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η εμπειρία από τις τεχνολογίες ελέγχου του αίματος

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ΤΡΙΜΕΛΗΣ ΣΥΜΒΟΥΛΕΥΤΙΚΗ ΕΠΙΤΡΟΠΗ:

Αριστοτέλης Τύμπας, Επιβλέπων, Αν. Καθηγητής, Τμήμα ΜΙΘΕ

Κώστας Γαβρόγλου, Μέλος, Ομ. Καθηγητής, Τμήμα ΜΙΘΕ

Αριστείδης Χατζής, Μέλος, Αν. Καθηγητής, Τμήμα ΜΙΘΕ

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Technological accidents and the concept of risk:
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PhD DISSERTATION

VLANTONI AIKATERINI

ADVISORY COMMITTEE:

Aristotle Tympas (Supervisor), Associate Professor

Kostas Gavroglu, Professor Emeritus

Aristeides Hatzis, Associate Professor

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Επταμελής εξεταστική επιτροπή:

Αρστοτέλης Τύμπας, Αναπληρωτής Καθηγητής ΕΚΠΑ, Επιβλέπων

Κώστας Γαβρόγλου, Ομότιμος Καθηγητής ΕΚΠΑ, Μέλος τριμελούς επιτροπής

Αριστείδης Χατζής, Αναπληρωτής Καθηγητής ΕΚΠΑ, Μέλος τριμελούς επιτροπής

Αλέξανδρος-Ανδρέας Κύρτσης, Καθηγητής ΕΚΠΑ

Παναγιώτα Τουλούμη, Αναπληρώτρια Καθηγήτρια ΕΚΠΑ

Θεόδωρος Αραμπατζής, Καθηγτής ΕΚΠΑ

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Katerina Vlantoni
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Dedicated to the memory

of my dad

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ABSTRACT

This dissertation presents research on the introduction and use of new technology in medicine. It focuses on the introduction of genetic technologies in blood screening, in the field of blood-banking and transfusion medicine. These technologies, based on molecular (biology) diagnostics, were promoted as inherently superior to existing chemical-serological technologies of blood screening. Their use, which relied on the availability of nucleic acid amplification testing techniques (NAT), was advanced by its proponents as a way to reinforce blood safety and reduce the risk down to zero. The debates in medical and media circles over the introduction of NAT -a version of biotechnology based on the infamous polymerase chain reaction (PCR) technique- represent a central episode in the history of recent and emerging medicine. In Greece, a paradigmatic national case, the introduction of NAT was the single most expensive investment in the public health sector, justified through its portrayal as a panacea for the risk of transfusion-transmitted infections. Taking advantage of approaches from the History of Science, Technology and Medicine and the interdisciplinary field known as Science and Technology Studies or Science, Technology, Society (STS), the dissertation covers in detail the formation of the public image of molecular screening technologies and the processes that led to the decision to undertake this investment (Chapters 3–6). The same scholarly fields are used to identify and interpret the contested policies that determined the prevalence of genetic technologies in blood screening in paradigmatic international cases, coming from the United States and Northern-Central Europe (Chapter 2). This introduction offers the context required to properly introduce the national case (Greece). In turn, this national case offers critical details for elaborating on the issues raised while studying the international context: the importance of successfully presenting subjective calculations of risk as objective; the key involvement of state institutions and the media; and the force of an ideology that assumes a linear-universal progress/evolution of science and technology, which favored the advance of molecular diagnostics and the associated genetic technologies of blood screening.

ΠΕΡΙΛΗΨΗ

Η διατριβή αυτή παρουσιάζει έρευνα για την εισαγωγή και χρήση τεχνολογιών γενετικού εντοπισμού ιών στον έλεγχο του αίματος στην αιμοδοσία. Οι τεχνολογίες μοριακής βιολογίας προωθήθηκαν ως εγγενώς ανώτερες από τις υπάρχουσες βιοχημικές, ορολογικές τεχνολογίες ελέγχου του αίματος. Η χρήση των τεχνολογιών ΝΑΤ, όπως έγιναν γνωστές οι τεχνολογίες πολλαπλασιασμού νουκλεϊκών οξέων, προχώρησε με στόχο την ενίσχυση της ασφάλειας του αίματος και την επιδίωξη της μηδενικής διακινδύνευσης από τη μετάδοση ιών. Τα πεδία που αποτέλεσαν βάση για τη μελέτη αυτή είναι η Ιστορία της Επιστήμης, της Τεχνολογίας και της Ιατρικής και το διεπιστημονικό πεδίο Σπουδές Επιστήμης και Τεχνολογίας (STS). Στη διατριβή παρουσιάζονται οι σχετικές αντιπαραθέσεις στην ιατρική κοινότητα για τη χρήση της ΝΑΤ στη διεθνή περίπτωση, στις ΗΠΑ και την Ευρώπη, και στην περίπτωση της Ελλάδας. Εξετάζονται τοποθετήσεις γιατρών, φορέων διαμόρφωσης πολιτικής καθώς και διαδικασίες κατασκευής της δημόσιας εικόνας μέσω του τύπου. Η ελληνική περίπτωση παρέχει μια λεπτομερή μελέτη που είναι σημαντική στην ανάδειξη των ζητημάτων που ανακύπτουν από τη διεθνή περίπτωση. Στην Ελλάδα η καθολική εφαρμογή της ΝΑΤ ήταν η ακριβότερη επένδυση του Υπουργείου Υγείας.

Chapter 1

1. Blood Banking and Blood Screening Technologies: From an Overview of the Literature to a Dissertation Outline

1.1. Dissertation topic

The research presented in this dissertation sought to retrieve and interpret aspects of the development and use of a biomedical technology, Nucleic acid Amplification Testing techniques - NAT, which is central to the screening of blood in blood transfusion medicine, in the context of the operation of blood banks. My research on the development of NAT was inspired by approaches from the History of Science, Technology and Medicine and from Science and Technology Studies (STS). These fields have suggested that one way to approach technologies is by focusing on the way they "perform" in concrete use, paying special attention to accidents, misses, and malfunctions. This dissertation started as a project focusing on the study of phenomena that may be best termed as "technological accidents". It took advantage of research on a topic of relevance to accidents: risk. The proliferation of studies on risk is apparent in almost every discipline, including many fields of the humanities and the social sciences. The topic of this dissertation is not accidents *per se*. This dissertation focuses on adverse transfusion-related events, which are more structural than accidental. They do, however, share one aspect with accidents: they are undesirable events with unintended consequences.

The debates at the center of this dissertation concern what John Pickstone and Michael Worboys describe as "questions about high-tech solutions versus social actions in the biotechnology era [that] echo older 'public health' debates" (2011, p. 98). In the 1990s, genetic screening technologies were considered by many to be "a state of the art" in the domain of biotechnology, associated with exotic progress in molecular biology. Their prospective use in blood transfusion systems for testing large volumes of blood donations was, however, not uncontested, and its added value to the safety of transfusions was questioned. Before I examine the debates and policy-making processes behind the adoption of NAT in Greece (Chapters 3–6), I introduce the debates surrounding the development of NAT in the United States (US) (Chapter 2). To reconstruct the story of the development and use of genetic screening, I focus on the processes resulting in the production of risk estimates about transfusion-transmitted infections. I do so

because, in the post-HIV era, the relevant discussions in the transfusion medicine community and the public policy arena have been preoccupied with blood safety and the risks of blood.

Some transfusion medicine specialists showed the estimated risks through modeling and suggested that the use of NAT would incrementally add to blood safety. Others were skeptical about the social implications of such a decision. They argued that the cost-effectiveness of using NAT was poor, and suggested more beneficial ways to advance the safety of transfusions and of public health more generally. Their skepticism took into account the context of decreasing public spending in health care and the limited resources available. In the aftermath of HIV crises, public concerns and the media added political pressure to adopt measures to handle the risks of transfusion-associated infections. This was a decisive factor in the decision to promote NAT. Regulatory bodies, whose role was condemned during the early 1980s, used the introduction of NAT to reaffirm their position and public trust through the use of sophisticated biomedical technology.

Four chapters of the dissertation address issues regarding the introduction of NAT in Greece. I consider both the policy-making processes and the debates among physicians over the benefits from the use of genetic technology in blood screening, in the blood transfusion system. The processes of adopting NAT were accelerated when a case of transfusion-transmitted infections was made public, spotlighting the relevant discussions around risk. The last two chapters are devoted to the role of the press in introducing a costly and debatable medical technology. Studying this role can offer crucial insight to the ongoing international discussion about the role of the media in pushing the use of genetic technologies in blood screening.

Studies on blood transfusion and the risks associated with it seem to be of broader interest, societal and scholarly. It has been argued that stories about blood transfusion offer privileged vistas for understanding biologic similarity and difference, in much the same way as developments in human genomics demonstrate the tension between genetic similarity and genetic difference (Lederer, 2008, p. 212). Such studies therefore provide insights about medical innovations. They show how particular situations and contingencies are connected to developments in medical science and, thus, in society. For Farrell, studying the blood supply is important because blood has sociocultural, scientific and commercial value, and therefore presents with exemplar challenges in terms of risk governance (2012, p. 3). Important recent developments in science and medicine are connected to blood banking. Bone marrow donation represents one such development. Cord blood banking and donation is also of major importance.

Transfusion medicine specialists from many developed and developing countries are already involved in the various phases of stem cell collection, processing, preservation and transfusion. A study on blood supply risks can thus illuminate the risk governance that involves multi-valued human biological materials, particularly given their use in a range of new health technologies like cellular therapies and tissue-engineered products.

Transfusion medicine and the operation of blood banks have co-developed dynamically. The medical practice of transfusion, a widely used lifesaving practice in recent decades, is part of a large sociotechnical system. I focus on the processes of blood screening in the preparation of blood after the act of blood donation and before the act of transfusion. According to Berner, "moving blood between bodies today involves a complex socio-technical system of donors, artifacts, hospitals, blood banks – in addition to medical, ethical and legal requirements" (2010, p. 179). Recently, blood banks have felt pressure to assume "their responsibilities as complex technical systems, in which changing biotechnologies of blood management have material consequences for the kinds of social relations and forms of health and illness produced" (Waldby & Mitchell, 2006, p. 57).

In the post-HIV era, blood banks have been transformed into "highly geared risk-management institutions" (Waldby & Mitchell, 2006, p. 57). However, as my research suggests, risk is not something given, even though its definition and calculation greatly influences decision-making processes. In this dissertation, the development of a biomedical technology is contextualized by presenting the sociotechnical trade-offs associated with its use. By focusing on the debates regarding the risk in medicine and the anticipated benefits from alternative policies, the addition of a technology assumed to be superior, based on technical parameters, is critically examined.

My aim throughout this dissertation is to contribute to the understandings of the construction of risk. I argue that uses of risk have been central to the formation of public health policy with regards to the use of a new blood screening technology. While working on this dissertation, I paid attention to the way technologies and risks were debated in the context of the introduction of molecular diagnostics in transfusion medicine in the 1990s and 2000s. My research has shown that the introduction of molecular screening of blood was not uncontested, to some extent due to its very high cost. By studying aspects of this contestation, I wish to add to academic research regarding the social construction of risk. At the same time, I hope to contribute to the

development of historically-informed policy approaches to public health, and more specifically to risk management.

1.2. Blood Banking, Blood Screening Technologies, Risk: a literature overview

1.2.1. Blood banking

Blood as a substance, as a medical concept, as something surrounded by many ideas and ideologies and as a metaphor, has a long and rich history. Going back in time, blood was uniformly considered to have mystical properties and was associated with vitality. For example, in many ancient contexts, bathing in or drinking the blood of the strong was thought to invigorate the weak. Blood has been historically connected to various religious and other spiritual beliefs and related practices, even in recent centuries.[1] It is beyond the scope of this dissertation to provide a full historical account regarding the multivalent quality of blood and the origins of blood transfusion; I will simply restrict myself to introducing some points of relevance to the topic under discussion.

For Douglas Starr, "the story of blood is one of metamorphosis, of a liquid that became symbolically transformed as society learned how to deconstruct and manage it" (1998, p. xiii). Historians of medicine have worked comprehensively on various aspects concerning the medical use of blood.[2] As in other scientific disciplines and fields of study, many blood practitioners, mostly physicians, have shown interest in histories surrounding the evolving practices of blood donation and transfusion. Physicians, transfusionists and professors of medicine specializing in

[1] For example see Camporesi, 1995. For a recent discussion of the cultural perspectives on blood and the origins of its various meanings in association with the attitudes and the responses formulated during the HIV crisis, see Nelkin, 1999.

[2] Extensive historical work (coming from the history of medicine and cultural history) has examined the knowledge and beliefs about blood in different eras and spaces. For historical studies focusing specifically on blood transfusions in the last two centuries, see, for instance, Pelis, 1997, 2001; Lederer, 2008; and Schneider, 1997, 2003. One can also find popular books on the topic written by special journalists and science writers, for example Starr, 1998 and Winner, 2007. The award-winning *Blood: An Epic Story of Medicine and Commerce* is indeed an "epic history" of blood written by a non-professional historian, Douglas Starr (Professor of Science Journalism at Boston University and former science journalist and biologist). It is a very comprehensive historical account of blood in different periods (from the 17th century until the end of the 20th century). Starr conducted extensive research in many countries, and his well-documented history has been frequently cited by historians and social scientists. Nevertheless, his work has also been criticized for omissions and minor inaccuracies (Lederer, 2000, p. 198).

the field of transfusion medicine have actually provided useful overviews of the history of blood transfusion and blood banking in medical handbooks, textbooks and journal papers.[3]

Before I present a historical overview of the development of blood banking, I will introduce some basic information regarding human blood and its medical use in recent times. Human blood (whole blood) consists of various components, which can be considered to belong in three parts. The red part is formulated by the red blood cells (erythrocytes). The red blood cells contain haemoglobin and carry oxygen to the body tissues. A smaller part, called the "buffy coat", contains the white blood cells (leukocytes) and the platelets. White blood cells are important for the immune reaction of the body to infections. The platelets are necessary for the coagulation process and, therefore, prevent haemorrhage. The remaining part, about 55% of whole blood, is the plasma, a yellowish liquid containing many proteins, salts, lipids and a variety of nutrients and products of metabolism.

The therapeutic use of blood is recommended for various conditions: to treat blood loss (for example, haemorrhage after a car accident or during a surgical procedure); for the treatment of bleeding disorders and related diseases; for the therapy of conditions or treatments that affect the ability of the body to produce blood (anaemia).[4] In recent decades the transfusion of whole blood has become less common and nowadays extremely rare. When we refer to "blood transfusion" we usually talk about the transfusion of red cells. During the 1970s, this change in the use of blood became obvious in the US. With respect to the total number of all types of transfusions, in 1971 whole blood transfusions were 67.5%, whereas in 1979 this decreased to 16.3% (Surgenor & Schnitzer, 1985, p. 11). In the same period, transfusions of separated red blood cells increased proportionally.

Over the course of the 20th century, blood transfusion gradually became common medical practice. At the start of the century, writes Lederer, transfusion "was more than a surgical procedure. It was a dramatic spectacle", covered in many newspaper articles in the US (Lederer, 2008, p. 51). The development of new surgical procedures led to the establishment of "direct"

[3] For example see: Alter & Klein, 2008; Boulton, 2013a, 2013b; Franklin, 2009; Diamond, 1980; Farmer, Isbister, & Leahy, 2014; Giangrande, 2000; Greenwalt, 1997; Learoyd, 2012a, 2012b; McCullough, 2012; Schmidt, 1968; and Sturgis, 1942.

[4] Such condition might be aplastic anaemia (a disease causing a decrease in bone marrow's ability to produce blood cells); genetic disorders causing defective haemoglobin/red cells, as in sickle cell anaemia and thalassaemia; and leukemia (malignant growth of white cells). Leukemia and the conditions caused by its therapies are often treated with transfusions of red cells, platelets, or both; anaemia can also occur in patients undergoing cancer therapies (chemotherapy, radiation therapy, etc.).

transfusion techniques, based on transferring blood from the donor to the recipient (Schneider, 1997). In the development of transfusion practice, a turning point was the identification of different blood groups in 1900 by the pathologist Karl Landsteiner. In the following years, many clinical studies provoked debates that increasingly led to the recognition of the practice of blood typing to ensure the compatibility of the blood types (A, B, AB and O) of the donor and the recipient (Lederer, 2008, pp. 143-150).[5]

In the early days of blood transfusion, another significant issue was that of blood clotting (coagulation), which led to the development of techniques to prevent clotting and permit blood storage. Many studies were performed in various countries to find effective methods to prevent clotting through the use of anticoagulants, mostly during World War I. By the 1920s, the use of sodium citrate was shown to be effective for the anticoagulation of blood to be used for transfusions. After World War I, the practice of direct transfusions was steadily replaced by indirect procedures in Europe and in the US.[6] As the number of transfusions grew, so did the need to recruit donors, either volunteers or compensated ones.

In the 1930s, there were many attempts to use stored blood for medical treatments, in parallel with the development of blood services. Physicians in the Soviet Union worked extensively on processes of storing human blood to be used in transfusions, blood from live persons and cadaver blood (Lederer, 2008, p. 56; Starr, 1998, pp. 66-71). One of the first organized blood services was established by the Republicans during the Spanish Civil War, 1936–1939 (Starr, 1998, pp. 78-83). In 1937 the first "blood bank" was instituted in the US, in a hospital setting. This is when this term was coined for the institution to provide blood-related services.[7] With the creation of blood banks in the late 1930s, the practices of blood donation and transfusion were transformed and removed to different spaces. This development signified the pursuit of an organized manner of collecting blood and introduced anonymity. For Berner, "technologies of blood donation thus contributed to form novel identities, and shape a particular subject: the

[5] The specification of blood groups helps explain the reactions of patients to blood transfusion, caused by agglutination of the red cells. Karl Landsteiner received a Nobel Prize in 1930 for his work on blood types. In the 1940s, the establishment of the Rhesus system (Rh-positive/negative) also became part of blood typing. The Rhesus system was further studied in conjunction with cases of haemolytic reaction after a transfusion and attempts to prevent Rhesus immunization.

[6] The aforementioned developments during the interwar period were largely debated. For more see Lederer, 2008; Schneider, 2003. For the debates surrounding the changes in the practices of blood donation and transfusion in Sweden in the first half of the 20th century, see Berner, 2010.

[7] The first "blood bank" was instituted in the Cook County Hospital, Chicago, US. The term was used by the physician Bernard Fantus (Lederer, 2008, pp. 56, 89; Starr, 1998, p. 71).

modern blood donor" (2010, p. 198). As interest in the medical practice of transfusion grew, the International Society for Blood Transfusion (ISBT) was founded at a meeting in Rome in 1935.

The practices surrounding blood transfusion and blood banking were greatly altered during World War II. During this war, the demand for blood fostered the development of techniques to collect, process and store it. From the 1930s, the biochemist Edwin J. Cohn and his colleagues worked extensively on methods of blood separation, which made blood components available. Cohn's projects resulted in techniques to separate blood components, as well as the various proteins or fractions from the plasma. These proteins were useful for certain purposes. For example, the use of the protein albumin was considered to offer a treatment for severe blood loss and shock, and its use had been proven valuable on the battlefield. This technique became known as the "Cohn fractionation method". It provided the basis for subsequent developments in blood product therapy that took place after the end of the war (Farrell, 2012, p. 29).

In 1940–1941, military initiatives led to cooperation with pharmaceutical companies to increase plasma production through a large-scale effort for the collection, processing, and transportation of plasma (Lederer, 2008, pp. 58-59; Starr, 1998, pp. 105-106). Whole blood could not endure transportation over long distances or storage for long periods of time, whereas plasma could be preserved and handled more easily. To collect large volumes of whole blood, which would be further processed to obtain dried plasma and albumin, the American Red Cross was mobilized by the US Army to recruit blood donors and to organize blood collection sites. An experimental program, taking into account the need for blood products in Europe amidst the war, led to shipping plasma from the US to Britain. The project soon continued with blood collection for the US military.

These wartime efforts also transformed the motivation for blood donation. The act of the blood donor became part of the war to save democracy and humanistic ideals (Lallemand-Stempak, 2016, p. 27). The conditions of the war were interrelated with the establishment of the practice of blood transfusion. A detailed presentation of the vast changes in the administration of blood during World War II and in the postwar era is beyond the scope of this introductory section; however, certain elements are relevant to this dissertation.

The efforts during the war had proven that large-scale blood services could be developed. In the first decades after World War II, blood and blood components were needed for various recently-established medical practices and treatments. The demand for blood was associated with attempts to organize national blood services. In most developed countries, these services

became connected with postwar national health systems as part of the welfare state. In many cases, national Red Cross societies became part of blood transfusion services, focusing on blood donation. The US was a notable exception. In the absence of a national policy on blood, and as demand was growing, a complex system of blood supply was developed (Lederer, 2008).

In 1947, the American Red Cross, in agreement with the Army, continued its work in the field of blood banking by developing and operating regional blood banks. At the same time, a group of physicians, knowledgeable about the blood banking practices, argued that the blood banks should be supervised by a physician. This was, in effect, a criticism of the management of the Red Cross, which was presented as incapable of understanding the medicine involved. In 1947, a coalition of independent and community-based blood organizations, led by physicians, founded the American Association of Blood Banks (AABB). The Red Cross and the AABB had conflicting perspectives on blood collection. The AABB members were collecting blood based on "individual responsibility", meaning that the recipient of a unit had to replenish it either by blood or by paying a replacement fee (Starr, 1998, p. 175). The Red Cross followed a doctrine of "community responsibility" in donating blood, and considered the AABB model to be "commercial". While the blood centers of these two organizations collected most of the blood supply during the 1950s, commercially operated independent blood banks operated by collecting blood from paid donors and selling it to the hospitals.

The expansion in the use of blood did not occur without great medical and social controversies. In the US, a complex issue concerned the racial separation of blood. The establishment of blood banks to manage the storage of blood made the blood donations anonymous. It was right then that the segregation of blood began in some blood banks. The American Red Cross, which collected blood during the wartime for the Army, first refused donations from black donors. After 1942, following strong reactions, it started accepting donations but labeled them to be used only in the treatment of black soldiers. For Lallemand-Stempak (2016), refusing the blood of blacks "amounted to denying their citizenship and their desire to save democracy" (2016, p. 28). Those opposing the segregation of blood compared the practice of segregation to the Nazi ideology of racial purity. The ideology about the difference of the blood of various ethnic groups (a prerequisite of the ideology about the superiority of the Aryan blood) had severely, and noticeably, restricted the blood supply of the Nazis during World War II (Starr, 2001, p. 120).

In the post-World War II decades, the collected blood was labeled according to the race of the donor. The scientific controversy regarding putative differences in the bloods of black and white people and their possible effects in transfusion lasted until the end of the 1960s.[8] It was explicitly connected to social and political issues. According to Lallemand-Stempak (2016), it was sustained by specific institutional arrangements. This was apparent in the organization of the hospitals, which were differentiated by race. Suggestively, even black and white doctors and surgeons were separated by belonging to different medical associations. The Civil Rights Movement fiercely fought against all this in the following years. For Lederer (2008, p. 115), "separating the bloods of whites and blacks represented more than a cultural preference. It reflected assumptions about blood purity and disease, especially the concern about syphilis", even though after the 1940s blood was routinely screened for syphilis. In 1952, a few years after the end of the war, the American Red Cross decided to abort racial classification of blood donors. In the middle of the 1960s, a federal regulation ordered the desegregation of blood supplies (after the Civil Rights Act in 1964). This regulation was not straightforward in some states of the South, and blood separation persisted until 1969 in Arkansas and until 1972 in Louisiana.

