The Case of HIV and Blood Supply in Germany

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The question the present paper will address is how the German administrative and political system responded to the risk of the transmission of HIV via contaminated blood. The transmission of AIDS through blood is known since 1982 and the prevention of contamination through blood is an important task for the public health system. Analysing whether and how this challenge has been taken up by those responsible for public health policy is important for at least three reasons. It tells us whether and how the infection of over 2000 persons with HIV in Germany could have been avoided, it gives indications on how such or a similar disaster can be prevented in the future and it relates to the more general question about the governance capacities of modern states.

I. The German Challenge in HIV and Blood Supply

In contrast to West Germany, East Germany (the former German Democratic Republic, GDR) was aiming at a national self-supply for blood and blood products very early. This resulted in the fact that in 1986 and 1987, only five HIV infections were detected among the estimated 1,300 East German haemophiliacs. These infections were caused by imported, HIV-contaminated blood products and did not influence the general epidemiology of HIV and AIDS in the GDR (Kiehl and Altmann, 1991). Consequently, the history of the HIV infection of haemophiliacs in Germany is the history of the West German blood system.

In Germany a total of 544 haemophilia-associated and 279 transfusion-associated AIDS cases have been reported as of the 31st of December 1998. A total of about 2000 HIV infections among haemophiliacs and about 600 transfusion-associated HIV infections are estimated (Robert-Koch Institut). This means that approximately 50% of haemophiliacs who receive treatment with coagulation factors have been infected with HIV. The first AIDS case in a transfusion recipient was diagnosed in 1983. Also in 1983, in October, the first AIDS case concerning a haemophilic was diagnosed. In 1984, 7 haemophiliacs with AIDS were diagnosed. The majority of transfusion-associated infections and infections among haemophiliacs occurred before October 1985, and before the mandatory HIV antibody testing for blood and blood products was introduced. There are data that suggest that the majority of infections among haemophilic population occurred in 1984 (Erfle et al. 1985).

At that time it was the responsibility and task of the former Bundesgesundheitsamt (Federal Health Office) to identify health risks for the general population (including risks by drugs, medical products and blood products) and to take adequate measures for preventing such risks. Formally speaking, it would have been possible for the Bundesgesundheitsamt to halt the distribution of possibly HIV-contaminated blood

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1 As of 30 September 1998, a total of 17,702 AIDS cases have been reported in Germany. 11,554 cases have been reported among homo and/or bisexual men, 2,646 cases among injecting drug-users. The heterosexual transmission route accounts for 1,057 cases. Annually about 900 new AIDS cases and about 2000 to 2500 HIV-infections are expected in Germany (Robert-Koch-Institut).
products in 1984. As will be described later in this paper, the Federal Health Office failed, however, to take such measures. What turned out to be a major health related crisis (i.e. the contamination of many thousands of persons and the related severe illnesses and deaths) was not responded to by an adequate crisis management. In the meantime the Federal Office of Health, exactly because of its malfunctions in this case, has been disbanded and responsibilities for blood and blood products have been clearly regulated in 1994 as a consequence of the HIV/AIDS scandal.

Consequently the main question becomes why the Bundesgesundheitsamt did not achieve the task of taking adequate measures for preventing the risk of HIV contamination through blood and blood products (see Part VI). But before turning to this main question first some contextual information will be given on the main actors and institutions involved in blood supply in Germany (see Part II) as well as on the political and institutional context of blood supply in Germany (see Part III). Secondly, a description of the events of HIV and blood in Germany in the early and mid-1980s will be given (see Part IV). This will help to assess the ineffectiveness of the Bundesgesundheitsamt in preventing HIV-prevention through blood and blood products (see Part V).

II. The Main Actors Involved and the Political Institutional Context in Blood Supply in Germany

The actors involved in blood supply in Germany can be grouped as users, producers, administers and therapists and policy makers and controllers of blood and blood products in Germany. In what follows a short overview of these actors will be given.

Users

The users of blood and blood products are on the one hand transfusion patients and haemophiliacs on the other. Whereas the first group is not a clearly identifiable group since transfusion is most of the time related to certain incidents (like operations or first aid in case of accidents), the second group is most clearly related to a group of patients with haemophilia. Of these patients, of whom the number in Germany is estimated to be between 3,500 and 6,000 (Schramm and Schulte-Hillen 1994), between 2,500 to 3,500 require substitution therapy with coagulation factors. Anticoagulant treatment with concentrates of human coagulation factors enriched for factor VIII was widely available in Germany in the early 1970s. Since the product is approved for marketing, German health insurances cover the cost of treatment with this product since no equivalent product is available at a cheaper price.

