the estimated number of new HIV infections (incidence), women account for approximately 13% of the approximately 2,600 infections for the year 2005. The number of newly diagnosed infections shows an upward trend since 2002. This estimate applies to infections in Germany, or rather to people residing in Germany at the time of infection; that is, infections in immigrants from so-called

high prevalence regions are not accounted for in this number. From the beginning of the HIV epidemic until the end of 2004, the total number of infected people is estimated at around 73,000.

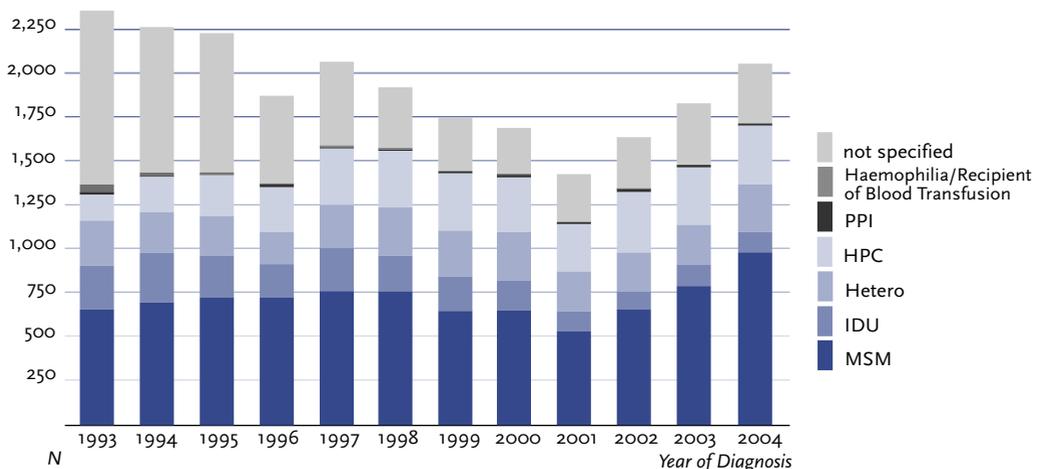
Given that the incidence of HIV can only be estimated (see obligatory reporting by the HIV laboratories), data on the evolution of HIV incidence over time relies predominantly on the results of statistical modelling [9]. According to this, the incidence of HIV infections peaked in 1983/1984.

The spread of HIV was particularly fast within the population of homosexual and bisexual men. As a result of behavioural and attitude changes (and also saturation processes), the incidence of HIV in this group has been declining since the mid-1980s. The incidence peak among intravenous drug users (IDUs) occurred later. In this group women make up just short of 30%. After a further one- to two-year time lag, infections acquired by heterosexual contact started to increase. Among people indicating infection via heterosexual intercourse, the proportion of women is 45%.

Trends in the various affected groups

Figure 2 demonstrates the evolution of new HIV diagnoses in the various affected groups.

Figure 2
Evolution of new HIV diagnoses since 1993 by stated infection risks and year of diagnosis
Source: Robert Koch Institute



MSM: Men who have Sex with Men; **IDU:** Intravenous Drug User; **Hetero:** Heterosexual Transmission; **HPC:** People from High Prevalence Countries, **PPI:** Pre-/Perinatal Infections

Men who have sex with men (MSM)

In Germany, men who have sex with men (MSM) remain the group most affected by the HIV epidemic. Currently, 1,800 new infections arise within this group per year. Initially as of 1993, the incidence trend among MSM had been declining. Since about 2002, however, the incidence in this group has again been rising. From 2002 to 2004, the registration of newly diagnosed cases of HIV among MSM rose by 50%. At the same time, an increase in Syphilis infections was also observed among MSM. The underlying behavioural changes responsible for this increase were found to be a reduction in condom use among both committed partners as well as casual partners, and an increase in the number of risky sexual contacts.

The age distribution of new HIV diagnoses among MSM has changed only slightly in recent years: the proportions of men younger than 30 and between 40-50 years old have increased marginally. Most new HIV diagnoses occur among men 30-39 years of age. Repeated cross-sectional studies [10] investigating the reactions of homosexual men to AIDS suggest that the proportion of infected men with lower education levels has risen in recent years. The proportion of men of non-German origin is also not proportional to the countries of origin of immigrants in the general population. HIV-infected MSM of non-German origin come mostly from other Western European countries as well as from North and South America.

Intravenous drug users (IDU)

Currently, approximately 200-250 intravenous drug users (IDUs) contract HIV per year and among them 28% are women. Behavioural changes have occurred to a significant degree among this group. The re-use, or rather shared use of insufficiently sterilized syringes and needles has been distinctly reduced as a result of syringe/needle exchange programs. Shared use still occurs, however, especially in places where clean drug use equipment (syringes, needles, spoons) is not unrestrictedly available (e.g. prisons), resulting in considerable infection risks [11].

The proportion of IDU among newly diagnosed HIV infections dropped from 13.2% in 1994 to 5.6% in 2004. This reduction was more

pronounced in major cities than in the remaining regions. The proportion of people of non-German origin, however, remains particularly high in this affected group (38% of reported cases with data on country of origin in 2001-2004). Among female drug users, the proportion of people of non-German origin is distinctly less (18%) than among male drug users (46%). The dramatic spread of HIV among drug users in Eastern Europe (former Soviet Union) seen at the end of the 1990s was also reflected in an increasing proportion of drug users originating from this region among new HIV diagnoses in Germany. In 2003 and 2004, for the first time since 1993, an increase in new HIV diagnoses by drug users was reported in some federal states: Bavaria, Baden-Württemberg and Nordrhein-Westfalen. At the same time, the proportion of drug users from Eastern Europe also increased. The increase likely represents a wave of HIV infections in drug users with close contacts to Eastern Europe, paralleling the HIV epidemic among drug users within this region. Whether this increase represents an emerging trend among all IDUs, or whether it is a problem unique to this population group remains to be seen.

Heterosexual Transmission (Hetero; not including people from high prevalence countries)

When compared to the evolution of the epidemic in the other affected groups, the HIV epidemic began after a distinct time lag among people infected via heterosexual contact. This is because it began as a result of secondary infections via partners from the other – primary affected – groups. In recent years in Germany around 200-250 new diagnoses have been consistently registered per year and the proportion of women lies around 45%. Despite there being no indication as of yet that HIV spreads largely independently in the heterosexual population outside of the primarily affected groups (MSM, IDU), an increase in heterosexual transmission in the coming years as a result of changes in risk behaviours and general conditions (e.g. larger heterosexual HIV epidemic in Eastern Europe) can not be dismissed. The trend of HIV infections among people presumed to have been infected by heterosexual contact was tracked with particular attention in the past. Although until now, HIV infections in this group represent a

small proportion of new HIV diagnoses in Germany, in recent years they account for the strongest percentage increase. The proportion of cases with presumed heterosexual transmission has risen significantly from 2.3% for the years before 1988 to 12.8% in 2004.

People from high prevalence countries (HPC)

People who come from countries with a high prevalence of HIV, in which heterosexual transmission is the predominant mode of transmission, represent an epidemiologically distinct group. High prevalence regions refer to those regions in which more than 1% of the adult population between the ages of 14 and 49 is infected with HIV. Currently, this includes all countries in Sub-Saharan Africa, three countries in Indochina, and some states in the Caribbean and Central America. As of yet (at the beginning of 2004), Eastern European countries do not yet fall in the category of high prevalence countries, although in some of these countries the 1% rate of infected people in the total population has already been reached. Most of these people, who are diagnosed with an HIV infection in Germany, likely acquired the infection in their country of origin. The HIV infection, however, may also be acquired during a visit to one's native country or via sexual contact in Germany with partners from the same regions of origin. The HIV surveillance system (see reporting procedures and epidemiological surveillance) can not differentiate between these possibilities, in light of the fact that in most cases the date of infection is unclear. Not enough is known about the increase of people from these regions who are currently living in Germany. Their number may lie in the range of around 500,000, with a presumably increasing trend. The proportion of women among people from high prevalence regions living in Germany and infected with HIV was just over 60% in the last five years (2000-2004). Among asylum seekers, however, a slight decrease of people from high prevalence regions has been reported in recent years.

People from high prevalence countries currently account for around 20% of all new HIV diagnoses in Germany. Due to the previously mentioned reasons as well as the lack of relevant research, it currently remains unknown to what extent HIV transmission within immigrant popu-

lations occurs in Germany or when people who have already been living in Germany visit their native countries. The proportion of people from high prevalence regions among new HIV diagnoses can reach up to 60%, particularly in the new federal states (but also in territories of the old federal states outside the major urban centres) where the total number of people infected with HIV is relatively small.

