

Legal, Financial, and Public Health Consequences of HIV Contamination of Blood and Blood Products in the 1980s and 1990s

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Ensuring the safety of the blood supply connects politics and science. The business and service sectors share responsibility for the collection and processing of blood donations, and government agencies perform regulatory and surveillance roles. The onset of the AIDS epidemic has challenged the interface among these systems, leading to widespread fears about compromised safety of the blood supply. Because of public concern about blood-supply decisions made in the 1980s, developed countries in the 1990s established reimbursement programs for persons with transfusion-acquired viral infections from blood or blood products, adopted diagnostic tests and procedures that improved the safety of the

blood supply, and held criminal judicial investigations of government officials and industry leaders accused of delaying implementation of potential blood-safety measures. In contrast, developing countries continue to struggle with blood-supply safety issues. This paper summarizes the current status of these safety concerns in developed countries, where viral transmission from contaminated blood or blood products is extremely rare, and in developing countries, where up to 10% of HIV infections result from transfusion of blood or blood products.

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During the onset of the AIDS epidemic in 1981, persons with hemophilia and blood-transfusion recipients throughout the world became infected with HIV through transfusion of contaminated blood products (1–7) (Table 1). In 1982, 1 year after the first AIDS cases were reported, the U.S. Centers for Disease Control and Prevention suggested that the syndrome was associated with blood and blood products (11, 12).

Several developed countries have recently completed criminal investigations, civil litigation, and monetary financing programs to deal with the compromised safety of the blood supply during the first decade of the AIDS epidemic. In contrast, developing countries face continued concerns about the safety of their blood supplies. We review the current status of blood-supply considerations in several developed and developing countries.

CRIMINAL INVESTIGATIONS

In France in 1992, Michel Garretta, former head of the National Blood Transfusion Center, and Jean-Pierre Allain, former head of research at the Center, were sentenced to prison for supplying HIV-infected clotting factors to hemophiliac patients (Table 2). Garretta and Allain were accused of having major roles in the National Blood Transfusion Center's decision not to use heated blood products after 1983—an action purportedly taken because of a belief that the French blood supply was safe. From 1983 to 1985, policymakers did not require that blood donors be routinely questioned

about drug use and homosexual experiences. Because of a desire to use only domestically obtained blood products, prisoners became a major source of blood products from 1983 to 1985, even though other countries, such as Finland and Canada, had discontinued this practice in the 1970s. Jacques Roux, the former director general of the Health Ministry, received a suspended sentence for his part in these actions. The French scientific community and 30 Nobel Prize winners petitioned for pardons of Garretta, Allain, and Roux (13–15). Controversy also surrounded French approval of the HIV enzyme-linked immunosorbent assay (ELISA). Although the ELISA manufactured by Abbott Laboratories (North Chicago, Illinois) was approved in the United States in March 1985 and was presented for approval in France in February 1985, the French National Public Health Laboratory ruled in favor of the ELISA from the Institut Pasteur in June 1985, reportedly because of economic considerations (16–19). The former Prime Minister, the Secretary of State for Health, and the Minister of Social Affairs were criminally charged with delaying the application. Public unrest, particularly among persons with hemophilia, led to court trials without convictions in 1994 and retrials in 1998 (20–23). Of the three officials charged, only the former Secretary of State for Health was convicted (of manslaughter), but he received no penalty.

Criminal investigations in Germany led to convictions of five officials of UB Plasma in Koblenz for inflicting bodily harm from 1987 to 1993 by selling thou-

sands of units of viral-infected blood products that were inconsistently tested for HIV (23). In 1993, Germany's health minister recommended HIV testing of persons who had received blood transfusions in the 1980s, fueling speculation of a cover-up. Afterward, Haemoplas, a German blood products company, was charged with having inconsistently tested for HIV in 1986 and 1987. Two officials were charged with murder, and one was sentenced to 6.5 years in prison (24–26).