The Deutsche Hämophiliegesellschaft (German Haemophilia Society) is an organisation for people with bleeding disorder and for their relatives. Although the organisation is generally described as a “self-help organisation” it is noticeably that physicians from haemophilia centres are members of the directorate of the organisation. Another organisation which could have represented the users of blood

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2 In Germany the majority of patients suffer from haemophilia A or B or from Wiilebrand's disease (lack of factor VIII respectively IX) (Braun 1994).
and blood products, the *Deutsche AIDS Hilfe*, did not play a major role in this context. As in many other European countries the non-profit organisations which developed in the early phase of the AIDS epidemic concentrated mainly on homosexual persons and later on drug users (Kenis and Marin 1997). It was generally felt that the problems of haemophiliacs are not understood by *AIDS-Hilfe* organisations\(^3\) (Der Spiegel 1992, Nr. 24).

**Producers**
The blood sector in Germany is a highly complex market, with an international component. The turnover is estimated at 500 million to 1 billion German DM (Der Spiegel 1993, Nr. 41). In 1992 was blood and blood products imported from 28 countries with a value of about 220 million DM and exported to 80 countries with a value of about 300 million DM (Die Zeit 1993, Nr. 47). Products include whole blood, blood components such as erythrocyte or platelet concentrates, and plasma derived products such as fresh frozen plasma and clotting factor concentrates.

A highly differentiated set of organisations and producers are involved in blood provision and the production of blood products. Next to local public institutions (i.e. hospitals and *kommunale Blutspendendienste* [local blood banks]) and the German red cross also private firms are involved. The most important private firms are the *Behringwerke-AG*, the *Immuno GmbH* and the *Troponwerke* (of which Bayer is the parent company). The pharmaceutical industry is mainly active in the area of plasma-derived products, such as clotting factor concentrates, anticoagulants, and hemostatics. All these firms are at the same time internationally integrated.

Erythrocytes, thrombocytes and other blood products used for transfusion were mostly supplied through national resources, mainly by governmental institutions (e.g. *kommunale Blutspendendienste* [local blood banks]) and non-profit organisations.

In the 1970s and 1980s, the majority of blood and blood products such as coagulation factor preparations were imported to the former West Germany.

Within Germany the Red Cross operates since 1952 blood banks (*Blutspendedienste des Deutschen Roten Kreuzes*). The Red Cross processed blood from more than 2 million donations in 1984 (Müller-Werthmann 1984), and today produces an estimated number of 4.5 million blood products annually. The blood banks are operated as non-profit organisations and blood donors do not receive money or financial compensation. The blood products are sold at a full cost-recovery basis.

According to results from a survey on blood donors in Germany, they cannot be considered a homogeneous group. Whether commercial companies rely on a particular group of individuals who serve as plasma donors and whether this group is biased because certain persons (homeless persons or drug users) are attracted as donors even by the small amount of money paid for compensation is unknown (Dressler 1997).

\(^3\) It should be mentioned, however, that the *Deutsche AIDS Hilfe* is a very decentralised organisation and that local AIDS-Hilfe organisations may vary considerable.
Also hospitals, university hospitals or specialised clinics often have their own blood banks. The products produced in these settings depend largely on the local needs.

Administers and Therapists
Blood and blood products are provided through the medical system. Blood is generally transfused in hospitals in case of medical necessity.

Anticoagulant treatment is administered through specialised haemophilia treatment centres, hospitals, ambulances or physicians in private practice. About 75% of haemophiliacs who need treatment receive home care treatment (Dressler 1997).

Home care treatment refers to a form of treatment where the patient receives a sufficient amount of clotting factors for self-administration. The clotting factor is stored in a refrigerator at home, and the patient keeps a supply which will last for a longer period of time (approximately six months). The self-administration will be performed according to a prescription by a physician, or according to the needs the patient.

The therapeutical freedom of physicians in Germany allowed the use of high doses of coagulation factors, and physicians as well as patient felt that high-dose treatment should be administered in order to enable the haemophiliac patient to lead a normal life. The same practice was followed by the majority of haemophilia centres and specialised physicians. In Germany, an average of 4 to 4.5 international unity of factor VIII per capita of the general population per year is prescribed. This massive amount exceeds by far the doses of factor VIII that are being used in other European countries or in the United States (Dressler 1997).

Policy makers and controllers
Under Germany’s federal constitution (the Grundgesetz), health and health related issues lie within the authority of the Länder (the states). The regulatory power of federal authorities is limited to certain issues which are delegated from the Länder to the federal authorities. The Federal Ministry of Health (Bundesministerium für Gesundheit) controls various federal institutes and is the supervisory authority for federal health offices. Whenever a health-related decision is due on a federal level and when the Federal Ministry of Health is involved, the federal agencies advise the Ministry and prepare the scientific background for the political decisions. For example, federal agencies such as the Paul-Ehrlich-Institut (PEI) or the Institute for Pharmaceutical and Medical Products (BfArM) may license blood products or new drugs for marketing, but the direct control of production facilities is under the authority of the state where the producer is based.