The increasing number of HIV diagnoses among people from high prevalence regions reflects on the one hand a better surveillance and registration of the regions of origin, and on the other hand, the still largely unrestricted rise of the prevalence of HIV in the respective regions of origin. In Germany, people from these countries typically live in more or less closed communities with limited access to the German healthcare system, particularly among illegal immigrants, and even worse access to common prevention messages. These factors may facilitate HIV infection in Germany and necessitate special prevention strategies.

The proportion of HIV-infected people in Germany who are from high prevalence regions but who leave Germany before the diagnosis of an AIDS illness remains unclear. In keeping with a decision by the European Court of Justice for Human Rights, an HIV infection constitutes a barrier to deportation to countries without the availability of adequate HIV treatment.

The special situation of women

Among men infected with HIV, the proportion of men infected by heterosexual intercourse is approximately as large as the proportion of men who originate from a high prevalence region (13% vs. 11% according to cases reported in 2001-2004). Among women infected with HIV in Germany, heterosexual transmission accounts for just over 30% of infections and represents a distinctly smaller proportion of reported cases as does origin from a high prevalence region (around 60%). The comparatively higher infection risk for women from high prevalence regions has many reasons. Biologically, there is a greater risk of transmission to a woman who has unprotected sex with an infected man than to a man who has unprotected sex with an infected woman. In addition, the in-

fection risk to women in many countries outside of Europe arises from their social position and a lack of power. The more women are emotionally or economically dependent on men, the more difficult it is for them to assert their health interests. Through their unequal position of power in sexual relations, young girls and women are often not in the position to control if and under what conditions sexual intercourse will take place and, for example, to insist on the use of condoms. It must therefore be the goal in these countries to improve the social and economic position of women and to systematically encourage men through prevention messages to protect themselves and their women from infection.

In every day life, but particularly in war and conflict situations, women and girls are exposed to the danger of sexual violence, thus increasing their risk of being infected with HIV. Particularly in developing countries, women are also more strongly affected by the indirect consequences of the immune deficiency diseases. Since women undertake the largest proportion of the support and care of the chronically ill and of the dependants of those affected by AIDS the disease results in a higher workload for women and girls. In adopting the responsibilities of this care, girls are no longer able to attend school; education, however, is a necessary factor to counter the spread of HIV/AIDS [12].

Women living in Germany with HIV are subject to social isolation, discrimination and difficult economic circumstances. The situation of HIV-infected currently drug-dependent women is especially dramatic, for whom the mental, physical and social problems of their drug-dependence are compounded by the burdens of an HIV infection. Among mothers infected with HIV, the disease threatens not only themselves, but may also threaten the survival of their child [13]. Immigrant women with HIV are in an especially difficult position, since they face in addition to cultural and language barriers, a partially immigration-associated disadvantage (see people from high prevalence countries). As a result, diverse and distinctly structured woman-specific services are required in order to reach each of the specific target groups of women.

Globally, almost half of all people affected by HIV/AIDS are girls and women. The UN initiative (The Global Coalition on Women and AIDS) there-

fore incorporates a wide spectrum of activities in order to reduce the devastating effects of AIDS on women and girls worldwide [14].

Children (pre-/perinatal infections; PPI)

Until 1998, the data collected from the HIV laboratory reporting scheme gave no exact information regarding the actual number of children infected with HIV in Germany. Estimates amount to a total number from between 300 to 500 children. On the bases of anonymously conducted studies on blood samples of newborns in Berlin, Lower Saxony and Bavaria during 1993-1998, it can be hypothesized that at that time approximately 80 to 100 children of HIV infected mothers were born each year in Germany. As of around 1993/94, the mother-to-child transmission rate was brought down to under 2% through a combination of various preventive measures (see prevention). With a constant number of HIV-infected pregnant women and optimal medical care, no more than 2 HIV-infected newborns would have been anticipated per year; the actual number of HIV infections in newborns is, however, distinctly higher. There are several reasons for this:

The number of pregnancies among women infected with HIV has risen significantly in the last few years. In HIV treatment centres for pregnant women, the number of pregnancies delivered per year by women infected with HIV is estimated at around 200.

Not all HIV infections in pregnant women are recognized early enough, therefore impeding a portion of the transmission prevention measures.

Among foreign-born children, an HIV infection is often only diagnosed after entry to Germany.

The proportion of German children (birthplace and country of origin of the Mother is Germany) among the total number of HIV infections in children lies (with the addition of the proportion of "unknown" country of origin of the mother) at a maximum of 20%. Studies based on data from the HIV registry have demonstrated that apparently peripartally acquired HIV infections are often first diagnosed by paediatricians within the scope of the differential diagnosis of clinically striking cases in children. Even women who receive prenatal care

in Germany are not always offered an HIV test, which could identify an infection in the mother and result in the use of measures to prevent transmission to the child.

Haemophilia

Haemophilia is a hereditary disease resulting in the defective clotting of the blood. Treatment occurs via the transfusion of so-called clotting factors (blood components), and is dependent on the degree of severity of the disease. Before the introduction of virus inactivation procedures for blood products, haemophilia patients were at risk of transmission of viral infections at the beginning of the 1980s. Tracking of the HIV epidemic in haemophiliacs depended on the use of models, which attempted to deduce the probable time point of the infection based on data from documented cases and estimates of the latency period between HIV infection and AIDS illness. As a result, it can be assumed that the peak of HIV incidence among haemophiliacs was reached in 1982 and that 66–81% of all eventually HIV-infected haemophiliacs (in Germany and Austria) acquired the infection before January of 1983 [15].

As a result of the advocacy of the German Haemophilia Association, and on the basis of data from the AIDS case registry and the HIV laboratory reporting scheme, the total number of HIV-infected haemophiliacs in Germany has been estimated at a maximum of 1,300. The number of HIV-infected haemophiliacs seeking compensation in response to the law mandating humanitarian assistance for people infected with HIV via blood products (HIV Assistance Act of July 24, 1995), lies around 800 people, including surviving dependents of those already deceased. With the introduction of virus-inactivated preparations and the routine testing of all donors as of October 1985, new HIV infections in this group have been virtually completely eliminated.

Recipients of blood transfusions or blood products

The highest risk of acquiring an HIV infection through blood transfusion probably existed between 1982 and 1984. It is to be assumed that in these years around 200 people were infected in this way. After 1985 – the year in which the obliga-

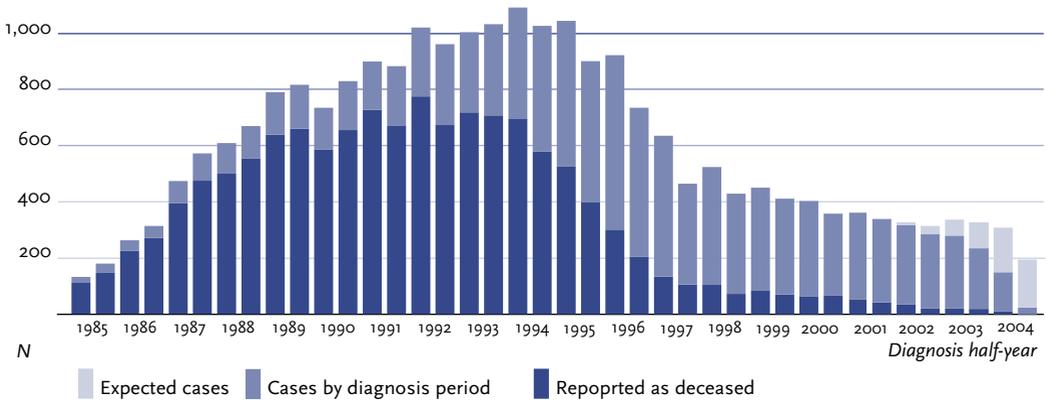
tory testing of all blood donors was implemented – the number of infections decreased to almost zero [16]. On the basis of the so-called diagnostic window, however, infections via blood transfusions can not be completely precluded to this day. Altogether, after the adoption of the donor screening program in Germany in 1985, 11 HIV transmissions via blood or blood products have nonetheless been recognized. It can not be exactly ascertained how many patients were infected via blood transfusion or treatment with blood products outside of Germany because the data on infection risks in these cases cannot generally be verified.

Evolution of AIDS cases in Germany

A total of 23,546 cases were reported to the AIDS case registry from 1982 to December 31, 2004. Of that number, 55.9% are known to be already deceased. Figure 3 describes the evolution of the AIDS incidence by half-year of diagnosis as well as the number of expected reports after adjustment for the reporting delay.

The number of reported cases adjusted for the expected reporting delay as well as for regionally variable under-reporting (cases that are never reported) results in an estimated total number of 31,000 AIDS cases at the end of 2004. Based on this estimate, a total of ca. 74% are already deceased; that is around 23,000 of all patients with AIDS. The number of living patients at the end of 2004 who have at some point been diagnosed with an AIDS-defining illness can therefore be estimated to be around 8,000. At the beginning of the 1990s, a maximum of around 2,000 new AIDS diagnoses per year was reached. With the improvement of the therapeutic options and, as a result, the earlier initiation of treatment, the number of AIDS diagnoses declined dramatically from the middle of the 1990s to presently around 850 cases per year. Also, the number of deaths among people infected with HIV has dropped from around 2,000 per year in the first half on the 1990s to currently around 750 per year.