As the use of blood grew in the postwar era, several developments affected the practice of transfusion. The use of plastic bags as blood containers in the 1950s eliminated the contamination of blood with bacteria and chemicals. It also permitted the separation of blood into its various components. Studies that aimed at a better understanding of red cells made it possible to develop methods to prolong red cell survival and storage for transfusion; by the 1970s, red cells could be stored for up to 42 days (Greenwalt, 1997). Studies indicating that leukocytes were connected to transfusion reactions led to the emergence of ways to remove them from the blood.

From the early years of blood transfusion, it became apparent that adverse effects and complications to the recipients could occur. As the practice of transfusion became more widespread, various hazards of transfusion were recognized and many efforts were put forward to handle them.[9] Haemolytic transfusion reactions, which could be fatal, were occurring. Blood grouping helped eliminate the transfusion of incompatible blood. Transfusion-associated infections were of great concern after the 1930s due to documented cases of syphilis

[8] For more see Kenny, 2006; Lallemand-Stempak, 2016; Lederer, 2008, pp. 107-142.

[9] These can grouped as immune and non-immune reactions. Immune reactions are those which are attributable to the immune system of the recipient. Non-immune ones can be of different types, including transfusion-transmitted infectious agents, bacterial contamination and others.

transmission. Starting in the 1940s, the blood collected was screened for syphilis (in the following subsection I refer more to the screening tests used in blood banking). There was a postwar increase in concerns about the transmission of hepatitis, with many cases showing that this transmission took place through blood transfusion. Testing for the Hepatitis B virus began in 1970.

The development of plasma derivatives also grew from the 1950s onwards. In 1946, Cohn and his colleagues were able to isolate clotting factors (the "anti-haemophilic" factor) from plasma, which were important to the treatment of bleeding disorders. People with haemophilia, a bleeding disorder caused by a deficiency in the clotting process, bleed longer than others because their blood does not contain enough clotting factors to stop it.[10] Haemophilia varies from mild to severe. Early treatment included blood transfusion to restore the lost quantity of blood. Later, people with haemophilia were transfused separated plasma (fresh frozen plasma), as it became known that the plasma was what included the clotting factors.

A new treatment was developed in the middle of the 1960s. With the use of the plasma fractionation method, concentrated clotting factor (factor VIII in the beginning) could be prepared. The subsequent production of these concentrated cryoprecipitate products impacted greatly on the treatment of haemophilia. By the early 1970s, the availability of certain concentrates (factors VIII and IX) permitted home treatment. This changed greatly the life of people with haemophilia, since hospitalization was no longer necessary for the treatment of bleeding episodes. Life expectancy was increased (Pemberton, 2011, pp. 157-162; Starr, 1998, p. 224).

The pharmaceutical industry in the US was involved in fractionation during World War II, when the government encouraged the commercial production of albumin for use on the battlefield. After the war, a niche industry within the pharmaceutical industry became devoted to the production of additional plasma products like immunoglobulins and, subsequently, clotting

[10] Various bleeding disorders and clotting factor deficiencies have been recognized in the recent decades. The most common bleeding disorder is von Willebrand disease, and its symptoms can be very mild so that many people do not know that they have it. Haemophilia is considered to affect about 1 in 10.000 people. Haemophilia A is the most common form and it is attributed to the deficiency of factor VIII. Haemophilia B is caused by a deficiency in factor IX and is found at about 15% of the people with haemophilia. Haemophilia is a genetic disorder that is mostly manifested in males (it is transmitted by females who are carriers). It is usually inherited; fewer than one third of the total cases are acquired. For more information about haemophilia, see the book *Living with Haemophilia* (Jones, 2002). For a social history of haemophilia and the related medical treatments in the US, see Pemberton, 2011.

factor concentrates.[11] The production of plasma products required large quantities of plasma. During the 1960s, the technique of plasmapheresis was employed to collect greater volumes of plasma for further processing. Through plasmapheresis, blood is removed from a donor and the plasma is separated and extracted, while the rest of the blood components (mostly red cells) are returned to the donor's body.[12] Two methods to collect plasma were then used. The plasma collected from apheresis was called "source plasma", while the plasma separated from whole blood donations was called "recovered plasma".

The pharmaceutical companies involved in the manufacture of plasma products bought the source plasma from dedicated commercial centers, which supplied plasma that had become available through plasmapheresis, collected from paid donors.[13] They also bought recovered plasma from the blood banks. With the plasma industry expanding during the 1970s, the demand was also satisfied through international trade in source plasma.[14] Many collection sites were functioning in developing countries, under questionable hygiene conditions. As Starr explained, "The industry collected plasma from areas rife with poverty, mal-nutrition, and hepatitis, concentrated and processed the material, and sold it throughout the world" (1998, p. 237). This practice was highly condemned, both in the US and internationally, by the Red Cross and the World Health Organization (WHO). By the end of the 1970s, the collection sites outside the US were closed down (Farrell, 2012, p. 40).

In connection to the production of plasma products, different institutional arrangements were developed. In Europe, both not-for-profit and commercial plasma fractionation centers

[11] Immunoglobulins are proteins found in plasma. They are the antibodies that can protect the human body (immune system) against diseases.

[12] The apheresis process is still used to collect raw plasma. In the 1980s, the technique became more automated. A donor undergoing plasmapheresis can offer plasma more often than whole blood since the red cells remain to the body. The human body restores plasma more quickly. A similar process of apheresis has been used to collect platelets.

[13] The main arguments used to make the remunerated donation in the plasma sector "acceptable" were the following: a) the process of plasmapheresis lasted longer than whole blood donation and justified the payment, and b) the payment would permit the collection of large proportions of plasma to be further processed, ensuring the availability of plasma products for domestic use and for exports. Large-scale fractionation by the industry involved pooling plasma from 1,000 donors to more than 50,000 when recovered plasma was used. The methods of fractionation were developed as to achieve economies of scale. Due to this method, a lot of concentrate plasma proteins could be contaminated by a unit of plasma. Thus, the size of the pool was a variable affecting the probability of infection of the recipient. Moreover, since the plasma donor donated more often, with shorter intervals, the rate of new infections (incidence) was different than that of whole blood donors.

[14] For more see Starr, 1998, pp. 231-249 (chapter "Wildcat days").

existed.[15] For instance, in the UK and in France the fractionation centers were close to the national blood transfusion services. In the case of Switzerland, the Red Cross undertook the task of collecting and processing plasma (for more see Hagen, 1993). To meet the growing demand, a considerable amount of collected plasma for fractionation and plasma products in Europe were imported from abroad. The US plasma products industry developed a large export market.[16] After the late 1970s, with blood donation being exclusively non-remunerated in the US, plasma was collected from paid donors.

I have noted that both paid and non-remunerated blood donations contributed to the supply of blood in the US. This was controversial from the beginning. During the 1920s, a blood donor service of the British Red Cross in London worked on a voluntary basis. In the early years of transfusions and blood banking, the donors were usually paid or received other types of compensation. For example, in some US states, citizens could donate blood instead of paying fines for traffic violations (Lederer, 2008, pp. 92-93). As late as the 1960s, the US blood banks operated on a mixed system of paid and volunteer donors. In many European countries, at about the same time, non-remunerated blood donation gradually became the standard. In 1975, the WHO recommended voluntary, unpaid, whole blood donation (Hagen, 1993, p. 89).

The debates surrounding blood donation were connected to fundamental medical and social issues. The issue behind the question of whether a donor should be compensated or not was whether blood should be viewed as a commodity, a commercial product, or a gift. This persistent question fueled various medicolegal debates. It was embedded in broader discussions about the commercialization of otherwise benevolent acts, like blood donation. The status of the donor was directly connected to issues of safety. Paid donors were associated with higher risk; volunteer donors with more safety. This was the case when syphilis was the major concern during blood transfusions, and also when hepatitis became the major concern.

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[15] In 1990, the not-for-profit plasma fractionators in Europe created the European Plasma Fractionation Association (EPFA). Later, organizations outside Europe also joined. It was renamed the International Plasma Fractionation Association (IPFA), and represents not-for-profit organizations from 13 countries around the world involved in the collection of human blood and plasma based on voluntary non-remunerated blood donation and in plasma fractionation. For more, see http://www.ipfa.nl.

[16] In 1972, the American Blood Resources Association (ABRA), a nonprofit trade association, was organized to represent the interests of businesses engaged in the collection, manufacturing, or distribution of the plasma products, including the for-profit source plasma centers and plasma brokers (OTA, 1985). Recently, it became the Plasma Protein Therapeutics Association (PPTA), representing the private sector manufacturers of plasma-derived products. For more, see http://www.pptaglobal.org/.

In early 1971, Richard Titmuss, a British professor of social administration, published his last book, *The Gift Relationship: From Human Blood to Social Policy*.[17] In this seminal book, Titmuss compared the blood banking systems of Great Britain and the US. Following an analysis of blood supply in the two countries, he argued against paid blood donation. For Titmuss, the American blood banking system was insufficient and unsafe, since blood from paid donors had a higher chance of being contaminated with serum hepatitis. Arguing against a trend toward the commercialization of blood that was noticeable in the UK at the time, he reasoned that an exclusively volunteer-based blood system, like the British one, was more efficient. From the end of the 1970s, the pursuit of social solidarity and safety linked to the altruistic donation of blood achieved the status of an "international orthodoxy" (Bayer & Feldman, 1999, pp. 7-8).

Titmuss' book influenced US politics, as did the publicity surrounding scandals about paid blood donation. At the time, the newspapers exposed stories about commercial banks recruiting paid donors among drug addicts and alcoholics, representing a higher risk of transmitting hepatitis (Lederer, 2008, p. 97). A report of the National Institutes of Health (NIH) showed that much of the collected blood was wasted, while the blood banks had unequal pricing policies. In 1972, a task force was set up by the Department of Health, Education, and Welfare (DHEW) to develop "a safe, fast, and efficient nationwide blood collection and distribution system" (OTA, 1985). The Nixon administration put forward a National Blood Policy at federal level in 1973. The DHEW (the predecessor of the Department of Health and Human Services, HSS) decided to move the supervision of the blood banks from the Division of Biologics Standards (part of the NIH) to the Food and Drug Administration (FDA). Blood and blood components would from that point on be regulated both as licensed biologics and as drugs.[18]

The newly established Bureau of Biologics (later renamed the Office of Biologics Research and Review) of the FDA would have to oversee all the blood centers, of which there were about

[17] Richard Titmuss (1907–1973) participated in many debates regarding social policy and the welfare state. Titmuss' social analysis was opposed to market-based blood collection systems (and, more generally, his work was at the heart of British debates around the liberal proposals coming from London's Institute of Economic Affairs). He was interested in showing the importance of giving blood for communities as an act of solidarity and altruism. The book had a significant impact, both inside academia and within society, and received praise and criticism from scholars representing many of the social sciences (sociologists, economists, anthropologists). For more, see the intriguing analysis of Philippe Fontaine (2002). The book *The Gift Relationship: From Human Blood to Social Policy* was reprinted in a revised edition, in which the editors supplemented new sections commenting on Titmuss' work in the post-AIDS era (Oakley & Ashton, 1997).

[18] For more on the regulation of blood, see Solomon, 1980, 1994.

7,000, which had to be registered.[19] By the end of the 1970s, the FDA had published regulations defining good manufacturing practices (GMP) for blood banks and had set up a mechanism to license them. It became responsible for the proper testing of blood. In 1972, the FDA started requiring that both whole blood and plasma donations be screened with a licensed test, to check for the presence of the hepatitis B virus (HBV).

In the early 1970s, only a small percentage of the US blood supply came from paid donors. Commercial blood collections sites were mostly devoted to supplying the plasma industry. Over the course of the same decade, the number of paid donors for whole blood was constantly reduced. In 1978, the FDA mandated that blood units ought to be labeled to indicate whether they came from a paid or a volunteer donor. This contributed to achieving blood sufficiency by volunteer donors in the US. The assertion of a safe blood supply from non-remunerated donors was greatly challenged at the beginning of the 1980s, when AIDS was recognized as a transfusion-transmitted disease.

The National Blood Policy, established in 1970s, did not alter the complex and "bifurcated" system of blood collection in the US (Bayer, 1999). The organization of the blood supply in the US at that time consisted of the American Red Cross, whose regional centers covered about half of the blood supply; the members of the AABB, which covered more than 40%; and hospital blood banks and community-based independent ones, which were much smaller in scope. Some Red Cross blood banks were also affiliated with the AABB, as were other blood banks organized under the aegis of the Council of Community Blood Banks (CCBC).[20] The not-for-profit blood banks were operating at a community or regional level and were not competing with each other; they had a monopoly over designated areas. The AABB grew to be a professional, not-for-profit, scientific, and administrative association for the individuals and institutions engaged in the many facets of blood banking and transfusion medicine.[21]

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[19] The Public Health Service Act and the Food and Drug and Cosmetics Act were the major pieces of legislation passed by Congress providing the authority for the FDA's work. Both acts applied to the regulation of blood, because blood has been regulated both as biologics and as drug. Plasma products were licensed as drugs. The same applied in European countries in which they were distributed and regulated as medicines.

[20] Hospital blood banks played less role in blood collection. In 1971, 69% of the blood collected came from regional and community blood centers, while in 1981 the percentage reached 91% (OTA, 1985, p. 5).

[21] Recently its members cover about 80% of the blood supply. There is overlapping membership; members of the Red Cross and other associations of community-based blood banks (recently the America's Blood Centers, ABC) can also be members of the AABB. AABB set the guidelines for the operation of blood centers in the US. The services and programs of the AABB included inspection and accreditation, standard setting, certification of reference laboratories, educational activities and other. In addition, the AABB provided scientific space through meetings in which results of new research in blood banking and transfusion medicine were presented.

The federal agency responsible for the blood resources, belonging to the Public Health Service (PHS), were the FDA, the National Institutes of Health (NIH) and the Centers for Disease Control (CDC). The FDA, as already mentioned, was responsible for regulating the efficacy and safety of all blood products and the technologies associated with them. The FDA inspected blood collection centers and source plasma establishments biannually. The NIH, in particular the National Heart, Lung, and Blood Institute (NHLBI), was expected to engage in research and development activities regarding the use of blood and blood products and the management of blood resources. The CDC (renamed in 1992 the Centers for Disease Control and Prevention) was responsible for the public health and the prevention and control of infectious and non-infectious epidemics. It had no direct authority over blood banks, but often worked with them, as happened during the AIDS epidemic.

The AIDS/HIV epidemic was complex and led to important changes to the blood supply.[22] In 1980, the initial observation of a condition occurring in persons with severely suppressed or defective immune systems alerted the CDC, which reported on this observation in June of 1981. The first cases observed were in homosexual males and Haitians who had recently migrated. The term "acquired immune deficiency syndrome" (AIDS), the first generally accepted name for this new disorder, was coined at a CDC meeting in 1982 (Oppenheimer, 1992, p. 49). In July 1982, epidemiologists at the CDC reported three cases of haemophiliacs with AIDS symptoms in connection to the possible transmission of an agent through blood products (Bayer, 1999).[23] At the end of the same year, the CDC reported five additional cases and started investigating whether the AIDS cases could be linked to past blood transfusions. One case was fully documented by the CDC: that of an infant who received blood from a donor who later developed AIDS.

Soon afterward, in January of 1983, the CDC held a public meeting at which representatives from the FDA, NIH, the National Hemophilia Foundation, the National Gay Task Force, plasma fractionators and blood banks were present. CDC epidemiologists presented the cases and recommended the exclusion of homosexual donors and/or the use of surrogate testing (Healy, 1999). The representatives of the blood banks opposed both measures, arguing that the data was insufficient and inconclusive, and therefore that the measures were not justified. At the

[22] The presentation has been reconstructed from secondary literature. To serve the scope of this dissertation, it will not be detailed. The published research on the early years of AIDS is vast. I will selectively comment on parts of it.

[23] People with haemophilia A were being treated with concentrated Factor VIII, a plasma derivative.

same time, a plasma supplier decided to begin excluding individuals specified by the CDC as high-risk donors. For blood bankers, there was a notable difference: these, the plasma donors, were paid ones, whereas theirs were volunteers. The blood bankers doubted the effectiveness of direct or indirect questioning of donors about their sexual preference (Healy, 1999). The gay community was also against such questioning.

More meetings took place, and additional data had been gathered by the time the Public Health Service recommended in March 1983 that members representing an increased risk should refrain from donating blood. According to the CDC, four groups represented an increased risk of AIDS: homosexual men with multiple sexual partners, users of intravenous drugs, Haitians who had emigrated to the US in the preceding years, and haemophiliacs. The CDC then called for the development of donor screening procedures (Oppenheimer, 1992, pp. 60-61). The blood bankers were still reluctant, but agreed to use educational material to inform donors. Most blood banks did begin donor screening. The response was not uniform. In New York, for example, the physicians, the gay community and the local blood center developed a method of self-exclusion. With reluctance, gay political leaders eventually came to accept the donor exclusion recommendations (Bayer, 1999, p. 25).

Regarding the measure of surrogate testing, different types of tests were proposed, but the one most heavily discussed was the Hepatitis B core antibody (anti-HBc) test, used to check past infection by HBV. Some blood bankers opposed this due to the added cost, arguing that it lacked scientific merit as a marker for the new disease (Bayer, 1999). They also believed that the non-specificity of the test would exclude a large number of healthy donors and attract high-risk donors to get tested. The Blood Products Advisory Committee (BPAC) of the FDA examined the issues pertaining to surrogate screening of blood in early 1984, concluding that the anti-HBc was not appropriate as a means of identifying those at high risk for developing AIDS because it screened out too much of the blood supply (Sapolsky & Bowell, 1992, p. 178).[24] However, some blood banks and some plasma collection centers began blood screening by surrogate tests. Other measures included directed blood donation (another proposal rejected by blood banks), more

[24] The FDA received input from an advisory committee regarding the regulations of blood products, called the Blood Products Advisory Committee (BPAC). The committee was constituted by senior professionals from blood banks, university professors and researchers and other experts from the transfusion medicine fields. It also included representatives from patients' groups and the industry who did not have a right to vote. The recommendations formulated by BPAC are not binding to the FDA.

extensive use of autologous donation (which did take place), and a more conservative use of blood (resulting in a decline in the number of blood transfusions and donations).[25]

According to Bayer (1999, p. 26), throughout 1983, the most forceful representatives of the blood banking community sought to "minimize the risk and to allay public anxiety about the threat of transfusion-transmitted AIDS." In August 1983, Dr Joseph Bove, director of the Yale-New Haven Hospital Blood Bank, testified before Congress that "[i]f – and there is no evidence yet that this is so – but if all 20 cases under investigation by CDC finally turn out to be transfusion related, the incidence will be less than 1 in a million" (Bayer, 1999, p. 26). In April 1984, when it was announced that the etiological agent of AIDS was a retrovirus (initially named HTLV-III and/or LAV), all the parties anticipated the development of a test. In March 1985, the FDA licensed the first test for the human immunodeficiency virus (HIV) antibody.[26]

As for the plasma products, manufacturers quickly accepted the association with the transmission of the new disorder when cases were recorded of people with haemophilia who had AIDS symptoms. The plasma collection centers adopted donor screening, and some of them also surrogate testing. The National Hemophilia Foundation took a conservative approach, arguing that the benefits of using plasma concentrates "were just too large to be outweighed by information about a new disease" (Healy, 1999, p. 551). The concentrated clotting factors were produced from pooled plasma lots composed of as many as 10,000 units; contamination could thus occur from a single infected donation. This greatly affected the infection of people with haemophilia, more than half of whom were infected with HIV in this way. In those with severe

[25] Blood transfusion refers to allogeneic blood transfusion. In this dissertation, when we talk about transfusion, we mean this practice as it is commonly understood. The distinction between allogeneic and autologous blood transfusion refers to the origin of the blood to be transfused. In the first case, it comes from another person who previously donated it. The latter case designates the reinfusion of blood or blood components to the same individual from whom it was taken. The most common use of autologous blood transfusion has been for elective surgery, meaning when the need for blood can be anticipated, a practice known as preoperative autologous blood donation. The use of autologous blood increased in the 1980s, after the recognition of HIV transmissions by transfusion, and stimulated further research for this practice in combination with educational initiatives for physicians and patients (Chernoff, Klein, & Sherman, 1989). This increase, also apparent in the early 1990s, did not persist in the US; in the mid-2000s autologous blood collections were remarkable reduced, from 1,117,000 units in 1992 to 335,000 in 2006 (McCullough, 2012, p. 101).

[26] While the use of the test in the blood banks was quickly introduced, several concerns were associated with it. In the US, concerns about false negative results, associated with the sensitivity of the first antibody tests, led to the creation of alternate sites in which people could be tested. This was a response to thoughts that people considering themselves to be at risk for AIDS could seek testing in the blood banks. In addition, the level of specificity of this early test would result in false positive results. For an early appraisal of the screening strategies demonstrating the role of social and epidemiological criteria in interpreting the anti-HIV test results see McCombie, 1986. For a further analysis of the ways the HIV test made its determinations of infection and transmission category against an implicit concept of the norm of "low risk" individuals, see Waldby, 1996.

haemophilia, the rate was estimated to be about 90% (Saul, 2005). The infection from the treatment with factor VIII was worldwide due to the exported products.

The plasma industry began research into viral inactivation methods to examine the effectivity in eliminating the causing agent of AIDS. Heat treatment was found to be effective for HIV (and HCV over the following years). Research on such methods by heat treatment had begun in the 1970s to treat hepatitis, but did not proceed. For the plasma industry, most haemophiliacs were already HBV antibody positive. There was complacency about this, however, since hepatitis was a manageable disease (Healy, 1999). For physicians and the people with haemophilia the emphasis was on the benefits of the treatment. The heat treated clotting factors were licensed by early 1984.

Healy argues that, in the early years of AIDS, the blood banks chose to defend their suppliers' interests as their own: "they acted as if reaffirming their trust in donors was the same thing as reducing the risk borne by recipients" (1999, p. 548). He juxtaposes this with the reaction of the plasma companies, which defended its consumers (the recipients). It was estimated that about 12,000 individuals were infected with HIV by transfusion, about 2% of the total cases. A higher proportion was estimated to have been infected before 1983, when the first measures on donor screening were taken (Bayer, 1999).

Both sectors of the "blood industry" – blood banks and plasma manufactures – were in the spotlight after the HIV crisis, and questions of blood safety have persisted since then. The public awareness of the risks of infectious diseases through transfusion was significantly raised. The HIV crisis differed from one context to another.[27] The most known case was that of France, where a "blood scandal" led to the trial of blood executives and government officials (Steffen, 1999). Official inquiries and examinations were undertaken in many countries, which led to the reorganization of national blood transfusion services. The HIV crises had lasting repercussions on the risk governance of the blood system, at a national and a transnational level (Farrell, 2012).

In the US, a persisting aspect that was further debated after 1985 was the exclusion of blood donor groups, as requested by the CDC in the early years of AIDS. The issue regarding the exclusion of homosexual men reappeared in debates and the protestations made by gay groups.

[27] For studies about the US, Japan, France, Canada, Denmark and Germany see Feldman and Bayer (Eds.), 1999; for a comparative analysis of HIV crises in blood products in US and France paying attention to the framing of the events by the actors, see Saul, 2005; for early historical studies about HIV/AIDS, see Fee and Fox (Eds.), 1992, and Berridge and Strong (Eds.), 1993; for a study focusing on blood donation and AIDS see Murray, 1991; for a study focusing on people with haemophilia, see Resnik, 1999.

The recommendation did not change. For Haitians, who were also excluded, the racial dimension in this decision was also controversial. After protests and demonstrations, the FDA lifted the ban on Haitian blood donations in 1990.