4 The Bundesinstitut für Arzneimittel und Medizinprodukte in Berlin (BfArM), the Robert Koch-Institut in Berlin (RKI), the Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin in Berlin (BgVV), the Paul-Ehrlich-Institut, Bundesamt für Sera und Impfstoffe, in Langen (PEI), the Deutsche Institut für medizinische Dokumentation und Information in Cologne (DIMDI), and the Bundeszentrale für gesundheitliche Aufklärung in Cologne (BZgA). The three first institutes, the BfArM, the RKI and the BgVV are the successors of the Bundesgesundheitsamt which was, as a consequence of the HIV and blood scandal closed down in 1994.
Before responsibilities for blood and blood products where clearly regulated as a consequence of the HIV/AIDS scandal in 1994\(^5\), it was the responsibility and task of the former Bundesgesundheitsamt (Federal Health Office) to identify health risks for the general population (including risks by drugs, medicinal products and blood products) and to take adequate measures for preventing such risks.

The history of the Bundesgesundheitsamt goes back to the in 1876 founded Kaiserliche Gesundheitsamt (KGA)\(^6\). In the Weimar Republic it was renamed as Reichsgesundheitsamt and in 1952 it was established as Bundesgesundheitsamt and was put under the supervision of the Home Office. It was established as an independent federal administration, which is responsible for the entire state territory. It is different from a Ministry because it is not directly involved in policy making but rather has implementation functions. In the 1963 the supervision of the Bundesgesundheitsamt was transferred to the Bundesministerium für Gesundheitswesen (Ministry of Health). Before it was closed down in 1994 the Bundesgesundheitsamt incorporated 6 institutes\(^7\) as well as the AIDS-Zentrum and a central department. Each of the Institutes had its own goals and functions and was divided in a number of departments. The organisations had a staff of 3000 of which 700 scientists.

The Bundesgesundheitsamt was the federal agency, which had not only the control of approval of new drugs but also post-marketing control of approved pharmaceutical substances and drugs. The major purpose of post-marketing control is to insure a positive risk-benefit ratio for new drugs. The procedure of post-marketing control not only involves federal agencies, but also involves state health offices and agencies as well as physicians who are obliged to report possible adverse effects of drugs and pharmaceutical products to the commission on pharmaceutical substances (Arzneimittelskommission) of the Federal Medical Council (Bundesärztekammer).

The most important legal instrument for post-marketing control is the so-called Stufenplanverfahren (graduated plan procedure) which was introduced on the 1\(^{st}\) of October, 1980\(^8\). The first step of the Stufenplanverfahren, i.e. Gefahrenstufe I (risk level I) enters when the Bundesgesundheitsamt (or today the Bundesinstitut für Arzneimittel und Medizinprodukte) receives first reports on possible adverse effects or new risks of pharmaceutical substances. Consequently, the Bundesgesundheitsamt had to share this information with the producer of the substance and with the health offices of the Länder. As such the information about the incidence of the adverse effects, its possible causes and the degree of risk can be collected. Gefahrenstufe II is activated

\(^5\) Gesetz zur Neuordnung zentraler Einrichtungen des Gesundheitswesens (GNG).


\(^7\) Robert-Koch-Institut, Institut für Arzneimittel, Institut für Wasser- Boden- und Lufthygiene, Max von Pettenkoffer-Institut, Institut für Sozialmedizin und Epidemiologie und Institut für Veterinärmedizin.

\(^8\) See the Arzneimittelgesetz (Medical Preparations Law) which regulates the production and distribution of medicines. § 63 of the Arzneimittelgesetz prescribes an evaluation of possible risks and adverse effects of new pharmaceutical drugs after approval of these substances.
when there are indications for the fact that the pharmaceutical substance is a health risk. Consequently, an expert commission (including representatives from federal health offices, the Länder, the pharmaceutical industry, health care professionals and external experts) will meet and discuss further actions to be taken.

The question of liability for blood-related injury or blood-related illness are regulated through the Arzneimittelgesetz (Medical Preparations Law) and through the Bürgerliches Gesetzbuch (German Civil Code). The laws require evidence of a causality between a product and its use or administration on the one hand, and a possible injury or illness on the other hand. The burden of proof is with the person harmed.