In 1973, the New York Blood Center established a relationship with the Swiss Red Cross, which had a history of innovation and professionalism. As a result, the Center began importing its blood supply from Switzerland (8). In 1985, using ELISA, the Center detected HIV in imported Swiss blood products (27). Alfred Haessig, former director of the Swiss Red Cross's Central Laboratory, was given a suspended sentence in 1998 for delaying introduction of donor screening questionnaires until May 1986, maintaining that HIV could be chemically inactivated, delaying use of imported heat-treated blood products, and testing only exported blood products for HIV (8, 28).

In 1996, Dr. Takeshi Abe, the former head of the Japanese AIDS Study Group, was charged with negligence in the death of a patient with hemophilia (29, 30). In 1983, Dr. Abe led a task force that allowed importation of untreated blood products. He was a prominent leader of hemophilia home treatment after government approval of reimbursement for factor VIII concentrate. In 1984, the National Institutes of Health found that 23 of 48 blood samples from Japanese persons with hemophilia were HIV infected (30). Dr. Abe reported this to the Japanese Health and Welfare Ministry but not patients or the public. A high percentage of a second set of blood samples also tested positive for HIV, but Dr. Abe again did not notify the public. As late as 1988, Dr. Abe and other hemophilia specialists did not inform patients that they were HIV positive, reportedly because they believed that since curative therapy for AIDS was lacking, there was no need to inform individuals about their HIV status. In 1989, legislation finally required notifying patients if they had AIDS (31). Factors that had contributed to poor decision making included statements by Japanese hemophilia specialists in 1983 that AIDS was not a Japanese problem and in 1985 that unheated factor VIII products imported from the United States were safe and constantly improving in quality; another factor was delayed adoption of heat-treated

Table 1. Persons with Hemophilia Who Developed HIV Infection from Transfusion of Contaminated Blood Products in Selected Countries*

Country	Persons with Hemophilia Who Became Infected, n (%)
United Kingdom	1700 (32)
Japan	1800 (45)
France	2000 (50)
United States	10 000 (50)
Canada	800 (55)†
Denmark	210 (64)‡§

* Except where otherwise noted, data in the table were obtained from Starr (8).

† Data obtained from Kondro (9).

‡ Data obtained from Feldman and Bayer (10).

§ Approximate number.

products due to concern that this would allow market dominance by Baxter Healthcare Corp. (Deerfield, Illinois). In 2000, Takehiko Kawano, former president of the Green Cross Corp. (Osaka, Japan), and two predecessors were sentenced to 16 to 24 months in prison for having sold non-heat-treated blood products in 1986 and for not recalling these products until 1988 (32–35). Akihito Matsu-mura, a former official in the Japanese Ministry of Health and Welfare, was indicted in 1996 and ultimately found guilty for perpetuating the spread of HIV through the blood supply (34). From 1983 to 1985, Japan accounted for one third of the world's annual use of plasma products, 90% of which were imported from the United States (35).

In Canada, Justice Horace Krever chaired the Commission of Inquiry on the Blood System, which began hearings in February 1994 and released its final report in March 1997. The report had four major findings: 1) Many blood safety problems resulted from poor coordination among organizations responsible for the blood system; 2) urgency in the provision of heat-treated factor concentrate had been lacking; 3) the 8-month delay between the time that the United States had approved an HIV ELISA in March 1985 and when Canada approved the test in November 1985 had resulted in HIV infection in many recipients of blood and blood products during this period; and 4) physicians and the general population had not been informed about AIDS and hepatitis risks (36, 37). Subsequently, the blood supply responsibilities of the Canadian Red Cross were eliminated and a new agency, the Canadian Blood Services, was charged with these responsibilities (38–42).