After 1985, transfusion recipients and haemophiliacs who were HIV infected turned to the legal system for redress, seeking financial compensation for their suffering, for the cost of medical care, for lost income, and for their shortened lives (Bayer, 1999). In almost all US states in the 1950s and 1960s, however, the so-called "blood shield laws" were passed, which exempted blood and blood products from strict liability and warranty claims (Healy, 1999). In terms of litigation, blood and blood products were a service, and any claims had to be based on negligence or fault. Nonetheless, more than 300 cases were examined in the courts. The plaintiffs could prove negligence in very few of them. The haemophilia community sought redress and support. In the early 1990s, haemophilia activism was vigorous in demanding an official investigation. Their petitions were heard by senators, who called for a committee to undertake an investigation. This committee was set up by PHS Secretary Donna Shalala in 1993 (see Chapter 2).[28] The committee issued its final report in 1995 (Leveton, Sox & Stoto, 1995). The report analyzed the events of the early 1980s and criticized the actions of the FDA. From the early 1990s, the FDA underwent changes that enabled it to extend its regulatory oversight of the blood industry.

To conclude this section, the practices of blood donation and transfusion were thus transformed during the course of the 20th century. In the US, this process was initially marked by the controversy about racial segregation of blood. Recently, comparable debates took place regarding certain population groups that were excluded from donating blood. In such cases, the discriminatory practice clashed with epidemiological evidence prompting a health-related grounding. Moreover, as the act of donation became an issue of public policy, the debate on paid versus voluntary blood donation persisted in various forms.[29] Although the collection of whole blood has in most developed countries been based on non-remunerated, voluntary blood donation grounded in both ethical and safety reasons, the type of donorship was further discussed regarding the resort to replacement donors.

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[28] The Institute of Medicine (IOM) undertook the inquiry. The goal of the inquiry was not to attribute blame but to "describe the science and policy formulation processes as they evolved, to review subsequent changes to decision-making, and to provide guidance regarding approaches to policy development to be pursued in future efforts to protect the blood supply". The initial response of haemophilia activists was one of disappointment; see Bayer, 1995. A compensation scheme for HIV-infected haemophiliacs was put forward in 1998.

[29] See Farrell, 2012; Waldby & Mitchell, 2006.

In the postwar period, the development of the blood services was based in two sectors: first, the not-for-profit sector, which was mostly devoted to the collection and processing of blood and blood components, and second, the commercial, for-profit sector, which became part of the pharmaceutical industry. Both contributed to the shaping of the blood industry and the overall health care economy. The separating line between them became less strict as the donated "surplus" blood components moved between the non-commercial and the commercial blood sectors.

The practice of blood banking was also transformed. The operation of the blood banks in the US was (and still is) organized at a local, community level. This meant they were closer to blood donors than to recipients and the medical practice of transfusion. From the 1980s, they transformed themselves into highly geared risk management institutions (Waldby & Mitchell, 2006). The organizations responsible for the blood banks embraced structures resembling those found in the pharmaceutical industry, adopting good manufacturing practices, quality assurance systems and computer systems.

In the early 1990s, in the aftermath of HIV crises, blood safety was at the center of attention as new measures were instituted to reduce risks. In Chapter 2, I present the debates regarding blood safety from the late 1980s until recently. This section provides the background to discuss the use of genetic technologies in blood screening after the 1980s.

This dissertation focuses on blood transfusion practices in the US and Europe, in other words in the developed parts of the world. Blood transfusions take place around the globe, yet not everybody has access to safe blood or to (quality) health care more broadly. The unequal distribution of pharmaceutical provision is reflected in the world's blood supply, with limited availability of blood in developing countries resulting in higher mortality. According to the WHO, of the estimated 80 million units of blood donated annually worldwide, less than 45% is collected in developing countries, home to 80% of the world's population (WHO, 2008). The WHO reported in 2000 that unsafe transfusion and injection practices cause an estimated 8–16 million HBV infections, 2.3-4.7 million HCV infections, and 80,000–160,000 HIV infections each year ("Blood safety", 2000).[30]

[30] According to WHO, 31 out of 145 countries that provided data on blood screening strategies indicated that they were unable to screen all donated blood for one or more markers of HIV, HBV, HCV and syphilis infections (WHO, 2009). The WHO published recommendations on *Screening Donated Blood for Transfusion-Transmissible Infections* to be used in developing and transitional countries with limited resources (a first edition in the early 1990s was revised in 2010); see WHO, 2010.

The WHO recommends establishing a national blood policy and a national organization to sustain it.[31] In recent years, WHO initiatives have included the Global Collaboration for Blood Safety and the Blood Transfusion Safety Programme to support transitional and developing countries to develop blood services by providing policy guidance and technical assistance in working toward equitable access to safe blood and blood products and their safe and rational use (WHO, 2008). In the developed world, according to many blood bank professionals, investing on new technologies that offer incremental benefits in blood safety further widens the gap between developed and less developed countries.

1.2.2. Historical outline of blood screening technologies

During the 20th century, transfusion gradually became a common therapeutic practice, based on an increasingly complex technological and medicolegal setting. The processes of collecting, processing and managing blood has changed over time. Very briefly, whole blood is currently collected by venipuncture from eligible donors into plastic bags containing a liquid anticoagulant preservative solution. The provisions as to who constitutes an eligible donor have been dynamic and often reviewed. Donor selection criteria are usually set by international and national legislation and regulation.[32] These criteria ensure the safety of the donor. At the same time, donor selection is an important step toward ensuring the safety of the blood supply, and ultimately toward the safety of the recipient. Donor selection became stricter in the aftermath of the HIV crises. It now included many questions to defer donors considered to represent a higher risk for transmission of infectious agents. The prospective donor is informed about the factors that constitute an eligible donor or that indicate deferral from donating blood. During the HIV crises, an additional procedure was introduced in many countries. The donor was asked to fill out a confidential unit exclusion form to have the opportunity to designate confidentially whether or not her/his blood should be transfused to others. The motivation, recruitment and retention of regular volunteer donors is a complex, time- and resource-consuming process. Dedicated research has focused on the motivations of donors to help ensure blood sufficiency. To this end,

[31] The WHO was also involved on developing guidelines and standards for the quality and safety of blood.

[32] In the US, the donor selection process must conform to FDA Requirements. For an elaborate listing of deferral criteria in the US see McCullough, 2012; for those specified in the European Directive 2004/33/EC, see Murphy & McSweeney, 2009; for the recent legislation in Greece, see Presidential Decree 138, 2005, based on the European directive. The International Society of Blood Transfusion (ISBT) adopted a code of ethics for blood donation and transfusion in 1981 (revised in 2006).

the donor exclusion criteria have also been carefully evaluated to avoid the loss of many potential otherwise qualified donors. Establishing a mature, altruism-based blood donation system is a social process that requires immense effort in education and public awareness.

Before the blood components are administered to hospitals, a sample of each unit undergoes a variety of laboratory tests. In most countries, blood is tested for ABO blood group, RhD blood group, and the presence of irregular red cell antibodies.[33] The results of the grouping tests are recorded, as they are of great importance to a safe transfusion practice and to avoiding potentially fatal reactions. The blood is also tested for certain infectious markers. In the event that screening tests detect infectious marker(s) in a blood sample, the donor is tracked and notified, while many blood banks offer counseling to encourage the donor to undergo treatment.[34]

In what follows, I will provide an overview of the screening technologies used for the detection of infectious markers and also briefly describe the testing methods. I focus on the screening technologies employed to reduce the risk of transfusion-transmitted infections. The use of a test for a transmissible disease depends on many factors, including the quality of the test, the prevalence of the disease in the donor population, and the likelihood of transmission of the disease to blood recipients. In epidemiological terms, prevalence is a statistical concept referring to the number of individuals in a particular population affected by a given disease at a given time. Incidence refers to the number of new cases, and of new individuals detected with the disease in a given period of time.

The use of a screening test in blood donor population (a population with a low prevalence of infectious markers) is a complex process. In general terms, screening a certain population means testing an otherwise healthy population for the presence of a disease, in contrast with diagnostic testing, in which an individual seeks testing due to observed symptoms.[35] A prospective

[33] Blood typing is important to ensure the compatibility of the donor and the recipient to avoid transfusion reactions. Donor samples are tested to exclude the presence of red cell antibodies that could cause reduced red cell survival or haemolysis when transfused into recipients whose red cells are positive for the relevant antigen(s).

[34] Following a positive screening test, further confirmatory testing takes place in the laboratory and, often, at a reference laboratory. This strategy is employed to determine the possibility of a false-positive result. Confirmatory tests, of a different method than the routinely used screening test, assist in determining whether a donor is truly infected, which can be communicated to the donor.

[35] The use of screening has evoked many social debates, for instance in relation to life insurance and to immigration. Foltz and Kelsey (1987) defined screening as "the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly to sort out apparently well persons who probably have a disease from those who probably do not" (cited in Towers,

screening test to be used in a blood donor setting is evaluated according to its sensitivity and specificity. Increased sensitivity, meaning the ability to detect the presence of an infectious marker, is of outmost importance to detect and remove potentially infectious blood from the blood supply and eliminate false negative results. At the same time, the test's specificity (the ability to not react in the absence of the tested marker) is also important in reducing the number of false positive results.[36] There is usually a trade-off between sensitivity-range and specificity-precision in the development of tests. In routine blood screening, a screening strategy usually includes repeated testing of reactive samples, followed by supplemental or confirmatory testing when available. Indeterminate testing results may produce a complex situation, which raises concerns on how the testing results should be communicated to the donor.

Before the beginning of the 1980s, screening tests were developed and used for testing for syphilis and the Hepatitis B virus. After the 1980s, however, blood screening became far more complex. Syphilis had been recognized as potentially transmitted through blood transfusion from an early period. Many cases were recorded after 1915 in connection with direct transfusions (Schmidt, 2001). Early in the 20th century, syphilis, an infectious disease caused by the spirochete *Treponema pallidum*, was a major public health problem. Screening donated blood for syphilis began in 1938 and became routine during the 1940s. Early serologic testing for syphilis was performed with a non-specific test.[37]

More recently, Treponema-specific antibody tests were developed and have been used for donor screening (Orton, 2001). Treponema was also shown not to survive in refrigerated blood for more than 72 hours. This refrigeration process, in combination with testing, resulted in very few documented cases of transfusion transmissions in the developed world since the 1940s. The last recorded case in the US was in the late 1960s (Alter & Klein, 2008). The effectiveness of further

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1993, p. 56). For more on historical aspects of screening, not in a blood banking context, see Reiser, 1978a, 1978b, and Towers, 1993.

[36] In the context of blood banking, where testing is performed on a large donor population, the specificity of a test has different ramifications than in the patient population. McCullough (2012, p. 155) provides the following example: a test with a specificity of 99.9% might be considered excellent, but still 0.1% of positive tests will be false. For instance, if this test is carried out on 12 million blood donors, 12,000 individuals will have a false positive result. However, if the disease being tested for has a very low incidence, such as 1 per 500,000 in a blood donor population, only 24 people would truly have the disease out of the 12 million tested. This means that even with this excellent test that would detect the 24 infected donors, 11,976 people could be falsely labeled as having the disease. The implementation of such a test should be undertaken at the planning stage to deal with the donors who have a false-positive test result. This is done by the use of confirmatory testing to distinguish between truly positive and false positive samples. This is important to the process of informing donors about the significance of a positive screening test result.

[37] For more on the historical aspects of testing for syphilis, see Löwy, 1993.

syphilis screening was debated after the 1980s. The testing was retained as a surrogate marker for other sexually transmitted diseases, mainly for HIV, and is still routinely performed (Perkins & Busch, 2010; Orton, 2001).

Post-transfusion hepatitis is the most common disease transmitted by blood transfusion. The most common cause of hepatitis (a liver disease) is one of the five unique hepatitis viruses, identified by the letters A, B, C, D, and E. After World War II, a disease called "serum hepatitis" was identified in surviving soldiers and prompted dedicated research, emerging as a major hazard of blood transfusion.[38] In the mid-1960s, collaborative research by Baruch Blumberg and Harvey Alter identified an antigen, initially called the "red antigen" and afterward termed the Australia antigen (Au), which was associated with leukemia (Alter & Klein, 2008). A few years later, further studies demonstrated a relationship between the antigen and the hepatitis virus. The antigen detected on the protein coat of the virus named HBV is known as the Hepatitis B surface antigen (HBsAg).

The first tests for hepatitis were based on detecting HBsAg. They provided the foundation for the development of a vaccine in the early 1980s. Donor screening for HBV began on a large scale in 1972. In 1973, the use of the more sensitive enzyme-linked immunosorbent assay (ELISA) screening assays to detect HBsAg further reduced the cases of transfusion-associated HBV. In the early 1970s, the decline in post-transfusion hepatitis was significant (from a 30% rate to about 10%) and was connected both to HBV testing and to the great increase in volunteer donors. Retrospective studies demonstrated that only a quarter of transfusion-associated hepatitis cases were due to HBV. In the mid-1970s, another hepatitis virus was recognized (Hepatitis A virus, HAV) but it was not associated with non-B hepatitis cases. A third type of hepatitis was designated as non-A, non-B (NANB). Its incidence was about 10%.

Further studies during the 1980s sought to find ways to reduce transfusion-associate hepatitis, termed "NANB by exclusion". Surrogate interventions were proposed, including routine screening of blood donors' antibody to the hepatitis B core antigen (anti-HBc) and testing of the levels of alanine aminotransferase (ALT) enzyme to exclude donors with elevated ALT. These two

[38] It is beyond the scope of this section to provide detailed historical information regarding Hepatitis B, for which see Muraskin, 1993. The Hepatitis B virus (HBV) is transmitted through exposure to infective blood, semen, and other body fluids. HBV can be transmitted from infected mothers to infants at the time of birth or from family member to infant in early childhood. Transmission can also occur through transfusions of HBV-contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. HBV also poses a risk to healthcare workers who sustain accidental needle stick injuries while caring for infected-HBV patients (WHO).

strategies were extensively debated, as they were not specific to NANB. The introduction of anti-HIV screening in 1985 and the initiation of surrogate screening in 1986, combined with a more judicious use of blood due to AIDS, led to a decrease in the incidence of transfusion-associated hepatitis by 1989. Over the following years, further research demonstrated that anti-HBc testing could detect HBV infectious donors who were negative to HBsAg test.

The incidence of post-transfusion non-A, non-B hepatitis cases in the 1980s was further investigated. In 1989, a research team at Chiron Corporation cloned the non-A, non-B agent, which was subsequently called the Hepatitis C virus (HCV) (Alter & Klein, 2008).[39] Anti-HCV antibodies were detected in NANB hepatitis cases, and as early as 1990 the first donor screening test for HCV antibody was developed and introduced in donor screening. A second-generation of anti-HCV assays with higher sensitivity was adopted in 1992, resulting in a further decline in incidence. The impact of screening donors for anti-HCV was significant worldwide. With the use of a specific test in donor screening, testing for ALT levels was advised to be discontinued, although some blood centers retained it (NIH, 1995).

As noted above, blood banks altered their medical screening practices in 1983 to defer potential donors considered to come from groups representing high-risk for AIDS. A screening test was developed following the identification of HIV, associated with AIDS, by late 1983/early 1984. Within a year, an assay for detecting HIV antibody was licensed and used to test all transfused products. A second type of HIV was identified in the early 1990s and a combination test for HIV type 1 and type 2 was developed and used in blood screening. The HIV-1/2 antibody test has been considered very effective; its sensitivity has improved as newer generation tests have been manufactured.

Other screening tests used in blood banking include testing for HTLV. Adult T-cell leukemia (ATL) was first recognized in Japan in the mid-1970s. The disease was later shown to be caused by the human T-cell lymphotrophic virus (HTLV), which became the first retrovirus shown to cause malignancy in humans. HTLV was also related to other neurologic diseases.[40] The incidence of anti-HTLV-I in blood donors in the US was low. Routine screening of donated blood

[39] The Hepatitis C virus (HCV) is mostly transmitted through exposure to infective blood. This may happen through transfusions of HCV-contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. Sexual transmission is also possible, but is less common (WHO).

[40] The virus can be transmitted vertically to newborns by maternal breast milk, and can also be spread by parenteral and sexual routes.

for anti-HTLV-I was initiated in the US in December 1988, and expanded to HTLV type I and type II in 1997.

Several viruses, bacteria and parasites have been linked to transmission by blood and blood products, but, for various reasons, not all would be routinely tested in blood banks. Blood screening of an infectious agent depends on many factors, including local epidemiological data. The greatest challenge for a blood supply comes from emerging infectious agents. During the 1990s, the variant Creutzfeld-Jakob Disease (vCJD) was due to an emergent agent. vCJD is not strictly an infectious disease, but it was treated as such because of transmissible, abnormally folded prions that caused the human equivalent of bovine spongiform encephalopathy (BSE, or "mad cow disease"). For many years there was uncertainty about the possibility of transmission by blood and blood products. The primary intervention in blood banks was to defer donors indefinitely who had a history of visiting BSE-affected European countries, particularly Great Britain, during years of likely exposure. Donor screening strategies are often implemented for emerging diseases. In the early 2000s, the West Nile Virus (WNV), which had previously been confined to Africa, India, and the Middle East, caused great concern. It was identified in the US in 1999, and in European countries thereafter. A NAT test for WNV was developed in the following years and was used selectively (based on seasonal criteria for the mosquito season).

The main screening tests are the basic syphilis test and those detecting syphilis and the viruses HIV-1/2, HBV, and HCV. In the following paragraphs, I describe the testing technologies. The enzyme-immunoassay (EIA) or enzyme-linked immunosorbent assay ELISA are biochemical techniques developed in the 1960s. Previously, immunoassays had involved the use of a radioactive label. EIA and ELISA are based on the use of an enzyme to be attached to the antigen or antibody the test is designed to detect without hindering the immunochemical reaction between antigen and antibody (Lequin, 2005). Commercialization of EIA/ELISA test kits were introduced in the early 1970s. In the 1980s, automated testing equipment was produced by diagnostic companies. Serologic tests of EIA/ELISA assays have been used routinely in analytical and clinical laboratories and many different formats have been developed.

The first ELISA test in blood screening was developed for the Hepatitis B antigen. In this case, that the test is looking for an antigen of the virus, antigens from the sample are attached to a surface. A specific antibody is then applied over the surface to bind to the antigen. A reaction is produced to show the detection of the antigen. In other cases, the test can detect an antibody to a sample by using an antigen to bind. These assays have been used as diagnostic tools and are

used to evaluate the presence of an antibody or antigen in a blood sample (plasma or serum concentrations). Since the first EIA/ELISA tests, diagnostic companies have developed tests of higher sensitivity and specificity, as denoted by the different generations of testing technology.

The detection of a virus-specific antibody of a virus with ELISA supposes the seroconversion of it (indirect detection). This means that once an individual gets infected with a virus, there is a time period from infection until the development of detectable antibodies, called a "window" period (or a window phase). This period also exists until the presence of detectable virus antigens. During this period, a virus cannot be detected, and the blood sample is characterized as false negative. These false negative samples mean that a potentially infectious blood donation will be released for transfusion. According to transfusion medicine specialists, this period constitutes the "residual risk" from blood screening, or the probability that a potentially infectious donation will be released into the blood supply. EIA/ELISA tests with higher sensitivity were developed to reduce this period. Another possibility was the introduction of new tests. For HIV, as I will describe in Chapter 2, a proposal was to use an ELISA test to detect an antigen of the virus directly (p24) instead of the antibody produced. This was estimated to reduce the "window" period by five days. Because the antigen disappeared after some time, the antigen test would be supplementary.

In the 1980s, other methods were used in laboratories to detect a virus directly, including virus culture and other molecular diagnostics. The polymerase chain reaction (PCR) technique was developed by the Cetus Corporation in the early 1980s.[41] In the PCR, polymerase – an enzyme that catalyzes the formation of DNA and RNA – could start and stop specific parts of DNA and amplify the region between them. With each round of reaction, the genetic material targeted could be further amplified. PCR and other methods of molecular biology were used for the genetic detection of viruses in research and clinical laboratories.

Research efforts demonstrated that PCR could detect the DNA or RNA of HIV in a recent infection before the development of antigens or antibodies (this held true for other viruses, too). The molecular techniques became significant in the diagnosis of infectious diseases; based on their use, the viral genome could be detected, especially by amplifying techniques. Nucleic acid amplification technology (NAT) is used to detect the targeted virus's genetic material by the amplification of nucleic acids (molecules that include DNA and RNA). The various techniques have

[41] For the development of PCR in Cetus, see Rabinow, 1996.

three steps in common: 1) sample preparation, including viral concentration and nucleic acid extraction; 2) amplification of the target DNA or RNA; and 3) detection of the amplified product.

The use of genetic/molecular technology was used in many laboratories. It was laborious and took a considerable amount of time to amplify and detect the targeted genome. These factors were very important for the throughput of the blood banks' laboratories, which screened a large number of donations. In the early 1990s, these technologies were considered problematic to large-scale screening. Their use could detect the viral genome before the detection of antibodies or antigens with ELISA tests. The period between infection and the time when the virus could be detected by the NAT assays was termed the "eclipse phase", during which the transmission of the virus was possible.

When the genetic technologies of PCR and TMA (transcription mediated amplification) were developed for use in blood and plasma screening, several factors determined the sensitivity and specificity of the assays, as well as their automation. Proposed testing in mini-pools meant that many samples were diluted and the small viral load was not as easily detected, meaning that there was a trade-off in the sensitivity. The gain was lower cost. NAT technologies could also fail in the detection of samples with very low viral load but with the presence of antibodies; their use would thus supplement the serologic tests. I discuss the development of NAT in more detail in the following chapter.

The first step regarding blood safety is the (strict) selection of candidate blood donors by attracting low-risk donors and the retention of regular, volunteer donors. National blood transfusion services aimed at reaching national sufficiency in blood through voluntary donorship. A second step has been the adoption of screening technology for transfusion-transmitted viruses to remove infected units from possible use. A third approach concerns procedures implemented to reduce or remove pathogens from the blood. For instance, viral and other inactivation procedures have been applied to plasma products after the HIV epidemic. Their use in cellular components, red blood cells and platelets has been under development since the 1980s.[42] Other developments were considered in connection to the prospect of blood substitutes, as associated with visions for artificial blood.

[42] The use of pathogen inactivation methods in red blood cells and platelets had been considered since the 1980s. It was a complex concept mainly due to these blood components not being stable as plasma products and with short self-life. During the 1990s, the methods were considered for future use but were not yet developed. Lately, clinical trials for inactivation methods of blood components have begun.

To be sure, the safety of a blood transfusion does not only affect the component of the transfused product. Within the wider context of transfusion therapy as a process rather than as a product, many more factors impinge on the quality and safety of the process than those covered by the product-safety area (Farrugia, 2002). Transfusion safety embraces a multitude of factors surrounding blood transfusion, including blood safety, transfusion of the correct blood component, the quality of administrative procedures in blood banks and hospitals and the decision to transfuse, among others. Transfusion is a process, a therapy or an act of medical practice involving a complex sociotechnical network of donors, artifacts, blood banks, hospitals, and medical, ethical and legal requirements.