Figure 3
Number of registered AIDS cases until December 31, 2004, adjusted for the reporting delay, by half-year of diagnosis
Source: Robert Koch Institute



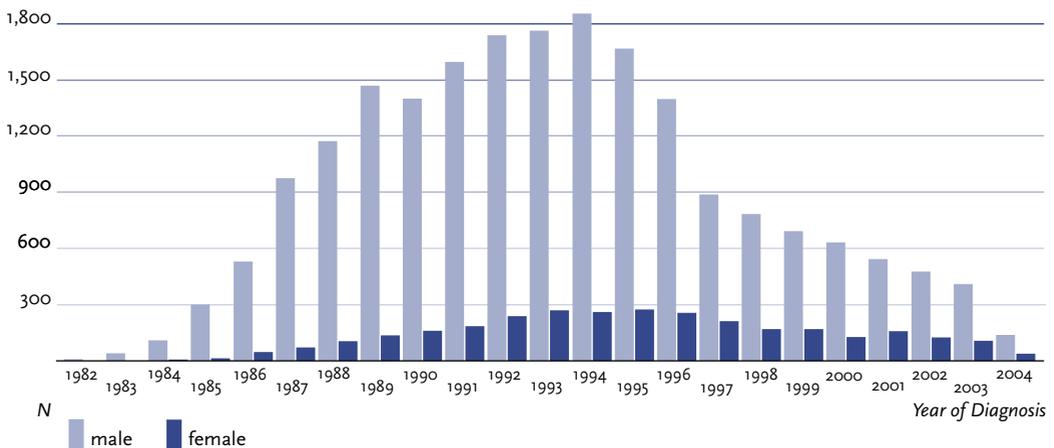
Evolution of the number of cases among women

Women currently account for 13% of all people with AIDS (see Figure 4). This proportion has increased over the years from 6.6% of diagnosed AIDS cases in the years before 1988 to over 20% for the years 2003-2004.

The increase of the proportion of women among the total number of AIDS cases reflects the increase of AIDS cases in affected groups with a higher proportion of women. Until 1989, the

increase of the proportion of women among AIDS cases was caused predominantly by an increase in the proportion of cases among drug users, of which around one third are women. Since 1990, the increase in the proportion of women has been caused predominantly through an increasing proportion of AIDS cases with heterosexual transmission risks, of which more than half (55%) are women. Furthermore, the majority of AIDS patients with heterosexual transmission come from high prevalence regions and the treatment-associated

Figure 4
Distribution of AIDS cases by sex and year of diagnosis
Source: Robert Koch Institute



decrease of AIDS cases since 1996 has fallen distinctly less in this affected group than in the other groups with definable infection risks.

Just under half (41%) of all women with AIDS have become infected via intravenous drug use. The proportion of women with AIDS who have been infected via heterosexual contact has more than doubled from 20% in the years before 1990 to 44% in the years after 1999.

Evolution of the number of cases by infection risk

The AIDS epidemic in Germany is shaped primarily through cases in the groups of the homosexual and bisexual men, as well as intravenous drug users, who together constitute approximately 80% of all cases.

The proportion of cases with presumed heterosexual transmission (including people from high prevalence regions), however, has grown disproportionately in recent years and will likely rise further in the coming years. Among currently diagnosed cases (in the years 2003-2004), this proportion is around 20%. It can predominantly be attributed to the fact that the number of cases among people from high prevalence regions with presumed heterosexual transmission have not subsided since the middle of the 1990s. People from high prevalence regions currently comprise about two thirds of AIDS patients infected via heterosexual contact.

From an epidemiological perspective, AIDS cases among children play only an ancillary role in Germany.

Epidemiological trends are largely defined by a few major cities. Over half of all people with AIDS live in the major cities like Berlin, Frankfurt am Main, Munich, Cologne, Duesseldorf and Hamburg; before 1987, this proportion was 60%. Of cases diagnosed in recent years (2001-2004), 48% stemmed from the remaining areas of the old federal states (not including the major centres). The proportion of patients who stem from the newly-established (after German reunification) federal states (except Berlin) rose from under 1% before 1990 to 2% in the years 2001-2004.

Age distribution

The average age of all patients (over 12 years old) at the time of an AIDS diagnosis is 39.1 years (men: 39.7; women: 35.5). The majority of patients are between the ages of 25 and 49 years old at the time of AIDS diagnosis (see Table 2).

Table 2

Proportion of registered AIDS cases by sex and age at the time of diagnosis (until December 31, 2004)

Source: Robert Koch Institute

Age group	male	female
<1 year	0,0%	0,5%
1-4 years	0,1%	0,9%
5-9 years	0,1%	0,3%
10-12 years	0,0%	0,2%
13-14 years	0,1%	0,0%
15-19 years	0,4%	0,7%
20-24 years	2,5%	5,9%
25-29 years	11,1%	21,1%
30-39 years	40,8%	45,0%
40-49 years	27,3%	15,4%
50-59 years	13,7%	6,2%
60-69 years	3,2%	2,9%
>69 years	0,5%	1,0%
Total	100%	100%

This differential age distribution is illustrated predominantly in the differential distribution of men and women within the respective affected groups, as well as in the varying age distributions within each group. Homosexual men average 40 years old at the time of AIDS diagnosis, and have the highest average age except for those infected by blood transfusion (49.9 years) and those with unidentified mode of transmission (43.2 years). Within all affected groups, women are on average around 2-4 years younger than men.

Prevention

Given the absence of a curative treatment or protective vaccine, the most effective method of controlling the HIV epidemic remains the prevention of new infections. To that end, the uninfected must be aware of the modes of transmission, and must avoid them or protect themselves accordingly. People infected with HIV must be aware of how they need to behave in order to prevent transmission of the infection and must act accordingly.

The conventional measures of infection prevention and containment of the spread of infectious diseases (identification of infected people, codes of conduct for infected people, quarantine measures, and treatment) are only partially applicable and effective with respect to the HIV infection. This is a result, amongst other things, of the long incubation period between infection and clinical manifestation of disease, and on the possibility of the transmission of the infection by asymptomatic infected people. The high infectivity of freshly infected but not yet diagnosed people increases the risk of the continued spread of HIV.

Since in Germany, as in most other developed industrialized countries, the infection risks are very unevenly distributed within the population, education and prevention measures must be addressed not only to the entire population, but to especially vulnerable groups via appropriately targeted methods. Such targeted measures can therefore only be successful if they are developed starting from the acceptance of the diverse lifestyles and sexual preferences. In implementing these measures a combination of mass media campaigns and personal communication strategies are required, with a combination of behaviour change messages and structural changes, which minimize the impact of risk environments. Also necessary is the cooperation of both governmental and non-governmental organizations. Prevention messages must therefore orient themselves to the reality of life and must take into account the social, cultural and religious backgrounds of the target groups. Moralizing messages with absolute claims never fulfil such criteria.

In the fight against HIV/AIDS and other sexually transmitted diseases in Germany, there has already been since the middle of the 1980s an ef-

fective task-sharing between the state-run federal centre for health education, which addresses its preventive measures to the general population with its campaign “Don’t Give AIDS a Chance“, and non-governmental organizations, like for example Deutsche AIDS-Hilfe (German AIDS-Help), the prevention-services group responsible for particularly vulnerable affected groups. The work of self-help organizations is indispensable because they represent the best entry point to their target groups. Informational and educational campaigns for the general population are the prerequisite for broad social acceptance of the prevention messages and in turn ensure the effectiveness of prevention in a climate of solidarity and non-discrimination. These activities are supplemented by the German AIDS Foundation, which is concerned primarily with the social dimension of HIV/AIDS, and supports both individual assistance for affected people as well as larger programs for people with HIV and AIDS in Germany and other countries.

The following prevention measures are designated according to modes of transmission:

Prevention of sexual transmission of HIV:

As a method of protecting against the sexual transmission of HIV, condoms should be used (safer sex), particularly with new or changing sexual partners. Before abandoning the use of condoms, the level of commitment in the partnership and, if necessary, the partner’s HIV status should be clarified.

Prevention of transmission via contaminated blood/blood products:

The risk of acquiring an HIV infection via blood transfusion in Germany has become marginal in the present time. Since 1985, all donors must be examined for the existence of antibodies for HIV, and are also examined for Hepatitis C and B virus infections as well as for Syphilis. This is laid out in Section 5 of the Transfusion Act. As of May 1, 2004, testing for the existence of HIV nucleic acids has also been introduced as a mandatory test before blood donation, making possible the detection of fresh HIV infections. This testing had been

introduced years earlier by the majority of blood donation services. As a result, the already minimal risk of an HIV transmission via blood transfusion was reduced even further and is presently estimated at less than 1 in 1.5 million transfusions.