Table 2. Individuals Criminally Indicted for Blood-Supply Safety Concerns

Country	Persons Charged	Affiliation	Charge	Year of Indictment	Court Decision
France	Michel Garretta	Former head, National Blood Transfusion Center	Poisoning in 1983–1985	1991	Convicted in 1992
	Jean-Pierre Allain	Former research chief, National Blood Transfusion Center	Poisoning in 1983–1985	1991	Convicted in 1992
	Jacques Roux	Former director general, Health Ministry	Poisoning in 1983–1985	1991	Convicted in 1992
	Robert Netter	Former director, National Health Laboratory	Poisoning in 1983–1985	1991	Acquitted in 1992
	Laurent Fabius	Former Prime Minister	Manslaughter in 1983–1985	1994 and 1998	Acquitted in 1999
	Edmond Hervé	Former Secretary of State for Health	Manslaughter in 1983–1985	1994 and 1998	Convicted in 1999; was never sentenced
	Georgina Dufoix	Former Minister of Social Affairs	Manslaughter in 1983–1985	1994 and 1998	Acquitted in 1999
Germany	Director and four staff members	UB Plasma Corp.	Inflicting bodily harm in 1987–1993	1994	Convicted in 1995
	Frank Giesbert and Günter Eckert	Haemoplas Corp.	Murder in 1986 and 1987	1995	Convicted in 1997
Switzerland	Alfred Haessig	Former director, Swiss Red Cross	Endangering the safety of patients with hemophilia in 1985 and 1986	1995	Convicted in 1998; received a 1-year suspended sentence
Japan	Takeshi Abe	Former head, government AIDS study group and chairman, internal medicine department of Teikyo University, Tokyo	Professional negligence leading to death in 1983–1988	1996	Acquitted in 2001
	Takehiko Kawano	President, Green Cross Corp.	Professional negligence leading to death in 1986–1988	1996	Convicted in 2000; sentenced to prison
	Renzo Matsushita	Former President, Green Cross Corp.	Professional negligence leading to death in 1986–1988	1996	Convicted in 2000; sentenced to prison
	Tadakazu Suyama	Former President, Green Cross Corp.	Professional negligence leading to death in 1986–1988	1996	Convicted in 2000; sentenced to prison
	Akihito Matsumura	Former official, Ministry of Health and Welfare	Knowingly perpetuating the spread of HIV infection through the blood supply in 1986–1988	1996	Convicted in 2000; received a 1-year suspended sentence

MONETARY COMPENSATION AND CIVIL LITIGATION

More than 20 countries have established compensation programs for persons infected with HIV as a result of HIV-contaminated blood products (43, 44). Funds have often been given to family members who were resultantly infected or to surviving family members of deceased persons who had been infected. To be eligible for monetary compensation, persons usually must renounce their civil rights to any future action against government entities. However, this stipulation has not prevented the filing of lawsuits against private institutions. In Canada, several suits were won against the Canadian Red Cross, which was found to have “failed utterly to provide the users of blood and blood products with authoritative, accurate and updated information” (45) (Table 3). In April 2001, the Canadian Supreme Court found the Canadian Red Cross guilty of negligence for failing to screen blood donors in the early 1980s, when the nation’s blood supply became infected with the AIDS vi-

rus. The Supreme Court upheld a judgment by the Ontario court of appeal, which had said that the Red Cross failed to exercise a proper standard of care in its collection of blood. The ruling stems from three cases brought by blood recipients who received blood from the Canadian Red Cross Society between 1983 and 1985. Two of the plaintiffs died of AIDS complications, and the third is alive and is HIV positive (46). Armour Pharmaceutical Co., which was a division of Rhône-Poulenc Rorer Pharmaceuticals, Inc. (Paris, France), paid six Canadians with hemophilia \$1.5 million each after discovery of a document indicating that some heat-treated products had not been fully deactivated in the mid-1980s (47). In Italy in 1998, a civil court ruled that the Ministry of Health was responsible for the consequences to patients who had received commercially available contaminated blood products in the 1980s. The Ministry of Health was found to have “omitted its duties of prudence, diligence, impartiality, and legality” in not recommending

viral inactivation treatment for human plasma until 1985, not withdrawing products that were not subjected to this treatment until 1988, and not instituting systematic blood-donor screening until 1994. Overall, 80% of the human plasma products sold in Italy by foreign manufacturers in the 1980s were processed without proper quality control (48).

