

2 HIV/AIDS Prevention and Treatment Strategies in Developed and Developing Countries

“The world must do more, much more on every front in the fight against AIDS. Of course, it means dramatically expanding our prevention efforts, but the most striking inequity is our failure to provide the lifesaving treatment to the millions of people who need it most. The single most important step we must now take is to provide access to treatment throughout the developing world. There is no excuse for delay. We must start now. If we discard the people who are dying from AIDS, then we can no longer call ourselves decent people.”

Nelson Mandela, 15 July 2003, International AIDS Society Conference in Paris

AIDS is a truly global disease. As such, it raises issues that local or regional diseases do not (although some issues may be the same). For example, because AIDS affects both rich and poor countries, AIDS has become a treatable disease far more quickly than regional, poor-country diseases such as malaria. However, patented treatments for AIDS, while affordable for patients in rich countries, have not been widely available to many patients in poor countries. AIDS is also an infectious disease that is largely preventable. This means that public education and prevention measures (such as free condom distribution and needle exchange programs) are capable of slowing the spread of the disease. AIDS is also a sexually transmitted disease (although it can also be transmitted through blood transfusions, needle-sharing, and mother-to-child). Many cultures have taboos about sex in general and homosexual intercourse in particular. This aspect of the disease complicates both treatment and prevention due to the stigma associated with sexually transmitted diseases. Combine such taboos with the fear associated with infectious, life-threatening diseases, and the discriminatory treatment of marginalized members of society, and you have a potent and complex global problem that defies easy solutions.

Due to the nature of the disease itself, prevention, treatment and human rights protection must all form part of any comprehensive AIDS strategy. These are the three central issues that must be addressed simultaneously in order to deal effectively with the AIDS pandemic. Each of these issues involves a host of subsidiary issues. For example, treatment raises issues such as the cost of patented medicine, the rights of governments to suspend patent rights, the availability of health workers and infrastructure and the availability of international aid to finance national AIDS strategies. Moreover, prevention, treatment and human rights protection are inter-related issues. For example, the rights of women affect their ability to use prevention strategies. Moreover, the stigma associated with HIV/AIDS, together with a lack of legal protection against discrimination, may deter people from seeking testing and treatment. Finally, a lack of access to treatment can create a sense of

futility with respect to seeking testing, which in turn can contribute to the spread of the disease.

This chapter will examine these issues in different parts of the globe. While AIDS is a global disease, its impact varies from one country to the next and from one region to the next. Variations in cultural values, affected groups, infection rates, legal systems, economic resources and human resources mean that HIV/AIDS must be considered in specific contexts. This chapter therefore seeks to paint a global picture of the AIDS pandemic one issue, one country and one region at a time, by analyzing the key issues in country-specific and region-specific contexts. The chapter ends with a consideration of how experiences with HIV/AIDS might inform the strategies adopted to address the global pandemics of the future, such as H5N1 influenza.

2.1 The Global Statistics

HIV/AIDS ranks among history's worst epidemics. With the 2007 revisions to the United Nations' global estimates of the number of people infected with HIV/AIDS, it now appears that this pandemic has peaked (UNAIDS 2007). (In Chap. 3, we analyze the methodology used for HIV/AIDS estimates.) In 2007, there were an estimated 1.8–4.1 million new infections (see Table 2.1), down from 2.1 to 4.4 million new infections in 2001. However, an estimated 1.9–2.4 million people died from AIDS-related illnesses in 2007 (see Table 2.2) and the number of people living with HIV/AIDS has continued to increase, rising to 30.6–36.1 million (see Table 2.3), compared to 26.9–32.4 million in 2001 (UNAIDS 2007). While the estimated number of new infections declined in sub-Saharan Africa and South and Southeast Asia between 2001 and 2007, they increased during this period in Eastern Europe, Vietnam and Indonesia (see Table 2.6). Moreover, a mutated HIV virus could emerge that might be more easily transmitted or more drug resistant. The battle against HIV/AIDS is far from over.

Low- and middle-income countries are disproportionately affected by HIV/AIDS, accounting for over 96% of new infections in 2007 (UNAIDS 2007). Table 2.4 shows the regional distribution of HIV/AIDS in 2007 and 2001 and the adult prevalence rate in 2007. Sub-Saharan Africa remains the region most affected by

Table 2.1 People newly infected with HIV in 2007

	Range of estimate
Adults	1.4–3.6 million
Children under 15 years	350,000–540,000
Total	1.8–4.1 million

Source: AIDS Epidemic Update, December 2007, UNAIDS, Geneva

HIV/AIDS, with 20.9–24.3 million individuals infected (68% of all cases worldwide) and 1.5–2.0 million deaths (76% of global deaths) in 2007. Almost 90% of children with HIV live in sub-Saharan Africa. Women are the most affected group in this region, making up 61% of the total number of people living with HIV, compared to 43% in the Caribbean, and 29% in Asia (UNAIDS 2007). HIV prevalence exceeded 15% of the adult population in eight southern African countries in 2007. According to population-based surveys, the highest adult (15–49 years of

Table 2.2 AIDS deaths in 2007

	Range of estimate
Adults	1.6–2.1 million
Children under 15 years	310,000–380,000
Total	1.9–2.4 million

Source: AIDS Epidemic Update, December 2007, UNAIDS, Geneva

Table 2.3 Number of people living with HIV in 2007

Group	Range of estimate
Adults	28.2–33.6 million
Women	13.9–16.6 million
Children under 15 years	2.2–2.6 million
Total	30.6–36.1 million

Source: AIDS Epidemic Update, December 2007, UNAIDS, Geneva

Table 2.4 Regional distribution of HIV/AIDS in 2007 and 2001

Region	2007	2001	Adult prevalence 2007 (%)
Sub-Saharan Africa	20.9–24.3 million	19.7–23.6 million	4.6–5.5
North Africa and Middle East	270,000–500,000	220,000–400,000	0.2–0.4
South and South-East Asia	3.3–5.1 million	2.9–4.5 million	0.2–0.4
East Asia	620,000–960,000	350,000–910,000	<0.2
Oceania	53,000–120,000	19,000–39,000	0.3–0.7
Latin America	1.4–1.9 million	1.2–1.6 million	0.4–0.6
Caribbean	210,000–270,000	180,000–250,000	0.9–1.2
Eastern Europe and Central Asia	1.2–2.1 million	490,000–1.1 million	0.7–1.2
Western and Central Europe	600,000–1.1 million	500,000–170,000	0.2–0.4
North America	480,000–1.9 million	390,000–1.6 million	0.5–0.9
Total	30.6–36.1 million	26.9–32.4 million	0.7–0.9

Source: AIDS Epidemic Update, December 2007, UNAIDS, Geneva

Table 2.5 Estimated adult HIV/AIDS prevalence rates, population-based surveys

Rank	Country	Population-based survey of adult prevalence (year)
1	Swaziland	25.9 (2006–2007)
2	Botswana	25.2 (2004)
3	Lesotho	23.5 (2004)
4	Zimbabwe	18.1 (2005–2006)
5	South Africa	16.2 (2005)
6	Zambia	15.6 (2001–2002)
7	Malawi	12.7 (2004)
8	Uganda	7.1 (2004–2005)
9	Tanzania	7.0 (2004)
10	Kenya	6.7 (2003)
11	Central African Republic	6.2 (2006)
12	Cameroon	5.5 (2004)
13	Cote d'Ivoire	4.7 (2005)
14	Burundi	3.6 (2002)
15	Chad	3.3 (2005)
16	Equatorial Guinea	3.2 (2004)
17	Rwanda	3.0 (2005)
18	Haiti	2.2 (2005–2006)
19	Ghana	2.2 (2003)
20	Burkina Faso	1.8 (2003)
21	Sierra Leone	1.5 (2005)
22	Guinea	1.5 (2005)
23	Ethiopia	1.4 (2005)
24	Mali	1.3 (2006)
25	Dominican Republic	1.0 (2002)

Source: AIDS Epidemic Update, December 2007, UNAIDS, Geneva. Note: Population-based surveys are not available for all countries

age) prevalence rates were as follows in the years in which surveys took place: Swaziland: 25.9 (2006–2007); Botswana: 25.2 (2004); Lesotho: 23.5 (2004); Zimbabwe: 18.1 (2005–2006); South Africa: 16.2 (2005); and Zambia: 15.6 (2001–2002) (see Table 2.5).

South and South-east Asia is the second most affected region, with 3.3–5.1 million people living with HIV, 180,000–740,000 new infections and 230,000–380,000 deaths in 2007. Latin America and Eastern Europe/Central Asia follow, with 1.4–1.9 and 1.2–2.1 million people living with HIV in each region, respectively. However, HIV is spreading more rapidly in Eastern Europe/Central Asia

than in Latin America, with 70,000–290,000 new infections in the former in 2007, compared to 47,000–220,000 in the latter (see Table 2.6). A decrease in new infections in Eastern Europe/Central Asia was mainly due to a decrease in the Russian Federation. However, the number of persons with HIV increased 150% in Eastern Europe between 2001 and 2007. The estimated number of deaths due to AIDS in Latin America in 2007, at 49,000–91,000, was greater than in Eastern Europe/Central Asia, at 42,000–88,000 (UNAIDS 2007).

Table 2.6 Newly infected adults and children by region in 2007 and 2001

Region	2007	2001	Change
Sub-Saharan Africa	1.4–2.4 million	1.7–2.7 million	Decrease
North Africa and Middle East	16,000–65,000	17,000–58,000	Stable
South and South-East Asia	180,000–740,000	150,000–800,000	Stable
East Asia	21,000–220,000	49,000–130,000	Increase
Oceania	11,000–26,000	3,000–5,600	Increase
Latin America	47,000–220,000	56,000–220,000	Stable
Caribbean	15,000–23,000	17,000–25,000	Decrease
Eastern Europe and Central Asia	70,000–290,000	98,000–340,000	Decrease
Western and Central Europe	19,000–86,000	19,000–76,000	Increase
North America	38,000–68,000	40,000–63,000	Stable
Total	1.8–4.1 million	2.1–4.4 million	Decrease

Source: AIDS Epidemic Update, December 2007, UNAIDS, Geneva

North America and Western/Central Europe also have large numbers of people living with HIV (480,000–1.9 million and 600,000–1.1 million, respectively), but had relatively fewer deaths from AIDS in 2007 (18,000–31,000 and less than 15,000, respectively), due to greater access to medical treatment. North America and Western/Central Europe also had fewer new infections than other regions, relative to the number of people living with HIV, at 38,000–68,000 and 19,000–86,000, respectively. While the Caribbean has fewer people living with AIDS than the foregoing regions, at 210,000–270,000, it has the second highest adult prevalence rate in the world, at 0.9–1.2%, behind sub-Saharan Africa, where the adult prevalence rate was 4.5–5.5% in 2007 (UNAIDS 2007).