At the end of the 1980s, the HIV transmissions by blood transfusion fueled increased interest in further analyzing the aspects of transfusion safety to gain an advanced understanding of the adverse outcomes of blood transfusions.[43] This increased effort began in France in the aftermath of the HIV scandal there, which led to institutionalizing a national haemovigilance network in 1994 (Drouet, 2001).[44] Since then, haemovigilance programs have been developed in many European countries.[45] Although the term haemovigilance was not used regularly in the US in the 1990s and early 2000s, a blood safety vigilance system and practices monitoring morbidity and mortality associated with blood transfusion were in place (Busch et al., 1999; Menitove, 1998).[46]

From the mid-1990s, a critique centered on the difference between blood and transfusion safety. Transfusion safety meant developing a more holistic approach to handle transfusion risks. These claims were also corroborated by studies in various countries, which pointed out that the

[43] The haemovigilance efforts provided updated and enriched understandings about various transfusion related complications and reactions, for example transfusion-related acute lung injury (TRALI), incompatible transfusion and bacterial contamination, which could be fatal to the patient. In this way, measures were developed and proposed to minimize the patients' reactions.

[44] The French term "hémovigilance" was coined in France in 1991, an analogy for the existing term "pharmacovigilance", deriving from Greek word "haema" meaning blood and the Latin word "vigilans" meaning watchful (de Vries, 2012).

[45] There is variation in the way the national haemovigilance programs operate. The scope of haemovigilance, or vigilance actions if not termed that way, has been notification of adverse or unexpected effects related to transfusion; the traceability of blood components, so that the complete transfusion chain can be pieced together for all blood components – without this element, adverse effect reports are no more than simple observations and case histories; and prevention of adverse effects, which depends on both of the previous procedures (Drouet, 2001). In 1997, the European Haemovigilance Network was founded and subsequently broadened in scope and renamed the International Haemovigilance Network in 2009. The European Union set provisions for certain aspects of haemovigilance (Faber, 2004). Directive 2005/61/EC6 implemented technical requirements regarding traceability and the notification of serious adverse events and reactions.

[46] See also Linden and Bianco (Eds.), 2001.

greater transfusion risks to patients were those associated with the medical practice in the hospitals. This was confirmed by data from the national haemovigilance programs. The regulatory efforts in shaping transfusion policy, in association with an increased research focus on the components of the product (the components the blood banks were processing), led to neglecting concerted efforts in other areas. These included the practices in the hospitals, donor management and blood usage, which were not easily assimilated into a product-based regulatory model.

1.3. The concept of risk: approaches

Conceptualizations of risk play a crucial role in the development and use of biomedical technology. Risks and uncertainties are considered pervasive aspects of daily life in modern societies, entrenched with the sociotechnical networks at place. In what follows, I present a brief overview of various perspectives on risk, then discuss the approaches to risk that have influenced the research undertaken in the context of this dissertation.

Changes in the meanings of risk are associated with the emergence of modernity (Lupton, 1999, p. 5). In the eighteenth and nineteenth centuries, statistics became part of risk, to measure the probability of gains and losses in the context of gambling, business and insurance (Dake, 1992). Risk now refers mostly to negative outcomes. A common definition of risk is the probability that an event with adverse outcomes may occur as a result of natural events or human activities in relation to the magnitude of its outcomes. Risk is an outcome-based concept denoting the use of preexisting knowledge to estimate the likelihood of the adverse effects. It is linked to efforts to modify the initiating activity or event, or to mitigate the impacts.

Since the 1970s, references to risk have proliferated in academic journals and practices devoted to risk analysis, risk assessment, risk communication and risk management (Lupton, 1999).[47] Techno-scientific approaches to risk, emerging from such fields as engineering, statistics, actuarialism, psychology, epidemiology and economics, begin from a defined hazard or danger that causes harm or loss of what humans' value. The calculation of probability is a necessary step to specifying the likelihoods of undesirable events. For these approaches, the importance lies in identifying a risk, defining the causal agent(s) and calculating the properties specified. Risk reduction policies can then be formulated. The calculation of risk resides with the individuals

[47] A useful, short overview of the conceptualizations of risk can be found find in Renn, 2008a, 2008b. For an analysis focusing on the social and cultural perspectives, see Lupton, 1999.

defined as “experts”. Meaning those who provide scientifically informed ways to measure the variables and show the directions of its possible mitigation.

The outcome in these approaches is usually termed as an “objective” or “real” risk.[48] This means risks preexist, and the models are used only to measure them. In these approaches, the measured risk is contrasted with the subjective views (or “perceived” risks) of those considered lay people (or non-experts). Those holding contrasting views are characterized as responding “unscientifically”, with views originating from non-legitimate sources of knowledge or even a lack of knowledge. This type of causal model to measure risk is the one used by the key actors in the story presented in this dissertation. They measure or estimate risk and they use produced estimates to conduct cost-effectiveness and cost-benefit analyses. In addition, some of the actors often use the distinction between real and perceived risks.

This distinction has also been at the focus of approaches from cognitive sciences. Psychometric studies seek to measure the factors that determine personal preferences and reactions to risk. Criticism to such approaches has been developed on many grounds (see Douglas, 1992). A commonly articulated one is that psychometric studies measure individual responses in an isolated context in which circumstances relating to risk are absent, as are the social relations that are part of attributing value to what is in danger.[49] An additional critique has to do with the fact that this type of research measures well-defined risks or objective risks, perceiving them as real. This position has also been criticized, as I show below.

Other types of criticism to what I present as techno-scientific approaches, following Lupton (1999), focus on a causality and interaction between human activities and consequences that are far too complex to be captured in models (Renn, 2008a). Many studies, from the social sciences and organizational theory, are published in the aftermath of disasters and accidents, seeking to situate these events in a broader spectrum of causes relating to the design and function of the sociotechnical systems (rather than trying to locate then in technical misses and individual errors). The work of Charles Perrow (1984/1999) are instrumental in this. Perrow covers sociotechnical systems such as nuclear power systems, giant oil tankers and large chemical

[48] See Adams, 1995, for the distinction between objective and perceived risk in the reports of the Royal Society (1982/1992).

[49] More refined psychometric approaches have been developed the past years, which have included the studying of groups instead of individuals.

plants.[50] Vaughan's (1996) sophisticated analysis of the Challenger explosion also shows how the technical factors of the explosion could not to be treated separately from the organizational culture of NASA.

Criticism in the 1980s also came from the disciplines of anthropology (Douglas & Wildavsky, 1982) and sociology (Beck, 1986/1992). Risks are social constructs, and cultural theory sought to understand how various groups formulated hazards into risks. In the macro-sociological approach, it is society *per se* that becomes a risk society, and risk is "as a *systematic way of dealing with hazards and insecurities induced and introduced by modernization itself*" (Beck, 1992, p. 21).[51] The literature offers a range of positions on risk, from relativist to realist. According to Lupton (1999, p. 29), risk is frequently talked about as if it is based on objective facts about dangers and hazards, amenable to rationalistic calculation, which are then mediated, perceived and responded to in particular ways via social, cultural and political processes. This may be described as the "weak" social constructionist thesis, which overlaps to some extent with those psychometric and psychological studies.

Proponents of constructivist approaches tend to argue that a risk is never fully objective or knowable outside of belief systems and moral positions. Summerton and Berner (2003) seek to understand the constructed nature of risks and hazards, or how the hazardous is constituted in contestations about risk and safety. Wynne argues that conflicts over risks should be understood within "the broader issue of how authority is generated and maintained" (1992, p. 276). Therefore, the "expert" knowledge producing "objective" risks has not been devoid of social and political considerations. Wynne (1983, 1995a) shows how the difference between the different risk assessments does not hold if the preexisting knowledge was shown to originate from social values; thus, what we measure, identify and manage as risks is always constituted via situated knowledges and discourses. The oft-used distinction between objective risk and risk perception does not, therefore, hold. Following this line of argumentation, risks cannot be conceptualized as an objective, quantifiable, context independent phenomenon; nor does it make

[50] Perrow (1999, p. 363) concludes that complex, tightly coupled, high hazard technological systems (those that are prone to normal accidents) should either be abandoned, drastically scaled down or drastically redesigned. Jasannof (2003) also observes that vast technological systems are not capable for prediction and control, questioning their operation as based on the faith of progress.

[51] For critiques of risk society from historical perspectives, see Boudia and Jas, 2007, and Fressoz, 2007. Boudia and Jas (2007) deploy an interesting critique of the questions for dealing with hazards that directed the political debate (experts and the rise of expertise through corresponding bodies/developmental procedures/risk in connection to capitalism and losses/compensation/learning from the past) following the adoption of the risk society.

sense to talk about the perception of such objective risks (Bijker, 2006). This approach to risk is heavily influenced by recent studies in the History and Sociology of Science and Technology and STS.

In this dissertation, the underlying hazards are considered as real in terms of the materialities involved. I would suggest that an additional type of analysis could focus on the deconstruction of the medical discourse with regard to risk and hazard/harm. The focus of my research was to capture the debates and to understand the positioning of the contrasting views. In doing so, the various (and competing) variables involved in risk estimates have been taken into consideration, while the relationship with harm was considered to be existent.

From the 1970s, John-Arne Skolbekken (1995) recognized an "epidemic" about references to risk in medical journals. Risk management practices were associated with the use of medical procedures and technologies designed to reduce risk, and to contain costs in health care (Gabe, 1995/2003). The notion of risk in medicine was associated with the emergence of the "risk factor" approach, obtaining a "scientific" character by the medical community through the use of statistics and quantification in the field of epidemiology (Aronowitz, 1998; Schlich, 2004; Skolbekken, 1995). "Risk factor" has been used as an umbrella term linking medical risks to individual choices.

David Armstrong contends that the language of risk entered into the everyday lexicon of medical practice at the point where the imperatives of health care moved beyond the treatment of bodily symptoms to understand and control social environments alongside an etiology of modern "diseases of affluence" (Armstrong 1995, p. 400). Risk management practices in health care can be seen as a further intensification and extension of processes of rationalization around the conduct of the individual and social body (Petersen & Wilkinson, 2008). Discussions on risk presuppose some preventive intervention; thus, the association of risk with policy again becomes evident. Since the mid-twentieth century, new technologies, procedures, and drugs have increasingly been evaluated in terms of risk. Risk plays a key role in this process, since whether a medical novelty gets accepted or not is, to a defining extent, the result of a process of negotiating its potential benefits and dangers.

Historian of medicine Thomas Schlich (2004, 2006) shows that a reductionist perspective, coupled with quantifiable data that reduces complex social relationships to measurable phenomena, is inherent in the mainstream technocratic approach in medicine. He proposes that "the concept of risk can be understood as a tool for dealing with uncertainty, but, like any other

tool, it is a tool that already embodies a whole range of political and moral values" (Schlich, 2006, p. 6). In discourses on risk, the non-neutral character of scientific knowledge also manifests itself in the assumption that risk involves only responsibility. This is a fundamentally political issue, since it involves ascribing the mandate and attributing the power to act on behalf of others. For Schlich, changes in the way risks are conceptualized lead to a redistribution of

> responsibilities for risks, change the locus of decision making and determine who has the right—and who has the obligation—to 'do something' about hazards. It makes a big difference whether the responsibility for unwanted side effects is seen to lie with the drug users, for example, or the manufacturers, or the doctors who prescribe them. Thus, risk discourses can be analysed in terms of their specific ways of distributing responsibility and ascribing trust (Schlich, 2006, p 7).

Framing potential dangers in terms of risks suggest that these are manageable. The way political problems are translated into technical ones is not always accepted by all those involved. The very act of quantification of ''actual risk'', for example, necessarily ignores all kinds of qualitative features that may be relevant for the social actors affected. It also tends to ignore the need for societal debate about all the factors involved in quantified factors. Scientists often forget that the complexity and multidimensional variability of real world problems requires real world rationality rather than statistics (Wynne, 1995b).

The theoretical framework I found especially useful while working on this dissertation was the one proposed by Stephen Hilgartner (1992). Hilgartner (1992) argues that even constructionist accounts tend to neglect the social construction of what he called "risk objects" (things, activities or situations to which harmful consequences are conceptually attached) or to examine systematically the construction of networks of causal attribution that links chains of risk objects to harm or danger. For Hilgartner (1992, p. 39), "[t]reating perceptions and definitions of risk as the dependent variable, the typical approach in psychological and social research, leads to a one-way analysis that neglects the dynamics of technological change. Perceptions of risk are not things that get tacked onto technology at the end of the day. Definitions of risk get built into technology and shape its evolution."

The first step is the definition of objects and their connection to the putative harm. That includes three elements: an object deemed to pose the risk, a putative harm, and a linkage alleging some form of causation between the object and the harm (Hilgartner, 1992, p. 40). The

object connected to the harm is what he calls the "risk object". The linkages between the object and the harm are part of the construction of risk by actors and social groups, and the definitions are not invariant, either historically or across social groups.[52] Thus, the second step is to construct linkages between the objects and putative harm. This process takes place within a sociotechnical network in which the technical and the social cannot be separated. The process of constructing a risk object "consists of defining an object and linking it to harm. This task is a rhetorical process, performed in texts that are displayed in specialized organizations or in public arenas, and it usually involves building networks of risk objects" (Hilgartner, 1992, p. 46). This process is often accompanied by conflicts that occur in specific areas or in public space; these disputes are about controlling the risk objects. Using Hilgartner's concepts, I suggest that, in the post-HIV era, the risk object as defined by the prevailing actors studied was blood. This risk object was constructed on the grounds of a possible release of infectious blood that could cause infections to the recipient (harm).

At a successive phase, explains Hilgartner, "[c]onstructing risk objects is a two way process, propelled by efforts to emplace risk objects within, and displace them from, sociotechnical networks. To emplace a risk object means to make the object, and -its risks, into significant actors in a sociotechnical network" (Hilgartner, 1992, pp. 48-49). In a dynamic process, struggles over the construction and control of risk objects take place constantly as sociotechnical networks change. This approach on risk leads to the understanding of the different political strategies for the control of risk objects, placing the emphasis on how the formation of the risk objects is associated with the promotion of political interests. Hilgartner (1992, p. 52) concludes that "[s]tudying risk objects offers a way to pry open networks of risk, and look at the dynamics of the process through which risks are created, controlled, and distributed. Research on the construction of risk objects can also contribute to improving risk management by revealing blind spots in the ways we conceptualize risk."

Drawing on this approach, I suggest that the debate over the use of genetic technologies in blood screening should be seen as a process of emplacement and displacement of the risk object. For several physicians and transfusion medicine professionals, the "scientifically" produced risk estimates were a way to displace blood as the risk object from the sociotechnical

[52] My theory was also influenced by Berner (2011), who examined the responses to the early HIV crisis in Sweden by looking at how actors relied on different situated forms of knowledge to arrive at different definitions of the "risk object".

network. However, this process was articulated in bounded calculations of costs and anticipated benefits. The regulatory body (FDA) promoted the control of the risk object based on the same premises of estimated risk to demonstrate the technical superiority of the new screening technology. Several specialized professionals had an opposite view regarding the control and the distribution of risk.

Anne-Maree Farrell (2012), professor of health law and society, examines the risk governance of blood systems in the aftermath of the HIV "political fallout" in different national settings in her book *The Politics of Blood*.[53] Her focus is on the regulatory responses. I refer to her work because she relates the prospect of zero risk to the recent transnational and national policies that focus on blood safety rather than holistic approaches about transfusion and patient management. In doing so, she refers to "stakeholder concerns" about adopting screening technologies of marginal benefit, like NAT (she does not refer to the debates before the establishment of NAT, but mostly notes the continuance of the discussions after 2000). To her, what appears "to be missing from arguments put forward in favour of the use of cost-effectiveness analyses [is] the extent to which other important ethical and socio-political values may necessarily impact on risk decision-making with regard to the adoption of new blood-related technologies, as well as healthcare interventions more generally" (Farrell, 2012, p. 192).

Farrell (2012) begins her analysis treating risk as a sociocultural construct that becomes the focus of regulatory bodies in the aftermath of HIV. I disagree, however, with her suggestion that the processes of regulatory control were led by the "politicization of risk". Such an approach assumes, misleadingly, that political and regulatory debates were irrelevant to the produced estimates of risk in general, and that risk did not encompass the political and social preferences connected with placing an emphasis on the technology.

1.4. Dissertation outline

1.4.1. Research questions

This dissertation presents research on the development and use of genetic technologies in blood screening. The use of these technologies in blood banks was debated at an international level. My research attempts to reconstruct the story of the development of these technologies by

[53] Coming from a different disciplinary interest, the work of Farrell (2012, 2013, 2015) has been unique and insightful regarding the way it analyzed the formation of the European transnational policy on blood.

focusing on the debates that took place in the US. Another goal of the dissertation is to examine the discussions over the use of NAT in Greece. Studying controversies and debates during the period when a new technology is being developed can be revealing about the multifaceted factors involved in that process. In this study, the central points of the discussion were related to risks. My analysis thus relied heavily on drawing the understandings of the debates based on contested views about risk.

The analysis of the debates and the contested argumentations demonstrate that there were many factors to be considered in association with the possible use of the new technology. By beginning from the principle of symmetry in explaining the success and failure of technologies, I question the assertion that technologies succeed because they are inherently better at tackling a problem. Their development and use is the outcome of a number of factors that may or may not produce success based on the contingency of prevailing claims of superiority made by various actors.

The research questions I seek to answer in this dissertation are:

Was the technology that prevailed inherently superior according to technical/scientific/medical criteria?

Which technical variables/parameters were arbitrarily privileged in estimates/calculations to present NAT as inherently superior?

Was there uniform support for NAT by transfusion medicine professionals?

What was the role of the state, and of the FDA as a key actor?

What was the role of the private sector?

What was the role of the media in the transition from ELISA to NAT?

What rhetoric surrounded the promotion of NAT?

1.4.2. Primary sources

To address these research questions, I undertook research that relied on various secondary and primary sources. I started by studying the secondary literature, and I read historical works about blood transfusion and related medical practices. In addition, I got information from the recent but already sizable literature on blood transfusion systems and the HIV crises. A broader spectrum of secondary literature that affected my research came from history and social studies of medicine and STS. I enriched my understanding about various theoretical perspectives about the concept of risk through the study of recent discussions on historical, sociological and STS perspectives on risk.

I present the development of molecular screening technologies to be used in blood banks by mostly focusing on the debates between physicians and transfusion medicine professionals. To do so, I became familiar with the field of transfusion medicine by examining a series of handbooks on haematology (particularly the parts about blood transfusion) and transfusion medicine for the period under study. In particular, I studied the consecutive editions of *Blood Transfusion Therapy: a Physician's Handbook,* published by the AABB (ed. 4, 1993; ed. 5, 1996; ed. 6, 1999; ed. 7, 2002). I also consulted the classic medical textbook *Blood Transfusion in Clinical Medicine*, first published in 1951 by the pioneering haematologist Patrick Mollison (ed. 8, 1987; ed. 9, 1993; ed. 10, 1997; ed. 11, 2005).

My main primary material was drawn from scientific papers and other publications by the transfusion medicine physicians and other actors who participated to the debates. I performed multiple searches in bibliographical databases.[54] I retrieved about 1,000 scientific papers from medical journals. Those closely associated with the field of transfusion medicine, which I examined thoroughly, were *Transfusion* (published by AABB), *Vox Sanguinis* (published by the ISBT), *Transfusion Medicine* (published by the British Blood Transfusion Society) and *Transfusion Medicine Reviews*. In addition, I studied many articles published in other medical journals, including *Biologicals, Blood Reviews, Transfusion Clinique et Biologique, JAMA: The Journal of the American Medical Association, The New England Journal of Medicine,* and *The Lancet*. I also studied the issues of the weekly newsletter of the AABB published between 1990 and 2001.

[54] To this end, an indispensable tool has been the exploitation of PubMed, a database that comprises over 25 million citations for biomedical literature from MEDLINE, life science journals, and online books. MEDLINE is the US National Library of Medicine (NLM) premier bibliographic database. For more, see http://www.ncbi.nlm.nih.gov/pubmed.

I also read press releases, news reports and relevant newsletters, and studied legislative documents (laws, orders and decisions, memoranda, recommendations and directives). Furthermore, I studied internal memos of the committees and agencies involved in health policy. My primary material also included proceedings of conferences, symposia and workshops.

During my fellowship at the History Office of the NIH, I had the opportunity to access key primary material. In the US National Library of Medicine, I retrieved the sources I had identified and which were not available digitally or otherwise accessible, such as the AABB newsletter. More importantly, I had the opportunity to acquire copies of important proceedings, such as the three-volume proceedings of the conference organized by the FDA in 1994 ("Conference on the feasibility of genetic technology to close the HIV window in donor screening", Silver Spring, MD, September 26–28, 1994).[55]

I supplemented my research with interviews conducted with actors who featured in the study presented. I performed several semi-structured interviews, each of about one hour's duration (recorded). On July 11, 2012, I interviewed Harvey G. Klein, MD, chief of the Department of Transfusion Medicine, NIH Clinical Center, Blood Bank in Bethesda. On July 28, 2012, I interviewed Roger Y. Dodd, PhD, Vice President of the Biomedical Services Research and Development, and Susan L. Stramer, PhD, Executive Scientific Officer, Biomedical Services, in the American Red Cross National Testing and Reference Laboratories, Gaithersburg. On August 2, 2012, I performed an interview with Indira Hewlett, PhD, chief of the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA, in Bethesda. I also benefited greatly from talking to Harvey Alter, MD, Distinguished NIH Investigator, Chief of the Infectious Diseases Section, Associate Director of Research, Department of Transfusion Medicine, NIH Clinical Center, and to Robin Biswas, M.D., Medical Officer, Division of Emerging Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

[55] I am grateful to historian John Swan, PhD, FDA, who assisted me in getting a copy of the proceedings. He introduced me to Dr John Finlayson (retired, Associate Director for Science, Office of Blood Research & Review, Center for Biologics Evaluation & Research, FDA) who provided me with a hard copy for inspection (and digital reproduction) and his office space. I am deeply indebted to Dr Finlayson for giving a tour of the Office of Blood Research & Review of the FDA, for explaining the way the FDA works to me, and for arranging for me to interview actors important to my research.

I used similar resources to study the introduction of NAT screening into the Greek blood transfusion service, including the following journals: *Haema, Archives of Hellenic Medicine, Hellenic Archives of AIDS* and *Iatriki*. This study led me to many relevant papers. I also searched health periodicals, for instance *Health Review.*

I paid special attention to the study of the relevant policy-making and law-making processes in Greece. I studied extensively the legislation about the blood transfusion service. For the period under examination, I scrutinized the parliamentary minutes of interest, which gave me vast material on official decisions, which I used to present the processes regarding the use of NAT in Greece in detail. An additional and prolific source was the periodical *Mediterranean Anaemia Issues*, published by the Panhellenic Association of People with Mediterranean Anaemia. In the last two chapters of the dissertation, I present my research regarding the public image of blood screening technologies in Greece. It is based on extensive research in newspapers, which I specifically present in Chapter 5.

1.4.3. Dissertation structure: reading guide

The dissertation contains seven chapters.[56] The first chapter introduces to the topic, the research questions, the primary sources used and the structure of the dissertation, while offering a synthesis of the relevant historical and STS secondary literature, especially the literature on blood screening technologies and risk. The second chapter relies on primary sources to reconstruct the story of the prevalence of genetic technologies of blood screening in the paradigmatic international context of the US. The second chapter shows that the turn to genetic technologies for blood screening represented a state investment that was questioned by many blood transfusion professionals.

To understand how questions by professionals were successfully sidelined, leading to the introduction of genetic technologies for blood screening, the dissertation turns to another paradigmatic case: Greece. Neither a third world country, nor one that belongs to the corpus of the world's richest countries, Greece made the transition to genetic technologies for blood

[56] I decided to use the APA style (6th edition) in writing this dissertation (with the exception of sections 5.3, 6.1 and 6.2, in which I chose to cite the primary sources in footnotes to make it easier for the reader). As this dissertation was written in English, I decided to follow American-English rules. However, for the words deriving from the Greek "haema" (αίμα), meaning "blood", I decided to retain the British/European spelling of "haema-" rather than the American "hema". Of course, many other stylistic choices have been made.

screening in the knowledge that the resources required would amount to the costliest investment made in the public sector of health.