The United States was one of the last developed countries to compensate persons with hemophilia. In 1995, an Institute of Medicine report (5) indicated that many organizations shared the blame for compromised blood safety in the 1980s, including the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), the National Institutes of Health, community blood banks, the American Red Cross, blood and plasma collection agencies, blood product manufacturers, and groups such as the National Hemophilia Foundation (5). The committee also reported that in 1983 and 1984, blood banks and fractionation companies should have initiated surrogate laboratory testing and should have excluded homosexual men from blood donation. In response, Thomas Zuck, a former FDA official, indicated that it was difficult to make decisions at that time given uncertainty about the estimates of risks to the blood supply (6). Before AIDS and during the period when hepatitis B had initially been a safety problem, policymakers concerned with international blood safety had operated under basic scientific principles, which held that policies were changed only after definitive results from empirical studies had

been reported. There also was an international sense of obligation to voluntary donors and a reluctance to include questions about potential high-risk behaviors given the uncertainty about whether these behaviors caused AIDS. As a result of civil lawsuits, HIV-infected transfusion recipients have received an unascertainable amount of awards and financial settlements. Fractionation companies subsequently completed a financial settlement with the Committee of Ten Thousand—a group of 10 000 HIV-infected persons with hemophilia who had lobbied for the Institute of Medicine report. This settlement authorized payments of \$100 000 to HIV-infected persons with hemophilia and to persons they had infected (49). In 1998, after years of lobbying by hemophilia organizations, Congress passed the Ricky Ray Hemophilia Relief Fund Act, which authorized \$750 million to support payments to persons with hemophilia who had received HIV-infected clotting concentrate. Over \$650 million has been appropriated by the Congress for the fund, and more than \$205 million in compassionate payments has been committed (50).

MAINTAINING A SAFE BLOOD SUPPLY

Steps were taken to ensure the safety of the U.S. blood supply during the first two decades of the AIDS epidemic. Early improvements were cost-effective, including universal adoption of HIV antibody testing (cost, \$3600 per quality-adjusted life-year saved) and alanine aminotransferase and hepatitis C virus (HCV) testing (which were cost-saving) (51). Recent interven-

Table 3. Compensation Schemes from Seven Countries for Persons Infected with HIV from Blood or Blood Products*

Country	Annual Compensation		One-Time Compensation	
	Amount	How Funded	Amount	How Funded
United States	–		\$100 000	Out-of-court settlement with plasma fractionators plus government fund
Germany	\$10 656 for HIV \$21 324 for AIDS	Government trust fund Government trust fund	–	
France	–		\$263 204 \$87 735 at the time of AIDS diagnosis	Government fund Government fund
Canada	\$22 096	Government fund	\$16 204 \$176 640†	Government fund Government fund
Switzerland	\$12 216 for AIDS	Government, plasma fractionators, and Swiss Red Cross	\$84 838 (maximum amount)	Swiss Red Cross
Italy	To be determined	–	To be determined	–
Japan	–		\$450 000	Settlement with the Ministry of Health and Welfare and plasma fractionators

* Compensation figures are expressed in 1998 U.S. dollars.

† For Canadians who contracted HIV from parents or partners originally infected through HIV-infected blood transfusions.

Table 4. Crude and Adjusted Incidence of Seroconversion Associated with Each of Four Major Bloodborne Viruses*

Virus	Crude Incidence per 100 000 person-years	Adjusted Incidence per 100 000 person-years (95% CI)†
HIV	4.01	3.37 (2.22–4.76)
Human T-cell leukemia	1.09	1.12 (0.51–1.98)
Hepatitis C	4.84	4.32 (2.35–6.87)
Hepatitis B	9.54	9.80 (6.74–13.42)

* Adapted from reference 52.

† Adjustments to crude incidence rates accounted for seroconverters whose last donation before the one in which antibodies were detected could not be used—because it tested positive for another marker, such as elevated alanine aminotransferase levels, or because of confidential unit exclusion.

tions have been less cost-effective and more controversial. In 1996, the FDA approved an HIV P24 antigen assay (at a cost of \$2 million per quality-adjusted life-year saved). Of 6 million donations tested in 1996, two were P24 antigen–positive but HIV antibody–negative. There is a controversial move towards universal leukoreduction of all nonleukocyte transfusion blood components, which is estimated to cost \$600 million annually. This change may not prevent transmission of any virus, except cytomegalovirus, a common infection that poses a risk only to some immunocompromised patients.