The press respectively the general public have in principal also an important controlling function. Until 1984, when the Federal Ministry for Health for the first time started a general information campaign on what was then called AIDS, the problem went almost unnotice in the general public. The general public as well as the press responded slowly to the new health problem. Hemophiliacs or transfusion recipients did not play a major role in the public debate on AIDS in Germany which reached its peak in 1987. This situation changed dramatically in late 1993 when it became public through the press that the company UB Plasma even in the 1990's had used blood and blood plasma, which was not tested for HIV antibodies. This scandal, finally, resulted in the establishment of an Untersuchungsausschuß (a parliamentary investigation commission on blood, blood products and HIV/AIDS).

III. Description of the Events Regarding HIV and Blood in Germany in the early and Mid-1980s

In what follows a description will be provided of the way in which the problem of HIV in blood and blood products was perceived and reacted to in Germany between 1982 and 1985 (i.e. the time in which most of the people which received transfusions and/or blood products were infected).9

In December 1982 an article published in the Morbidity and Mortality Weekly Report (MMWR 1982) mentioned and discussed for the first time the possibility of transmission of AIDS through blood. In the same month the Federal Health Office reacted already to this article. The working group on AIDS (composed of virologist and specialists on internal medicine and infectious diseases) of the Federal Health Office published a Schnellinformation (rapid note) on AIDS (Weise and L'age-Stehr 1982) which also explicitly mentioned the possibility of transmission through blood.

9 The information given here is mainly based on four sources: the 700 page final report of the investigation committee of the German Parliament which was published in 1994 (HIV-Infektionen durch Blut und Blutprodukte. Schlußbericht des 3. Untersuchungsausschusses. Deutscher Bundestag); press articles mainly from Der Spiegel, Die Zeit and Focus; a book by the investigation journalists Koch and Meichsner written in 1990 and with a foreword by the at that time Minister of Health, Horst Seehofer (Böses Blut—Die Geschichte eines Medizin-Skandals). The second edition of the book which was published in 1993 includes the case of the Koblenz-based company UB Plasma which even in the 1990s had used blood and plasma which was not appropriately tested for HIV antibodies; another source used is a paper by Stephan Dressler (HIV and AIDS, Blood and Plasma Products in Germany: A Tragedy of Errors?)
and blood products. It was published in the Bundesgesundheitsblatt which meant that it was in the first place read by administers and therapists (i.e. physicians).

As early as January 1983 the German Red Cross (being the most important supplier of blood) introduced measures to exclude donors at risk for AIDS (i.e. people with weight loss, lymph node swellings and other clinical signs) from the donation of blood. The effectiveness of these measures can be doubted but it indicates that the Red Cross considered the transmission of AIDS via blood to be a possible risk.

From June 1983 onwards most Red Cross leagues and most other blood banks and transfusion centres started to exclude so-called “risk groups” (i.e. intravenous drug users, homosexual men) from blood donation.

Also in June 1983, a decline of T helper cells in German haemophiliacs was described for the first time (Marcus 1993).

In August 1983 the Federal Health Office released an AIDS summary for physicians which pointed out the risk for recipients of coagulation factors and other blood products. At about the same time (the beginning of September 1983) a press release was distributed. At this time the Federal Health Office started to take actions other than merely information against HIV transmission via blood and blood products.

In November 1983 the Federal Health Office introduced a Stufenplanverfahren (graduated-phase procedure) for the reduction of risks associated with coagulation factors. The Stufenplanverfahren was started for factors VIII. As usual the procedure started with a Sachanhörung (hearing) on November, 14. Representatives form pharmaceutical companies\(^\text{10}\), representatives of the Bundesverband der Pharmazeutischen Industrie (Federal Association of the Pharmaceutical Industry), representatives of several Red Cross leagues as well as representatives from different hospitals participated in this meeting. In this meeting representatives from the pharmaceutical industry emphasised that no proven AIDS case among haemophiliacs in Germany had been described and denied a causal link between factor VIII concentrates and AIDS and the fact that AIDS is caused by an infectious agent. Several aspects, including donor selection in the USA and in Germany, documentation of products and an anti-hepatitis core test for potential donors were discussed.

In June 1984, the Federal Health Office announced that a hepatitis B core antibody test as a surrogate marker should become mandatory on January 1, 1985. The idea for the test was grounded on the believe that it could be a good marker for the risk of infections with sexually transmitted diseases. This test was not introduced because of the objections of the blood industry. It was argued that these surrogate marker tests have only a limited validity but also the expenses involved for the laboratory procedure played an important role.