A set of four dissertation chapters (relying heavily on primary resources such as reports and articles containing medical and journalistic perspectives) offers a critical account of this transition, bringing the complex interaction between the state, communities of experts and the press to the fore. The dissertation ends with a concluding chapter summarizing the answers to the research questions and pointing to ways to apply the Greek experience to enrich the understanding of the international case, and *vice versa*.

The author has already published parts of this research: Vlantoni, K. (2016). Ειδημοσύνη και Διακινδύνευση: Συνδιαμόρφωση στο πλαίσιο της Ιατρικής Βιοτεχνολογίας και Επιστήμης [Risk and expertise: on the co-shaping of medical biotechnology and science]. *Neusis*, *23*, 99-117 (in Greek); Vlantoni, K. & Morfakis, C. (2015). Η δημόσια εικόνα της βιοϊατρικής τεχνολογίας: η περίπτωση των τεχνολογιών ελέγχου του αίματος στην ιατρική των μεταγγίσεων στον ελληνικό τύπο [The public image of biomedicine: the case of blood screening technologies in transfusion medicine in the Greek press]. In S. Arapostathis, F. Papanelopoulou, & A. Tympas (Eds.), *Τεχνολογία και Κοινωνία στην Ελλάδα, Μελέτες από την Ιστορία της Τεχνολογίας και τις Σπουδές Επιστήμης και Τεχνολογίας* [*Technology and Society in Greece, Studies from History of Technology and Science and Technology Studies*] (pp. 259-282). Athens: Ekdotike Athenon (in Greek); Vlantoni, K. (2013). Βιοτεχνολογία, Ιατρική, Κοινωνία: Η κατασκευή της έννοιας της διακινδύνευσης κατά τη διαδικασία εισαγωγής μοριακών διαγνωστικών τεχνικών ελέγχου του αίματος [Biotechnology, Medicine, Society: the construction of the concept of risk during the introduction of molecular diagnostics in blood screening]. In E. Mergoupi-Savaidou, G. Merianos, F. Papanelopoulou & Ch. Christopoulou (Eds.), *Επιστήμη και Τεχνολογία. Ιστορικές και ιστοριογραφικές μελέτες* [*Science and Technology. Historical and Historiographical Studies*] (pp. 379-394). Athens: Ekdotike Athenon (in Greek).

Chapter 2

2. Debating Genetic Technologies in Blood Screening: Aspects of the International Experience

This chapter introduces the history of molecular biology technologies for use in a blood bank context to screen donated blood. It focuses on relevant discussions that took place in the paradigmatic case of the US. Selected European developments are presented to introduce the broader context. I present arguments by physicians, blood bank professionals and policy-makers from the field of transfusion medicine. In doing so, I introduce the use of genetic technologies in blood screening and the persisting debates surrounding the use of new screening technologies. First, I present some remarks about the scope of the study and the discussions about risk in transfusion medicine; then I focus on the discussions about the possible development of genetic technologies for blood screening. In the last section, I present the processes that led to the use of these technologies.

2.1. The prevalence of risk in transfusion medicine

2.1.1. Introductory remarks

My analysis starts at the end of the 1980s and continues until the period that NAT began to be used in the blood banks. NAT technology is the abbreviation of nucleic acid amplification testing technology, meaning gene-based, genetic, technologies of molecular biology that detect the genetic material of a virus in a blood sample. I referred in Chapter 1 to the complex organization of the blood supply in the US, the country on which I focus in this study. The US blood supply during the 1990s exceeded 12 million donations per year. About 18 million blood components were produced and ready for distribution on demand by a treating physician.

The aim of this chapter is to demonstrate the interplay of various actors during the development and use of a biomedical technology. To do this, I present the actors' opinions and positions, seeking to unravel the various factors that led to the adoption of a new screening technology in a particular setting. The story takes place during the years immediately following the worldwide HIV crisis, which was manifested to varying degrees in different countries. As

already said before, many studies focus on analyzing the decision-making processes during the early years of HIV/AIDS and their impact on the blood supply and the blood transfusion services in many settings. These studies have illuminated various aspects regarding the governance of the blood supply and the consequent attempts to address those institutional factors that contributed to what was named the "AIDS disaster", and to the political fallout from the crises. Although such studies have been intriguing and resourceful in pinpointing the complexity of the decision-making and regulating of the blood supply at times of uncertainty, to my knowledge there has not a been a study from the humanities and the social studies of science, technology and medicine to further examine the connection between the HIV crises and the use of molecular screening technologies.

The importance of this study lies in the fact that the debates over the development and use of molecular screening constitute a complimentary arena in which competing views were expressed, which can therefore add to the better understanding of the repercussions of the HIV crises. In this debate, the various actors presented their "scientific" opinions and their value judgments in direct relation to the discussions and policy-making efforts in the post-HIV era. The use of molecular screening represented a vast change in the blood banking laboratories, a costly investment and a decision that would have long-lasting effects. I decided to organize the presentation of the debates around the concept of risk, which overwhelmed the discussions about the operation of the blood banks and the then current state of the blood supply. I also chose to conduct this analysis by focusing in the US, although a global perspective cannot be avoided since there is a global trade of blood and blood products and a global market for biomedical technologies (global meaning mainly for the high-income countries).

The analysis focuses on the discussions regarding the risks associated with transfusion-transmitted infections. The relevant discussions deal with the efforts to better understand the risk of viral infections through transfusion; to measure the risk; and to propose ways of reducing it. To carry on from the notes presented in Chapter 1 about this study, many practitioners recognized the increasing importance of transfusion-transmitted infections to the transfusion medicine community in the post-HIV era. This was further remarked on by Perkins and Busch (2010) in an article published in the special issue of the 50th anniversary of the journal *Transfusion,* in which they document the number of publications focusing on transfusion-transmitted infections relative to the number of total publications. They note that the publications focusing on transfusion-transmitted infections "grew from just a handful of papers per year that represented a minor proportion of the journal's publications to more than 50 papers per year

representing 25% of articles appearing in *Transfusion* in the late 1980s and 1990s" (Perkins & Busch, 2010, p. 2080). The number of papers the articles rose slightly in the 2000s, and the percentage to the total publications became less significant as the total publications grew greatly. While this signified the intense interest in addressing blood safety concerns, and the concerted efforts devoted to it, which were associated with the subsequent use of NAT technology, an account of the debates that took place during the 1990s would be necessary to further demonstrate how this decision was made and to bring the contestations that occurred during that time to the fore.

From my reflections on the variety of haematology and transfusion medicine textbooks and handbooks that I came across (for instance Hoffman et al., 2005; McCullough, 2012; consecutive editions of Mollison's *Blood Transfusion in Clinical Medicine*), the presentation of the use of molecular screening was contextualized by presenting alternative blood safety initiatives to allocate the resources and concerns about the incremental safety benefit. This view could be contrasted to the way in which the use of NAT was presented in books aimed at clinical microbiologists and molecular biologists. In that case, I noted a narrow focus on the superiority of the new technology over "conventional tests" due to improved sensitivity (for instance, see Hu & Hirshfield, 2006; consecutive editions of AABB *Technical Manual*).

2.1.2. Considerations about transfusion-transmitted infections and risk

During the years after 1985, when the anti-HIV test was adopted in blood screening, the routine use of serologic testing and the continuous improvement of the tests' sensitivity in detecting viruses (combined with the establishment of strict donor selection criteria, deferring potential donors at risk and utilizing mechanisms of confidential self-exclusion of donors) led to the reduction of the risk of transfusion-transmitted HIV infection. A decrease in the incidence of anti-HIV positive donors was significant every year after 1985 (Menitove 1989). However, the possibility of HIV transmission was of major importance and crucial to the safety of blood, since there were recorded cases of post-transfusion HIV transmission after 1985, despite the universal screening of blood with ELISA anti-HIV testing (Donahue et al., 1990; Ward et al., 1988). At the same time, there was a marked decrease in post-transfusion hepatitis (HBV and NANB, named HCV in 1988). This was attributable both to the initiation of surrogate testing and to the

concurrent changes in blood donor selection procedures, which mainly targeted possible HIV-infected donors (Dodd et al., 1991). Screening tests for anti-HBc and ALT tests levels were implemented in 1986, as non-specific, surrogate tests for NANB.

In 1987, in the editorial of the journal *Transfusion*, Thomas Zuck, head of the editorial team of the journal between 1981 and 1987, director of Hoxworth Blood Center and professor of transfusion medicine at the University of Cincinnati, expressed his great concerns regarding the directions of the future policies to ensure the blood supply. Zuck (1987, p. 447) referred to the focus on achieving zero risk for transfusion recipients as the only approach that was "politically acceptable". He criticized this policy because he considered it was not achievable and futile. The years immediately after AIDS appeared as a severe and lethal disease and the association of HIV with blood transfusion had had an impact on the formation of new policies. Zuck (1987) suggested that a risk-reduction policy ought to depend on the established efficacy of a new procedure to be adopted. Zuck made these comments in connection with the development of a new test to detect HIV antigen, which had already been debated since its efficacy had not been proven (I will refer more to this test later). Zuck concluded that the dilemma about using a new testing technology based on its availability would be encountered again in the future; policy-making would thus have to take into consideration the documented benefits of further reducing low risk of HIV transmission, rather than acting in pursuit of zero risk.

From a public policy perspective, John Petricciani, deputy AIDS coordinator for the Public Health Service, and Jay Epstein, FDA, remarked that blood had become very much safer in the two years after 1985. Nonetheless, they argued, "the public and the scientific community continue to seek the elusive goal of risk-free transfusions and blood products. The challenge remains to develop forms of testing which can detect the AIDS virus prior to the development of antibodies" (Petricciani & Epstein, 1988, p. 241). They presented the general features of the disease and the biological events that occurred after infection with HIV to describe the rationale for the various types of laboratory tests (and consider its possible use as screening tests): those detecting antigens, antibodies, the genetic material of the virus, and T4 lymphocytes.

In early 1989, AABB organized a "Think Tank" meeting to discuss research opportunities in transfusion medicine for the following five years and the scientific issues of blood banking (Chernoff et al., 1989).[1] The participants remarked that a process had to be developed to

[1] The AABB Foundation organized the meeting. Scientists devoted to transfusion medicine were invited, as well as scientists from the federal government, from non-federal academia and from private industry. Six working

determine those measures needed to improve the safety of the blood supply. To this end, they argued, "among the issues to be considered in establishing this process are the futility of setting a zero-risk blood supply as public policy, the potential of regionalizing protective measures for some risks, and the minimum number of errors that is inevitable when more complex testing systems are implemented" (Chernoff et al., 1989, p. 724). The participants further considered the possibility of future mechanisms to enhance viral detection and of methods to inactivate or remove microbial agents potentially present in blood.

Specific approaches were proposed for the reduction of post-transfusion infections. In the case of hepatitis, the participants noted that, while post-transfusion incidence was reduced and the developent for anti-HCV test was underway, it was difficult to plan new strategies without knowing the current risks. To them, it was critical to initiate new prospective studies "that would define hepatitis incidence in the 'post-AIDS era' "; such studies were in progress for HIV (Chernoff et al., 1989). With regard to HIV, the participants called for research into viral inactivation methods. Until then, for the further reduction in HIV transmission, they identified the following approaches: 1) use of more sensitive HIV antibody assays, 2) tests for HIV antigen, and 3) the use of molecular probes in combination with gene amplification. They remarked that the latter, coming from the area of molecular biology, was not yet a practical approach, "but many feel that PCR can be adapted to widescale use in blood centers" (Chernoff et al., 1989, p. 728).

With regard to the development of newer diagnostic tests for the detection of HIV between infection and seroconversion, i.e. during the "window" period, serologic tests directed at detecting the HIV antigen (p24) became available. The antigen testing proved useful in the following settings: in predicting the course of HIV infection in seropositive persons; in monitoring the effectiveness of antiviral therapy; in early diagnosis of patients at risk when they present with an illness suspected of being acute HIV-1 infection (Busch et al., 1990). A screening procedure to detect the virus itself, like the antigen test, rather than to test the immune response to the virus (antibody), could reduce HIV transmission; its potential use in blood screening was thus considered. Since it had been demonstrated that the antigen could be detected in the blood

groups were formed to reflect the state of science in the following areas of interest: 1) blood and component collection and preservation, 2) blood products, 3) transfusion physiology, 4) transfusion-transmitted diseases, 5) alloimunization and its consequences, and 6) immunology. The members of the fourth working group, dedicated to transfusion-transmitted diseases, were Harvey G. Alter, MD (Chairman), NIH; Jean-Pierre Allain, MD, PhD, Abbott Laboratories; Friedrich Deinhardt, MD, University of Munich; Jay S. Epstein, MD, FDA; Thomas F. Zuck, MD, University of Cincinnati. The proceedings of the meeting appeared in Chernoff et al., 1989. An additional meeting was organized for the administrative think tank. For more see Malloy, McDonough, & Fuller, 1991.

sample a few days before the HIV antibody, two studies were performed in the US to examine the new test's effectiveness in blood bank setting (Busch & Alter, 1995).

The results of the studies were published in 1990. According to these, no positive samples tested with the p24-antigen test and negative with anti-HIV test were identified (Alter et al., 1990; Busch et al., 1990).[2] The same was also found in a study in Germany. At that point, therefore, it was argued that the antigen test would not help in reducing the transmission of HIV cases due to the "window" period of early infections. Mendelson and Sandler (1990) estimated, with the use a probabilistic model, that the probability of the HIV antigen testing detecting an additional HIV-infective blood component was 1 in 4,860,000. Each potentially preventable case of transfusion-transmitted HIV infection would cost approximately $18–24 million. Based on the studies' results, the use of available antigen tests for screening in blood banks did not advance.

Joel Solomon (director of FDA Division of Blood and Blood Products) addressed the AIDS Commission in May 1990 and stated that the FDA was involved in research on new HIV tests. However, the studies on HIV antigen testing did not prove that its use would alter the level of safety ("FDA Briefs AIDS Commission", 1990).[3] Moreover, he stated that the "FDA is still committed to the concept of an HIV screening test for a direct virus marker rather than for antibody." As proof, he cited ongoing research on gene detection by PCR, improved virus culture using genetically-engineered target cells, and increased sensitivity antigen tests ("FDA Briefs AIDS Commission", 1990). At the end of 1990, the FDA decided not to recommend routine use of the antigen test ("HIV Antigen Studies Published", 1990). As I will show later on, in the following years its use was re-evaluated.

Other approaches to reducing the risk of transfusion-transmitted infections were connected to a more careful examination of the suggestion to use blood components. It was recommended that physicians should consider and encourage the use of autologous donation where applicable (Chernoff et al., 1989; Dodd, 1992).[4] It was also proposed that physicians should

[2] The first was undertaken by the HIV-Antigen Study Group and was a large clinical trial to evaluate the new screening assay, following the FDA regulations. Alter et al. (1990) tested 515.494 blood units in 1989 without detecting antigen positive - antibody negative blood units. The second study, by Busch et al. (1990), was part of the Transfusion Safety Study (TSS), a larger study funded by NHLBI. The evaluation of the antigen test was performed by testing 8,597 units of blood collected in late 1984, selected because of characteristics indicating a high prevalence of HIV. Again, the result was no unit only antigen positive to be found.

[3] Congress established the AIDS Commission in 1988, a bi-partisan panel to advise the government on the AIDS epidemic and on other AIDS-related issues.

[4] Autologous donations did increase the years after 1983 (Surgenor, Wallace, Hao, & Chapman, 1990; Heaton, 1994).

be educated to avoid unnecessary use of blood transfusions and to reconsider the amount of blood transfused to a patient to reduce her/his exposure to risk (Chernoff et al., 1989; Cumming, Wallace, Schorr, & Dodd, 1989; Menitove, 1989).

I have mentioned that donor selection processes contributed to reducing the risk of viral transmissions. Following the introduction of new donor screening processes, studies were performed to assess them more concretely. Mayo et al. (1991) performed such a study, funded by the FDA, which led them to argue that the use of improved donor screening materials could reduce the number of donors with identifiable risk factors still further (persons described to be at risk for HIV). With regard to this study, Zuck (1991, p. 390) argued that, in the era of biotechnology when some advocated the development of automated technology in the genetic detection of HIV, "low-tech" solutions should again be considered. De Saussure, Yerly, Tullen, and Perrin (1993, p. 166) suggested "the importance of efforts aiming at the improvement of the nontechnical exclusion procedures." Their study in Geneva reported the detection of a seronegative donor (with a recent HIV infection) who was interviewed, and pointed to the failure of the donor screening process to exclude him.

During these years, the measures that were implemented had contributed to reducing the risk of viral transmissions; it was therefore important to "know" the current risk of transmission from screened blood to formulate new strategies for its further reduction. As has been stated above, the FDA was committed to the development of more sensitive tests for the detection of HIV, preferably detecting the virus itself. In the following subsection, I discuss the methods employed to estimate the risk of viral transmissions.

2.2. The emergence of genetic technologies and their possible use in blood banks

2.2.1. Specifying the window period and measuring/estimating risk

From the end of the 1980s, the risk of transfusion-transmitted infections decreased, posing a challenge as to how risk could be accurately specified or estimated. Michael Busch (1992, p. 22), scientific director of the Irwin Memorial Blood Centers and assistant professor in the Department of Laboratory Medicine at the University of California, posed the question: "Given the low level of risk, how do we document further reduction due to a proposed new measure?" Researchers in the field of transfusion medicine and from the area of public health policy put a lot

of effort into specifying the period before seroconversion, the "window" period, which was directly connected to the levels of the residual risk. During these years, a big shift emerged. This was the transition from empirical studies, which involved large epidemiological studies, to the use of mathematical models (Busch & Alter, 1995).

A large prospective study took place between 1985 and 1991, which provided direct measures of risk for transfusion-transmitted infections of retroviruses (HIV and HTLV). Patients undergoing cardiac surgery were recruited for the purpose of the study. Preoperative and postoperative serum samples of patients who were transfused blood were examined to identify possible infections (Cohen et al., 1989; Donahue et al., 1990; Nelson et al., 1992).[5] Even though the results were not drawn from nationwide research, the importance of this study was that it measured actual cases of post-transfusion HIV infections. The study identified two seroconverted patients (positive to HIV antibody) among patients transfused with 120,312 units of blood. The residual risk for HIV infection was estimated to be 1 in 60,000 (Nelson et al., 1992).

Another prospective study was undertaken by a research group in San Francisco, aiming to identify the rate of HIV-infected, seronegative donations by testing them further with laboratory testing methods considered to be of higher sensitivity (Busch et al., 1991).[6] This method was again a direct measure of the risk in donated blood issued for transfusion. The blood donations were collected between November 1987 and December 1989 and had been fully tested. With this method, the probability that a screened donor would be positive for HIV-1 was estimated to be 1 in 61,171, or 1 unit in 88,561 units of blood (Busch et al., 1991).

As said before, various approaches had been employed to estimate the residual risk of HIV transmission. The use of statistical models to estimate the risk was based on data on the incidence and prevalence of HIV-1 infection among blood donors, the reported sensitivity of the HIV-antibody screening test used and the length of the period from infection to seropositivity. These studies provided varying estimations. Dove (1987) provided a simple statistical calculation that suggested the risk to be 1 in 250,000 donations. Ward et al. (1988), provided calculations that included worst-case estimates of the proportion of repeat blood donors that were recently

[5] The study was funded by the National Heart, Lung and Blood Institute (NHLBI) to evaluate the effectiveness of serologic testing to blood donors. The study took place in Baltimore and Houston, areas with relatively high incidence rates of HIV infection. Interim results were published in 1989 and 1990.

[6] This study was also funded by NHLBI. Polymerase chain reaction (PCR) gene amplification and viral culture techniques were used in the research laboratory to detect blood units without detectable HIV-1 antibodies. The authors noted that these techniques were not practical for routine donor screening (Busch et al., 1991).

infected with HIV (incident cases) and represented a likelihood of having donated blood before the development of detectable HIV antibodies.[7] Their estimation indicated that as many as 460 recipients of screened blood could become infected annually, or a risk of 1 in 38,000 per unit transfused. Cumming et al. (1989) based their study on data from the prevalence and incidence of HIV among American Red Cross blood donors. Their median estimate for 1987 was that the probability of HIV infection from the transfusion of a unit of blood was 1 in 153,000 units. As one can note, these estimates differed significantly from one to another.

Another approach to estimate the infectivity of HIV seronegative blood was based on look-back investigations of recipients of HIV seronegative units collected from donors who subsequently developed positive anti-HIV tests (Kleinman & Secord, 1988). This approach was grounded on documented cases of HIV transmission by seronegative blood, which were examined to determine the rate of recipient infection and the duration of the "window" period. Kleinman and Secord (1988) calculated the risk of HIV transmission to be 1 in 68,000 units transfused. Petersen et al. (1994) utilized a look-back model to estimate the "window" period of infectivity in HIV-1 antibody negative donors. The researchers from the CDC and the American Red Cross used this estimation in combination with the rate of seroconversion in a large donor population, and produced a national estimate of the risk of HIV-1 infection in 1990 of 1 in 225,000 units transfused (cited in Busch, 1992, p. 13; Dodd, 1994, p. 4).

The low incidence of post-transfusion HIV infections, in combination with the large volume of the transfusions carried out, made direct measurements of risk a complex and demanding endeavor, both in terms of funding requirements and time. These different approaches were therefore explored, and resulted in varying estimates. Moreover, these studies provided estimates about the risk in reference to donor screening processes and blood screening in the past. Their estimates did not refer to present risk, and they were therefore of little value to the future because of the use of more sensitive tests and revised donor deferral criteria. Busch (1994b, p. 13) stated that "part of the problem is that the current risk of HIV infection from contemporary, screened blood transfusions in developed countries is so low that documentation of the residual risk is exceedingly difficult."

[7] This study identified cases of HIV transmission by antibody-negative donations and investigated 13 persons who were seropositive for HIV and who had received blood from 7 donors who had been screened negative for HIV antibody at the time of donation. The donors were interviewed to determine their risk factors for HIV. The researchers suggested that during the donor selection process the communication of the reasons for deferral to blood donors who were at high risk of HIV infection needed to become more effective (Ward et al., 1988).

Since measuring risk had become problematic, novel approaches were sought to evaluate proposed new measures and estimate their incremental benefit. The cases of transfusion-transmitted HIV infections were mostly due to donations given in the "window" period. Thus, a better understanding of the seroconversion was needed. Two large studies were carried out to define the duration and progression of seronegative HIV infection (some researchers participated in both studies). Petersen et al. (1994) estimated the time from the onset of infectivity to the development of detectable HIV-1 antibody by examining seropositive blood donors who made a previous seronegative donation at 40 US blood centers.[8] Using a look-back model that was combined with statistical analysis, the "window" period was estimated to be 45 days.

In the second study, Busch et al. (1995) collected selected samples of pre-seroconversion specimens that were known to have seroconverted, and tested them.[9] The specimens were tested with anti-HIV serologic tests (including third generation tests), p24 antigen tests, DNA PCR and RNA PCR, to compare the performance of the assays and the reduction in the window period achieved by each. The results determined the mean infectious window period as 42 days, with the anti-HIV tests used up to 1990. The third generation anti-HIV1/2 tests detected an infected unit 22 days after infectiousness, DNA PCR and p24 antigen assays at approximately 16 days and HIV RNA PCR at approximately 11 days. The window period estimates permitted them to project reduction of the risk by adding to donor screening direct virus detection assays, such as p24 antigen or PCR. Busch et al. (1995, p. 96) concluded that a precise definition of the seroconversion window was needed to enable more accurate estimates of the residual risk of HIV transmission from blood transfusions and the corresponding value of implementing new screening tests and/or virus-inactivation procedures.