UNAIDS developed a special program called “3 by 5”. The aim of the program was to deliver antiretroviral therapy (ART) to three million individuals with AIDS in developing countries by 2005. However, the goal was not met. The program managed to reach around one million individuals by December 2005 (<http://www.eurosurveillance.org/ew/2005/051124.asp>). A 2007 report found that scaling up access to treatment was being impeded by high prices, patent barriers, registration barriers and misinformation, with the result that many countries were using AIDS treatments that are not preferred by World Health Organization (WHO) guidelines (International Treatment Preparedness Coalition 2007).

2.2 The African Epidemic: HIV/AIDS Becomes a Security Issue

The African HIV/AIDS epidemic represents the worst-case scenario. The severity of HIV infection rates in Africa prompted the United Nations Security Council to treat the AIDS crisis as a security issue. UN Security Council Resolution 1308, passed in July 2000, states that “the HIV/AIDS pandemic, if unchecked, may pose a risk to stability and security.” This was the first time the United Nations had ever considered a health issue to be a security issue.

The epidemic threatens security in many different ways. HIV threatens individual security. Most of HIV sufferers live in developing countries. Most people in developing countries depend on agriculture. Agricultural production will be threatened by the lack of young people working the fields. Lack of food supply puts strains on families and communities. Tension between ethnic and social groups mounts. Economic migration gets worse and more refugees are created (Garrett 2005).

AIDS is an economic security problem. If economic progress is threatened, violent conflicts become more common. Daly (2000) suggests that even an adult prevalence rate of 10% would reduce the *growth* of GDP by 30%. At infection levels above 20%, a report by the WHO shows that the GDP would *decline* between 1 and 2% per year (WHO 2000).

AIDS is a communal security issue. It directly affects police forces, civil servants, teachers, and healthcare professionals. In South Africa, one in seven civil servants was HIV positive in 1998 (McNeil 1998).

AIDS is also a national security problem. The effect on military personnel can be devastating. In many African countries, peacekeeping forces transmit the disease from one area to the other. The military is vulnerable to HIV/AIDS for four main reasons. (1) The majority are men under 25 years of age who spend long periods deployed away from family and partners. (2) The military tend to have access to cash, enabling soldiers to “buy” sex partners, to drink heavily, and to use drugs off duty. When they are drunk or drugged, people are more likely to have unprotected sex. (3) Military work increases opportunities for men to use coercion to obtain sex. (4) The vast majority of (voluntary) military come from poorer and less educated families. Lower education and unprotected sex go hand in glove (UNAIDS 2005). For example, South Africa, with the best-equipped and best-trained military force on the African continent, does much of the region’s policing. Seven out of ten military deaths in South Africa are AIDS-related. A quarter of its uniformed soldiers are infected with HIV/AIDS. Since the United Nations bars countries from sending HIV-positive soldiers on international missions a quarter of South African troops are unable to engage in UN peacekeeping missions.

US Vice President Al Gore, in an address to the UN Security Council, in January 2000 put it all very succinctly. He declared that HIV/AIDS is a security issue because “it threatens not just individual citizens, but the very institutions that define and defend the character of a society. This disease weakens workforces and

saps economic strength. AIDS strikes at teachers, and denies education to their students. It strikes at the military, and subverts the forces of order and peacekeeping.” (<http://www.aegis.com/news/usis/2000/US000102.html>)

The severity of sub-Saharan Africa’s AIDS crisis is the result of a number of factors. First, since the AIDS epidemic originated in Africa, most probably through the transmission of a mutated virus from primates, it has had more time to spread there than in other parts of the world. Indeed, there is a high probability that people were dying from AIDS-related causes in Africa long before the appearance of AIDS in North America led to its diagnosis. One doctor reports having treated patients in Africa in the 1970s with symptoms that were consistent with an AIDS diagnosis. Second, a lack of public education programs aimed at prevention, combined with a cultural resistance to the use of condoms, allowed the virus to spread. Third, many in the affected societies responded to the crisis with denial, resulting in silence rather than a search for solutions. In South Africa, for example, President Thabo Mbeki (Nelson Mandela’s successor) continued to question whether AIDS was caused by HIV even as the World Conference on AIDS was convening in his country in 1999. In 2000, he condemned the view that HIV/AIDS was sexually transmitted as a racist Western view (Cullinan 2004). Fourth, neither African governments nor the vast majority of infected individuals have the financial resources to pay for treatment. Pharmaceutical manufacturers resisted providing AIDS drugs to African countries at prices they can afford. Greater access to drug treatments could have reduced infection rates in Africa. By lowering the amount of virus in the blood, the drugs may significantly reduce the risk of sexual or intravenous transmission. Short-term treatments can substantially reduce mother-to-child transmission for a relatively low cost. Similarly, short-term treatments can be used as a prophylactic measure immediately after exposure to the virus in cases of rape or accidental exposure of healthcare workers.

To deal effectively with the crisis, African nations need to reduce both infection rates and mortality rates. They must use public education to change cultural attitudes to reduce infection rates. They also need access to the relatively inexpensive drug treatments to prevent mother-to-child transmission and accidental transmission to health-care workers. Both of these strategies are affordable enough to be viable options. With respect to mortality rates, these societies require affordable access to drug treatments.

2.3 South Africa: International Politics and Lack of Political Leadership

South Africa is the most populous country in the sub-Saharan African region. It has approximately 45 million people (estimate of December 2005). The adult prevalence rate of HIV/AIDS for South Africa is 16.2% (see Table 2.5). Few countries in the world have a higher prevalence rate. South Africa has the most people with HIV/AIDS of any country in the world.

In spite of the severity of the AIDS epidemic in South Africa, the South African government has been remarkably slow to develop an effective AIDS strategy. AIDS is the object of strong social stigma in South Africa and hinders prevention and treatment efforts, but has not been addressed. It took until 2004 for South Africa to launch a public anti-retroviral drug program and the program's implementation has remained slow, with tens of thousands of prospective patients still unable to access treatment. The private sector in South Africa began to provide ART treatment to employees at least 2 years before the South African government, in mining companies such as Anglo American and De Beers, and in manufacturing companies like DaimlerChrysler. Right into the twenty-first century, South African president Thabo Mbeki raised doubts about whether HIV causes AIDS and questioned the basic strategies to address the epidemic, even suggesting that the drugs commonly used to treat HIV would be ineffective. In 2005, South African Health Minister Manto Tshabalala-Msimang continued to espouse garlic and olive oil instead of antiretroviral drugs for people with HIV. President Mbeki's predecessor, Nelson Mandela, was also slow to address the AIDS issue during his presidency, although he has dedicated time to lobbying for greater action during his retirement.

On 12 December 1997, South African President Nelson Mandela signed into law amendments to the South African Medicines Act (www.polity.org.za/html/govdocs/legislation/1997/act90.pdf). This amendment prompted a group of multinational pharmaceutical companies to sue the South African government (www.cptech.org/ip/health/sa/sa-timeline.txt). In May 1997, a representative of the Pharmaceutical Research and Manufacturers of America (PhRMA), Mr. Harvey Bale, sounded the alarm over how the proposed changes could affect the rights of the owners of patented medicine. Different representatives of the federal government of the United States, along with PhRMA representatives, pressured the government of South Africa to abandon the amendment. The US government implicitly threatened trade sanctions and the revocation of reciprocal tax treaties. The response of South African Health Minister Nkosazana Zuma was to declare that "It is unacceptable for South Africa to pay higher prices than Australia" for medicine.

The eye of the storm was centered on the following passage:

Section 15C

The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may

(a) Notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

(b) Prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have

the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported:

(c) Prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

In essence, paragraph (a) establishes a system of international exhaustion of patent rights and paragraph (b) authorizes parallel imports. Under a system of *international exhaustion*, as soon as the product is put on the market of any country by the patent holder, he can no longer block the importation of that product into any other country. Such importations are known as parallel imports. Exhaustion of patent rights cannot be raised in a dispute before the World Trade Organization (WTO), meaning that the member countries are free to establish a system of international exhaustion of patent rights and to authorize parallel imports, just as South Africa did with its Section 15C amendment.

While the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that patent holders be granted the exclusive right to prevent third parties from making, using, selling or *importing* their product without consent, Section 15C could not form the basis of a WTO complaint under TRIPS. Members of the WTO must seek permission through the WTO dispute settlement system in order to impose trade sanctions for violations of WTO agreements. Thus, while the South African amendment might violate one provision of TRIPS, a different provision of TRIPS prevents the use of the dispute settlement system to resolve the matter. As a result, any trade sanctions imposed unilaterally against South Africa for this alleged violation of TRIPS would be illegal under WTO law. This meant that the international dispute settlement system of the WTO could not be used against South Africa in this case. Nevertheless, the potential threat of WTO action was used, together with other threats, to pressure the South African government.

It was not just the US government that raised concerns about Section 15(c). The Vice President of the European Commission, Leon Brittan wrote (on 23 March 1998) to the then Deputy-President, Thabo Mbeki, arguing that the Act “would appear to be at variance with South Africa’s obligations under the WTO TRIPS agreement ... and its implementation would negatively affect the interest of the European pharmaceutical industry.” (www.oxfam.org.uk/policy/papers/safrica/safrica3.htm). In July 1998, the President of France voiced his concern over the issue as did the heads of state of Switzerland and Germany. Thus, governments of most developed countries with high concentrations of pharmaceutical patents sided with the Pharmaceutical Manufacturers’ Association of South Africa in pressuring the South African government to withdraw Section 15(c) of the Act.

The next step the American government took to pressure South Africa was the introduction of the omnibus appropriations law, which contained a provision inserted by Rep. Rodney Frelinghuysen (R-NJ) that cut off aid to the government of South Africa. This provision established that “..None of the funds appropriated under this heading may be available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of Section 15 (c) of South Africa’s Medicines and Related Substances Control Amendment Act No. 90 of 1997” (See Omnibus Consolidated and Emergency Supplemental Appropriations Act, Public Law No 105–277, 112 Stat 2681 1999). This bill was originally part of the House of Representative Bill HR 4328 (available at www.bts.gov/lawlib/docs/hr4328.pdf).

The position of the American government kept hardening. In April 1999, the United States Trade Representative put South Africa on the so-called 301 Watch List – a list of countries that could face trade sanctions over laws that affected American business interests. Vice President Al Gore continued to express his displeasure at the passage of the South African Medicines Act. Thus, both the executive and legislative branches of the American government got involved in the campaign against South Africa’s quest for more affordable medicine to treat the world’s largest population of people with HIV/AIDS.

In the case of Mr. Gore, the dramatic turn around came when he wrote on, 25 June 1999, the following letter to James E. Clyburn, the Chair of the Congressional Black Caucus, “I want you to know from the start that I support South Africa’s efforts to enhance health care for its people including efforts to engage in compulsory licensing and parallel importing of pharmaceuticals – so long as they are done in a way consistent with international agreements” (Love 1999). Why did the dramatic turn-around take place? There are two possible reasons. First, on June 16, 1999, Mr. Gore declared that he would run for the presidency of the United States in 2000. Immediately, he was attacked by AIDS activists on the ground that he was fighting against South Africa’s position on parallel imports. Given that Mr. Gore was trying to get the support of the gay community, this might have influenced his view. Second, perhaps more importantly, on June 24, 1999, the US Supreme Court ruled that state governments cannot be sued for patent infringement (*Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank et al.*). Thus, it became amply clear that if the states within the United States could not be sued for patent infringement, it would be all but impossible to make the political case for taking action against another sovereign nation like South Africa. (As noted above, there was no basis for filing an international legal complaint against South Africa at the WTO).