\(^\text{10}\) Alpha, Armour, Beecham, Behringwerke, Eurim, Hoechst, Hormonchemie, Intersero, Immuno, Medac, Mérieux, Nordisk, Rhone Poulenc, Schering, Schwab, Serlac, and Travenol/Cutter.
On June 8 1984 the Federal health Office issued a Bescheid (administrative decision) based on the November meeting. The Bescheid demanded a declaration of the country of origin of products, a declaration of the donor pool size, limited indication for use, and warning with regard to a possible transmission of AIDS as well as a definition of criteria for donor selection and additional laboratory test (such as hepatitis B core antibody testing). The plan was to introduce these measures by September, 1st 1984 but almost all regional Red Cross blood banks and many producers of blood products objected these measures. Because of these Widersprüche (objections) only some of the measures were implemented and then even with a larger time delay. One of the major objections was that a limitation of the indication for factor VIII concentrates for the treatment of severe haemophilia would interfere with therapeutical freedom of the physician. Other objections were that evidence about the country of origin, number of donors and pool size would not contribute to the safety of the blood product. Moreover, it was even objected against a warning against AIDS because the producers of blood products still believed, in the second half of 1984, that there was no evidence that AIDS could be transmitted through factor VIII concentrates.

On December 12 1984 the Bundesgesundheitsamt issued a Widerspruchsbescheid (an administrative decision on the objectives) whereby the original Bescheid was changed in a number of ways. The use of factor VIII should not be limited to severe forms of haemophilia, evidence on the country of origin and of the factor concentrate was not required anymore. Also would products consisting of pooled plasma be admitted, and only pools with material from more than 20 single donations had to be tested for quality and safety. From March 1, 1985 onwards producers of coagulation factors had to declare whether the product had undergone an inactivation procedure and if so, which method was used.

Since February 1985 only factor VIII products which were heat-inactivated for hepatitis B virus have been used.

In April 1985 the HIV antibody test was licensed for marketing and was immediately used by most transfusion service centres, although the test became only mandatory on the 1st of October 1985. At the same time some transfusion centres introduced a confidential donor self-exclusion form, asking donors to fill out a questionnaire and to declare that they do not belong to a risk group”. In the meantime blood “on the shelf” was not rejected, but used for transfusion.

On the 1st of October 1985 the HIV antibody test became mandatory. The introduction of HIV antibody testing was probably the most effective measure in preventing HIV infections via blood transfusions and in securing safety of coagulation factors (Dressler 1997).

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11 Two Red Cross leagues even filed a disciplinary complaint against the president of the Federal Health Office. A disciplinary complaint is an appeal to the superior authority (in this case the Federal Ministry of Health) and a legal control within Germany's administrative system. Professor Karl Überla was alleged of misconduct in his position and to be dangerous to the general public (Koch and Meichsner 1993: 85). The complaint was rejected by the Ministry on the grounds that the president's conduct was in accordance to existing laws and legal duties of the Bundesgesundheitsamt.
Only in **July 1987** a confidential self-exclusion form as a mandatory procedure was introduced for transfusion service centres. Blood donors filled out a questionnaire, received a leaflet about the possibility that HIV/AIDS could be transmitted through blood and blood products, and donors were asked to abstain from donation if they considered themselves to be at risk for an HIV infection. This procedure was recommended in 1987 but became only mandatory from the 1st of April 1988 onwards.

On the **1st of June 1989**, the second-generation HIV-1/HIV-2 antibody tests were introduced.

On the **1st of June 1990** the test for anti-hepatitis C virus antibodies was introduced, but became only mandatory on **April 25, 1992**.

In **October 1993**, the case of the company UB Plasma shocked the German public. Even in the 1990's this company had used blood and blood plasma, which was not tested for HIV antibodies.

This scandal gained wide media attention and shocked the general public. It resulted in the establishment of an *Untersuchungsausschuß* (a parliamentary investigation commission on blood, blood products and HIV/AIDS). In this case, the responsibility laid with the regulatory authorities from the state *Rheinland-Pfalz*, but the company's offence against regulations was noticed by the Federal Health Office which routinely re-checked positive results from HIV antibody tests. It was more or less a matter of chance that the illegal activities of UB Plasma were detected. Regular control procedures had failed. It was a cynical result that the Federal Health Office which had a major contribution in detecting the scandal was dissolved as an entity by the end of 1994.

Today, all plasma derived products must be stored for a quarantine period of six months. The donor has to undergo a second HIV antibody test three months after donation, otherwise the blood product may not be used and will be rejected. Alternatively, virus inactivated plasma from one single donor may be used. Until this measure was introduced as a recommendation from September, 1994 and became mandatory on July 1st, 1995, blood and blood products were subject to the same laws and legal measures.

**IV. Assessment the Political and Programmatic Failure**

The parliamentary investigation commission concluded that what had happened was a scandal and concluded that pharmaceutical companies, physicians, blood banks and hospitals and the Federal Health Office share the responsibility for the HIV infection of many PPSB (prothrombin) recipients, haemophiliacs and recipients of other blood and plasma products. Rather than asking how the responsibility of the scandal has to be devided among these different actors the main question to be addressed here is whether the *Bundesgesundheitsamt* as the major public institution formally responsible for avoiding health risks in Germany, as well as its controlling institution, the Federal
Ministry of Health, have failed in their functions. In the next part, when trying to explain the failure of the Bundesgesundheitsamt, the role other actors played will be brought in.