With a focus on how to increase blood safety, and especially on how to reduce HIV transmission, updated estimates of the residual risk were required. To better estimate the

[8] The members of this research group were from the Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; the Jerome H. Holland Laboratory, American National Red Cross, Rockville, Maryland; the Irwin Memorial Blood Centers, San Francisco, California; the American Red Cross, Los Angeles-Orange county Region, Los Angeles, California; and the American Red Cross, Atlanta Region and South Florida Region.

[9] The members of the research group were from the Irwin Memorial Blood Centers and the University of California, San Francisco, California; the Centers for Disease Control and Prevention, Atlanta, Georgia; the Abbott Diagnostics Division, Abbott Park, Illinois; Johns Hopkins University, Baltimore, Maryland; the Hospital for Sick Children, and the University of Toronto, Toronto, Ontario, Canada; and the American Red Cross, Jerome H. Holland Laboratory, Rockville, Maryland. The study was supported by grants from the CDC, NIH, the Ontario Ministry of Health, and the National Health Research and Development Program, Health and Welfare Canada.

residual risk, the researchers had to measure the incidence of new HIV infection in the donor population. This endeavor would involve large-scale research in a country like the US, where about 12 million blood donations were collected per year. To further comment on the research efforts during this period, I should mention that, by the end of 1988, the NHLBI announced a multicenter, epidemiological research program focused on blood safety and human retroviruses. This was the Retrovirus Epidemiology Donor Study (REDS), which was projected to run up to 2003. The REDS group conducted various large-scale donor surveys and laboratory studies and developed a repository of saved samples (Zuck et al., 1995).[10] The REDS and the large-scale collaborative effort of CDC and the American Red Cross (Petersen et al., 1994) provided updated data on infectious disease incidence in donors. This data, combined with estimates of the "window" period, generated estimates of the residual risk that were published in 1995 and 1996 (I refer to these in more detail later).

As for the risk of transmission of the other infections agents, the research during this period was less concerted. The probability of HBV transmission was estimated to be 1 in 200,000 units of blood (Dodd, 1992). For HCV, a study showed a decrease in the post-transfusion HCV, following the introduction of the first generation anti-HCV test. The study directly measured the risk in transfusion recipients (Donahue et al., 1992). When the test was used, the risk of post-transfusion HCV was measured to be 1 in 3,300 units transfused. The subsequent use of more sensitive anti-HCV tests was expected to reduce it further. The risk for HTLV-I/II was measured at 1 in 70,000 (Nelson et al., 1992).[11]

As noted, the risk estimates for the transfusion-transmitted viruses were expressed in connection with the probability of a transfused unit being infected, rather than as a percentage of transfused patients infected. A further point to be taken into account is that official records of transfusion-related infections, although mentioned, were not considered accurate due to underreporting. It was also noted that many studies had demonstrated that an individual patient in need of transfusion was likely to die within one year of the transfusion, often due to the underlying disease (about 50% of those transfused). This meant that the patient would die before developing a disease transmitted by transfusion (Dodd, 19994). This affected some risk estimates

[10]The NHLBI had funded more studies that made available repositories of saved samples to study infectious complications of transfusions since the 1970s (Busch et al., 1999). The Transfusion Safety Study (TSS), which ran from 1984 until 1998, established a large repository of donor samples from 1984–1985, which proved valuable for the evaluation of screening tests for HIV and HTLV (such as for the evaluation of the p24 antigen test).

[11] Blood screening for HTLV began in 1988.

for HIV transmission, since it became known that AIDS was the end stage of the disease and that it took years before this became manifest. According to 1993 data, out of 6,311 transfusion-transmitted AIDS cases recorded in the US, 29 occurred after the anti-HIV screening had begun (Dodd, 1994). Similar considerations about the development of a disease to the recipient affected the estimates for the other viruses. For HBV, a chronic state of the disease would develop in about 20% of the recipients, and of those, only a small percentage would have serious clinical symptoms. For HCV, it was estimated that about 90% of the infections became chronic, and of those about 10–20% would develop clinical liver disease over approximately 20 years after transfusion.

In the beginning of the 1990s, transfusion medicine researchers and practitioners very often expressed in journal papers and other publications their assertion that the risk of transfusion-transmitted infection was lower than ever before. They recognized that intense political pressure was exerted to reduce it further (perhaps until it reached zero risk) due to great public concern about the safety of transfusions after the emergence of the HIV epidemic (Busch, 1992, 1994; Dodd, 1992; McCullough, 1993). Roger Dodd, head of the Department of Transmissible Diseases and later in charge of Research and Biomedical Services at the American Red Cross, commented that those "who are professionally responsible for the provision and oversight of the blood supply continue to add and improve measures to ensure its safety and adequacy; yet these efforts do not appear to satisfy the public or their representatives" (1994, p. 1).

I have already mentioned attempts to quantify the risk of potentially infectious blood donations with a focus on HIV transmission. This risk was considered by Ward et al. (1998) as "remote but real", and by Busch (1992, 1994b) as "extremely low" and "very low". Notably, when Busch et al.'s (1991) paper, entitled "Evaluation of screened blood donations for human immunodeficiency virus type l infection by culture and DNA amplification of pooled cells", appeared in *New England Journal of Medicine,* a reply was sent to the editor of the journal. Its author, Tessman (1991), questioned whether a residual risk of 1 in 61,171 could be characterized as "extremely low". Tessman (1991, p. 1743) argued that his evaluation of the subjective expression "extremely low" (after surveying 64 scientists) meant "a risk no greater than 1 in 100,000" in objective terms. This was significantly smaller than what was reported by Busch et al. Moreover, he questioned the estimation of the residual risk, since only one positive result was detected. The evaluation of risk was also considered by him to be problematic due to the greater risk in 95 percent upper confidence bound, which would be 1 in 10,695.

Busch, Perkins and Vyas (1991) replied that the confidence bounds around their estimate were wide because they observed only a single positive event, arguing that their point estimate was remarkably similar to that of other studies of the risk of HIV infection from transfusions. This observation led them to focus on that. More importantly, they argued that the choice of the words "extremely low" in reference to the risk estimate was made in relative terms. They considered the 1 in 61,171 ratio "extremely low" in comparison to, first, the 1 in 100 of HIV infection per unit transfused in 1982 and 1983 (before any screening measures were instituted), and, second, to ordinary everyday risks (Busch, Perkins & Vyas, 1991, p. 1747).

For many of the authors of the publications referred to in this subsection, the evaluation of the residual was considered in comparison with other risks, either medical or everyday. Based on the analysis above, it is necessary to add some comments. On the one hand, the risk of transfusion-transmitted infections was strictly defined by professionals in relation to risk calculations and measurements. This definition led to quantification. The risk was expressed as the quantified probability of a virus to be transmitted with regard to the total number of blood transfusions, or as the number of new post-transfusion infections. On the other hand, it was accepted that the "subjective perception of risk" by citizens (non-experts and lay people) was not in line with the "real, objective" measured risk. To them, this disregarded the extensive efforts in place to increase blood safety after the HIV crisis. Dodd remarked that there was a need to inform the medical community and the public about "a realistic assessment of the risk of adverse events following transfusion" (Dodd, 1994, p. 2). He and other prominent transfusion medicine professionals expressed sharp criticism in positioning the objective of achieving zero risk as the primary goal in the public sphere.

In connection with the proposals for the reduction of risk, it was widely accepted that the sensitivity of serology screening methods had been improved. The future possibility of using new diagnostic technologies, such as those for the genetic detection of viruses, was recognized. Another proposal was to focus on developing methods for viral inactivation for cellular blood components, as had been done for the plasma derivatives. In addition, changes in the donor selection process were examined. In this context, behavioral studies took place to promote changes in blood donor selection that would target the reduction of risk.

Concurrently with this discussion, there was a debate about the cost-effectiveness of new medical interventions, since the limited resources available for public health policies ought to be allocated in effective interventions, with demonstrated public health benefit. Regarding the

decision not to proceed with the introduction of testing for HIV antigen, Busch commented that "if someone considers the prioritization of limited health care resources and recognizes our professional and ethical responsibilities to donors as well as recipients, one could conclude that implementation of this test would be inappropriate" (1992, p. 30).

In most cases, many stakeholders emphasized that it should be essential to have more specific studies about the estimated cost-effectiveness and the impact of the proposed measures to address the reduction of risk (Busch, 1994, p. 17; McCullough, 1993, p. 2243; Perkins, 1992, p. 146). It was clear that the proposed interventions at that time had very small marginal benefit. Thus, transfusion medicine specialists and professionals of blood banks, defined as experts in their field, contributed to the production of updated scientific knowledge. These endeavors mostly focused on the calculation of risk and the specification of the "window" period. The knowledge produced was not accepted equally when they expressed their opinion about the calculated risk in relation to the expected benefit for public health, suggesting different strategies to increase transfusion safety.

With regard to the decision-making processes, according to Herbert Perkins (1992), professor of medicine and chairperson of the Irwin Memorial Blood Centers in San Francisco, given the organizational structure of the US blood supply, transfusion medicine and blood banks professionals were directly involved in shaping policies. Perkins (1992) draw on his experience to remark that the groups which influenced decision-making in transfusion medicine were the following: a) the public, b) legislators, c) the media, d) the federal government (the relevant organizations CDC, FDA, NIH), e) lawyers (and legal precedent) and f) transfusion medicine experts (1992, p. 128). According to Perkins, the fact that transfusion medicine specialists played a major role in making decisions related to blood safety had both advantages and disadvantages (1992, p. 134). The fact that they had a deep knowledge of the scientific and practical matters of their profession was of great importance to policy-making, but it meant they were potentially biased because of their direct involvement in the operation of blood banks. Their role was described by some as biased, especially when they argued against decisions that burdened the blood banks' operating costs, as with the proposal for surrogate testing in the early years of AIDS (Galel, Lifson & Engleman, 1995, p. 217; McCullough, 1993, p. 2244; Young, 1995, pp. 47-48).

2.2.2. The role of the FDA and the 1994 Conference

In the 1990s, the routine screening of donated blood was performed with serologic screening assays. For HIV, the enzyme-linked immunosorbent assays (ELISA) assays for HIV-1 antibody were used for diagnostic purposes and for blood screening, after being licensed by the FDA. The first screening assay was developed in 1985; since then, assays that were more sensitive were produced. After 1992, combination HIV-1/2 assays were introduced, referred to as third generation assays, a designation inferring that these assays represented different generations of increasing sensitivity (George & Schochetman, 1994). As mentioned above, the use of such assays narrowed the "window" period and reduced the risk of HIV transmission (Busch, 1994a). Tests detecting the HIV antigen (p24) were useful in clinical settings, even though their use in blood screening was considered of little value (George & Schochetman, 1992).

By the end of the 1980s, further research on the characteristics and progression of HIV was available, associated with the development of ways to detect directly the virus, mainly with virus culture and PCR. In the study of HIV, the use of PCR had demonstrated clinical and research utility for the direct detection and quantification of HIV DNA and RNA from cells of infected person, including seronegative persons; for typing HIV infections (type 1, 2 and later 0); for early diagnosis of perinatal transmission; and for resolving indeterminate testing results with western blot or other confirmatory tests (Schochetman & Sninsky, 1992).

Research laboratories in Europe and the US had demonstrated that HIV DNA and RNA were detectable before the antibody (see, for instance, de Saussure et al., 1993; Horsburgh et al., 1989; Yerly et al., 1992). It is of importance to note that researchers in the Laboratory of Molecular Virology at the FDA had also undertaken work on the PCR amplification techniques to detect HIV (Hewlett, Ruta, Cristiano, Hawthorne, & Epstein, 1989; Nedjar, Biswas, & Hewlett, 1991). Nonetheless, the use of PCR or other gene amplification techniques was too complex, labor- and time-consuming to be used routinely in the laboratories of blood centers. Busch noted that "several significant problems and questions remain to be resolved, however, before PCR or alternative nucleic acid amplification techniques are seriously considered for donor screening" (1994a, p. 233).

In September of 1994 the FDA organized a conference entitled "Conference on the feasibility of genetic technology to close the HIV window in donor screening" (Silver Spring, MD, September 26–28, 1994). According to the organizers, "experts" from the blood supply system had been invited, meaning scientists from public health services, blood banks, academic centers

and universities, and representatives from pharmaceutical companies, hospitals, and patient advocacy groups (FDA, 1994, vol. 1, pp. 8, 10). As specified in the program, the focus of the three-day conference was on finding ways to make genetic detection technologies commercially available to use in blood banks and blood centers. Thus, many of the presentations in the conference discussed the multiplex issues surrounding the development and use of technologies for the genetic detection of viruses, mostly referring to the HIV as the title of the conference implied.

To take the story from the beginning, the conference commenced with the speech of the FDA deputy Commissioner Mary Pendergast, who stated that "the HIV window has to be closed and the best way to close it, we believe, is by developing a commercially-viable test for viral detection (...). [The barriers] can be overcome if we find a way to mount a coordinated effort by the many groups in the health care community, and that is why we have called this Conference" (FDA, 1994, vol. 1, pp. 7-8).

The Commissioner of the FDA, David Kessler (term 1990–1997), presented the rationale of the conference. Kessler said that, when "confronted with the knowledge that science has developed new molecular methods to detect viruses themselves, knowing that the window period continues to pose risks for the blood supply, and still lacking commercially-available tests sensitive and specific enough to screen directly for HIV, I [he] personally asked FDA Center for Biologics to convene a group of experts to explore promising new technologies" (FDA, 1994, vol. 1, p. 10). The aims of the conference could be summarized in his following statements:

> We absolutely want this technology to advance if it has merit. In the end, we want and expect nothing less than the ability to detect sensitivity the HIV itself in mass screening centers. We want to eliminate the HIV window. (…) We want to encourage the development and commercialization of useful techniques for direct viral detection. We want to encourage these advancements not only to eliminate the HIV window, but to enhance our ability to deal with infectious agents that may be discovered in the future. The public health of this Nation deserves nothing less (FDA, 1994, vol. 1, pp. 20-21, 24).

Kessler highlighted the importance of the use of genetic screening techniques in blood banks for the benefit of public health. He further asked the transfusion medicine professionals not to focus on risk "estimates" of HIV transmission, regardless of the risk being 1 in 60,000, 1 in 200,000 or 1 in 400,000 units. These, to him, were "just estimates of risk". Kessler also stated that

the FDA disagreed with the concerns regarding the poor cost-effectiveness from the possible use of genetic screening.

The first sessions of the conference were devoted to the presentation of the current situation about the transfusion-associated transmission of HIV. The blood screening strategies to reduce the risk of HIV transfusion-transmitted infection were discussed at length. To be more specific, the speakers presented the latest evidence, gathered from the time when the use of the third generation anti-HIV1/2 ELISA screening tests had begun. The implementation of these tests led to the reduction of the "window" period from about 42 days to 22. The estimations, at that time, projected that the testing for p24-antigen would further reduce the "window" period by 5 to 6 days. The same reduction was estimated with HIV DNA testing, while, the testing for HIV RNA would reduce the seronegative period by 11 days (combination of data from the presentations of Busch, Dodd, and Peterson: FDA, 1994, vol. 1, pp. 57, 63, 93-95).

During the sessions, several issues were discussed relating to the development of genetic testing, with the PCR or another molecular method. For example, a question that arose was whether the new tests would replace serologic techniques, something that was not considered feasible. Furthermore, some participants queried whether genetic testing could lead to achieving the objective of zero risk, something that was also rejected. In addition, a topic discussed was the possibility to screen blood samples individually or grouped in pools (single-donation testing versus mini-pool testing); (mini-)pool testing was unprecedented in blood screening with the serologic tests.

During the conference, various techniques of molecular testing were presented, with greater emphasis on the PCR technique.[12] Representatives from the pharmaceutical industry and researchers who had laboratory experience of using genetic detection techniques focused on the technical challenges regarding their possible use in a blood bank setting. The main problems identified in connection to the prospective use in massive blood screening were related to the cross-contamination of the samples with viruses during testing and to the lack, until then, of (semi- or fully-) automated equipment to conduct the various steps of the testing. The generally

[12] The company Roche had obtained the patents regarding the PCR from Cetus Corporation. In 1992, Roche released a new licensing policy, providing laboratories with access to PCR to spur development of new or improved tests for genetic and infectious diseases and "to facilitate PCR's further domination of amplification technology" ("News Summaries", 1992). The other molecular methods considered were ligase chain reaction, nucleic-acid based sequence amplification, strand displacement amplification, branched DNA and transcription mediated amplification.

accepted assessment, as expressed by the representative of the diagnostics company Probe Diagnostics-Abbott, was that in the following three to five years it would become possible to develop automated infrastructure for the genetic amplification technology to be used in blood banks (FDA, 1994, vol. 3, pp. 183-184).

Dr Indira Hewlett, chief of the Laboratory of Molecular Virology in CBER at the FDA, gave a presentation entitled “PCR-based applications for the detection of HIV”. She talked about the laboratory research efforts at the FDA on understanding PCR methodology, about its technical modifications and about issues in assay optimization and development (FDA, 1994, vol. 2, p. 74). The research focus was on exploring the possibility of developing an assay detecting the HIV RNA in plasma and serum, and on developing a multiplex amplification assay to detect more than one viral agent. The research undertaken within the FDA, which had demonstrated the possibility to close the “window” period, was the driving force for the organization of this conference and for the further push on developing commercial molecular screening systems. The commitment of Kessler, and the FDA as a whole, was key to the subsequent use of the technology.

The intention of the organizers to encourage the development of genetic testing technology was also reflected on the third day of the conference, which focused on patent issues, technology transfer, licensing issues and guidelines for validation of nucleic acid based assays for HIV. To be more specific, in the dedicated session, the legal framework was presented for patents in the US, with examples of the use of PCR technology in tests in blood banks. The process of licensing screening tests from the competent authority had been described as meticulous and time-consuming, especially in comparison to that of diagnostic tests. With regard to the process of commercialization and licensing of new screening assays, the prospect of building synergies between companies and the FDA was provoked. Jay Epstein, acting director of the Office of Blood in CBER at FDA, answered many questions in the closing session about tackling obstacles that would delay or prevent the introduction of genetic technology in blood banks (FDA, 1994, vol. 3, pp. 132-133).

Let us now turn to the opinions expressed by transfusion medicine professionals. At certain points their view was critical to the future adoption of molecular screening. Harvey Klein, director of the Department of Transfusion Medicine and the Blood Bank at the NIH Clinical Center, was as hesitant as other blood bank professionals (personal communication, 11 July 2012). Their hesitance was partly related to possible problems during the implementation of new screening technologies in the blood banks. This implementation meant a vast change in laboratory practice,

which demanded new equipment, staff training, and other costly changes, such as the interconnection of information systems. Concerns were also expressed by some physicians about the susceptibility to making errors due to additional screening tests. The reluctance of several physicians was, however, considered an expression of complacency due to the advances in blood safety up to that point (H. Klein, S. Stramer, personal communication).

I have already mentioned that one of the main objections to the development and use of molecular screening assays came with concerns about the anticipated benefit. It was not a given that adding a costly screening test, which was estimated to have minimal marginal benefit, would adequately address priorities in public health. During the discussions on the final session of the conference, Lyle Peterson, the representative of CDC, emphasized the disparity between the cost and the anticipated benefits provided by the reduction of transfusion-transmitted infections:

> The cost (...) would be about $200 million a year, which is about $10 million per life (...). This is far greater than the increment -the cost per life saved in other regulatory decisions by the government. The $200 million figure, I'd like to also add, is about equal to the cost that CDC is incurring per year for all HIV prevention strategies combined. So this would mean that the cost of saving the 10 or 20 additional transmissions is equal to the cost that we currently spend to save the other 39.990 that occur per year by other routes (FDA, 1994, vol. 3, pp. 199-200).

In his final speech, Busch stated that the conference had left him with a dichotomous view. First, he expressed his enthusiasm about the innovation in the development of the new technology and its possible use, but then he said

> As an individual (...), both scientist and health care consumer, I think the cost benefit equation is way out of line and that it would be a real inappropriate action to recommend moving forward toward implementing these technologies. I think our efforts should be directed rather than toward closing the window, toward filling what I see as a canyon between the perceived risk on the part of the public and the actual risk and the perceived benefit of adding these technologies would achieve versus what I think would be the actual benefit of implementing these tests (FDA, 1994, vol. 3, p. 201).

Busch and other participants stressed the importance of better communication to the citizens of the data regarding the risk of transfusion-transmitted HIV infection and the small anticipated benefit from the new screening technology. To them, the political pressure ought not focus only

on this issue. More beneficial interventions in the health sector (including transfusion medicine) were a priority.

A report of the conference was published in the journal *Transfusion* in March 1997 (Hewlett & Epstein, 1997). Reading this report confirms that the view of the head the FDA, as expressed over the course of the conference, had a significant impact on accelerating the development of commercial molecular screening technology. The conference as a whole demonstrated the strong commitment of the FDA to assist in making genetic screening commercially available for blood screening. According to Busch, Stramer and Kleinman (1997, pp. 161, 165), Kessler's commitment for the use of genetic screening shifted the balance because as late as in 1994 “the balance of opinion opposed the eventual introduction of nucleic acid amplification assays. Now [1997] the decision to implement NAA screening of blood and plasma donors is unequivocally supported”. The same authors thought that the decision “was made despite a lack of data establishing the efficacy of such testing with currently available technology, and without thorough consideration of cost-benefit analyses or parallel developments of virus inactivation procedures for cellular blood components” (Busch, Stramer & Kleinman, 1997, p. 165).

2.2.3. Calculating risk and safety / Calculating cost

The political determination of the FDA, as expressed in the course of the conference, led to a revision in 1995 of the previous decision (of 1990) regarding the use of the p24 antigen test. New data, as presented in the 1994 conference and in scientific publications, provided refined estimates of the seronegative period and the estimated shortening of the “window” period by its use. In addition, the retrospective testing of four cases of HIV transfusion-related transmissions, in which the p24 antigen test was found positive, further supported the opinion of those in favor for its use. Moreover, only antigen positive HIV blood donations had also been detected in Thailand, a country, though, with higher HIV incidence compared to the US (Busch & Alter, 1995).

In February 1995, the AABB board of directors recommended the licensing of the antigen test as a screening test for use in blood banks (“AABB Releases”, 1995). Then, in August 1995, the FDA issued a memorandum to recommend donor screening for HIV-1 antigen(s) (the recommendation was issued in advance of the approval so that blood and plasma establishments could prepare for the implementation) (FDA, 1995). The FDA made this decision even though the BPAC (Blood Products Advisory Committee) had advised against introducing the test in routine

screening ("BPAC Fails", 1995). In particular, 9 of the 15 BPAC members present at the meeting on 23/06/1995 were of the opinion that donor screening for HIV-1 antigen was not likely to provide a significant public health benefit, one that would outweigh the potential risks.

According to the FDA, the reasoning behind the introduction of the antigen test was that it would be a safety measure against the possibility of any increase in HIV-1 "window" period donations and would decrease the virus burden in plasma pools for fractionation. Moreover, the FDA considered this to be an interim measure "because HIV-1 antigen testing will only reduce but not eliminate the residual risk of HIV-1 from transfusion (…) pending the availability of better technology for this purpose. FDA encourages continued development of new methods to further reduce the risk of HIV transmissions" (FDA, 1995). In the memorandum was noted that the conference that took place in 1994 indicated that the technology of genetic detection, although capable of HIV-1 detection prior to seroconversion, were not ready for use in mass screening. Nonetheless, the conference had sparked interest in considering other direct viral detection methods for donor screening, like the antigen testing (FDA, 1995).