Nevertheless, in the very early phase of the infection it is theoretically possible for all HIV tests to turn out negative (“window phase”) however, a blood donation during this time can already be infectious. Therefore, blood donors are still asked about possible risk factors for the acquisition of an HIV infection; where these exist, donation is forbidden. Blood should also never be donated with the intention of getting an HIV test because this poses a threat to the patients for whom transfusions are ordered.

In addition to testing and donor-selection, plasma is stored in quarantine for four months to help ensure its safety. The plasma may only then be transfused if the donor again tests negative for HIV four months after the donation. In this way, the residual risk via “window phase donation“ is practically eliminated. Plasma that is used for the manufacture of plasma products, for example clotting factors for people with blood diseases, is obtained using the same criteria with respect to HIV as are normal blood donations. In addition a minimum of two effective methods of HIV inactivation must be used in the production process. As a result, the transmission of HIV via these products is nearly eliminated. Adherence to these provisions is assured through licensure and regular surveillance of blood donor services and their products through the responsible authorities of the states and through the Paul Ehrlich Institute. Moreover, the Robert Koch Institute collects anonymized data regarding HIV infections among blood donors quarterly according to Section 22 of the Transfusion Act in order to quickly measure and evaluate changes in this population group.

Prevention of mother-to-child transmission of HIV:

A combination of preventive measures makes it possible to prevent the transmission of HIV from mother to child including antiretroviral therapy during pregnancy, caesarean section, antiretroviral prophylaxis in the newborn and the abandonment of breastfeeding. In order for these measures to be successfully introduced, the HIV status of the pregnant woman must be known. To that end, all pregnant women should be offered an HIV antibody test along with competent counselling. If necessary, interpreter and telephone services should be included in order to ensure that the pregnant woman is referred to appropriate counselling facilities. With these measures, and optimal care of the pregnant woman, the rate of mother-to-child transmission can be reduced to below 2%. Without adequate medical support around 20-40% of children of HIV positive mothers are infected, which is particularly the case in poor countries. These countries often fail to provide medication, medical infrastructure (laboratory diagnostics, caesarean sections) and clean water for bottle-feeding. Other obstacles include inadequate prenatal care with corresponding counselling, and insufficient knowledge of the HIV status of pregnant women.

Prevention measures in the main affected groups

Men with same-sex sexual contact

After the emergence of AIDS, men who have sex with men (MSM) normalized the use of condoms for anal intercourse. In the meantime, unprotected anal intercourse has been either completely shunned, taking place only within committed partnerships, or occurs sporadically, practiced with exclusive partners on the basis of more or less appropriate considerations of risk. Regardless, more than half of new HIV infections in Germany occur among MSM, something that relates primarily to the comparatively high number of partners and the rising prevalence of HIV in this group. Furthermore, since the mid 1990s, a gradual decrease in condom use has been observed. In addition, the decreasing mortality rate and improved quality of life contributes to an increasing number of sexu-

ally active HIV-infected men. Subcultural scenes have emerged, particularly in major cities in which a larger number of HIV-infected men with same sex sexual contacts live, in which unprotected anal intercourse is practiced under the assumption that the people involved are aware of their infection status and therefore knowingly accept any associated risks. Exaggeratedly optimistic estimates of treatment options as well as a transition from risk elimination strategies towards risk minimization strategies, which has to be expected for arrangements with new, enduring risks seem also to play an important role in the declining willingness to protect oneself consistently through condom use.

Intravenous drug users

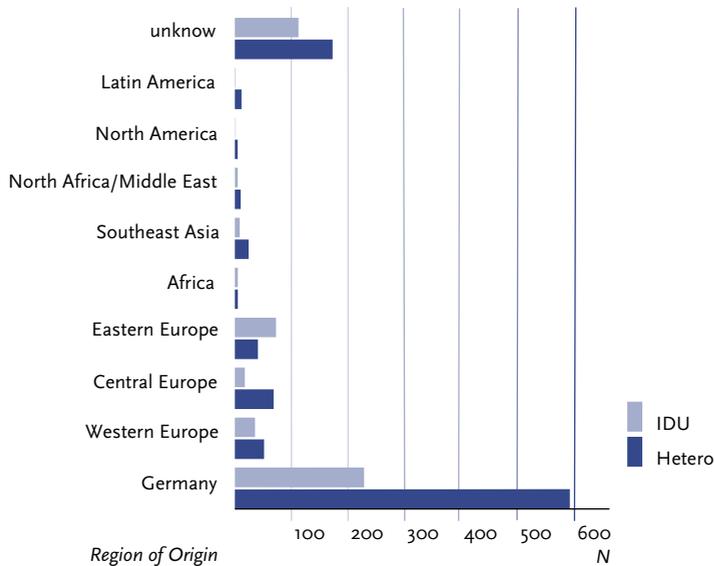
The shared use of syringes and needles as a transmission risk for HIV by IDUs in Germany has been significantly reduced through the abolition of barriers to the access of sterile single-use syringes and needles, the implementation of low-threshold needle exchange programs, as well as through changes to the basic legal framework (possession of needles by potential drug users is no longer criminally enforced). Also, the expansion of substitution therapy has contributed to a reduction of new HIV infections. Obstacles to HIV prevention among drug users include the unsatisfactory situation in detention centres, where the few effective pilot projects for infection prevention by needle exchange have not been expanded, but have been discontinued on financial grounds. Privately organized rural drug scenes have also proven challenging to prevention offers as these are difficult to access. Another problem area is the intravenous drug use by immigrants from Eastern Europe who have little or no contact with the established drug-treatment system in Germany.

Necessity of cross-border prevention

Prostitution, human- and drug-trafficking in border regions, particularly in those regions with strong economic disparity, are problems relevant to HIV. These problems cannot be remedied via police measures alone. Policing should therefore be complemented by low-threshold prevention and treatment services. The coordination of such offers and measures with police and border control agencies is indispensable in order not to compromise the effectiveness of these assistance services or to keep people from seeking help due to fears of persecution. In addition, services should be available on both sides of a border, and should include multilingual prevention and education materials, anonymous counselling and testing, and possibilities for the treatment of sexually transmitted infections, including the HIV infection, for people without health insurance and those without residence permits.

In the coming years, the HIV problem is expected to grow, particularly on the eastern borders of the European Union as a result of the evolution of the HIV epidemic in Eastern Europe. There, the number of new HIV infections has dramatically increased since the second half of the 1990s. Until now, this has predominantly been due to intravenous drug use, though HIV transmission by heterosexual contact is increasingly being reported. Furthermore, a considerable proportion of women who sell sexual services are also intravenous drug users; for these women a double risk of HIV infection exists. Until now, little political attention has been given to the problem of HIV/AIDS in this region, and therefore decisive prevention successes are not foreseeable in the near future and a further increase in the number of infections must be anticipated. It is possible that a situation comparable to that in Sub-Saharan Africa will emerge in the countries of the Commonwealth of Independent States (CIS). The failure to implement HIV primary prevention in a timely manner in particularly vulnerable groups like IDUs and prostitutes may lead to an independent epidemic in the heterosexual general population. In line with the eastward enlargement of the EU and the anticipated heightened exchange of people and services between Germany and Central and Eastern Europe, the evolution of the HIV epidemic in this region

Figure 5
New HIV diagnoses in Germany among people with heterosexual and drug-use associated infection risks by region of origin of the affected people (2001-2004)
 Source: Robert Koch Institute



undoubtedly will have effects on the further evolution of the HIV epidemic in Germany. Already now (the end of 2004), an increasing number of new HIV diagnoses in Germany can be attributed to people originating from Eastern and Central Europe, particularly in drug users and people with heterosexual transmission risks (see Figure 5).

Consequences

Health afflictions, sequelae

The manifestation of AIDS-defining illnesses can presently be largely prevented via timely begun, effective antiretroviral therapy (see treatment). When antiretroviral therapy is started after an AIDS manifestation, a distinct improvement in virologic and immunologic parameters, as well as the clinical condition and survival time can be anticipated, provided that this initial manifestation is therapeutically controllable and survived.

AIDS-defining malignant tumours and co-infections can pose a problem. These show, along with effective antiretroviral therapy, a higher progression rate, that is a progression or rather a worsening of the disease among people infected with HIV than among those who are not infected. Of particular note are chronic hepatitis C (HCV) and hepatitis B (HBV) infections as well as genital or anal infections with oncogenic (cancer-causing) Human Papilloma Viruses (HPV). Moreover, the rates of treatment success are lower with co-existing HIV infection, side effects of treatment are

common and more severe (with HCV, HBV), and rates of recurrence are high (with HPV). In HIV patients with hepatitis C co-infection, HCV-dependent cirrhosis of the liver has overtaken AIDS as a predominant cause of death.