In what follows it will be argued that the case of the contamination of a large number of people through blood and blood products can be considered a programmatic as well as political failure in Germany. The programmatic failure has to do with the way in which the Bundesgesundheitsamt has dealt with this issue and the political failure has to do with the role of the Gesundheitsministerium (Federal Ministry of Health) in the early and mid-1980s as well as in the aftermath of the crisis.

The Bundesgesundheitsamt failed in a programmatic way because it has been incapable of implementing the necessary measures or because it has implemented them too late. The Bundesgesundheitsamt was very fast in recognising and informing physicians about the possibility of transmission of AIDS through blood and blood products (in 1982) but rather reluctant in formulating strategies and especially implementing strategies to prevent transfusion through blood and blood products.

There has never been introduced the above described Stufenplanverfahren (graduated-plan procedure) with regard to whole blood and blood products and concerning the transfusion of cellular components. There has been only a Stufenplanverfahren for factor VIII but not for factor IX concentrates or other plasma-derived products such as PPSB, despite the fact that a possible risk of transmission of viral diseases through these products had been reported. Moreover, in the case where a Stufenplanverfahren (for factor VIII in November 1983) was initiated, only some of the measures, which were according to international standards considered effective, were implemented and then even with a larger time delay. Noticeable is also that it took the Bundesgesundheitsamt almost 7 months to produce a Bescheid (administrative decision) on the basis of the Sachanhörung (hearing) in the Stufenplanverfahren for factor VIII.

In 1981 heat inactivated factor VIII was licensed in Germany (which was at that time known to lead to an inactivation of the hepatitis B virus and which also, as we know since 1985, leads to an inactivation of the HIV). The majority of HIV infections might possibly have been prevented if heat-inactivated factor VIII-concentrate for treatment of all haemophiliacs had been mandatory since 1981 instead of tolerating that only haemophiliacs who tested negative for hepatitis B could receive reimbursement for heat-inactivated coagulation factors through their health insurance's.

The Bundesgesundheitsamt also failed in taking measures to decrease the doses of units. Physicians argued that only this treatment would enable haemophiliacs to live a normal life, and denied that it increased the risk of HIV transmission. This issue remains controversial, even after the parliamentary debate\textsuperscript{12}.

\textsuperscript{12} The ignorance and the quality of the debate the Bundesgesundheitsamt was confronted with but seemed not to be able to counteract becomes clear from a statement made by Johannes Eibl, founder of IMMUNO AG (which has a market share of 25% in Europe in the production of coagulation factors): "Außerdem hätte auch eine Reduktion der Dosis um die Hälfte kaum zu einer Senkung der Infektionsrate der Patienten geführt, da es sich hier ja in den meisten Fällen um eine Dauerbehandlung..."
In April 1985 the HIV antibody test was licensed for marketing but became only mandatory half a year later, on the 1st of October 1985\(^\text{13}\). This is again a case where the *Bundesgesundheitsamt* profiled itself as being a retardant instead of acting as the institution responsible for minimising health risks for the German people. To many transfusion service centres this seemed to be totally unacceptable and irresponsible policy and they immediately started to use the test.

On the 1st of October 1985, when the HIV antibody test became mandatory, the *Bundesgesundheitsamt* did not recall untested blood or coagulation factors since they seemed to be ignorant of the fact that many haemophiliacs who participated in homecare had stored large quantities of coagulation factors in their private refrigerators- supplies that would often last for another six month.

In summary, what we find here is a public administration which seemed to have lot of expertise on the problem of AIDS and the ways of transmission but was often acting very slow and passive and often was ineffective in implementing decisions or policies.

The political failure of the *Gesundheitsministerium* has mainly to do with the fact that the Ministry obviously did not recognise the deficiencies of the *Bundesgesundheitsamt* described above. It was only in October 1993 when the German Federal Minister of Health, Horst Seehofer, made public what he himself called a scandal which occurred many years earlier: the infection of haemophiliacs with HIV through contaminated blood products before 1985. As a consequence a parliamentary investigation commission was installed, the *Bundesgesundheitsamt* was closed down (a in the history of Germany unique incident) and a foundation was established for patients who are suffering from possible drug-related injuries or illnesses and for whom a proximate connection between the causes and consequences could be established.