Soon after the aforementioned meeting of the BPAC, the FDA decided to release most of its members and reconstitute the BPAC committee ("FDA Releases Ten", 1995).[13] This decision was made in the process of reconstituting all the FDA advisory committees, but only the members affiliated with blood banks and blood centers were dismissed. In the announcement of the FDA, it was noted that there was a conflict of interests from those members, those from blood banks and blood centers, and a single "industry" representative would replace them. Greater representation would be sought from university affiliated transfusion medicine specialists and consumers ("FDA Releases Ten", 1995). The president of the AABB, Jane Mackey, expressed the association's concern on this decision and noted that the recent vote of the BPAC on the HIV p24

[13] Concerns regarding the over-representation of industry representatives on the BPAC of the FDA had been expressed in the past, for example in July 1991, when the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (chaired by Rep. John D. Dingell [D-MI]) began a series of hearings "on the present and future safety on the blood supply". The committee wanted to investigate whether the blood supply system and its regulators were able to ensure blood safety in the aftermath of the HIV crisis ("Dingell Hearing Faults", 1990). The same committee in 1993 asked FDA Commission D. Kessler about what they described as poor oversight of the blood industry from CBER ("FDA Oversight", 1993). In January 1995, J. Epstein, acting director of CBER Office of Blood Research and Review, said that the BPAC was a communication tool between the FDA and industry, and that the FDA was broadening the representation on the committee beyond the industry ("IOM Forum Focuses", 1995). Epstein presented his views at one of the workshops organized in 1995 by the Institute of Medicine as part of the Forum on Blood Safety and Blood Availability. This was a means to provide an environment to discuss these topics in four workshops; these resulted in three monographs, which included overviews of the presentations.

antigen issue reflected a split in the blood collecting and transfusing community. She argued there really was no single voice from the "industry" ("News Summaries / Regulatory", 1995).

During this period, the FDA had been under increased Congressional scrutiny following criticism of the agency's actions during the early years of AIDS. This resulted in a tougher regulatory approach, following a reorganization in 1992 (McCullough, 1993). In July 1995, many ongoing processes at a federal level impacted on the FDA's decision-making. On July 12, 1995, Christopher Shays (R-CT), the Chairman of the Subcommittee on Human Resources and Intergovernmental Relations of the Congress, addressed a letter to Commissioner Kessler, "urging" him to not accept the BPAC recommendation and to license the antigen tests (Shays, 1996). He said the BPAC decision was "illogical" and suggested disbanding the committee.[14] The following day, the report that investigated the HIV transmissions during the early 1980s was published.[15] The IOM report was critical to the actions of the FDA and other federal organizations at that time (Leveton, Sox & Stoto, 1995). Secretary of Health and Human Services (HHS) Donna Shalala (Department of Health and Human Services, HSS) responded to the report by taking a number of initatives in the name of ensuring proper blood supply.[16] It was thus in this climate of public scrutiny and political pressure that the FDA did not accept the BPAC recommendation

[14] The letter was very critical of the decision of the BPAC. Shays further remarked that the FDA had failed in the past, in the early 1980s, and that this should not be allowed to happen again. The letter ended by reminding that Kessler had stated in September 1994 that "we need to close that window", and that he now had the opportunity to do so (Shays, 1996).

[15] In April 1993, in response to concerns voiced by the community of people with haemophilia, Senators Edward Kennedy (D-MA) and Robert Graham (D-FL), and Representative Porter J. Goss (R-FL), requested the Secretary of Health and Human Services Donna Shalala to open an investigation into the events leading to the transmission of HIV to individuals with haemophilia from contaminated blood products. The Secretary agreed, and the Department of Health and Human Services requested the Institute of Medicine (IOM) to establish a committee to study the transmission of HIV through blood supply. As a result, the Committee to Study HIV Transmission through Blood and Blood Products was formed. The report *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking*, edited by Lauren B. Leveton, Harold C. Sox, Jr., and Michael A. Stoto, was published on July 13, 1995.

[16] The Committee on Government Reform and Oversight's Subcommittee on Human Resources and Intergovernmental Relations initiated an investigation into the safety of the blood supply in April 1995. The subcommittee sought assurance that the US Department of Health and Human Services' Public Health Service (PHS) agencies, particularly the FDA, were aggressively maintaining safeguards to detect emerging infectious agents and to eliminate blood-borne pathogens from the Nation's blood supply ("Protecting the Nation's", 1996a). Secretary Shalala had created a task force of PHS agencies (FDA, CDC, NIH) to evaluate the recommendations of the IOM report and develop an implementation plan. The hearings were held on October 12, 1995 and November 2, 1995. At these hearings, the HHS Secretary Donna E. Shalala announced the response to the IOM report recommendations. HHS officials then decided to create a Blood Safety Committee consisting of the CDC Director, the NIH Director and the FDA Commissioner ("Protecting the Nation's", 1996b). The committee would be chaired by the Assistant Secretary for Health, and would be advised by the Advisory Council on Blood Safety and Availability, which would include representatives of industry, consumers, scientific experts, and ethicists.

against routine HIV-1 antigen screening, and put forward the licensing of the test and its subsequent use. According to Dodd, Stramer and Klein, this was a political decision (personal communication).

In December of 1995, a multi-authored paper based on the collaborative research of CDC and American Red Cross reported on the estimated risk of transmission of the HIV by screened blood in the US (Lackritz et al., 1995). The paper did not directly measure the risk, as noted before, but it provided a calculated estimate that encompassed the use of third generation anti-HIV assays. It was based on an average "window" period of 25 days. The calculations on the incidence of HIV were performed on data of more than 4 million blood donations collected by the American Red Cross across the US in 1992 and 1993. Their estimation of the residual risk of HIV transmission was from 1 in 450,000 screened donations to 1 in 660,000. On a yearly basis of 12 million donations in the US, it was estimated that 18 to 27 units could result on HIV infections.

The authors noted that the estimated risk was "very small". In the conclusion, the authors of the paper commented on the recent decision of the FDA to recommend the p24 antigen testing. Since the risk was considered very small, "new interventions will be of decreasing benefit, particularly in areas where the probability of a window-period donation is too small to be quantitated" (Lackritz et al., 1995, p. 1725). Their estimate was that the antigen testing would detect four to six infectious units per year.

Schreiber, Busch, Kleinman, and Korelitz (1996) published the findings from the large-scale Retrovirus Epidemiology Donor Study (REDS) on the risk of transfusion-transmitted viral infections in June 1996. This study provided estimates for the major agents transmissible by transfusion (apart from HIV for which recent estimates had been published, also for HCV, HBV and HTLV. The estimates were founded on the same model like the study of Lackritz et al., a model that became known as the "incidence rate/window period model". They calculated the incidence rates of seroconversion of screened blood donations (in this cases by using data on half a million donors and in total more than 2 million units of blood between 1991 and 1993). The estimate was multiplied by the length of the "window" period. This way, the probability that a potentially infectious unit of blood would be released in the blood supply was taken into account during the calculation (the residual risk). Of course, each research group would make adjustments based on the several factors used in the model to calculate the residual risk, so the estimates came with limitations.

The study indicated the following mean residual risk estimates: for HIV, 1 in 493,000; for HTLV, 1 in 641,000; for HCV,1 in 103,000; and for HBV, 1 in 63,000. Thus, HBV and HCV accounted for 88% of the aggregate risk of 1 in 34,000 units (Schreiber et al., 1996). In addition, the authors estimated the mean risk reduction by projecting the results to reduced “window” periods from the use of more sensitive screening tests. For HIV, the use of the antigen test or DNA PCR test would reduce the 22-day “window” period by 6 days, resulting in the detection of 7 infectious units among the 12 million units collected annually; the RNA PCR would reduce the “window” by 11 days, detecting 12 units. For HCV, the RNA PCR would reduce the “window” period by 59 days with a projected yield of 84 units. For HBV, with the DNA PCR the estimated reduction in “window” period was 25 days and the yield 81 units of blood.

The authors commented that the use of nucleic acid screening assays would “substantially reduce the residual risk” of transmitting infectious disease by transfusion; however, it would have a “limited effect” on HIV compared to the greater effect on HCV and HBV (Schreiber et al., 1996, p. 1688). They also argued that the use of the serologic and molecular tests was complementary, while the use of the latter would not actually achieve zero risk. They concluded that “the yield and cost effectiveness of new, direct assays for virus will be low, and decisions about their implementation will be difficult, given the many demands on health care resources” (Schreiber et al., 1996, p. 1689). This paper has been recognized as a seminal ever since its publication. Its estimates regarding the residual risk were cited in many following papers, and its approach served as the basis for future research. The paper was widely accepted as the outcome of a large, collaborative research project (REDS) of well-recognized scientists.

The discussion regarding the possible use of the new screening assays in comparison to the projected costs continued. In a paper published in 1996, Dodd observed that "such technology is unlikely to meet current norms for cost-effectiveness, at least in the US" (Dodd, 1996, p. 2). The complexity of decision-making in the field of transfusion medicine was growing as the risk was diminishing. Since a number of measures to promote safety were initially promoted as supplementary to the ones already established, their value had to be weighed against many considerations, in addition to the direct costs of additional or more technologically demanding tests. These were the wastage of discarded blood and unnecessary loss of potential donors due to false-positive results, and the importance of transfusion-related illness prevented (Sloand, Pitt,

& Klein, 1995).[17] Many protagonists argued that the decision of whether to implement additional tests should be made in the context of examining the benefits that might be achieved if comparable resources were allocated to alternative strategies. This context was not institutionally established in the US.

James AuBuchon, professor of medicine at Dartmouth College and medical director at Dartmouth-Hitchcock Medical Center, published several papers on this topic during this period. Seeking to become more specific, he suggested that decision analysis techniques could be appropriated in transfusion medicine to identify those measures worthwhile the commitment of resources, at a time when considerable additional resources were needed for smaller incremental gains (AuBuchon, 1996). His proposal was to use cost-effectiveness analysis, a statistical tool, to define the resources committed in comparison to the health benefit obtained from an intervention, to compare alternative interventions. This tool would serve the purpose of putting competing proposals for new health care measures into context at times of significant limitations on healthcare funding.

Aubuchon (1996) noted that cost-effectiveness analyses were macroeconomic decision aids and their use had several limitations. Such analyses would not reflect the effects of "public pressure" or the weight of regulatory oversight in decision-making. The analyses would also assess benefit and cost to populations, i.e. average outcomes. As a result, their implementation would not be intended for individual situations. At a societal level, the analyses would assist physicians and the public to discuss the allocation of limited resources. The cost-effectiveness analysis sought to define the difference in the amount of resources consumed by two different approaches to a problem compared to the difference in the health benefits they provide, using outcome measures that could be applied to any medical intervention. A common measure was the quality-adjusted life year (QALY), defined as a year of patient life modified for the quality of that life in terms of health level.[18] A commonly accepted threshold in the medical literature for generally

[17] As noted before, although the risk of exposure to hepatitis virus was (and still is) much higher than that of exposure to HIV, the adverse outcomes of HIV disease are much worse. It was estimated that about 90% of HCV infections would become chronic, and of those about 10–20% would develop into clinical liver disease during a period of approximately 20 years after transfusion. For HBV, a small percentage would develop the disease, while the majority of such infections in adults were transient and asymptomatic.

[18] Cost-effectiveness analysis involves the quantification of benefits and costs associated with the adoption of a particular technology or other (medical) intervention. It shares the same risk estimates as risk assessment, and further explores costs and long-term outcomes of a given disease(s) by using the QUALY, which was developed as an "objective" measurement. QALY, as any other knowledge produced method, has been criticized for that very

accepted diagnostic and therapeutic interventions was a ratio of cost-effectiveness less than or equal to $50,OOO/QALY.

AuBuchon, Birkmeyer, and Busch (1997a) estimated the cost-effectiveness of various measures to supplement the existing anti-HIV screening of blood. They calculated the costs per unit of blood; the estimates of survival of patients with and without transfusion-related complications in relation to the survival of patients infected with HIV; and the risks of infection (as reported from the REDS). Their analysis suggested that the use of anti-HIV screening was cost-effective (marginal cost-effectiveness $3,600/QALY). The addition of the antigen test would have a cost-effectiveness estimate of $2.3 million/QALY (or 8 HIV cases per year), while the RNA PCR testing would have an estimate of $2 million (or 16 HIV infections prevented).

The three authors noted that, despite the diminishing risks associated with transfusion, public concern about HIV and the safety of the blood continued unabated. They admitted that their analysis could not take into account these concerns (AuBuchon, Birkmeyer, and Busch (1997a). In their view, in the case of the use of the antigen testing of donated blood "increased protection from HIV transmission was politically necessary at any cost, rendering economic considerations irrelevant" (AuBuchon, Birkmeyer, and Busch, 1997b, p. 908). However, when considering transfusion safety in broader terms, more attention would be needed, in their opinion, to develop measures to deal with other transfusion risks related to fatal outcomes (AuBuchon & Kruskall, 1997).

2.3. The development and use of NAT

2.3.1. Developing commercial assays: the US, Europe and the plasma industry

Following the 1994 conference, the commitment to the development and the future use of nucleic acid amplification technology (NAT) was further advanced by the announcement of NHLBI's intention to fund the commercial development of the new tests (McCullough et al, 1998, p. 903; S. Stramer, personal communication, July 27, 2012; I. Hewlett, personal communication, August 2, 2012).[19] Federal funding in 1996 boosted the interest of the industry in developing NAT

"objectivity". For more on the construct of health-related quality of life tools, see Armstrong, 2009a, 2009b; Armstrong & Caldwell, 2004.

[19] I should note that, in previous sections, NAT was not referred to using this abbreviation, since other terms were used in the literature until the actual commercial development and use of the tests. Thus, nucleic acid amplification

testing technology for blood banks, which formed a large market worldwide. The Division of Blood Diseases and Resources of the NHLBI proposed to support, through research contracts, the refinement of nucleic acid-based assays to identify infection of blood and organ/tissue donors by blood-borne viruses, most notably HIV and HCV. The contract stated that the primary focus was on the earliest detection of infection by HIV. NHLBI signed a contract with the company Gen-Probe to develop the technique Transcription Mediated Amplification (TMA).[20]

In the same year, Gen-Probe obtained two relevant patents expanding the company's position in the area of genetic screening. In 1998, Gen-Probe formed a strategic alliance with Chiron Corporation, which had filed for numerous patents on the genome of HCV and its diagnosis, to develop and market NAT systems for blood screening. When Gen-Probe won the first contract, Roche Molecular Systems, which had acquired the patents on PCR, began manufacturing screening tests based on the PCR method. Roche was one of the largest companies and had a firm position on the field of diagnostics. Moreover, the PCR method had been used in the detection of viruses for diagnostic purposes and in many clinical and research laboratories. The course of the manufacture of the commercial NAT systems would deserve its own lengthy analysis and historical examination since it is a story featuring patent disputes, merges and acquisitions among companies belonging to the worldwide multi-billion medical diagnostics industry.[21] Here I simply note that in 1998, Chiron, which had filed for numerous patents on the HCV virus, filed patent infringement suits in Europe, Japan, and the US against Roche over its HCV products. The dispute was resolved and Roche would have to pay Chiron, and pass though royalties on the HCV test to its customers (Storz, Flasche, & Driehaus, 2012).

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testing was mentioned in some papers, but not consistently. Other terms used were gene-amplification techniques or genome-amplification testing (GAT), in addition to genetic testing and molecular screening. Since PCR was the most commonly used method in research laboratories, the models estimating the residual risk referred to the viral detection by PCR.

[20] The funded project was Project N01HB067130-000, "New Assays for Direct Detection of viral nucleic acids" (Retrieved from NIH Research Portfolio Online Reporting Tools). The project ran from September 30, 1996 until September 30, 1999, later extended until March 31, 2001. The grant was $7.7 million, and an additional grant of $4.3 million was awarded in 1998 (provided in the respective fiscal years). The company was further funded by the NHLBI in 2000, to incorporate HBV detection capability in a single nucleic acid amplification assay, and in 2002, to develop an assay for West Nile virus.

[21] These aspects cannot be analyzed in the present dissertation due to space limitations. They constitute an important part of the development of the commercial NAT assays and their pricing, availability and diffusion. The patent disputes were also part of the discussions and negotiations during the manufacture of the tests. I suggest that further research devoted to these issues would be highly beneficial in gaining a deeper understanding of the commercial development of the NAT systems.

A further impetus for the development of NAT systems in the mid-1990s came from Europe. In 1993–1994, there was an outbreak of HCV infection in recipients of an intravenous immune globulin (IVIg), from a product made by only one manufacturer. This outbreak became known, due to the trade name of the product, as the "Gammagard incident". It affected recipients in many European countries and the US.[22] The transmission of HCV occurred in the context of IVIg preparations that were not subject to specific viral reduction or inactivation treatments. In the post-HIV era, plasma products were undergoing virus inactivation/reduction procedures that had eliminated cases of viral transmission.

This case led the plasma industry to begin developing these plasma products by implementing procedures to inactivate viral agents, including HCV. However, the cases of HCV transmission also provoked a regulatory response. In 1994, in the US, as an extra safety precaution measure, the FDA decided that IVIg products manufactured without virus-inactivation/removal procedures had to be tested for HCV RNA (the final product, not the raw plasma). According to Hewlett, chief of the Laboratory of Molecular Virology in CBER at the FDA, this was the first implementation of an in-house NAT assay testing for a viral agent, though in the final product (I. Hewlett, personal communication, August 2, 2012). She further mentioned that this was another reason to consider the use of NAT to test blood donations at that time.

In 1995, in Europe, the Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products (EMEA) also decided to test the final products. In addition, it considered the use of technology for genetic detection of HCV for the plasma before the manufacturing of finite products (Grant & Busch, 2002). This interest provoked a series of international cooperation efforts to push the use of the technology in the plasma industry. In 1995, the WHO International Working Group on the Standardization of Gene Amplification Techniques for the Virological Safety Testing of Blood and Blood Products (SoGAT) was established, as a technical discussion group to address the aforementioned developments.[23] Though its focus was on detecting the HCV, the Group also considered other viral agents (Robertson, 1998). The plasma industry also responded to these initiatives by supporting the

[22] About 200 recipients of Gammagard IVIg products in Europe and US were affected by HIV transmission. For more about this case and the production of plasma products in general, see Foster and Bienek, 2008.

[23] The purpose of this group was to promote the standardization of amplification methods through the exchange of information on scientific aspects of the technology, the exchange of data on its evaluation for the testing of products and the organization of international collaborative studies for the development, evaluation and provision of reference materials and working standards. To this end, several workshops took place (Robertson, 1998).

development of NAT assays to test plasma pools for HCV in Europe (Rogers, Saldanha, & Allain, 1997). However, in 1996, representatives of the plasma industry remarked that the NAT technology was not yet developed for routine screening of plasma (Rogers et al., 1997).

In 1997, the CPMP proposed that all fractionated plasma should be tested with NAT for the genetic detection of HCV. The decision was made in 1998 (CPMP/BWP/390/97) to require HIV RNA testing as of July 1999 (CPMP, 1998).The decision of CPMP was considered by some plasma industries and transfusion medicine specialists to be redundant due to the safety measures of viral inactivation that all the plasma products were then undergoing (Allain, 2000). According to Foster and Bienek (2008), it was a reactive decision with poor added benefit to the safety of plasma products, but of significance in imposing safety measures to the plasma industry. The actors involved cooperated to conform to it. This CPMP regulation accelerated the standardization and validation of NAT systems to make them available to use by 1999.

The manufacturing of plasma products, which were considered medicinal products, was regulated separately. Since, however, the raw material for plasma also comes from blood donors, the blood collection centers (blood banks) were also affected. The recovered plasma, separated after the donation of whole blood, was directed at the manufacture of plasma products (commonly by pharmaceutical companies, but in some European countries also by not-for-profit fractionators). Part of the European demand for plasma products was covered by exports of US plasma or plasma products. Therefore, this decision would affect the exports of plasma and plasma products from the US to Europe.

The European regulation put pressure on the US blood banks and plasma manufacturers exporting plasma and plasma products to Europe to rapidly introduce NAT in the US (Gallarda & Dragon, 2000). According to Susan Stramer, Executive Scientific Officer, Biomedical Services American Red Cross National Testing and Reference Laboratories, this was the key reason why NAT was introduced in such quick pace in the US (personal communication, July 27, 2012). The recovered plasma, just like the plasma products to be prepared with this, would be exported, without disrupt, to the European market.

The processes that led to the standardization and validation of NAT assays for the detection of HCV RNA in plasma were complex and would deserve a dedicated presentation. I should note that the WHO established standards for the quality requirements of the detection limit for HCV RNA in plasma. Further collaboration among the plasma industry and the NAT manufactures took place to be able to have the technology in place before July 1999. The plasma

industry favored the use in NAT in mini-pools, before the preparation of the large plasma pools for further manufacture, as the only feasible at that time.[24] In both the US and in Europe, the processes were very intensive.[25] In the US, plasma manufactures introduced NAT in centralized centers, using NAT infrastructure developed for this purpose. They applied to FDA to use these NAT systems under an Investigative New Drug (IND) protocol (for more, see Preston in McCullough et al., 2000).

During the development of NAT, as described by Hewlett, the testing of blood samples in mini-pools was proposed for the screening in the plasma industry. This was a new paradigm for the blood banks (I. Hewlett, personal communication, August 8, 2012). The process of the configuration, validation and stabilization of the new commercial NAT technology for blood was very demanding and close cooperation between the manufacturers, the FDA, and the blood bank associations proved essential. The FDA organized a dedicated workshop in September 1998 to bring together industry representatives and other actors to discuss the development of screening strategies for HCV, the processes of evaluation with regard to the sensitivity and specificity of the tests, and the methods for quality-control safeguards (FDA, 1998; Tabor, Hewlett, Yu, Farshid, & Epstein, 1999).[26] In addition, the AABB set up an Interagency Genome Amplification Task Force to review the aspects regarding the use of NAT to develop implementation plans for the blood banks (McCullough et al., 1998, 2000). In the US, the NAT screening for plasma and for donated whole blood for HIV and HCV began at about the same time, in 1999.

From the mid-1990s, similar efforts regarding the evaluation of the use of NAT were made in many European countries. A detailed account cannot be offered here, but some developments should be noted. The interest to use NAT was stronger in research laboratories that relied on genetic assays for virus detection. When the plasma industry was getting prepared to implement NAT for HCV, this interest grew (Flanagan & Barbara, 1999). Apart from the commercial NAT systems, on which I focus, blood services in several countries developed assays and in-house systems based on these commercially available methods (Grant & Busch, 2002). These modified

[24] Plasma products are produced from large pools of plasma (varying pools containing up to 50,000 units). Testing the large plasma pools was considered economically challenging to the industry because it would lead to discarding a large pool of valuable plasma (worth about $1 million) (Busch, Stramer & Kleinman, 1997).

[25] Although not mentioned during this analysis, representatives from Japan, Canada and Australia also participated in these processes.

[26] Again, the processes that led to the manufacture of the commercial systems and the interplay of the relevant actors with the manufacturers would require further analysis and examination. These aspects are also connected to the patent disputes to which I have referred.

systems were used in some blood centers in Europe. Their development deserves to be studied further, especially in comparison to the later development of "black box" type technology that exemplified the tendency toward automated systems (Grant & Tedder, 2008).