In 1999 and 2000, more than 90% of the U.S. blood supply underwent nucleic acid amplification testing. During this testing, 16.3 million donations were evaluated for HCV RNA and 12.6 million were evaluated for HIV RNA. This testing detected 62 donations that were HCV RNA positive but serologically negative. Four donations were HIV RNA positive but serologically negative. Only one blood component that tested positive for HCV was transfused (52). Red blood cells have not been quarantined nationwide until such test results are known, seemingly because some shelf supplies have been insufficient to allow an additional 2 to 3 days of quarantine (53). Overall, testing of the blood supply costs \$25 to \$35 per unit, accounting for 13% to 20% of the total retail charge. In addition, recent blood-supply shortages have led to delays of surgeries; some blood centers have less than a 1-day supply of type O blood (54). Today, the rates of seroconversion among blood donors are 1 to 4 per 100 000 person-years for HIV, human T-cell leukemia virus, and HCV (Table 4) (55). Plasma concentrates are also very safe; all are heat treated, and some are exposed to solvent detergents

(cost, \$300 000 per quality-adjusted life-year saved) (51).

Because of concern over Creutzfeldt–Jakob disease transmission, the FDA published a guidance in November 1999 recommending deferral of blood and plasma donors who had visited the United Kingdom for 6 months or longer between 1980 and 1996, a policy that eliminates 2.2% of otherwise qualified blood donors (56). The Transmissible Spongiform Encephalopathies Advisory Committee to the FDA published interim recommendations in August 2001 supporting deferral in 2001 of donors of all blood and blood components who had lived in the United Kingdom for 3 months or longer between 1980 and 1986 or who had lived 5 years or longer in France between 1980 and the present. The interim recommendations also supported deferral after October 2002 of blood donors, but not plasma donors, who had lived in Europe for 5 years or more between 1980 and the present (56).

Organizational changes and improvements in blood products oversight have occurred in the United States over the past 15 years. A centralized Blood Safety Committee and additional blood surveillance centers were authorized, and the FDA Blood Products Advisory Committee was advised to consider safety and efficacy, but not cost-effectiveness, in its decision making. Large organizations—including the New York Blood Center; the Red Cross in Los Angeles, California; United Blood Services in Tucson, Arizona; and two plasma-product companies, Centeon, LLC (originally a joint venture between Rhône-Poulenc Rorer, Inc., and Hoechst AG; now known as Aventis Behring, LLC; King of Prussia, Pennsylvania), and Alpha Therapeutic Corp. (formerly a U.S. subsidiary of Green Cross Corp., Osaka, Japan)—were issued federal consent decrees and have recalled blood products.

Policy changes have also been adopted in other countries. French transfusion centers are now controlled by a Transfusion Agency, which reports directly to the Minister of Health. Japan no longer imports factor VIII but still imports albumin and gammaglobulin. In 1998, a smaller pharmaceutical company, Yoshitomi Pharmaceutical Industries Ltd. (Osaka, Japan), took over Green Cross Corp. (55). The United Kingdom centralized its blood industry and completed work on a fractionation facility that provides almost 75% of the country’s blood product. Many blood-supply policies in the United

Kingdom have been based on concerns about the prion-caused illnesses bovine spongiform encephalopathy and new-variant Creutzfeld–Jakob disease. Bovine spongiform encephalopathy contamination has affected almost 180 000 British cattle and 230 to 540 total cattle in Ireland, Portugal, Switzerland, and France (57, 58). Cases of new-variant Creutzfeld–Jakob disease have occurred in 88 persons in United Kingdom, 1 person in France, and 1 in Ireland, and a maximum epidemic size of 500 000 has been estimated. While new-variant Creutzfeld–Jakob disease has not been identified from recipients of blood from donors who eventually developed clinical Creutzfeld–Jakob disease, no diagnostic tests can screen for Creutzfeld–Jakob disease in the blood supply, and bovine spongiform encephalopathy theoretically can be transmitted through blood transfusions from persons who have eaten contaminated beef (59, 60). The British government has destroyed pooled plasma products from British blood donors; instead, Britain now uses pooled plasma products imported from the United States and has adopted a policy of universal leukoreduction of all other blood products from British donors. These blood-supply policies cost \$165 million annually—half of the National Blood Service budget—and have adverse funding implications for other areas of the National Health Service.