A number of institutional changes followed the parliamentary investigation commission. In July 1994 the the Paul-Ehrlich-Institute became the central federal institution responsible for blood and blood. Moreover a working group on blood and blood products has been established at the Robert Koch-Institute in 1993. The purpose of the group is to support the work of the federal and state government and of the health offices with expert advice\(^\text{14}\). Also the necessity of national self-supply of blood and blood products has been stressed repeatedly as a result of the HIV/AIDS crisis.

\(^{13}\) A similar latency between the availability of a test and its mandatory usage occurred with regard to hepatitis C antibody test which became available in 1990 but did not become mandatory before April 25, 1992.

\(^{14}\) Members of the group are federal and state experts, representatives from the pharmaceutical industry and blood banks, as well as external experts.
V. Explaining Political and Programmatic Failures

In this last part some hypothesis will be formulated on why the Bundesgesundheitsamt did not respond in an adequate way to the challenge of HIV and blood and blood products. Two main arguments will be advanced here. The first argument relates to the type of problem the Bundesgesundheitsamt had to deal with. It will be argued that the AIDS problem was an ill-structured problem and would have asked for a different response than routine responses. This situation was not adequately recognised by the Bundesgesundheitsamt. The second argument relates to the type and structure of the external relationships of the Bundesgesundheitsamt. It will be argued that, in the first place, the type of relationships this organisation did have with other organisations can explain the type of response it developed to the problem of HIV and blood.

The problem of AIDS as it appeared in the early 1980s can be characterised as an ill-structured problem. An ill-structured problem is according to Simon (1973) (1) new, without familiar clues, (2) complex, with many clues to be taken into account or (3) contradictory, with different elements suggesting different interpretations. The epidemiological pattern of what is known today as HIV infection was largely unknown in the early years of the epidemic, and the size of the epidemic was either over- or underestimated. At this time, it was uncertain how risky blood and blood products were. The main challenge in dealing with ill-structured problem is that imposing familiar structures upon them does not only not solve these problems but often even deteriorates the problem at hand. “Business as usual” can thus be very harmful in a situation where an ill-structured problem is at hand. Ill-structured problems are best dealt with when common routines for problem solving are abandoned and integrative ways of problem solving are sought. Given the “empty world hypothesis” of Simon (1969), where the structure of the problem is not known, the most effective solution is to use no more co-ordinating apparatus than is absolutely necessary to bring about a satisfactory level of co-ordination; that is, favour lower levels of interdependence rather than higher, in order minimise cognitive complexity. It is not clear whether the Bundesgesundheitsamt was incapable of judging the situation and problem adequately as an ill-structured problem or not. What they certainly did not, however, was to react to the problem in a way, which would have been adequate. The situation at hand would have asked for facilitating decision-making structures, which would have been based on a problem orientation rather than on the common and classical bargaining structures between different stakeholders. The fact that the Bundesgesundheitsamt could not create such a context for problem solving has on its turn a lot to do with its position in the network of relationships of the different actors in the area of blood and blood products as we will see in what follows.
Figure 1: Types, direction and intensity of control relationships among the actors involved in HIV and blood in Germany between 1982 and 1986

What the above figure illustrates, is that the Bundesgesundheitsamt was on the one hand only controlled to a very limited extend by those one would have expected to control it, i.e. their clients and their controlling institution, the Federal Ministry of Health. On the other hand, they themselves had only very limited control over those they were supposed to control, the blood banks, the pharmaceutical industry and the administrators and therapists. It was rather the opposite, the blood banks and the pharmaceutical industry seemed to have more control over the Bundesgesundheitsamt than vice versa. It thus becomes clear that the Bundesgesundheitsamt had far from a central position in this network and that the most significant influence in this network originated from the pharmaceutical industry and blood banks. They not only exerted substantially control over the Bundesgesundheitsamt but also over the administrators of blood products and indirectly over the receivers of blood products and the German Haemophilia Society. The control of the administrators of blood products over the patients is not only illustrated by the fact that in the Board of the Haemophiliac Society (a so-called self-help group) a number of physicians had a seat but also by the fact that most physicians and haemophilia specialists did not inform their patients about the possible risk of AIDS. Some of them continued this information policy as long as possible, declaring that AIDS was an insignificant risk for haemophiliacs. Cases have been reported where patients were told by their physicians even as late as 1985 that the risk of AIDS was only a minor risk (Dressler 1997).

15 For example, it is indicative for this situation that the alterations in the Widerspruchsbescheid were accepted with some feeling of relief not only on the side of the pharmaceutical companies, but also by haemophiliacs and their physicians—treatment could continue as usual.
Such an actor constellation seems to explain reactions such as the following. When the use of national blood supply for the production of coagulation factor concentrates was first discussed in the context of HIV/AIDS in the 1980s, representatives from the pharmaceutical industry as well as from self-help organisations for haemophiliacs argued that national resources would not be sufficient to meet the demand for coagulation factors. Thus a situation was created in which an adequate supply of coagulation factors seemed to be of greater importance than the safety of products. Physicians and their patients feared that a legal restriction on the use of imported clotting factors would lead to a shortage in supply. The Bundesgesundheitsamt seemed not to have the potential to contribute anything constructive to these discussions.