While the international legal route was doubtful, and the international political campaign was in progress, pharmaceutical companies launched a third prong in

their attack on the South African law. On 18 February 1998, the Pharmaceutical Manufacturers' Association of South Africa, along with 39 pharmaceutical companies, sued South African President Nelson Mandela over this issue (Pharmaceutical Manufacturers' Association of South Africa v. President of the Republic of South Africa, Case No 4183/98).

Despite the three-pronged campaign, the South African government still refused to budge. For example, in December 1999, South African Health Minister Nkosazana Zuma declared:

We have a right in South Africa to put public health before profit – public health should be supreme and commercial interest second. The most important asset of South Africa is its people. That does not mean that pharmaceutical companies should not make a profit. But their profit margins should still allow people to afford medicine. We need to fight for this position in multilateral organisations. Even the World Trade Organisation (WTO) intellectual property rights regime recognises that you cannot leave essential medicines to unfettered market forces. There has to be intervention to make sure that medicines are affordable. This is not a uniquely South African problem. It is an issue that developing countries should take on together. But, poor people in developed countries also cannot afford these medicines. (www.igd.org.za/pub/g-dialogue/interviews/zuma.html)

On 10 May 2000, President Clinton signed an Executive Order which prohibited sanctions against sub-Saharan African countries that violated American patent law in obtaining AIDS medications and/or treatments (for the full text of the Executive Order, see Appendix). There are two notable features of the Executive Order. First, it refers *only to HIV/AIDS*. In other words, the Executive Order cannot be applied to other kinds of diseases. Thus, for example, in the case of malaria, the Executive Order would have no effect. Second, it only exempted sub-Saharan Africa. Any other country anywhere else cannot benefit from this Executive Order. For example, Haiti has an HIV/AIDS infection rate comparable to some sub-Saharan African countries. But, by definition, it would be excluded.

Remarkably, the pharmaceutical companies did not change their position on the South African law even after this Executive Order. They continued to hold the line. Only after the inauguration of George W. Bush and his clear message that he would not reverse the Executive Order did the pharmaceutical companies back down. They dropped the case unconditionally in April 2001. This also coincided with a turn of events in the South African court hearing the case that would have required the patent owners to disclose confidential information regarding the cost of producing the medicines at issue. Others believe that “international outrage” played a pivotal role. For example, ‘t Hoen (2002) wrote, “Eventually, the strong international public outrage over the companies’ legal challenge of a developing country’s medicines law and the companies’ weak legal position caused the companies to unconditionally drop the case in April 2001.”

Why did the pharmaceutical companies invest so much in opposing that particular clause in the South African law? Given that South Africa only represents a very tiny part of their global profits, it seems unlikely that this effort resulted from a desire to maintain economic incentives to engage in research and development for South African diseases (see Lanjouw 2001). A more logical reason would be a concern that price reductions in developing countries might increase pressure from governments in developed countries to lower prices there as well. In the case of South Africa, the battle between patent owners and the government centered upon the issue of parallel imports. In the next section, we examine the case of Brazil, where the main issue in this regard was the compulsory licensing of patented medicine (see Harris 2001).

The case of South Africa is instructive in many ways. The legal dispute over parallel imports in South Africa set an important precedent that influenced the perception of developed country governments, such as the United States and European governments, on the correct balance between the rights of patent owners and the rights of patients, particularly in developing countries that face serious AIDS epidemics. A more unfortunate lesson from South Africa is that failure to address the AIDS epidemic early and effectively can have disastrous consequences for a country and, indeed, a region – as it has in many parts of sub-Saharan Africa. In retrospect, the lack of political leadership in South Africa – which prevails even as we write this book in the form of bizarre and dangerous statements on the part of the minister of health – has been a significant factor in the spread of AIDS in a middle-income country that might have faced a brighter future had its leadership responded differently. South Africa stands as a cautionary tale regarding the danger of inaction and denial.

2.4 AIDS Strategy in Brazil: Integrating Prevention, Treatment and Human Rights

In terms of *absolute numbers*, Latin America and the Caribbean have the third highest number of cases of any region, after Africa and South/Southeast Asia (see Table 2.4). In terms of infection rates, the Caribbean has the highest infection rate outside of Africa (see Table 2.5). In 2007, there were an estimated 1,610,000–2,170,000 people living with HIV/AIDS in Latin America and the Caribbean (see Table 2.4). This compares to 480,000–1,900,000 in North America (the United States and Canada), 3,300,000–5,100,000 in South and Southeast Asia, and 20,900,000–24,300,000 in sub-Saharan Africa. In Latin America and the Caribbean, the highest infection rate is 2.2 in Haiti (2005–2006), while Brazil has the highest number of cases, with an estimated 620,000 (370,000–1,000,000) (figures for 2005) people living with HIV (UNAIDS 2007). Between 1980 and June 2007, 474,273 cases of AIDS were reported in Brazil: 289,074 in the Southeast; 89,250 in the South; 53,089 in the Northeast; 26,757 in the Central/West; and 16,103 in the North (Brazil Ministry of Health 2007).

In 1992, the World Bank predicted that 1.2 million Brazilians would be infected by 2002. The actual number is half of that figure and demonstrates Brazil's success in tackling the epidemic. Moreover, the epidemic shows signs of stabilization in Brazil, with the incidence (of new cases) now decreasing. In 2006, 32,628 new infections were reported, compared to 38,816 in 2002 (Brazil Ministry of Health 2007). However, the trends in Brazil vary by region, with new infections on the rise in the North and Northeast and declining in the rest of the country (see Table 2.7).

Between 2002 and 2006, the number of AIDS-related deaths increased in the North (42.4%), Northeast (15.7%) and Central/West (14.9%) regions of Brazil, but decreased in the South (46.5%) and Southeast (11.76%) (Brazil Ministry of Health 2007) (see Table 2.8).

Table 2.7 Incidence of new infections in Brazil in 2002 and 2006 per 100,000 by region

Region	2002	2006
North	10.8	13.6
Northeast	9.4	10.1
Southeast	29.2	20.5
South	33.3	25.6
Central/West	20.1	15.8

Source: Brazil Ministry of Health, Boletim Epidemiológico, 2007

Table 2.8 AIDS-related deaths in Brazil in 2002 and 2006 by region

Region	2002	2006
North	415	591
Northeast	1,341	1,552
Southeast	6,496	5,732
South	2,246	1,046
Central/West	557	640

Source: Brazil Ministry of Health, Boletim Epidemiológico, 2007

Brazil's AIDS program dates from 1982, when the first AIDS cases were diagnosed there. Brazil adopted a three-pronged strategy based on (1) early and sustained prevention (since 1983, starting in Sao Paulo with gay NGOs), (2) the promotion and protection of human rights (since 1988), and (3) universal access to treatment and care (starting in 1991 with AZT and with ART in 1996, the year effective triple-combination therapy became available). Most critically, Brazil's state-of-the-art prevention program has focused on high-risk groups (men who have sex with men (MSM), injection drug users (IDUs), and commercial sex workers (CSW)), but has also expanded to at-risk populations (female sex partners

of MSM and IDUs and persons with multiple sex partners) and, more generally, women, youth, rural populations and the poor. This has increased awareness and healthier sexual behavior among the general population, especially younger populations and high-risk groups. Brazil has kept higher prevalence rates largely limited to high-risk groups: IDUs (36.3%), MSM (10.8%), and CSW (6.5%) (World Bank 2004).

Brazil has contained the epidemic, with adult prevalence in the general population at 0.6% (Brazil Ministry of Health 2007). Since the beginning of the epidemic in Brazil, there have been 314,294 cases of AIDS reported in men and 159,793 in women. However, the nature of the epidemic in Brazil has changed over time. In 1985, the ratio of men to women with HIV/AIDS was 15 to 1, whereas this ratio was 1.5–1 in 2007 (Brazil Ministry of Health 2007). In 1996, of the men, 29.4% were homosexual or bisexual; 25.6% were heterosexual; and 23.6% were intravenous drug users. In 2006, 42.6% were heterosexual; 27.6% were homosexual or bisexual; and 9.3% were intravenous drug users. Among women over 13 years of age, in 1996, 86.1% were heterosexual and 12.6% were intravenous drug users. In 2006, 95.7% were heterosexual and 3.5% were intravenous drug users (Brazil Ministry of Health 2007).

In 1988, the new Brazilian Constitution made health a universal right and a duty of the state. That same year, Congress passed a law that expanded the human rights of workers with incapacitating or terminal illness to include people living with AIDS. Since the 1980s, all levels of government and civil society have been involved in human rights activities related to HIV/AIDS. In 2003, there were about 140,000 patients receiving ART and a further 196,000 HIV-positive asymptomatic cases being monitored. Between 1997 and 2001, Brazil saved approximately USD 2.2 billion by reducing hospitalizations by 70% and by reducing the cost of ART through local manufacturing of generic drugs and aggressive negotiation of price reductions for patented drugs. Mortality and opportunistic infection rates have declined sharply since 1997 and incidence rates have also dropped considerably (World Bank 2004).

Figure 2.1 shows the dramatic decline in the new infection rate in Brazil since 1995. This decline can be attributed to the vigorous campaign that Brazil has pursued among different risk groups. It also shows the drop in the rate of new infections in the United States. However, the new infection rates (or incidence rates) in the United States are still far ahead of the other three countries in the figure. It is important to keep the terminology consistent. In epidemiology, the term *prevalence rate* is used to mean the proportion of population infected with HIV/AIDS whereas *incidence rate* refers to the number of new cases in a given year. They can represent quite different things. For example, the prevalence rate might fall simply because of death of a large number of HIV/AIDS patients.