DEVELOPING COUNTRIES

Blood safety continues to be a concern for developing countries, as up to 45% of donations in these countries are untested for HIV, HCV, or hepatitis B virus, and such donations account for hundreds of thousands of infections (61). A Red Cross Society blood bank in Bombay was closed in 1995 for supplying HIV-infected blood to hospitals between 1992 and 1994. Almost 9% of the 2574 cases of AIDS in India reported by 1996 were from transfusion recipients of HIV-infected blood or blood products, and 95% of the blood supply was estimated to be unsafe (62, 63). The government undertook extensive measures to improve blood safety, such as making HIV screening mandatory at all blood banks, banning professional blood donations, establishing National and State Blood Transfusion Councils to oversee all aspects of the blood safety program, and launching a program to modernize and strengthen the management of blood banks (63). Nonetheless, significant problems persist. The 3-year-old order by India's Supreme Court

banning professional blood donations has worsened blood shortages and raised the cost of blood in the underground market. India's requirement of blood is estimated at 7.5 million units annually, while currently only 4 million units per year are collected. Blood screening practices continue to be poor. A survey of blood bank directors done in 2000 found that while 87% of respondents screened blood for hepatitis B virus and 95% for HIV, only 6% screened for HCV (64).

India plans to phase out paid donors, who have provided half of India's blood supply, and to revamp its 1400 blood banks, which are inadequately supplied (65). In Pakistan, a Red Cross consultant reported infrequent HIV testing of donated blood. In many parts of Southeast Asia, there is a market for blood donors (66). In 1990, 1 in 2644 blood donations in Thailand came from donors in the window period between HIV infection of such donors and the time when their viral levels are first detectable (67). That number has decreased, but levels of HIV infection in Thai donors are still high. In Vietnam, the director of the Central Haematology and Blood Transfusion Institute announced in 1997 that 100 persons contracted HIV infection through blood transfusions. Paid professionals made up 80% of the blood donors in Vietnam, and although all blood was screened for HIV, professional donors had high rates of donations in the HIV window period (68). In the late 1990s, Ethiopia received screening equipment but lacked trained staff to operate such equipment (69).

China faces one of the most severe HIV-related blood-supply problems today. In the 1980s, paid blood donors with HIV infection introduced the virus into China. Because Chinese culture considers blood sacred, donors, who earn about \$250 for donations of 1 to 2 units, have been the primary source of blood in China for several decades. In 1993, the demand for blood expanded as the Health Minister at that time, Chen Mingzhan, approved a plan to export blood products. Middlemen, called "blood heads," purchased blood from farmers and sold the blood to hospitals, blood banks, and blood-product suppliers. In 1994, tests of units of blood from Guan County, near Beijing, provided the first evidence that HIV-infected persons were donating blood. In 1995 and 1998, the National People's Congress passed laws to stop the selling of blood and to re-establish a voluntary donation system to improve blood supply safety (70). Despite these laws, paid do-

nors continue to supply 60% of the country's blood donations (71). Testing of the blood supply for HIV, although mandated, has been infrequent. Moreover, the donation process often results in HIV infection through re-use of needles, mixing of blood products while obtaining plasma from several donors simultaneously, and reinfusion of HIV-infected blood to donors in an effort to reduce the time between donations. Hundreds of thousands of the 600 000 HIV-infected persons in China are believed to have been infected through unsafe blood-donation practices (70, 71).

CONCLUSIONS

Up to 10% of HIV-infected persons in developing countries were infected by virally contaminated blood or blood products. In developed countries, lessons learned from the AIDS crisis have led to implementation of many viral-inactivation policies and technologies that suggest a "zero tolerance" approach to maintaining blood supply safety. Fear of future litigation may be influencing policymakers in some countries. However, discussing a new technology without considering cost-benefit factors or cost-effectiveness may also be problematic. In a world of limited resources, implementing costly but not highly cost-effective procedures or policies may result in constraints in other areas and loss of previously realized benefits to a greater number of persons. There is at times a tension between societal and personal viewpoints about risks and benefits of medical procedures. This tension cannot be resolved by implementing all available new technologies when the cost is high compared with the potential benefit. Only rational policy backed by scientific evidence is likely to achieve the greatest good for the greatest number of persons in a society.

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