The situation is completely different when antiretroviral therapy is limited or not possible due either to the development of resistance against available medications or to infection with an already resistant strain of HIV. In these cases, prophylactic measures to prevent the most severe opportunistic infections can still be used, but effective prophylaxes are not available for all opportunistic infections and pharmaceutical prophylaxes do not exist for AIDS-defining malignant tumours. The progression and prognosis of an AIDS manifestation therefore depends considerably on the patient's history of antiretroviral treatment.

Antiretroviral combination therapy can lead to unwanted adverse effects and sequential illnesses both acutely at the beginning of treatment and after months or years of therapy. Acute, predominantly gastrointestinal problems develop only temporarily during uptake of therapy and can often be controlled by exchange of specific medications. With regard to long term adverse effects, mitochondrial toxicity (nerve damage, disruption of blood regeneration, disruption of adipogenesis and of cellular respiration) and liver toxicity play a major role, as do changes in lipid and carbohydrate metabolism. The most frequent and significant adverse effects

due to antiretroviral combination therapies are: Lipodystrophy Syndrome (perturbation of fat distribution), an increase of the blood-lipid levels, the development of insulin resistance (metabolic condition with high insulin levels despite normal or increased blood-sugar concentration), hypertension, neuropathy, toxic hepatitis (inflammation of the liver) and lactic acidosis (acidemia through an accumulation of lactic acid (lactate), which in pronounced cases can lead to liver failure). It remains unclear to what extent the appearing changes in metabolism expedite the development of vascular disease (coronary heart disease, stroke).

Recent studies [17] document gender-specific differences in the progression of the illness and in the treatment of HIV infection. The medical and psychosocial characteristics of women, however, have not been extensively included in AIDS research. A research need exists therefore with respect to a range of questions concerning, amongst other things, the differential spectrum of adverse effects of medical treatment and their implications with respect to the adherence to treatment (compliance). In addition, the effects and interactions of medical treatment on the female hormone system, as well as the psychosocial aspects of the illness are a subject of investigation. (A summary can be found on the website of the German AIDS Association: www.daignet.de.)

In recent years, changes could be observed in the absolute numbers of the illnesses that

Figure 6
Percentage of illnesses of the first manifestation by year of diagnosis
(AIDS cases registered up to December 31, 2004)

Source: Robert Koch Institute

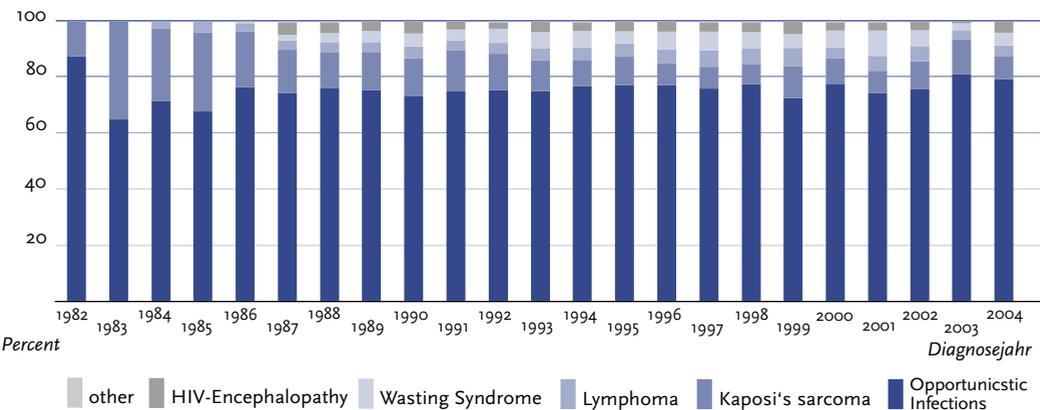
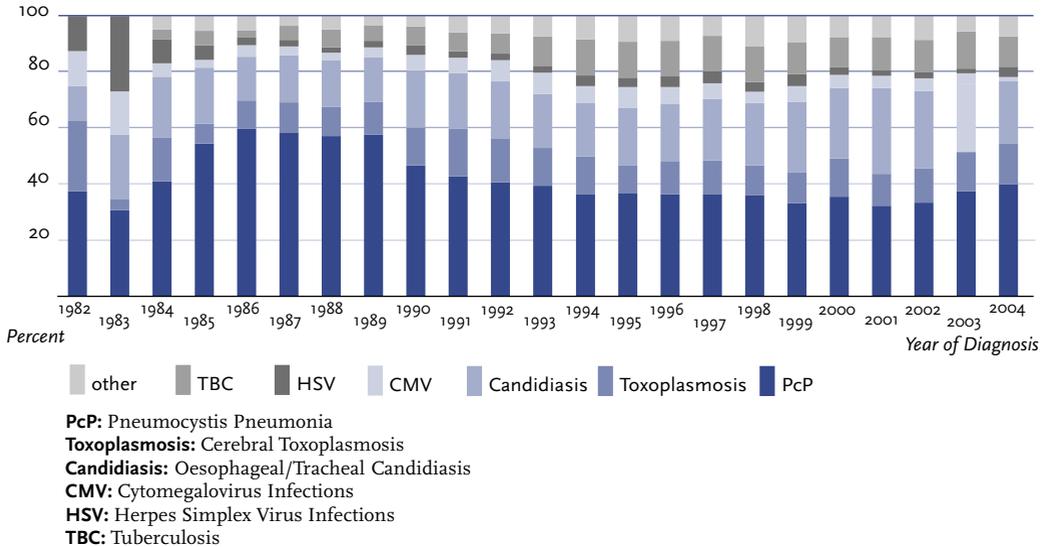


Figure 7
Percentage distribution of opportunistic infections (as first manifestation of AIDS)
by year of diagnosis (AIDS cases registered until December 31, 2004)

Source: Robert Koch Institute



lead to the diagnosis of AIDS. The improvement in treatment availability since 1996 had little effect, however on the percentage distribution of the diagnoses (see Figure 6). This suggests therefore that the large majority of people currently being identified with AIDS did not previously receive antiretroviral treatment for the most part because their HIV infection had not yet been diagnosed. The majority of current AIDS patients are people who only first learned of their HIV infection together with the manifestation of AIDS. In comparison, the number of people who develop AIDS despite prior antiretroviral therapy is quite low.

Particularly noticeable is the relative decrease in cases of Kaposi's sarcoma as the first manifestation of AIDS (including those cases in which Kaposi's sarcoma appeared in combination with an opportunistic infection) from 30% in the years before 1987 to below 10% in the years after 1995.

Since 1989, an effective chemical prophylaxis has been available for the most frequent opportunistic infection, Pneumocystis Pneumonia (PcP). One would anticipate, therefore, that the proportion of opportunistic infections relative to the total first manifestations of disease would

have decreased. Over the years, however, this has remained consistently around 75%.

A distinct indication of the effectiveness of the PcP-prophylaxis can be seen, however, in the decrease of the proportion of PcP among cases with opportunistic infections as the first manifestation of AIDS after 1989 (see Figure 7). The proportion of PcP decreased overall from 60% in 1987 to between 25-30% in the years after 1993. Infections caused by the Herpes Simplex Virus (HSV), which cause an illness of the skin and mucous membranes, also decreased since the 1980s. In exchange, other opportunistic infections for which comparatively effective prophylaxes have not yet been developed increased proportionally. Of particular note are cerebral toxoplasmosis, illnesses caused by cytomegalovirus (CMV) and affecting various organs (e.g. eyes, bowel, lungs), as well as infections by mycobacteria, which are causing a number of illnesses like, for example Tuberculosis. It must be remembered, however that these changes may partly also be accounted for by changes in diagnostic practices.

Survival time and age of death

An obvious effect of the improved therapeutic options is the distinctly improved survival time after the diagnosis of AIDS that has been observed over the course of the epidemic. In the interpretation of survival times after an AIDS diagnosis, however, one must bear in mind: a distinct prolongation of survival time can only be expected among people who only begin antiretroviral therapy after the appearance of an AIDS defining illness. In contrast, short survival times after an AIDS diagnosis have to be expected, if the AIDS manifestation is a consequence of the virologic, immunologic and clinical failure of previous antiretroviral therapy.

The median survival times by year of death are displayed in Table 3. These calculations of the time between AIDS diagnoses and death refer only to patients who were reported to the Robert Koch Institute with known dates of death until the end of 2004 (N=13,064).