In contrast to the lack of leadership in South Africa, strong leadership in Brazil's government and civil society created effective partnerships among governmental, non-governmental and private sectors. These partnerships created synergies of

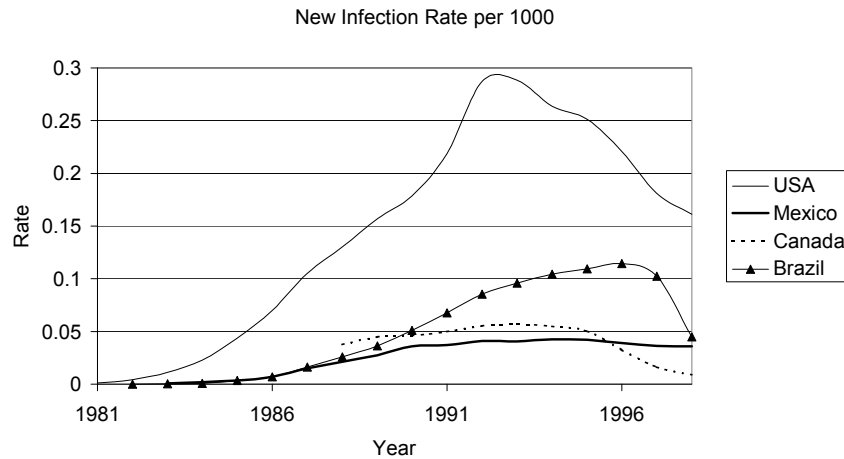


Fig. 2.1 New infection rate per 1,000 people in Brazil, Canada, Mexico and USA. *Source:* Data from UNAIDS Country Fact Sheets, 2002. Population figures from the CIA Factbook, 2002

expertise and resources that expanded the range and coverage of HIV/AIDS programs. In this regard, key elements contributing to Brazil's success have been democratic institutions (public accountability, channels for public opinion, and a free press) and the participation of NGOs in policy formulation and evaluation and program delivery, particularly among vulnerable groups. Human rights protection has proved to be an essential component, encouraging high-risk individuals and communities to address the disease openly and to get diagnosed and treated. Brazil benefited from better health infrastructure (hospitals, clinics, counseling centers and laboratories) and human resources (other than the number of nurses) than most middle-income developing countries. Brazil's prevalence rate (0.6%) is relatively low compared to sub-Saharan African countries, and its per capita expenditure on health (USD 308) is relatively high compared to other developing countries, making Brazil's HIV/AIDS program affordable at 0.07% of GDP (Oliveira-Cruz et al., 2004). However, the average cost of treatment has risen quickly, from USD 1,350 per patient in 2003, to USD 2,500 in 2005 (Camacho 2006).

Making universal access affordable has been a key element of Brazil's HIV/AIDS strategy, through manufacturing generic drugs and rigorous price negotiations with patent owners. In 2001, Brazil extracted price concessions from Merck and Roche by threatening to issue compulsory licenses on their patents in order to manufacture generic versions of their HIV/AIDS drugs. The TRIPS Agreement permits WTO members to issue compulsory licenses on patents without negotiating compensation in cases of non-commercial public use, national emergency or extreme urgency. The term "non-commercial public use" would cover the manufacture of generic AIDS drugs for free distribution through the government's

AIDS program. Brazilian law incorporates these TRIPS provisions and provides that a national emergency might arise from a threat to the public's health or nutrition, the environment, or the country's social, economic or technological development (Chartrand 2001). Thus, in addition to the "non-commercial public use" basis, compulsory licenses could also be issued for AIDS drugs on the grounds of "national emergency". The effect of TRIPS rules on compulsory licensing on the bargaining power of Brazil in its negotiations with patent owners has had a direct impact on the cost of providing access to HIV/AIDS treatment for Brazilian patients.

In 2001, the United States filed a complaint at the WTO over Brazil's requirement that patent owners manufacture their products in Brazil in order to maintain full patent rights (Brazil – Measures affecting patent protection, Complaint by the United States, WTO Document WT/DS199). Brazil's Industrial Property Law (which came into effect in 1997) also makes patents subject to compulsory licensing if the product is not manufactured in Brazil. Had the dispute proceeded, the outcome would have been uncertain, since a lack of consensus on the issue of local working requirements resulted in ambiguous WTO provisions on this issue (Champ and Attaran 2002). The United States argued that the Brazilian law violated TRIPS obligations to make patents available without discrimination as to whether the products are imported or produced locally. However, the United States dropped the case after world leaders and health organizations said the case could hurt Brazil's HIV/AIDS program. The United States and Brazil notified the WTO of their mutually agreed solution on 5 July 2001.

Brazil has been manufacturing HIV/AIDS drugs in its government laboratory, which make generics for the free drug program. Brazil did not need to issue any compulsory licenses to manufacture these AIDS drugs in Brazil. These HIV/AIDS drugs produced by the government laboratory (called "Farmanguinhos") were not protected by patents in Brazil, as patent protection for pharmaceuticals only began after 1997 with the Industrial Property Law, and those drugs were already on the market before that. Consequently, anyone was free to produce them without a (compulsory or voluntary) license from the patent holders, as they were off-patent. However, on 5 September 2003, Brazil implemented legislation to authorize imports of generic versions of *efavirenz*, *lopinavir* and *nelfinavir* from India and China after it failed to reach a satisfactory agreement in price negotiations with the patent owners.

Brazil's HIV/AIDS program has driven down both drug prices and deaths from HIV/AIDS. The program has reduced the nation's death rate from HIV/AIDS by half. The health ministry spent \$444 million on HIV/AIDS drugs in 2000, 4% of its health budget. The decline in hospitalizations from opportunistic infections from 1997 to 1999 saved the health ministry \$422 million (Rosenberg 2001). The money that the government saved on treatment for patients who would otherwise have been hospitalized exceeds the cost of the drugs by 60%.

Since Brazil began making the generic copies of HIV/AIDS drugs, it has reduced the price of the patented equivalents. The Brazilian state laboratory makes eight of the 15 HIV/AIDS drugs used in the country. The price of HIV/AIDS

drugs with no generic competition fell 9% between 1996 and 2000 (Baldwin 2002). The price of those that faced generic competition fell 79%. This has enabled Brazil to produce some triple therapy for USD 3,000 per year and to expect the price to drop to \$700 per year in the future. This compares to a cost of USD 10,000 to USD 15,000 per year in the United States (Rosenberg 2001).

In August 2001, the Brazilian health minister announced that his government would issue a compulsory license on Roche's HIV/AIDS drug *nelfinavir* and begin manufacturing a generic copy in government laboratories in 2002. The announcement came after negotiations between the Swiss drug company and Brazil failed to produce an agreement on price reductions. The health minister said that over a quarter of his HIV/AIDS program budget was being spent on *nelfinavir* alone. Even if the company agreed to reduce its price by an additional 40%, the health minister said that would be insufficient to stop the government from proceeding with its plan (Petersen 2001). The reason for the government's refusal of the offer was that it would still be less expensive for the government laboratory to carry out the local manufacturing of *nelfinavir* than to accept Roche's proposal. The government reasoned that in order to avoid the compulsory license, the price reduction by Roche would have to be as advantageous as the cost of manufacturing in the government laboratory.

The company responded by pointing out it had already reduced the price in Brazil to 50% of the cost in the United States and had donated thousands of doses of the pediatric syrup version to Brazil. The company stated its intention to begin manufacturing Viracept (the brand name of *nelfinavir*) in Brazil in 2002 and to continue to provide the medicine free to Brazilian children with HIV/AIDS. It sought further negotiations, which the health minister described as an attempt to delay preparations to manufacture the drug in the government's laboratory. Financial analysts said the dispute would affect public relations more than finances, with Roche's overall sales of Viracept rising 5% to USD 132.6 million in the first half of 2001 (Shields 2001).

On August 31, 2001 the Brazilian health minister announced an agreement with Roche to reduce the price by a further 40%, making the Brazilian price 30% of the US price. In March 2001, a similar threat to the patent on two HIV/AIDS drugs produced by Merck led to an agreement to reduce the price of *indinavir* and *efavirenz* by about 60% in Brazil (Rich 2001). In both cases, the decision of the Brazilian government to purchase the patented drugs, rather than issue compulsory licenses to government laboratories, indicates that the negotiations succeeded in reaching the optimal price for the drugs. Assuming that Brazil's decision was based on cost alone, the difference between the cost of manufacturing in the Brazilian laboratory and purchasing the patented drugs at a discount must have been too small for Brazil to issue a compulsory license.

Brazil, as a developing country that did not provide patent protection when TRIPS came into force, was not required to fully implement its TRIPS obligations until 2005. However, Brazil chose not to use the full transition period that was available.

TRIPS requires patents to provide patent owners with the exclusive right to prevent third parties from making, using, selling or importing a patented product without the owner's consent. Articles 30 and 31 authorize exceptions to these rights. Article 30 permits "limited exceptions". Article 31 permits WTO members to allow "other use of the subject matter of the patent", and covers compulsory licensing of patents. The term "other use" means "use other than that allowed under Article 30". Under Article 31, a government may issue a compulsory license authorizing the government or a third party to produce generic drugs without the authorization of the patent holder where negotiations fail to obtain authorization on reasonable commercial terms. However, the use of the patent must be to supply "predominantly" the domestic market and the patent holder must be paid adequate remuneration, based on the economic value of the license. As noted above, the negotiation requirement may be waived in cases of national emergency, extreme urgency, or non-commercial public use. Members are not obliged to comply with the negotiation requirement or to serve predominantly the domestic market where the use is permitted to remedy anti-competitive practices.

The TRIPS provisions relating to compulsory licensing strengthened Brazil's position in its price negotiations with Roche and Merck. Brazil met the necessary conditions to halt negotiations because the generic versions would have served a non-commercial public use and predominantly supplied the domestic market. Since the term "adequate remuneration" is not defined, the pharmaceutical companies could not predict with certainty what compensation they would have received in the Brazilian courts had Brazil walked away from the negotiations (see Box 2.1). This gave the companies an added incentive to determine the price through negotiation.

At Doha in 2001, the WTO Ministerial Conference agreed in the Declaration on TRIPS and Public Health that TRIPS "does not and should not prevent Members from taking measures to protect public health...and, in particular, to promote access to medicines for all". This Declaration also confirms that WTO members have "the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". It also clarifies that members have "the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, *including* those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency" (emphasis added). Thus, the scope of this Declaration is not limited to a specific number of diseases (such as HIV/AIDS, tuberculosis or malaria), nor to specific types of health crises, such as epidemics. The definition of "national emergency" or "extreme urgency" is not limited to public health problems and could cover other matters as well.

In the context of HIV/AIDS, the Declaration clarifies that "national emergency" and "extreme urgency" can be interpreted according to the *nature* of the disease rather than just the *number* of infections in a particular country. There is research that suggests that once a population reaches an adult infection rate of 1%, it becomes much more difficult to prevent HIV/AIDS from spreading much more

Box 2.1 Determining compensation for compulsory licenses in the courts

Calculating compensation for compulsory licenses is likely to be an uncertain process in any legal system. Since TRIPS permits the process for calculating remuneration to differ from one WTO member to the next, uncertainty increases in the international context. TRIPS Article 31(h) requires that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the [compulsory license].” Article 31(k) allows “the need to correct anti-competitive practices” to be taken into account in determining the amount of remuneration. Article 31(j) requires that “any decision relating to remuneration...shall be subject to judicial review or other independent review . . . in that Member.” Article 1 provides that “Members shall be free to determine the appropriate method of implementing [TRIPS] within their own legal system and practice.” The general nature of these compensation obligations, together with the flexibility permitted under Article 1, means that the specific manner in which compensation is determined may vary from one WTO member to the next, as may the principles that apply to judicial review or its equivalent in each legal system.

For example, in the United States, courts apply a 15 factor test to assess damages as a reasonable royalty (*Georgia-Pacific Corp. v. United States Plywood Corp.* 1971; *Gargoyles Inc. and Pro-Tec Inc. v. The United States* 1997). Moreover, in the words of the United States Court of Appeals for the Federal Circuit, “the facts of each case (and royalty determination) differ”, making it difficult to predict the outcome (*Gargoyles Inc. and Pro-Tec Inc. v. The United States* 1997, p. 9).