The importance of the pharmaceutical industry in this network is also illustrated by the fact that the perspectives of this industry are clearly represented in the final report of the investigation commission. It is consistent with the statement of Vogel, the executive director of the federal association of Germany's pharmaceutical industry, who stated already in May 1987 that the HIV/AIDS scandal should be regulated in a way which is acceptable from the pharmaceutical industry's perspective (Koch and Messner 1983: 140). The investigation commission had generally voted for changes, which could simplify the process of establishing proof of evidence, but detailed recommendations or votes which would have had a major impact on the pharmaceutical companies were missing. The recommendations related in the first place to compensations and not so much to structural changes, which could avoid similar problems the next time.

The reason why the pharmaceutical industry seems to have a stronger position towards the Bundesgesundheitsamt than vice versa seems to have to do something with the fact that a considerable information asymmetry existed between the pharmaceutical companies and the Bundesgesundheitsamt. Although the Bundesgesundheitsamt was the agency which had a monopoly on the authorisation of new drugs, the pharmaceutical companies themselves had (and still have) an important role in the definition of the authorisation criteria, the implementation of the authorisation process and the control about the incidence of the adverse effects. It is clear that within such a system the Bundesgesundheitsamt becomes heavily dependent on the information provided by the pharmaceutical industry. In such a situation a climate develops where informal communication and a preference for solutions through bargaining becomes predominant. The reluctance in implementing security measures, as described above, can be better understood in such a context. In order not to harm its peculiar relationship with the pharmaceutical industry the Bundesgesundheitsamt could have been reluctant in proposing too radical and especially too costly measures.

Also the fact that the Bundesgesundheitsamt was only weakly controlled by the Federal Ministry of Health played an important role. This control, for which Manfred Steinbach was responsible, was extremely underdeveloped. According to an article in Der Spiegel “löste der frühere Leistungssportler durch seinen lässigen Umgang mit
Also the different Ministers of the Federal Ministry of Health (Heiner Geißler, Rita Süsmuth and Gerda Hasselfeldt) did not consider the AIDS-problem to be a very important one and therefore did not pay particular attention at what was going on. It is only when the highly ambitious Horst Seehofer became Minister that the relationship between the Ministry and the Bundesgesundheitsamt became very different.

Also in the case of the relationship between the public and the press and the Bundesgesundheitsamt a clear information asymmetry did exist. In this case it was at the advantage of the Bundesgesundheitsamt which could provide information in a selective way. Consequently, only limited control by the public and the press became possible. As a consequence, the Bundesgesundheitsamt could be expected to take the pressure from the public and the press not too seriously.

Also the fact that the Bundesgesundheitsamt was dismantled in the end can be explained by the above figure. The problematic compulsive marriage of the Bundesgesundheitsamt with the pharmaceutical industry led not only to specific resource dependencies but also to a certain blindness towards other relevant environment aspects: the obvious and energetic action orientation of the new health minister was not observed as something significant, the significance product controlled, i.e. blood and its potential relation to a health risk like AIDS was underestimated, the sensibility for the AIDS issue in the public was not anticipated. Moreover, the potential influence of the media on such a "thematic" issue was not properly recognised. This is a case where the behaviour of the organisation and the issues which were at play in the environment drifted significantly apart.

VI. Conclusions

The paper presented the failure of the responsible public institutions to avoid that 50% of all of haemophiliacs who receive treatment with coagulation factors have been infected with HIV as well as the failure to avoid the infection of about 600 persons who have received blood through transfusions. It has been illustrated that this failure has to do with the sluggishness with which programmatic as well as political responses have been developed.

Rather than concluding that this was the result of a "cartel" of different institutions (such as pharmaceutical companies, health insurance's, the Red Cross, the medical profession and state agencies), as has been argued by some (see e.g. Koch and Meichsner, 1993) it has been shown that it rather resulted from a lame duck-policy. This lame duck policy resulted mainly from the network of relations the duck (i.e. the Bundesgesundheitsamt) was embedded in. It did neither receive pressure from above (the Federal Ministry of Health) neither from below (the patients, the haemophiliac society or the press). It was rather committed to secure its relationships to the pharmaceutical industry and the administrators of blood products, relationships which were and still are characterised by resource dependency (in particular information
asymmetry). Instead of identifying health risks for the general population and taking adequate measures for preventing such risks the Bundesgesundheitsamt was busier with securing its position within the network. This could be seen as classical case of goal-displacement.
References


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