Table 3
Time period between AIDS diagnosis and death by year of death for all reported deceased patients
Source: Robert Koch Institute

Years of death	N	Median survival time (months)
1984	47	2
1985	148	4
1986	270	4
1987	451	5
1988	570	7
1989	805	11
1990	1 052	13
1991	1 161	14
1992	1 308	13
1993	1 453	15
1994	1 496	14
1995	1 364	14
1996	1 052	17
1997	498	18
1998	312	24
1999	263	27
2000	241	25
2001	193	24
2002	166	28
2003	140	60
2004	74	53
Total	13 064	13

The median time between AIDS diagnosis and death more than doubled from 10.8 months in the years before 1991 to 27.9 months for those deceased after 1995. Survival times after an AIDS diagnosis are, as already suggested, only one indicator for improvements in the treatment of the advanced HIV illness. The success of the early use of antiretroviral therapy lies predominantly in the prolongation of the asymptomatic period before AIDS. Only in rare cases, however is the exact time point of infection known, making such effects unquantifiable using the data in the AIDS case registry.

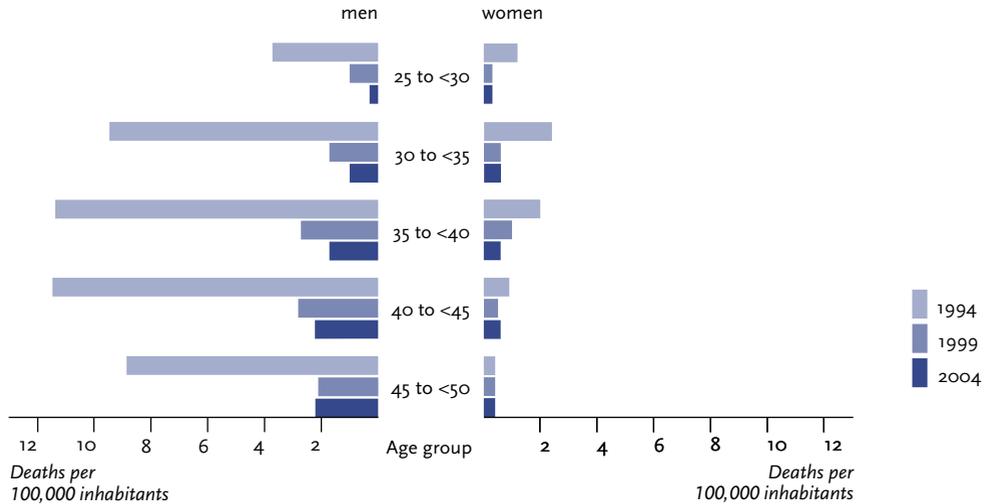
The average age of death for all AIDS patients (over 12 years old) is 41.2 years (men: 41.5 years; women: 37.9 years). Over time, the age of death has increased slightly from 40.1 years for those deceased before 1990 (men: 40.3; women: 37.3) to 42.8 years for those deceased since 1996 (men: 43.5; women 39.4). Analogous to the age distribution in the different affected groups, the ages of death for people from high prevalence regions, at 34.4 years (men: 35.6; women: 33.1), and for IDU, at 35.6 years (men: 36.2; women: 34.5) are less than for homosexual and bisexual men (42.1 years) and the heterosexually infected (42.5 years; men: 46.3; women: 39.7)¹.

With respect to the total population, the improved treatment options for HIV infection, or rather HIV disease, have led to a decrease of HIV/AIDS as cause of death in the mortality statistics from 2.6 deaths per 100,000 inhabitants in the “peak year” of 1994 to 0.6 deaths per 100,000 in 2003. The decrease is more pronounced in men than in women (see Figure 8). Despite the distinct decrease in HIV-related mortality, HIV infection, or rather AIDS, remains a significant cause of death particularly among men in major cities in the median age groups. For example, in Berlin in 2003, HIV infection took rank ten among the causes of death among 20-30 year olds².

¹ Robert Koch-Institute, AIDS Case Registry

² Causes of death statistics, Federal Statistical Office

Figure 8
Evolution of cases of death due to HIV in Germany by
age group and sex (per 100,000 inhabitants)
 Source: Causes of death statistics, Federal Statistical Office



Impact on the quality of life

As a result of improvements in the therapeutic options, HIV infection has come to be considered more and more as a chronic disease, giving it considerable influence on the quality of life. Of particular note is a constant worry about potential treatment failure. Fears about the future, social isolation, sexual problems, and possible occupational as well as financial difficulties all contribute to a deterioration of the quality of life and may often lead to depression and mood disorders in affected patients. The mental situation of those affected can furthermore affect one's capacity to take the required medications regularly, at the required dosage and at the proper time point (medication adherence). This is affected by fears of side effects, particularly those like diarrhoea and weight loss that make the illness socially visible and may impact on social relations. Depression and lowered feelings of self worth can also be significant risk factors for the practice of unprotected sex.

The success of antiretroviral therapy depends strongly on the regular administration of the medication. Low drug levels through irregular administration leads to unchecked proliferation of the HI-virus and to the selection of resistant

viruses. Reasons for not taking medication often include oblivion, desire to keep HIV disease secret from other people, unanticipated changes in daily routine, as well as depression and other mental difficulties. The amount of pills, repeated daily ingestion and diet restrictions, which, in the early years of antiretroviral combination therapy were obstacles to compliance with the agreed treatment goals of doctor and patient, no longer play a crucial role due to current improved pharmaceutical combinations.

Treatment

Diagnostics and detection measures

The diagnosis of HIV infection relies primarily on the detection of specific antibodies. These are generally formed from the first four weeks until three months after infection. After about three months it can be shown with high certainty if HIV antibodies have been formed (positive test result) or not (negative test result). The detection of antibodies is carried out in two steps: first, with an antibody-screening test, and after a positive result, with a subsequent confirmatory test. A negative test result is only meaningful when the last infection risk dates back a minimum of three months. A positive result from both the screening and confirmatory tests indicates the presence of an HIV infection.

In addition to the HIV antibody test, the direct detection of the virus itself, or its constituent parts, is possible. Of increasing importance is the detection of the HIV genetic material using nucleic acid amplification procedures, both in the scope of the diagnosis of acute HIV infection as well as in monitoring the progression and treatment of the disease. A subordinate role is played by virus detection in the blood or lymphocytes of infected people. This procedure is experimental and time consuming and therefore inappropriate for routine diagnostics. To perform an HIV diagnostic test is only permissible after informing and counselling of the patient and after receiving his or her consent.

A negative test result after a risky situation does not mean that the affected person is immune or especially resistant to HIV, but only that he or she was lucky. Adherence to the standards of prevention remains the ultimate method of protecting oneself from infection. An HIV test itself offers no protection against a later HIV infection.

Therapy

HIV disease can be medically treated; a cure, however, is not yet possible. Presently, lifelong treatment with antiretroviral drugs is required. The currently available medications act on various points in the life cycle of the HI-virus. Until the

mid-1990s substances from only one drug class (nucleoside analogues) were available, which were initially employed as mono- or double therapy. With these medications the concentration of the virus in the blood could be temporarily reduced, and this resulted in a prolongation of life of around one to three years. Because suppression of virus replication was mostly incomplete, resistance against the used medications developed relatively quickly; that is, the sensitivity of the virus to the antiretroviral inhibitors was reduced.

With the development and approval of a new class of drugs (protease inhibitors) in 1995/1996, the concept of “highly active antiretroviral therapy” (HAART) emerged. This treatment consists of a combination therapy with usually three or more individual drugs, whose goal is to suppress the replication of the virus as fully as possible. As long as the treated virus exhibits no resistance against the drugs, most combination therapies succeed in bringing down the concentration of the virus in the blood to a level below the detection limit of the currently available commercial testing methods, which currently lies at 20-50 virus genome copies per millilitre of blood. This is a matter of a pure suppression therapy; that is, after ceasing the administration of the drugs the virus concentration re-increases within a few days.

Currently, more than 16 individual substances from four classes of drugs are available, as well as a couple of co-formulations for antiretroviral therapy. These substances cannot be indiscriminately combined, as a result of numerous interactions with synergistic and antagonistic, those are cooperative or oppositional, effects. Knowledge regarding advantages and disadvantages of defined combinations is constantly in flux. The most up-to-date knowledge is summarized in national and international treatment recommendations developed by expert bodies.

Treatment goals include the suppression of virus replication as completely as possible, avoidance of the development of drug resistance for as long as possible, and the improvement and stabilization of immune function. To monitor treatment efficacy, the T-helper cell count and concentration of virus in the blood are regularly determined. The suppression of virus replication, however, is usually not complete, and the initial hope of eliminating the virus from the body altogether has been found

to be unrealistic. Therapy is considered successful when the concentration of virus in the blood drastically decreases and the T-helper cell count re-increases. While symptoms caused by HIV replication or resulting from HIV induced immune deficiency may for the most part disappear, some functional changes and defects of the immune system remain. The more effectively virus replication is suppressed, the less is the danger that the virus will develop resistance against the used medications. As a result, it is necessary to permanently maintain sufficiently high drug levels. With new medications and advances in treatment strategies, treatment schemes have been developed in recent years in which this goal can be reached with one to two administrations of medication per day. It has been shown that women may react differently than men to the individual medications, necessitating gender-specific research as to the effectiveness and side-effects of antiretroviral therapy.