In addition, the patent owner may fail to prove a claim for lost profits. In *Gargoyles Inc. and Pro-Tec Inc. v. The United States* (1997), the US Federal court upheld the finding of the Claims Court that: (1) due to insufficient manufacturing capacity, the plaintiff could not have met the demand for its product had no compulsory license been issued; (2) there was an acceptable substitute product that could have been used in place of the plaintiff’s product; and (3) the plaintiff did not properly quantify its lost profits. Under US jurisprudence, the correct measure of compensation is what the owner has lost, not what the taker has gained (*Leesona Corp. v. United States* 1979; *Hughes Aircraft Co. v. United States* 1996; *Gargoyles Inc. and Pro-Tec Inc. v. The United States* 1997).

A final factor that currently contributes to the uncertainty surrounding the level of compensation that may be forthcoming under US law is the standard of proof required. The standard is clear with respect to lost profits in private cases for damages, where the patent owner must show only a “reasonable probability” that, but for the infringement, it would have made the sales made by the infringer (*Rite-Hite Corp. v. Kelley Co.* 1995). However, it is not clear whether the same standard applies in cases that involve the government, where lost profits are awarded only after the strictest proof that the patentee would actually have earned and retained those sums in its sales to the Government (*Gargoyles Inc. and Pro-Tec Inc. v. The United States* 1997; *Tektronix Inc. v. United States* 1977). Moreover, a royalty

could not be awarded in addition, since that would constitute double counting (Leesona Corp. v. United States 1979). Since TRIPS permits the process for calculating remuneration to differ from one WTO member to the next, uncertainty increases in the international context.

On 7 September 2007, the U.S House of Representatives passed the Patent Reform Act of 2007 (H.R. 1908, <http://www.govtrack.us/congress/billtext.xpd?bill=h110-1908>). The bill still had to pass in the Senate in 2008. The proposed law would allow a court to replace the existing 15-factor test with a single concept of “apportionment.” Under Section 5, damage calculations could be limited to the economic value properly attributable to the patent’s specific contribution over prior inventions. However, where the patent’s specific contribution over prior inventions is the predominant basis for market demand for an infringing product or process, damages may be based upon the entire market value of the products or processes involved that satisfy that demand. The bill could significantly limit damage awards. The US pharmaceutical industry opposed to the Patent Reform Act of 2007.

rapidly and widely in the population (see Box 2.2). Indeed, the nature of HIV/AIDS is such that the United Nations views HIV/AIDS as not only a global health crisis, but a threat to peace and security. Thus, countries with relatively low prevalence rates for HIV/AIDS, like Brazil’s rate of 0.6%, could consider HIV/AIDS a national emergency or a situation of extreme urgency, although the threshold at which a situation would qualify still remains somewhat ambiguous. Greater clarity would be useful so that WTO members can take action in borderline cases with greater confidence that it would not result in a complaint being filed at the WTO or the withdrawal of international aid or other benefits from developed countries whose pharmaceutical lobbies exert pressure on their governments.

The case of Brazil demonstrates that developing countries with manufacturing capacity have the power they need to reach the optimal price in negotiations with patent owners. If the cost of manufacturing generic versions under compulsory license (or of importing from generic producers in other countries) is lower than the cost of buying from the patent owner, the country will do the former. This price competition ensures that the drug in question is supplied at the lowest possible cost. Thus, the level of bargaining power a country enjoys ultimately affects the price it pays for medicine and the affordability of treatment for HIV/AIDS. This has a direct impact on the number of patients that get access to treatment.

Brazil’s AIDS program has been remarkably successful on many measures. It’s three-pronged strategy – prevention, human rights protection, and universal access to treatment – serves as a model for other countries to follow, whether developed or developing. Universal access to ART is a hallmark of the success of Brazil’s program, but having brought the epidemic under control is Brazil’s most important achievement (Oliveira-Cruz et al., 2004). However, high drug prices could still threaten the sustainability of universal access to ART (Galvao 2002).

Box 2.2 The one percent debate

The exact 1% figure is subject to assumptions in a mathematical model. However, the general thrust of the result is as follows. If the infection rate is below some threshold level, the disease eventually dies out. If it is above certain threshold, then the disease grows according to a Gompertz curve, first rising rapidly to some level of the population and then stabilizing. The early model where this was demonstrated was known as the SIR model with three stages of an organism: susceptible (S), infective (I) and removed (R). In biomedical literature, the first such demonstration was provided by Barbour (1975). However, the theorem was derived under the condition that there is equal likelihood of disease transmission in the entire population. In the case of HIV/AIDS, this is not true. The transmission mechanism in the developing countries tends to follow poverty, not ignorance and sexual “promiscuity” as is popularly believed. In reviewing the evidence, Galvao (2002) write “Many of those at greatest risk already know that HIV is a sexually transmitted pathogen and that condoms could prevent transmission. Their risk stems less from ignorance and more from the precarious situations in which hundreds of millions live; gender inequality adds a special burden, and is the main reason that, globally, HIV incidence is now higher among women than among men.” (p. 404). Given that poverty occurs in clusters or networks (that is, if I am poor, my relatives and my children are likely to be poor as well), we need a different model for explaining the propagation of HIV/AIDS. A model with correlated agents can produce “synthetic communities.” A recent example of such a model has been powerfully illustrated by Boguna et al. (2003). Such models have been used in studying patterns of clustering of collaborative research, connectivity of pages on the Internet, growth of cities and many other phenomena. They all point to the same general conclusion. Beyond a certain threshold, there is takeoff point. Dezsó and Barabási (2002) show that in the presence of a threshold value of an epidemic, a policy of containing the disease by spending resources in a random fashion (without attacking the nodes of the network) can never eradicate the disease.

In 2006, Brazil continued to play a leading role in tackling the AIDS pandemic, hosting 18 other Latin American countries to discuss ways to achieve universal access to anti-retroviral drugs by 2010 in the region, through collective purchasing and production of medicine. Pedro Chequer, coordinator of Brazil’s National STD/AIDS Program, urged other countries to reject non-scientific approaches to prevention, such as the refusal to use condoms for religious, philosophical or cultural reasons. Brazil itself planned to distribute 1.5 billion condoms in 2006.

In May 2007, Brazil issued a compulsory license to import generic versions HIV/AIDS drug *efavirenz* from laboratories certified by the World Health Organization. Merck’s patent for *efavirenz* is in force until 2012. *Efavirenz* costs Brazil USD 580 per patient per year for the 75,000 patients taking this medication in Brazil, whereas the generic version costs about USD 166 per year.

2.5 Thailand: Successful Prevention in the Sex Trade

In 2007, there were about 500,000 people living with HIV/AIDS in Thailand, of whom approximately 100,000 were receiving first-line retroviral treatment and 50,000 will require second-line treatment in the near future, due to the virus developing resistance to first-line treatment (Thai Ministry of Public Health 2007). In 2007, Thailand issued compulsory licenses for *efarivenz* (the preferred first-line treatment) and Kaletra (the preferred second-line treatment), in order to achieve universal coverage for HIV/AIDS treatment using the best available medicines (Thai Ministry of Public Health 2007). We discuss these compulsory licenses at the end of this section.

In the case of Thailand, our focus is on prevention strategies in the sex trade. Thailand adopted early a strategy of 100% condom use in 100% of sexual contacts in risk groups. This strategy was pursued vigorously over a decade. In this way, Thailand has essentially avoided an explosion in the number of infections that would have almost surely happened had it not taken this strategy. It shows us how a middle-income country can devise a behavior-modifying strategy to cope with the disease if adopted early enough.

The explosion of HIV infection in Thailand came in the late 1980s. In 1988, a repeat survey among drug users found that, in one single year, the prevalence rate of HIV increased from 1 to 44% (Uneklabh et al., 1989). A study by Weniger et al. (1991) found that, in the northern province of Chiang Mai, 44% of commercial sex workers were HIV positive. In addition, in a survey among 16–49 year old males, 28% admitted having premarital or extramarital sex during the past year. Of these, 75% said they had sex with commercial sex workers (Sittitrai et al., 1992).

Thailand has had a long history of controlled commercial sex. Commercial sex was tolerated in certain zones (the most famous being the Patpong district of Bangkok). As a result, sex workers were centralized and highly structured.

After HIV infection hit, the Thai government undertook a program to ensure 100% condom use in brothels. The program launched a mass advertising campaign to promote condom use in commercial sex. The federal government sponsored explicit television commercials as part of a massive education campaign. It started a workplace education program targeting the potential brothel visitors. The government undertook a direct education campaign targeting male and female sex workers and their clients. It started distributing free condoms where high-risk commercial sex was taking place. Government doctors tested and treated individual sex workers with routine examinations and distributed condoms. The government set up a system of prevention, testing and treatment for health workers. The government instituted a reporting system for male patients with sexually transmitted diseases, a system which triggered outreach programs. Finally, the program introduced a series of mobile clinics.

In Thailand, there was strong political and financial commitment at local and national levels, including: local STI/AIDS units, provincial health officers, provincial governors, district officers, the police and regional disease control offices. The police held formal meetings with brothel owners to ensure compliance with the program. Thai Prime Minister Anand Panyarachun appointed Mechai Voravaiya, an individual with strong NGO roots, to be in charge of HIV issues and to report directly to the Prime Minister.

To ensure compliance in the sex trade, the government introduced “secret shoppers” – inspectors who visited brothels at random. Violators faced the threat of sanctions, such as brothel closures. The government monitored data on sexually transmitted infections. There was testing and treatment of sex workers through routine examinations. The inspectors also monitored the number of condoms used in each brothel (Weniger 2006).

The results of the Thai measures can clearly be seen in Fig. 2.2. Between 1989 and 1994, condom non-use fell dramatically as well as sexually transmitted diseases reported in males. Since HIV is a slow-moving *lentivirus*, often researchers see early results of behavior change in other sexually transmitted diseases. By 1995, it became very clear that the program implemented by Thai government had worked.

The effect can also be seen by how HIV/AIDS has unfolded in Thailand over time. Figures 2.3 and 2.4 show how the spread of HIV/AIDS would have taken place had there been no change in behavior. Assuming no behavioral modification, a model generated the projection figure to 2020. It shows that by 2004, there would have been more than 8 million people with HIV/AIDS in Thailand. That would have meant a prevalence rate of 13% by the end of 2003. Instead, in 2003, Thailand only had a prevalence rate of 1.5%.

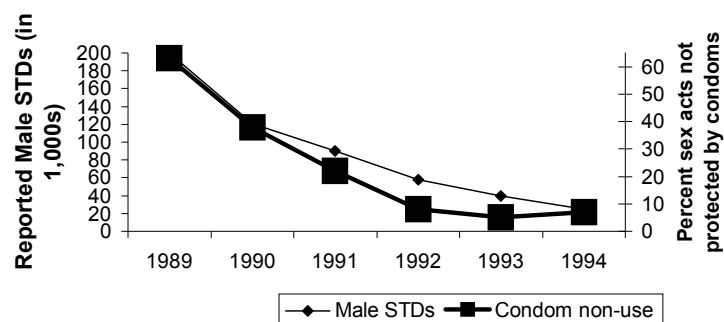


Fig. 2.2 Reported male STDs and percent of sex acts without condoms. *Source:* Ministry of Health, Thailand, 2000

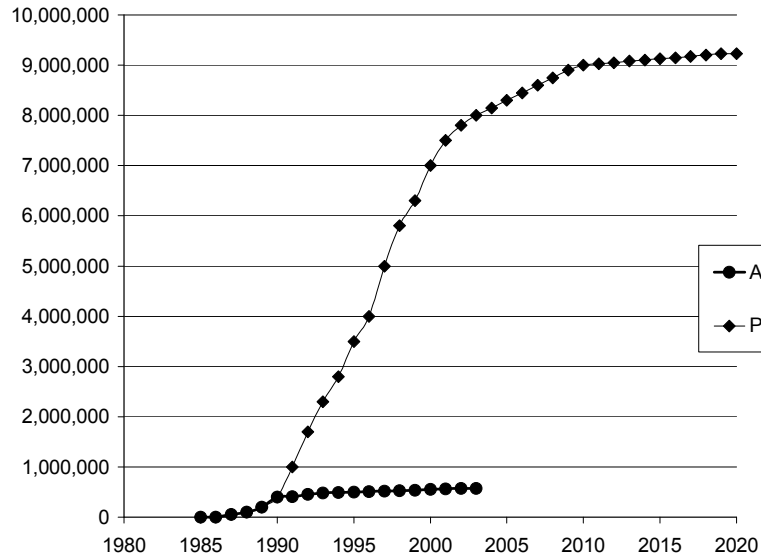


Fig. 2.3 Actual and projected HIV patients in Thailand. *Source:* Ministry of Health, Thailand, 2002

Thailand provides a number of lessons for other middle-income countries. However, it does not mean that we could expect the same degree of success in all countries. Timing is crucial, and Thailand was able to time its interventions very well. Thailand already had an infrastructure for detecting sexually transmitted diseases among sex workers. In other countries, where the sex industry is more diffuse and less organized, this kind of success might be hard to achieve. There are other factors that could complicate the implementation of such programs in other countries. Lack of political commitment could be an important obstacle to the successful implementation of a program like Thailand's. Limited financial resources could be another problem for less developed countries (Smith-Fawzi et al., 2001). In Thailand, the police chose to cooperate with the brothel owners. In other countries, this kind of cooperation may be harder to achieve. Finally, Thailand's focus on the sex trade was well suited to Thailand's situation, since that was the main source of the threat. The difference in the number of actual and projected cases of HIV/AIDS shows that this was the right strategy for Thailand to pursue.

In November 2006 and January 2007, the Thai government announced that it would issue compulsory licenses to produce lower-cost generic versions of Merck's antiretroviral *efavirenz* and Abbott Laboratories' Kaletra, respectively (Kaiser Daily HIV/AIDS Report 2007). Thailand also announced that it planned to issue a compulsory license for Sanofi-Aventis' anti-blood clotting pill Plavix, which is used to treat heart disease, not HIV/AIDS. In issuing the licenses, Thailand would set an important precedent for other developing countries by extending the use of

compulsory licensing beyond health emergencies such as HIV to treatments for heart disease (Kazmin and Jack 2007). In the case of Plavix, the justification for the compulsory license under TRIPS Article 31 would be non-commercial public use, rather than national emergency, which the 2001 TRIPS Declaration indicates as the basis for HIV/AIDS medications. The US threat to issue a compulsory license on Cipro, in order to reduce the cost of stockpiling that drug in case of a terrorist attack using anthrax, preceded the similar actions of the Thai government by over 6 years (see Chap. 5).

A controversy erupted, even though Thailand, like other members of the WTO, has a right to issue compulsory licenses for domestic manufacture of patented products by virtue of TRIPS Article 31 or for importation under the Paragraph 6 Decision. The United States placed Thailand on a priority watch list of countries. The European Union's Trade Commissioner Peter Mandelson sent a letter lamenting Thailand's disregard for Abbott's intellectual property. However, the US government routinely grants compulsory licenses for purely commercial reasons, largely to streamline production of consumer electronics and military hardware. Five such licenses were issued in the last year alone, one of them specifically to Abbott. More than half of all antiretroviral drugs were researched entirely on US government grants. Both *lopinavir* and *ritonavir*, the two antiretroviral agents in Kaletra, were researched with public money. The reason for the protest over Thailand's action is the pharmaceutical industry's fear that Thailand's compulsory license could inspire other developing countries to issue licenses for a series of drugs (Santoro 2007).

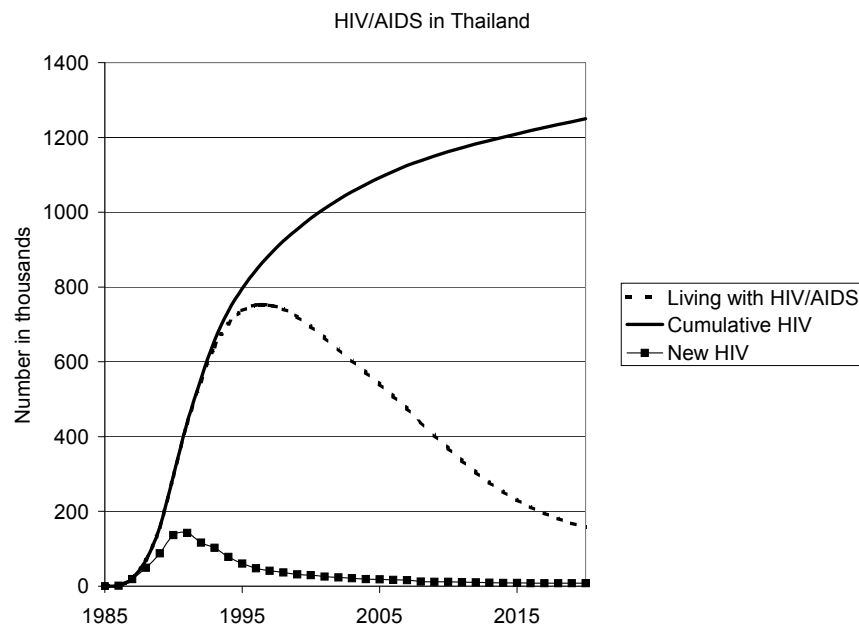


Fig. 2.4 HIV/AIDS in Thailand 1985–2020. Source: Ministry of Health, Thailand, 2007

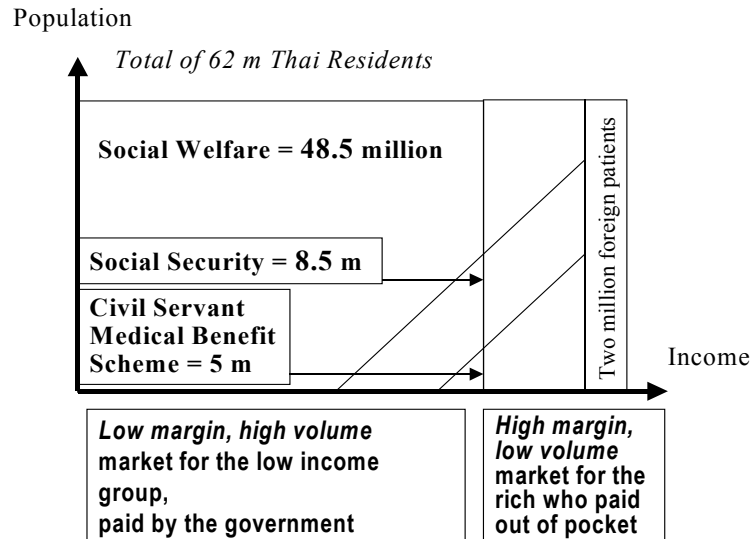


Fig. 2.5 Private and public drug markets in Thailand. *Source:* Facts and evidences on the ten burning issues related to the Government use of patents on three patented essential drugs in Thailand, Ministry of Health, Thailand, 2007 [http:// www.moph.go.th/hot/White%20Paper%20CL-EN.pdf](http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf)

However, as Fig. 2.5 shows, compulsory licensing of drugs for the public health care system in Thailand is not likely to affect sales in the relatively small private market for the patented drugs, although it will affect sales to the government.

The Thai government planned to use the nearly USD 15 million it would save from issuing compulsory licenses for prevention activities. From 1991 to 1994, the Thai budget for AIDS prevention activities increased from USD 2.6 million to USD 462 million. As a result, new infections fell by more than 80%, preventing an estimated two million AIDS cases (see Fig. 2.4).

A 2006 World Bank report estimated that Thailand had saved about \$43 in treatment for every \$1 spent on prevention. However, from 2001 to 2006, the Thai government reduced prevention budgets by about two-thirds in favor of offering universal access to anti-retroviral drugs for AIDS patients (see Table 2.9). However, prevalence rates increased among specific groups, including teenagers, the spouses of men who visit sex workers, intravenous drug users, men who have sex with men and migrants.

One series of safe sex television advertisements, targeted at Thai teenagers, stopped airing in October 2007 because the grant from the Global Fund that was funding the program was set to expire. (See Chap. 7 for a more detailed discussion of the Global Fund and other international donors). With a limited budget for

Table 2.9 Budget for universal access to ARV (million Bahts) and universal care (Bahts per capita)

Year	Napha (million Bahts)	Global fund (million Bahts)	Total (million Bahts)	Per capita in Bahts
2002	278	–	278	1,202
2003	282	–	282	1,202
2004	715	96	811	1,308
2005	1,118	199	1,317	1,393
2006	2,542	307	2,849	1,659
2007	3,473	226	3,699	1,899

Source: Presentation of Suwit Wibulpolprasert, M.D., Senior Advisor on Disease Control Ministry of Public Health, Thailand May 10th, 2007, Berlin, Germany. www.medico-international.de/kampagne/gesundheits/downloads/ppp_panel1_suwit.pps

HIV/AIDS, Thailand has had to make choices in the allocation of funds between prevention and treatment. This highlights the need for sustained funding from donors, such as the Global Fund, and the importance of compulsory licensing as a means to reduce the cost of treatment, even in middle-income countries (Ten Kate 2007).

One day after Abbott Laboratories and Thailand failed to reach an agreement on the price of Abbott's antiretroviral drugs Aluvia and Kaletra, the Thai Health Minister offered to not issue compulsory licenses if the pharmaceutical companies offered prices lower than those charged by generic drug makers. Aluvia is a heat-stable version of Kaletra that eliminates the need for refrigeration and doesn't need to be taken with food, both advantages in a tropical developing country such as Thailand. (In other markets, such as Mexico, the heat-stable version of Kaletra is also called Kaletra and has replaced the older version of the drug.) Abbott offered to sell Aluvia in Thailand for USD 1,000 per person annually on the condition that the country agree not to allow generic versions of the drug into the market, that Thailand not to seek compulsory licensing for Aluvia and that the price of Aluvia could not be reduced any further. Indian generic drug maker Matrix Laboratories offered to sell a generic version of Aluvia to Thailand for USD 695, per person annually (Kaiser Daily HIV/AIDS Report 2007). Abbott had reduced its price for Kaletra in Thailand to USD 2,200 per patient per year in 2006 (Kazmin and Jack 2007).