The medical treatment and care of people infected with HIV should be carried out by specialized physicians and clinics or, at minimum, in close cooperation with experienced practitioners, according to the German-Austrian guidelines on antiretroviral therapy (see appendix). Specialized ambulatory clinics or HIV-specialized practices with experienced physicians can be found in most major cities in Germany.

Treatment needs according to phase of illness

As long as HIV infection remains asymptomatic and no indication exists for the beginning of antiretroviral therapy, medical care is restricted to the education of patients about the course of the disease, treatment options, transmission risks, and the implementation of prophylactic measures (vaccinations) and regular monitoring of parameters such as T-helper cell count and viral load. Non-medical care in this stage is also required in the form of counselling regarding social, occupational and psychological consequences of the infection for the individual, as well as help coming to terms with emerging issues.

After beginning treatment, regular monitoring of treatment success, adherence, and possible side effects is required. It is therefore also important that patients are encouraged to main-

tain as high compliance as possible (cooperative attitude of the patient with consistent adherence to therapy). Possible interactions between medications must also be observed, not only between the antiretroviral drugs themselves, but also interactions between these and other prescription and non-prescription drugs, which may be used alongside treatment.

The symptomatic HIV disease leads to increased diagnostic, medical treatment and care expenditures, and also to heightened occupational, financial and social problems. The need for counselling with regard to labour and social laws rises distinctly in this phase. The new treatment options have created new life perspectives for people with HIV, and also new problems like, for example, re-entry into occupational life and the implementation of medical and psychosocial rehabilitation measures.

Organization of care and resources

As a result of the currently improved therapeutic options and the consecutive prolongation of the time between HIV infection and the diagnosis of AIDS and, as the case may be, death, the number of patients living with HIV/AIDS in Germany has increased since the middle of the 1990s by about 1,000 per year. Based on data from clinics and specialized practices, it can be hypothesized that currently around 35,000 of an estimated total of about 46,500 patients in Germany receive regular medical care. Of these, between 22,000 and 24,000 are treated with antiretroviral combination therapy. Unrecognized HIV infections among people with heterosexual transmission risks are assumed to be disproportionately high. The same is also expected of immigrants from high prevalence regions, except those who are examined for HIV in the scope of asylum-seeking procedures. On the basis of restrictions to medical treatment, allowed by the asylum-seeker service laws, the medical care received by asylum-seekers is not always of the same quality as that of other HIV patients.

The care of HIV infected people posed a number of challenging problems particularly at the beginning of the epidemic when little was known about the illness and its modes of transmission. At

that time, homosexual men and drug users were the predominant affected groups, resulting in the creation of fears about contact with and discrimination toward people infected with HIV in hospitals. In Berlin in the 1980s the “Schöneberger Model“ was established to exemplify cooperation between primary care physicians and two hospital departments. The main objective was to overcome fears about contact with HIV patients. In addition, they aimed via close cooperation between the ambulatory and in-patient practitioners to achieve a faster exchange of information, continuous accumulation of knowledge about HIV and AIDS and to ensure that treatment could be carried out with as short as possible hospital stays. The concept of integrating specialized practices with general practitioners, specialists, nursing services, and inpatient facilities has become established as the standard of care for HIV/AIDS patients.

Psychosocial care

HIV infection is often associated with multifaceted psychological and social problems that necessitate professional and semi-professional help. For these, particularly in major cities, affected people may turn to local AIDS services and to publicly or privately funded HIV/AIDS counselling sites (a selection of addresses are found in the Appendix). Already at the beginning of the HIV epidemic in Germany, AIDS self-help groups emerged, primarily in major cities and predominantly established by homosexual men. Over the years, both the scope of the patients and the volunteers of the self-help groups were broadened to include also drug users and heterosexuals. The self-help initiatives are active in the domains of HIV education and prevention as well as in the psychological and social treatment and care of affected people, and are strongly concerned with the containment of the HIV epidemic in Germany, with the individual and collective coping with the disease, and to the establishment of newer treatment and care structures for HIV patients. Of particular note is the Deutsche AIDS-Hilfe (German AIDS-help) with around 120 local chapters (regional AIDS-services, other member organizations), and various networks, which inform and counsel people from all population groups and locations (personally, by

telephone, or by email). Since 1987, the German AIDS Foundation has been helping HIV positive and AIDS-affected people in substantial need, and sponsoring special projects for affected people.

Competence network HIV/AIDS

The Competence Network HIV/AIDS (KompNet HIV/AIDS) is one of 17 competence networks in Medicine currently supported by the federal Ministry for Education and Research (BMBF). The primary goal of KompNet HIV/AIDS is to combine as much as possible all the available experts in Germany into one collective research and communications network, thus achieving favourable conditions for the improvement of the treatment of HIV disease, the associated quality of life, and the increase of the life expectancy of patients infected with HIV. With the development of KompNet HIV/AIDS, a structure was developed that can assimilate and implement medical and scientific problems and developments more quickly and more efficiently than can individual studies and expert groups. Furthermore, KompNet HIV/AIDS offers, as a national research network, the opportunity for efficient cooperation with European and other international research networks [19].

Costs

Direct costs

Health expenditures of individual classifications of illnesses are calculated in the cost-of-illness accounts of the Federal Statistical Office for the year 2002³. Direct costs include expenses for ambulatory and in-patient care, pharmaceuticals, and prevention, rehabilitation, and support measures in health care, among others. 140 million Euros can be attributed to HIV disease (ICD 10:B20-B24), corresponding to 0.06% of the total healthcare costs for this year. 76% of the costs are attributable to men. For both sexes, the majority of the costs are incurred among people between 30-45 years of age.

³ Federal Statistical Office (2004) Costs Of Illness 2002. Wiesbaden

Because of the rapid changes in the treatment of HIV infection, few current calculations are available of treatment costs per case in Germany. The most meaningful calculations come from a study conducted in Hanover; this study consisted of a single-centre estimate of the costs of illness for 1997, and was updated in 2000, permitting conclusions about the current course of the costs due to HIV [20]. Based on 201 patients for the year 1997, direct costs were calculated and averaged 35,858 Euros per patient. The leading share of direct costs (around 50%) was attributed to antiretroviral therapy, followed by hospitalization costs, corollary medications, labour costs, physician costs and imaging procedures. In 2000, the calculation of the costs for a cohort of 156 patients surprisingly indicated a decrease in direct costs in all substantial areas (average costs 26,017 Euros), although the share of patients receiving antiretroviral therapy and the intensity of treatment had increased. This cost reduction was due primarily to the more frequent use of cost-saving and clinically effective treatment schemes, and to a decrease in the use of corollary medications, physician visits and labour costs. The costs per year vary by phase of illness between just under 19,000 Euros for a patient in the CDC-Phase I, around 25,000 Euros for a patient in CDC-Phase II, and an average of 34,000 Euros for a patient in CDC-Phase III. Symptomatic and advanced-illness phases are over-represented in this study population. Therefore, the actual direct costs per patient for all people infected with HIV are probably here overestimated.

Indirect costs

Indirect costs represent the loss of resources for the national economy resulting from inability to work, invalidity and premature death of gainful workers presented in the form of potential years of gainful employment lost and potential years of life lost, which also include the unemployed population. An overall estimate of the indirect costs of HIV is currently not available.

Inability to work

Numbers regarding HIV/AIDS-dependent inability to work are only available for members of

the General Local Health Insurance (AOK) with around 33% of members of social health insurance (reference date, July 1, 2004). In 2004, 1.2 men and 0.8 women per 10,000 members were registered with the diagnosis of HIV/AIDS. The average length of inability to work per case was 34 days for men and 28 days for women and had distinctly shortened after the introduction of improved therapies⁴.

Early retirement

The number of people driven to early retirement by HIV/AIDS was subjected to distinct fluctuations in the 1990s as a result of changes in the course of the disease due to changes in treatment options. The number of people entering retirement as a result of HIV/AIDS rose from 586 in 1992⁵ to a peak number of 1,179 in 1996. In the following years, this number dropped to 385 (334 men and 51 women) in 2004⁶. The average age at the beginning of retirement was 44 years for men and 41 years for women.

Years of Life Lost and Years of Gainful Employment Lost

In 2002, the total years of life lost due to HIV were 23,000 years for men and 6,000 years for women. Years of Gainful Employment Lost due to HIV totalled 10,000 years for men and 2,000 years for women.

Different methods of calculation yield very different indirect costs of the HIV infection. This difference depends largely on the ways in which the various models incorporate the economic situation of the labour market. Using the human capital approach [21] the average indirect costs per patient are 27,781 Euros; using the friction cost approach [22], however, only a tenth of these costs are estimated (2,730 Euros). The human capital approach tends to overestimate the real economic costs of longer absences from the workplace and contains no correction for re-organization in the

⁴ Illness statistics 2004, General Local Health Insurance (AOK)

⁵ Retirement statistics 1992, German Annuity Insurance Federation

⁶ Retirement statistics 2004, German Annuity Insurance Federation

workplace and/or the addition of new employees, both of which may reduce economic damage. The friction cost approach calculates the economic loss due to illness using the longest average time period until the vacant job is filled. In the above calculations, this period was presumed to be six months.