Abbott threatened to not register the patent for Aluvia in Thailand and to not sell it in Thailand, in order to block the option of compulsory licensing (Health News 2007). By not registering the patent, Abbott would not have to disclose to the Thai government its patented process for making Aluvia and there would be no Thai patent for which to issue a compulsory license. Thus, Abbott's strategy would undermine the credibility of Thailand's threat to issue the compulsory license on Aluvia (though not on Kaletra) and strengthen Abbott's negotiating power with respect to the price for Aluvia in Thailand. Abbott also withdrew applications to sell six other new medications in Thailand (Stone 2007).

The Thai government applies the following criteria to determine whether to issue a compulsory license on patented drugs and medical supplies: (1) they are listed in the National Essential Drugs list; or (2) they are necessary to solve important public health problems; or (3) they are necessary in emergency or extreme urgency; or (4) they are necessary for the prevention and control of outbreaks/epidemics/pandemics; or (5) they are necessary for saving life. Moreover, the price of the patented product must be too high to be affordable by the government to supply the beneficiaries of the national insurance health schemes in order to achieve universal coverage. In the case of Kaletra, the cost of achieving universal coverage was equal to the government's entire budget for anti-retroviral drugs (Thai Ministry of Public Health 2007).

According to the Thai government, only 15% of all patented medicines are eligible for compulsory licensing under the foregoing criteria. Moreover, most of the new patented drugs do not have any significant benefit compared to existing non-patented drugs, obviating the need for compulsory licensing. Finally, compulsory licensing of drugs in Thailand for the public healthcare system does not remove the patented versions from the market, which still exists for two million foreigners and wealthy Thais that buy their medication privately, which is the principal market for patented drugs in Thailand. The Thai government implemented TRIPS in 1992, 8 years before it was required to do so, but this did not have a positive impact on investment in the pharmaceutical industry, with the number of drug factories in Thailand declining from 188 in 1992 to 166 in 2006 (Thai Ministry of Public Health 2007).

Following its decision to issue compulsory licenses on these drugs, the Thai government received letters of support from the Executive Director of UNAIDS, the Director General of the World Health Organization, Médecins sans Frontières and the Clinton Foundation, among others (these organizations are discussed in Chaps. 7 and 8) (Thai Ministry of Public Health 2007).

2.6 Japan: The Xenophobic Denial Strategy

HIV/AIDS was first reported in Japan in 1983. Since then, the incidence of HIV and AIDS (the number of new cases) has gone up almost continuously (see Fig. 2.6). The absolute number of cases is still very small compared with other developed countries. There have been just over 5,000 cases of HIV since 1983.

During the first decade of the spread of HIV and AIDS in Japan, Japanese politicians, commentators and other Japanese experts argued repeatedly that HIV/AIDS was not a Japanese problem – it was the “foreigners” who were infected. Indeed, although the foreigners represent less than 2% of the population living in Japan, they represent over 30% of the HIV cases in Japan (Nemoto 2004).

In Fig. 2.7, we plot HIV incidence every year by nationality and sex. There are several notable features. (1) The number of Japanese females with new infection has stayed very low over the past two decades. (2) The number of foreign male

workers with HIV is fairly low. However, as a proportion of population in Japan, the number is high. (3) Among the female foreign workers, the incidence grew quickly between 1990 and 1994 but fell later in the decade. (4) The incidence of HIV among Japanese males has outstripped all other groups over the past two decades.

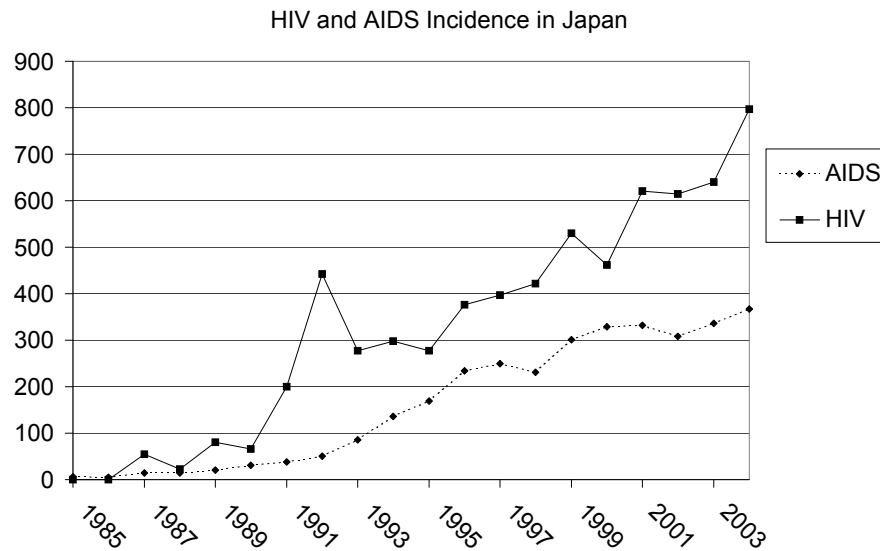


Fig. 2.6 Incidence of HIV and AIDS in Japan 1985–2004. *Source:* Database of the National Institute of Infectious Diseases, Japan

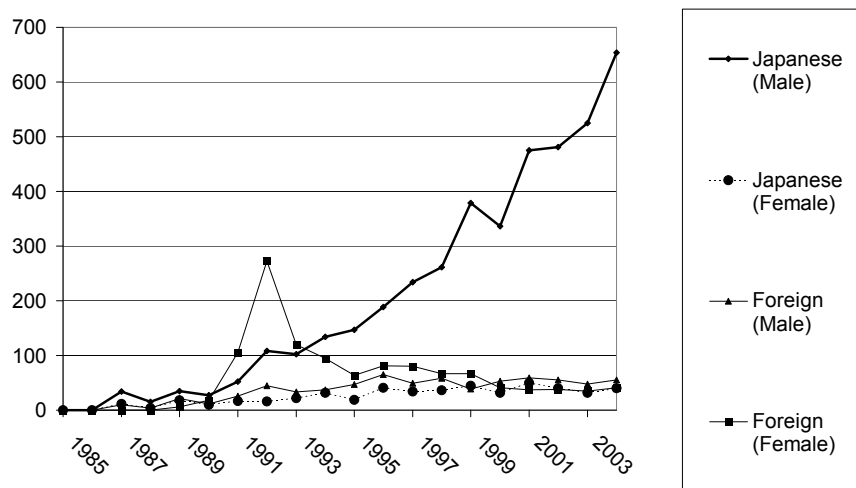


Fig. 2.7 HIV Incidence by sex and nationality 1985–2004. *Source:* Database of the National Institute of Infectious Diseases, Japan

Due to labor shortages during the Japanese boom in the 1980s, many foreign male workers were brought into Japan for construction and other manual work. Most female workers were brought in to work in brothels, massage parlors and other high-risk activities. Not surprisingly, many of these female sex workers were infected. It is not clear whether they were infected before they came to Japan or they were infected after they came to Japan (Kihara et al., 2003).

In Japan, most of new cases of HIV have occurred through Japanese men. There are two main sources of HIV infection among men: through heterosexual activities or through men who have sex with men (MSM). Figure 2.8 shows that, until 1996, heterosexual infection and MSM infection numbers were very similar. After that, MSM numbers have doubled over the next years whereas heterosexual infection numbers have stayed relatively stable.

Where are Japanese males contracting HIV? Are they coming from Japanese tourists abroad (such as Bangkok or Hawaii)? Nemoto et al. (2003) argued that such tourists could potentially be a factor. Anecdotal evidence from the 1980s suggested that many Japanese tourists went on “sex tours” of high-risk areas around the world, contracted HIV and brought it back to Japan. However, systematically collected data about the origin shows (see Fig. 2.9) that at least since 1990, more than 80% of infections among men occurred in Japan. By 2003, this proportion had risen to over 95%.

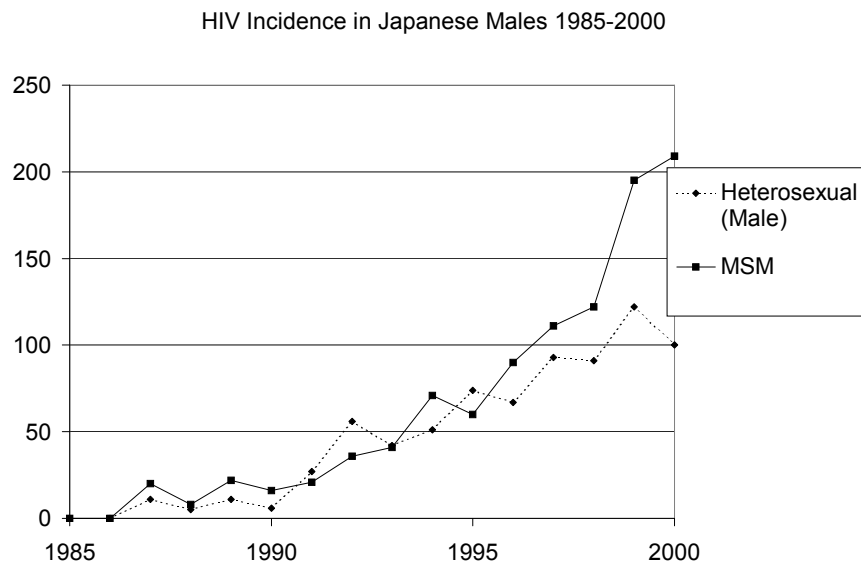


Fig. 2.8 Male HIV infections in Japan by type of sexual activity. *Source:* Database of the National Institute of Infectious Diseases, Japan

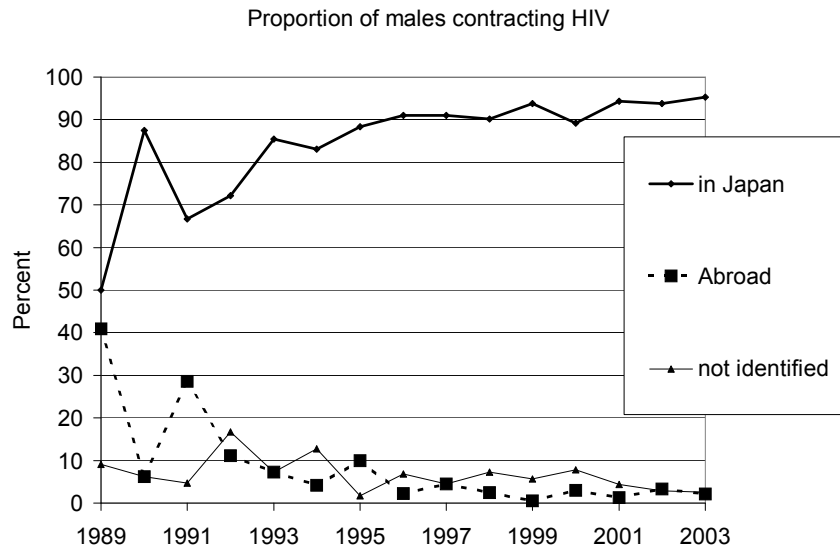


Fig. 2.9 Place where Japanese men contracted HIV. *Source:* Database of the National Institute of Infectious Diseases, Japan

Japan has been fortunate in that the absolute number of HIV/AIDS cases is very low. However, this appears to be based on luck more than a well-designed HIV/AIDS strategy. Xenophobia has colored Japan's response to HIV/AIDS, resulting in a strategy that might be described as xenophobic denial – that is, denying that HIV/AIDS is a problem for Japanese people based on incorrect assumptions that it is a problem for foreigners and Japanese who interact with foreigners.

2.7 Australia: Nondiscriminatory Education and Prevention

The incidence of HIV rose rapidly in the early 1980s in Australia. The government took prompt and rational actions. It instituted several programs immediately. There was remarkable consensus about the policies across the political parties.

It became clear that the single biggest risky group was men who have sex with men. Government at the federal, state and local levels started various campaigns among gay and other homosexually active men between the mid 1980s and the late 1990s. The mobilization and action of the gay community has been central to the effectiveness of these campaigns. Education and prevention were linked with nondiscriminatory HIV/AIDS testing, treatment and care.

Australia instituted a needle and syringe program to keep HIV/AIDS rates low among injection drug users. The program made fresh needles accessible to all the injection drug users. They were not only available in the hospitals and clinics but

also community centers and even in churches. The results are dramatic. In the United States and Canada, about 25% of newly acquired HIV infections are attributed to injection drug use, whereas in Australia, less than 5% of newly acquired infections occur among injection drug users (Department of Health and Ageing 2002).

Australia has the lowest rate of HIV/AIDS among sex workers in the world. This was achieved through the work of community-based sex worker organizations and projects conducted in partnership with State, Territory and Federal Australian governments, and with other agencies. The foundation has been a peer education program among sex workers. It includes the provision of information on safe sex practices, requires new workers to implement these practices and includes outreach services. The results can be seen in Fig. 2.10. The incidence of HIV has fallen from a peak of about 1,800 in the mid 1980s to under 700 in the twenty-first century. In 2003, there were a total of 14,000 people living with HIV in Australia. More than two thirds of them got infected via MSM, while around 20% were infected through heterosexual activities.

To put Australia's success in perspective, we plotted AIDS incidence per 100,000 people across four countries: Australia, Canada, United Kingdom and United States. There are remarkable differences in AIDS incidence among these English-speaking countries (see Fig. 2.11). The rate in the United States has stayed ten times as high as Australia. Australia has followed in the footsteps of the

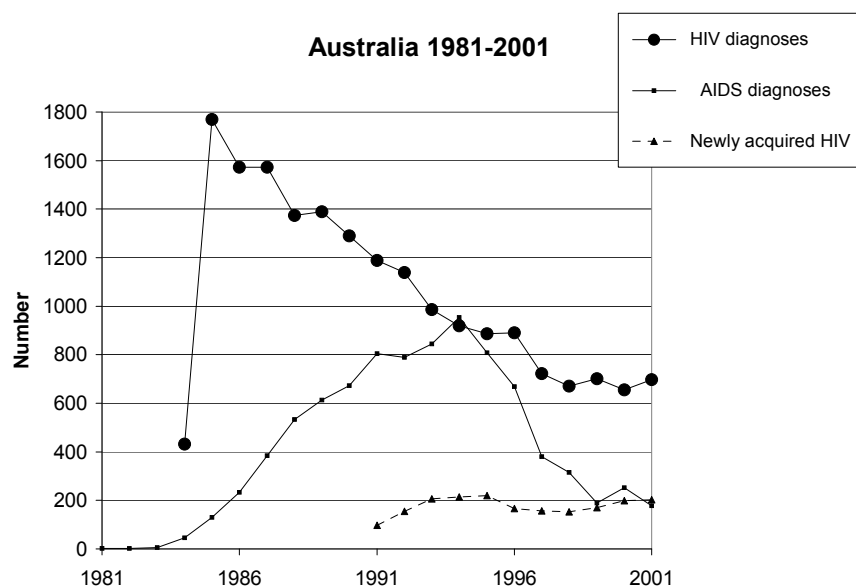


Fig. 2.10 HIV and AIDS diagnosis in Australia. *Source:* National Notifiable Diseases Surveillance System, Australia

United Kingdom. In fact, many of the safe sex practices in Australia were imported from the UK. Weaver et al. (2005) have shown that sex education has also produced a better set of results in Australia compared with the United States (but not as good as in the Netherlands).

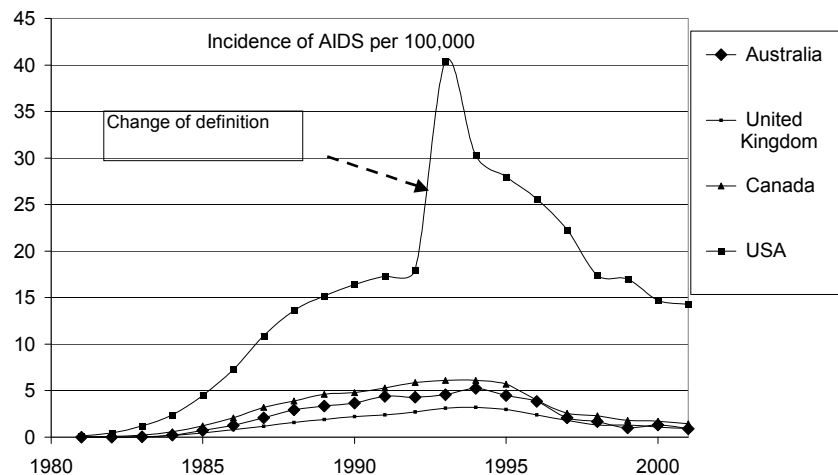


Fig. 2.11 AIDS incidence in Australia, Canada, UK and USA. *Source:* National Notifiable Diseases Surveillance System, Australia

Australia, in contrast to Japan, represents a case of a developed country that has been successful in keeping the number of HIV/AIDS cases low through a well-thought-out strategy, rather than relying on luck. Unfortunately, Australia is now having problems sustaining this success. The National Notifiable Diseases Surveillance System showed that from 1999 to 2004 the notification rate of chlamydial infection increased from 76.1 to 179.7 per 100,000 persons. There has been a corresponding rise in hepatitis C infection among the population. A clear but smaller increase in gonorrhea has also been noted during the same period (Mindel and Kippax 2005). Whether these increases in other sexually transmitted diseases will be followed by an increase in HIV/AIDS we do not know. However, Australia's success with respect to HIV/AIDS stands in sharp contrast to its current experience with other sexually transmitted diseases.

2.8 Implications for Other Global Diseases

This brief survey of the course of the AIDS pandemic in different settings underlines the importance of early intervention with appropriate policies to prevent and contain the spread of global diseases. The source of AIDS in animals and its

transmission to humans through *zoonosis* shows that the world community needs to be vigilant regarding other such events. The most obvious contemporary parallel is avian influenza. As a more infectious disease and one that is transmitted more easily (that is, in the environment and through casual contact), avian influenza would spread much more rapidly than HIV/AIDS and kill more quickly too. Thus, in the case of a potential global influenza pandemic, the lessons of the AIDS pandemic would have to be applied *before* the pandemic occurs.

The AIDS epidemic in Africa has demonstrated how health issues can become security issues. It has also demonstrated the importance of political leadership and accurate information in containing the spread of disease.

The AIDS pandemic has had a much more severe impact on developing countries than on developed countries. However, the experience in Brazil and Thailand indicate that a well-designed HIV/AIDS program that is tailored to the specific epidemic and in the specific context of the country in question can be successful, at least in middle-income countries with relatively low prevalence rates. The lesson from Brazil and Thailand is not that other countries should duplicate blindly the successful elements of these two countries' programs. Rather, it is that responses to HIV/AIDS need to be tailor-made. Certain elements may prove to be common to all settings, such as the crucial role played by the governmental and NGO leaders in both Brazil and Thailand and the need for early intervention to contain the spread of the virus. Another element that may be a common denominator is the need for adequate health infrastructure and human resources. However, the absence of this element does not necessarily mean that taking action would be futile. In Haiti – a very poor country with a relatively high prevalence rate where social institutions have broken down – NGOs have managed to deliver treatment and testing to people living with HIV/AIDS in remote areas of the country. Similarly, the role played by democratic institutions in Brazil does not appear to have been an essential element in Thailand. However, the incorporation of the human rights element appears to be an important element that has contributed to Brazil's success. The stigma associated with HIV/AIDS in South Africa has hampered that country's efforts, whereas the relative absence of stigma surrounding the commercial sex trade in Thailand has meant the absence of such a barrier to action in that country. Similarly, the stigma associated with injection drug users in Russia has hampered the implementation of an effective HIV/AIDS strategy in a country where injection drug users make up 50% of the epidemic (Rhodes et al., 1999). Thus, social conditions can be highly relevant to the design of an effective HIV/AIDS program. Finally, the nature of the epidemic must be taken into account in each context. In both Brazil and Thailand, efforts have focused on high-risk groups, which differed in the two settings – with commercial sex workers being the main focus in Thailand and Brazil's efforts focused on MSM, injection drug users and commercial sex workers.

Providing universal access to ART requires adequate financial resources in the face of a particular prevalence rate. The manner in which governments deal with

negotiations with other governments and patent owners has a direct impact on the cost of treatment, as demonstrated by South Africa, Thailand and Brazil.

Financial resources do not necessarily correlate with the design of an effective program, as the case of Japan demonstrates. Moreover, even middle-income countries can face disaster where political leadership is replaced by inaction and denial, as the case of South Africa shows. Both the Japanese and the South African experiences demonstrate that cultural or psychological predispositions can hobble the capacity of a country to respond effectively to the threats posed by epidemics. These factors therefore need to be taken into account in the design of international responses to the threat posed by global diseases.

The difficulties faced by developing countries in confronting the HIV/AIDS epidemic have direct effects on the developed world. The epidemic has influenced WTO policy regarding patent protection for pharmaceutical companies that are primarily located in the developed countries. In this regard, the epidemic has begun to change an important element of international economic policy. The migration of natural persons across the borders of an increasingly integrated global economy means developed country interests are also at stake in addressing the epidemic in developing country neighbors. Borders do not prevent the spread of the virus and closing borders is not an option. Perhaps most significantly, national and global experiences with the AIDS pandemic provide lessons for addressing not just HIV/AIDS, but other global diseases and pandemics as well. A complete picture of the AIDS pandemic requires an analysis of its effects on human health, security, international relations, business, international economic policy, national economic growth and social dynamics. However, this multi-faceted analysis serves not only to ensure effective strategies for confronting this disease and this pandemic, but to underline the importance of a multidisciplinary approach to other global health issues.

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