Currently, improved therapeutic options and therefore prolonged survival times, both result in an increase in the duration of treatment as well as the number of treated patients. In comparison with the situation before the introduction of antiretroviral combination therapies, the direct and indirect costs of the treatment of an HIV infection per year have been reduced. However, mortality has also been effectively reduced, therefore resulting in the longer accumulation of costs per patient. Altogether the costs of the HIV infection make up an increased part of the healthcare budget.

Needs for action, Perspectives, Goals

The early and pragmatic implementations of HIV prevention strategies, along with clear task-sharing agreements, have succeeded in restricting the number of HIV infections to a relatively low level in Germany. However, after the initial generous funding of HIV prevention, the resulting minor social pressure has led to a distinct reduction in the availability of funds for prevention measures. Whereas, at the federal level, expenditures for educational measures have remained largely stable since 1996 (for 2005: 9.2 million Euros), expenditures for AIDS prevention at state and municipal levels have dropped in recent years. An advancement of HIV prevention, which must also adjust to continuously changing conditions, is therefore made difficult. At the same time, the reduced social perceptibility of HIV and AIDS, the loss of its novelty, the social downward trend of the epidemic, and the improved options for medical treatment for HIV/AIDS have led to a reduced attractiveness of the field for voluntary engagement and self-help. It is therefore urgently necessary to resume the financial support of HIV prevention and particularly to uphold the infrastructure of institutions, and to provide personal education, counselling and care.

Complacency over current achievements in the area of HIV prevention would be fatal. Social and economic changes, particularly in Eastern Europe, have led to a broadening of the HIV epidemic since the middle of the 1990s, where only a decade previously only sporadic infections had occurred. Also, the currently reported increase of new HIV diagnoses among men who have sex with men in Germany must be seen as a serious warning regarding further disregard for HIV prevention efforts.

When developing and implementing preventive measures, it must be considered that with the increasing duration of the threat of HIV, individual and collective risk communication strategies substitute for the initially predominant strategies of risk avoidance. A consequence of this has been a renewed increase in sexually transmitted infections (STIs) in recent years, particularly among homosexual men, which points to, among other things, an increase in partner numbers. The dominant opinion in the 1980s and 1990s was that HIV prevention efforts made separate prevention strategies for other STIs redundant. This opinion must be revisited, however, at least for homosexual men. A more widely applied and integrated HIV and STI prevention strategy should be developed. This would necessitate a strengthening of local prevention efforts and the success of low-threshold STI prevention and treatment offerings, alongside mass media educational and motivational campaigns. Indeed, the number of newly diagnosed HIV infections among drug users has also been declining in recent years, however among this group the first signs of a trend-reversal are becoming apparent and a second large infection problem, Hepatitis C infection is also being seen. New drug trafficking routes through Eastern Europe, which have resulted in a dramatic epidemic of HIV among drug users in this region, as well as the spread of synthetic drugs are changing the framework of the HIV epidemic in Germany.

The progression of the HIV epidemic in Eastern Europe is also providing new risks and influences the heterosexual spread of HIV in Germany.

The areas of legal and illegal immigration include considerable shortcomings in all areas of prevention, care and treatment. Unlike many other countries with comparable or even higher

immigration, Germany lacks, for example opportunities for illegal immigrants to receive adequate medical care. As of yet, the problem of HIV/AIDS has only in a few exceptional cases been integrated into work programs for foreign nationals. There are no standards for HIV testing and counselling offers for asylum-seekers, or for the consideration of HIV status and local availability of treatment in the assignment of residency. The capacity to uphold the principle not to deport people in need of treatment to countries in which treatment of HIV infection is not possible is hindered by unfounded claims and inaccurate evaluations of treatment possibilities.

Appendix:

Counselling

- Deutsche AIDS-Hilfe e.V. (German AIDS-Help):
At www.aidshilfe.de are addresses, phone numbers and email addresses of local AIDS-services available.
- Bundeszentrale für gesundheitliche Aufklärung (BZgA) (Federal Centre for Health Education):
At www.aidsberatung.de are addresses for personal AIDS counselling and phone numbers for telephone counselling available.
- Deutsche Arbeitsgemeinschaft niedergelassener Ärzte in der Versorgung HIV-Infizierter e.V. (German consortium of doctors caring for HIV-infected people):
Addresses for doctors who specialize in treating HIV infections can be found at www.dagnae.de

Treatment guidelines

The current HIV treatment guidelines are published on the websites of the German AIDS Association (www.daignet.de) and the Robert Koch Institute www.rki.de

Epidemiology of HIV/AIDS

Worldwide

The portal for HIV programs of the United Nations: www.unaids.org and/or the World Health Organization: www.who.int

Europe

The portal of the HIV/AIDS surveillance in Europe (EuroHIV): www.eurohiv.org

Germany

The portal of the Robert Koch Institute: www.rki.de/

Donations, Help for affected groups

The German AIDS Foundation helps affected people and sponsors assistance projects in Germany and since 2000 also worldwide, www.aidsstiftung.de

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Die weltweite HIV/AIDS-Epidemie hat sich zu einem der größten Gesundheitsprobleme der heutigen Zeit entwickelt.

Die Weltgesundheitsorganisation (WHO) rechnete Ende 2005 mit weltweit knapp 40 Millionen HIV-Infizierten, bei jährlich fünf Millionen Neuinfektionen und drei Millionen Todesfällen.

Die Infektion mit dem Human Immunodeficiency Virus (HIV) führt nach individuell unterschiedlich langer Inkubationszeit aufgrund einer schweren Schädigung der Immunabwehr zu einer lebensbedrohlichen Erkrankung, die ohne therapeutische Intervention zum Tod führt. Jeder mit HIV infizierte Mensch ist lebenslang potentiell ansteckungsfähig.

Weltweit wird HIV am häufigsten durch ungeschützte sexuelle Kontakte übertragen. Weitere Infektionswege sind die Übertragung von HIV durch erregerrhaltiges Blut und die Mutter-Kind-Übertragung.

Die Situation der Verbreitung von HIV/AIDS in Deutschland stellt sich im europäischen und internationalen Vergleich relativ günstig dar. Die Zahl der Menschen, die mit HIV/AIDS leben wurde Ende 2004 auf ca. 46.500 geschätzt. Die Schätzung für die Zahl der jährlichen HIV-Neuinfektionen beläuft sich gegenwärtig auf etwa 2.600. Nach Infektionsweg unterschieden, bleiben Männer mit gleichgeschlechtlichen Sexualpartnern in Deutschland die zahlenmäßig größte Betroffenengruppe. Verglichen mit den 1980er Jahren ist der Anteil der Personen, die sich über heterosexuelle Kontakte infiziert haben, angestiegen. Die Zahl der Erstdiagnosen in dieser Gruppe ist aber in den letzten Jahren stabil geblieben. Die Tatsache, dass sich vor allem jüngere Menschen mit HIV infizieren, eine Heilung nicht möglich ist und die lebenslange Therapie mit hohen Medikamentenkosten und einem erheblichem medizinischen Betreuungsaufwand verbunden ist, bestimmt die gesundheitspolitische Relevanz dieser Erkrankung.

The global HIV/AIDS epidemic is one of the greatest health problems of our time. The World Health Organization (WHO) estimated the total number of people living with HIV worldwide at the end of 2005 at almost 40 million people, with five million new HIV infections occurring per year and an annual death toll of three million due to HIV/AIDS related causes.

The infection with the Human Immunodeficiency Virus (HIV) results, after variable incubation times, in life-threatening illnesses, which arise as a consequence of the virus-induced destruction of the immune defense. This acquired immunodeficiency is invariably fatal without therapeutic intervention.

Any person infected with HIV remains infectious lifelong. The most frequent way of transmitting HIV is through unprotected sexual intercourse. Transmission by infected blood and mother-to-child transmission are the other primary modes of transmission of HIV.

In European and international comparison the situation of the HIV/AIDS epidemic in Germany is relatively favorable. The estimated number of people living with HIV/AIDS in Germany at the end of 2004 was 46,500. The number of new infections with HIV per year is currently estimated at about 2,600. In Germany, men who have sex with men account for the majority of people diagnosed with HIV/AIDS. Compared to the 1980s the proportion of cases attributable to heterosexual transmission of HIV increased, but in recent years the proportion has remained stable.

The health policy relevance of this illness is determined by the facts that primarily younger people become infected with HIV, a cure is not possible and the necessary lifelong therapy is fraught with high treatment costs and requires considerable efforts to maintain treatment adherence.