The first use of NAT in blood services took place in Germany in 1996 (Gerlich & Caspari, 1998; Roth, 1998). A Red Cross transfusion service tested plasma for all three viruses. NAT was performed in an external laboratory in pools consisting of 500 samples. Starting in January of 1997, the Red Cross transfusion service in Frankfurt was the first to introduce in-house NAT for all blood components (red cells, plasma and platelets), for HIV, HCV and HBV in pools of 96 samples (Roth & Seifried, 2002). This confirmed that NAT was feasible but did not prove the necessity of its use. Other German services followed. NAT screening of blood for HCV became obligatory in Germany in April 1999.[27] While the use of NAT was expanded for the three viruses, this did not happen immediately. The low expected yield and low observed yield for HIV and HBV respectively, the high cost, and the unavailability of automated systems were the reasons that triggered further consideration. Roth (2008) and Gerlich and Caspari (1998) noted that the diagnostics industry was reluctant to work together with the German Red Cross to develop NAT systems in the mid-1990s.

As in Germany, all European countries introduced NAT to test plasma for HCV as required by the CPMP, although not all were ready on the date set. The use of NAT by the plasma industry fueled discussions about its use in blood centers. Especially in the cases that the blood centers would test their recovered plasma "an especially difficult and ethical question" arose: would these products be released or "blocked for at least several days, creating shortage and loss of product, or the results of mini-pool screening tests will not affect these products" (Reesink & Engelfriet, 1998). The concerns about having different levels of safety and the fact that the plasma industry would use more sophisticated screening methods, led many European countries to implement NAT for donated blood. The mode of implementation varied greatly. For example, only France implemented NAT in a one-step process. UK was rather reluctant to implement NAT before automated systems would be validated and the benefit would be demonstrated.

[27] The Paul-Ehrlich Institute, the German regulatory authority for transfusion medicine, sets the requirements for blood screening. The Institute was involved in the collaborative efforts for NAT standardization and validation. As a result of the decision of 1999, it set detection limits for NAT HCV RNA blood testing that were followed by many European countries.

2.3.2. The use of NAT: considerations about cost analysis and public health policy

In the US the decision to use genetic technologies in blood screening, as presented above, was associated to policy initiatives within this country and in Europe. In the post-HIV era, a policy toward zero risk in the blood supply resulted in adopting measures to reduce the residual risk of HIV primarily. To this end, the development and use of NAT was encouraged in various ways. When the European regulatory body decided to require NAT testing for HCV in the plasma industry, closely associated with the US exported plasma, the procedures were accelerated. In the US NAT was implemented to test both HIV and HCV. Nonetheless, negotiations and compromises were made. NAT was developed for testing (mini-)pools in the plasma industry. The same testing method was used in the blood banks for the first time. FDA had specified that mini-pools that tested positive by NAT would have to be checked to identify the original reactive donation. This compromise partially reduced the total cost from using NAT. This resulted in lower sensitivity. Yet, higher sensitivity was once the guiding principle in introducing new tests.

As shown above, the close cooperation of the blood industry, plasma and blood banks, with the manufacturing companies and the regulatory agency permitted the use of NAT in the summer of 1999. This collaboration was also manifested during the licensure by modifying the usual, and sometimes time-consuming, clinical trials process. The NAT tests were directly implemented in the blood banks after the two manufacturing companies had applied for referring to them as “Investigational New Drug” (IND), while submitting Biologics License Applications (BLAs) in 1999 (FDA, 1999b). This amended procedure was chosen because it would allow for large volumes of blood units to be screened rather quickly. Since the frequency of “window” period donations was low, vast data would be collected and the efficacy of the new tests would be demonstrated.

Following assays validation, considering their sensitivity and specificity, the process of licensing would be facilitated in a timely manner (Busch & Dodd, 2000, pp. 1157-1158; Stramer, Caglioti, & Strong, 2000, p. 1165). According to Perkins and Busch (2010), this was an unconventional regulatory pathway. Universal donor screening was actually introduced as part of a national “clinical trial”, using an IND exemption. The blood centers introduced donor screening as part of a “study” and paid the diagnostic companies “cost recovery” to use the test in the clinical trial (Perkins & Busch, 2010). Hewlett argued that all this was due to the potential public health benefits of NAT. It was expected that screening of blood and plasma donations for HIV and

HCV nationwide would produce sufficient data, to validate NAT's utility for donor screening (in Cuypers, 2002).

NAT testing in the US blood banks was performed with one of the two commercial technologies, one based on the Gen-Probe/Chiron TMA method and one on the Roche Molecular Systems PCR method, in mini-pools consisting of 16–25 samples. The American Red Cross and the America's Blood Centers (ABC) chose to centralize NAT testing in a few laboratories. According to early accounts, the process of introducing NAT occurred without major problems despite the size of the project and the many challenges it posed to the availability of blood (Busch & Dodd, 2000; Stramer et al., 2000). After the first years of NAT blood screening, 62 donations were found to be HCV positive and 4 HIV positive, while negative with serologic tests. In February 2002 the first commercial NAT assay, the Procleix HIV-1/HCV Assay of Gen-Probe, was licensed by FDA. Soon after, FDA also licensed the Roche COBAS tests for HIV and HCV.

The debates regarding NAT persisted even after its introduction. These debates concerned new manifestations of the trade-offs involved. One was about the possible future move to testing individual donations rather than mini-pools. Another was about introducing NAT to test for HBV. Many scientific papers reported on the yield of NAT (only NAT positive donations) in the US and in Europe. The yield of the p24 antigen screening had been lower than projected. The American Red Cross had identified 6 antigen positive donations in 24 million (1 in 4 million). Since NAT could detect HIV RNA in the donations in which the antigen was positive, the antigen screening was expected to be discontinued when the NAT tests would be licensed (something that indeed happened).

Dodd, Notari and Stramer (2002) published a paper with updated data from the Red Cross's blood donations on the incidence and prevalence of viral markers, to estimate the residual risk of infection. Their data showed a continuing downward trend in the prevalence of the key infectious viral markers in the donor population while the incidence was about double on first time donors than on repeat donors. When they estimated the yield of NAT with a model and compared it to the actual yield for HIV and HCV, they noted that the results were rather consistent. Glynn and colleagues from the REDS (2002) reported on the utility of the incidence rate/window period model by comparing estimates and screening results in different countries. The comparison shown low yield of NAT in some countries, and more consistent results in others (in all the cases the actual yield was lower that the projected one). They suggested, that the

overestimation could be attributed to the assumption that a blood donor recently infected was likely to donate on any day of the "window" period (Glynn et al., 2002).[28]

A study the reported the yield of NAT after screening more than 3.6 million donations in central Europe concluded that it was less than expected from calculated estimates (Roth et al., 2002). The authors examined if the results were due to lower sensitivity of the NAT assays, but in lookback investigation they did not identify any viral transmissions. Thus they also assumed that less seroconverting donors were donating blood. In the first year of NAT screening in France, out of the 2.5 million donations tested, the NAT yield resulted in one HIV-1 RNA positive and and one HCV RNA positive (Assal et al., 2003).[29]

Studies regarding the cost-effectiveness of the testing were also performed. Jackson, Busch, Stramer and AuBuchon (2003) estimated the cost-effectiveness of NAT in various strategies and concluded that the cost-effectiveness ratio was poor. They specifically estimated the cost-effectiveness of mini-pool NAT for HIV and HCV to be $4.3 million/QALY, while in single donation NAT would be $7.3 million/QALY. The addition of HBV NAT resulted in poorer cost-effectiveness ratio, despite the many cases of HBV projected to be averted because of less severe clinical consequences. The use of this model, the authors suggested, served the useful purpose in clarifying the trade-offs made in health care policy; for instance, the cost-effectiveness of systems to prevent mistransfusions was estimated about $200.000/QALY, far better that that of NAT (Jackson et al., 2003, p. 726).

Marshall et al. (2004) published another study on the cost-effectiveness of NAT. Their model indicated a smaller ratio of cost per QALY with the use of mini-pool or single donation NAT for HIV, HCV and HBV. This difference was attributed to different assumptions in models. Marshall et al. (2004) overestimated the yield of NAT as compared to the actual yield in the US and more recent modeling data. They also included the cost of recent treatments for HIV and HCV. Moreover, they estimated the outcomes of infections in infected transfused patients by three age groups instead of an average age use in other models. They estimated mini-pool NAT cost-effectiveness to be $1.5 million per QALY, a ratio not extraordinary in the context of established blood safety measures (Marshall et al., 2004, p. 38).

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[28] The REDS group analyzed data from 7 million donations, and suggested that HIV seroconverters delayed their return for donation around the time of seroconversion. This could explain the low yield of antigen testing and a possible similar low yield of NAT (Schreiber et al., 2002).

[29] For a comparison of international data up to 2003, see Coste et al. (2003).

Many of papers published during this period remarked that a further improvement in blood screening, with the use of single-donation NAT, would have small incremental benefit. It would therefore be preferable to focus the attention on other risks of transfusion such as those caused by bacterial contamination and mistransfusion (Dodd et al., 2002; Glynn et al., 2002; Jackson, et al., 2003). While it was anticipated that NAT systems would be commercially available to test single donations with the addition of HBV, this option was not favored in the US due to the higher costs and the limited benefits.

With regard to the use of NAT to detect HBV, several papers that were published in the mid-2000s were examining the magnitude of yield of mini-pool detection over serological screening (this was considered a "controversy" over the use of NAT testing for HBV). Their authors noted that the use of mini-pool testing for HBV would have limited impact on detecting HBV, because of low viral load of HBV it would only reduce the window period a few days (Busch, 2005). Noticeably, a new serologic screening assay for HBV was more sensitive than the previous ones and could have similar yields with mini-pool NAT (Kleinman & Busch, 2006; Laperche, 2005). While NAT for HBV was performed in Germany and Japan, and then in some European countries, the discussions lasted for a while.[30] NAT screening for HBV was introduced in the US in late 2012 in blood banks. Some blood banks selectively introduced the test earlier, when it became available, while the plasma industry had used it beforehand.

Once in place, NAT would permit the addition of tests for emerging agents transmitted by blood. In 2003, the NAT procedure was rapidly modified to detect an additional viral agent, that of the West Nile virus (WNV). Cases of WNV transmission had been detected in the US. In 9 months, an assay for WNV was developed and approved by the FDA. The use of NAT assays for WNV identified infected blood donors, especially in the geographical areas affected. The use of the testing in single donations was also considered because of higher sensitivity to detecting the WNV (Kleinman et al., 2009).

While the use of NAT had begun, the availability of more sensitive serologic assays for the detection of HCV and HBV was presented as an alternative for the countries that did not use NAT, especially for those with fewer resources (Laperche, 2005). In 2002, a commentary in the journal *The Lancet* by Simmonds, Kurtz and Teddler (2002a), from the UK, criticized the use of NAT for HCV, based on the low yield in the country (three positive donations instead of the 50–100

[30] I have not referred to Japan in this chapter, which was also one of the first countries to use NAT. Future research on this topic could include Japan.

projected). They argued that the cost was disproportionate to the benefits, given the royalty payments for testing for the HCV genome patent. On this grounds they suggested that "a more open discussion is needed of the cost-effectiveness of HCV NAT and other future screening tests designed to increase blood safety" (Simmonds, Kurtz, & Tedder, 2002b, p. 1714). Laperche and colleagues (2002), from the French National Blood Center, replied that in France, as in the UK, the effect of NAT in terms of public health was not clear for HCV infection. They further added that in France NAT was an "irreversible strategy" because the French health authorities recommended adopting all "reasonable measures increasing the safety of blood' (Laperche et al., 2002).

Van der Poel (2001), from the Dutch Blood Center, remarked that HCV NAT was adopted as a requirement; however, HIV NAT was used "because it was there". He noted that NAT might have increased safety but at a relative high cost; "in the light of the limited health care resources available, the cost-effectiveness of NAT should be studied preferably before this technique is introduced" (van den Poel, 2001, p. 241). Van Hulst, de Wolf, Staginnus, Ruitenberg, and Postma (2002) argued that the pharmaco-economic evaluations on transfusion safety played a minor role in health policy. They claimed "safety of blood transfusion seems largely determined by the available technology and not by its pharmaco-economic profile" (Van Hulst et al., 2002, p. 154).

To sum up, once the technology of genetic detection of viruses was available, its use was pursued, largely because blood safety was a politically charged issue. Given the regulatory efforts to gain trust and authority, the use of a novel technology that reassured blood safety was favored. There were, however, critiques about its use. In what follows, I present some relevant commentaries and personal recollections by transfusion medicine professionals.

Dodd (2001a) and Stramer et al. (2001) thought that the impetus for using NAT in the US came from both Kessler's vision and the European regulatory initiatives. Others argued that the crucial factor for using NAT was the European regulation, which would have financial repercussions on the US blood centers, based on selling their "surplus" recovered plasma (Benjamin, 2001; Farrugia 2002; Gallarda, 2000; Goodman et al., 2003). Dodd (2001b, p. 177) further argued that "[u]ltimately, it must be recognized that the marginal gains that might be achieved by additional measures may not justify the resources required to implement them". Busch (2001, p. 49) commented that "despite high cost and low yield, the current political, regulatory and medicolegal environment in the US and other developed countries has dictated the implementation of mini-pool NAT, and will likely drive the introduction of further safety

initiatives (...) the investment appears necessary to regain the trust of the public in the safety and stewardship of the blood supply."

Jean-Pierre Allain (2001, p. 107), professor in Division of Transfusion Medicine, Department of Haematology at University of Cambridge, wrote that "the impetus to apply NAT to blood screening did not originate from the need for extra safety. It essentially came in the aftermath of HIV crisis in blood banking, and was driven by political considerations and, to some extent, commercial issues." He added that "the uncomfortable situation in which the cost of NAT testing can be afforded by populations who do not need it but cannot be afforded in areas where it would be effective is now reached" (Allain, 2001, p. 107).

Albert Farrugia (2002), Australian Therapeutic Goods Administration in Department of Health, argued along the same lines. To him, the drive for zero risk in the developed world might by impeding efforts to enhance blood safety, by consuming resources that could be directed to international aid by establishing realistic standards to be followed also in developing countries. The use of NAT, a costly and sophisticated technology, was widening the gap of accessing safe blood between the developed countries and the rest of the world and to preventing new infections, something mentioned in many of the papers I have referred to above. This was "hardly a responsible global outlook" (Klein, 2000, p. 239). The cost of blood screening placed even the rudimentary transfusion safeguards beyond the reach of many developing nations and should prompt international action, argued Klein.

In the writings of blood transfusion professionals that I have studied, blood safety held a distinct position in the healthcare policy-making, especially after the HIV crisis. This can be confirmed by reviewing recent policies adopted in blood transfusion safety in comparison with other interventions in medicine and healthcare (Farrell, 2012). The availability of new technologies and the quest for zero risk in blood transfusion, a political goal, appeared to be the driving force for these interventions. As shown above, the decision-making processes were far more complex than the quest of safety would imply.

2.4. Concluding remarks: risk conceptualization and the use of a new screening technology

In this chapter, I have presented aspects of the course of the development and the use of the molecular screening technology in the US blood supply. I introduced to the considerations of

the field of blood banking and transfusion medicine in the late 1980s. I showed that, in the years after the HIV crisis, great research efforts were oriented toward producing knowledge about the risks of transfusion-transmitted infection, with direct and indirect approaches to measure and estimate risk. I retrieved the discussions about the possible use of genetic technologies through time and interpreted the debates between the actors involved. I then presented the development and use of commercial NAT technologies in blood screening and the debates it induced. In the conclusion, Chapter 7, I provide a table in which I summarize my research findings.

Based on the research presented in this chapter, I argue that in the post-HIV era the object of risk was blood as appropriated by the use of screening. The focus on estimating the risks of transfusion-transmitted infections, or in other words on advancing blood safety, positioned blood as the object of risk on the center of the debates. With this in mind, risk reduction would be achieved by increased involvement in developing a new screening technology. Therefore, the construction of the risk object set the agenda. As I have already argued (Vlantoni, 2016), a crucial part of the debate was about setting the agenda around blood safety instead of transfusion safety or patient safety, which directed decision-making to certain options.

For many of the rest of the actors, physicians and other transfusion medicine professionals, blood was not the risk object. Based on Healy (1999) and Waldby and Mitchell (2006), I would argue that before the HIV, blood was not the risk object for any of the actors involved. The risk object for clinicians was inseparable from the full practice of transfusion. For transfusion medicine professionals, the estimated risk (residual risk) would mean displacing it from the sociotechnical network, and possibly emplace the practice of transfusion. In the debates over the construction and control of the risk object, these actors were unsuccessful.

The discussions went over ways to estimate risks, the estimated risks, the estimated benefit and considerations about cost-effectiveness ratios. While some argued that it was not ethical to make decisions about preventing disease or saving human lives on the basis of cost considerations, there were others who argued that it was unethical to not take into account such considerations, given a context of limited resources that could have saved more human lives if invested in an alternative manner. This dissertation does not deal with moral/ethical issues. It stays at retrieving the sociotechnical trade-offs involved in decision-making.

Through retrieving these trade-offs, the debate about using a new medical technology was discussed in some detail. The decision to use a new screening technology, a molecular biology technology that represented the possibility to detect a viral genome, was based largely on the

assumption about the higher sensitivity of this screening technology regardless of context of use. Its use was supposed to reaffirm the status of the regulatory body (FDA) in protecting the safety of the blood supply by all means and therefore the health of the patients. It would serve as a key legitimizing tool for the role of the FDA regarding regaining its authority in the aftermath of the HIV crisis and when it was on the spotlight of political and public attention.

I argue that it permitted the FDA to regulate further the blood industry to restore its authority. In addition, it strengthened its role as a mediator and facilitator in the broader health care industry, by working together with the two corporations. This approach also made the FDA seek direct viral testing once it seemed possible to develop it. This approach was not compatible with many of the considerations brought about by several transfusion medicine professionals. The cost/benefit ratio estimates were not fully considered, just like the risk estimates. The discussion on the cost and the anticipated benefits brought up social factors that were quickly overlooked due to the alleged superiority of the new technology, based, supposedly, on technical factors, those that had to do with the calculation of risk. For this reason, I suggest that the focus on the risk was crucial to the policy-making regarding the development and use of a new technology.

Following the scheme by Hilgartner, I argue that the FDA put effort into controlling the risk object through building a complex network that included the companies, Congress and other federal agencies. Through this network, it managed to enclose the risk object in a network of control, through the development of NAT, which would eliminate the risk as matter of concern (Hilgartner, 1992, p. 48). Based on the study of the relevant medical literature, I argue that, from the mid-2000s, the efforts have been on constructing the medical practice of transfusion as the risk object.

The comments and discussions regarding the importance of the residual risk were not able to gain the same status during the debates. Transfusion medicine practitioners have noticed that commercial interests were also involved. The present analysis did not deal with this issue in detail. It simply noted that once the pursuit of genetic technology was perceived as a national strategy, the federal investment further accelerated the development of the tests. The process of licensing the tests was also altered. As for the cost for the clinical trials for evaluating the screening tests, part of it was transferred from the companies to the blood banks. This unprecedented process also assisted the FDA to quickly regain societal trust, as prolonged processes of licensing new medical treatments or devices had been condemned in the past.

The commitment to reducing the "window" period and the need to screen plasma and fulfill the European regulatory requirements seem to have played a crucial role in the way NAT was introduced. The support of the commercial companies to develop the NAT assays had a cost, which was transferred to the blood banks under the IND scheme. However, it was the need of the blood centers to be able to sell their plasma that quickened the labor-intensive process required to have the screening infrastructure on time. During the process of validation of the tests, the choices that prevailed were not those of greater of sensitivity, or of eliminating the "window" period. This was done as if there was an emergency, yet many of the relevant writings proved that neither an emergency existed nor the support to the new tests was beneficial to the public. However, at that point more actors were included on the complex network of control that FDA had developed.

To sum up, the above analysis shows that the focus in the field of transfusion medicine was on the advancement of blood safety through technical arrangements that were supposed to be superior. The measurement of risk in the work of physicians and clinicians, biologists and laboratory staff had asserted this focus. The strong public/political pressure on adopting NAT was not in line with discussions within the community of blood transfusions professionals. The whole field was actually directed at estimating the "window" period; measuring and modeling risk; estimating residual risk; considering technical solutions. On the other hand, some actors brought up the issue of transfusion safety, in which transfusion would be the "risk object".

They did so by using cost-effectiveness analysis. No one would object a policy of adopting all measures to prevent an HIV infection. However, in a context of finite resources and, in particular, decreasing health care investment and funding, the consideration of decision-making tools that provide a comparative perspective like that, could be useful, especially when the risk is not objective. In the context of disease prevention, the prevention of a small fraction of new HIV infections in relation to the incidence of infections from other route in the society, as remarked by Petersen of the CDC, would be important to reconsider the trade-offs in the use of genetic technology in blood screening. I then argue that the use of the new technology, with poor cost-effectiveness ratio, operated further downstream at a societal level.

In the aftermath of HIV, the FDA did not accept the justification of estimated cost-effectiveness analyses as part of the ongoing process of restoring its authority. The critique of the actions during the early years of AIDS pointed to complacency and underestimation of the risks by the blood industry in the US, as well as limited regulatory oversight, all connected to cost

considerations. In the mid-1990s, the risk calculations were unanimously accepted. For some of the actors, their part in decision-making was to add perspectives by comparing the benefit of alternative interventions. By contrast, the FDA assumed that the risk management approach was straightforward.

Chapter 3

3. Blood Banking and Transfusion Medicine in Greece before Genetic Technologies in Blood Screening

This chapter deals with blood banking practices in Greece, focusing on the technologies used in blood screening. It also covers aspects of the operation of the "blood donation system" (σύστημα αιμοδοσίας) in Greece over a longer period. In English-speaking countries, the usual term used to describe the institutions engaged in the overall process of supplying blood is "blood transfusion centers/system". Blood banks (τράπεζες αίματος) collect blood and separate it into its various components to be used most effectively according to the needs of a patient. In Greek, the term used is "blood donation" (αιμοδοσία). It is usually translated into English by Greek physicians and practitioners as "blood transfusion". In this chapter, I begin by providing a short overview of the blood transfusion services in Greece up to the beginning of the 1980s. In the subsequent section, I present a historical outline of the European regulatory efforts regarding the safety and quality of blood supplies. Following this, I analyze the organizational and institutional aspects of the blood transfusion service in Greece after the 1980s. I cover the developments in this service in relation to the HIV/AIDS crisis and their impact on the blood supply, paying special attention to blood screening technologies.

3.1. Blood banking in Greece in historical perspective

In this section, I provide an introduction to the operation of the Greek blood transfusion service, a critical infrastructure of the health system. The blood transfusion services are organized nationally and are responsible for collecting, processing and making available the units of blood for transfusions. The outline regarding the historical aspects of the blood transfusion services in Greece has been reconstructed from historical accounts provided by physicians and practitioners in the field of transfusion medicine. The first blood transfusion service in Greece was instituted by the Hellenic Red Cross in 1935, but the first transfusion in the country was recorded in 1916 (Mandalaki-Giannitsioti, 2004, p. 6). The Red Cross transfusion service was based on remunerated

blood donation. It was the sole provider of such a service for more than a decade, including throughout the period of the Second World War (Paidousis, Politis, & Tsevrenis, 1972, p. 75).

In the postwar years, several doctors advocated a centralized state-organized blood transfusion system, as such systems were then being institutionalized in many European countries. Among these advocates was professor A. Gouttas, President of the Coordinating Committee for Blood Transfusion, who argued for the reorganization of the service on a national basis. In the aftermath of the Second World War and the Civil War that followed, Greece did not have an organized national healthcare system; parts of the population were uninsured and had no access to health services. The first decades of the postwar period saw attempts to develop regional health services, but these were not established. Entitlement to healthcare was based on membership to social insurance funds, i.e. for the insured (Polyzos, Economou & Zilidis, 2008, p. 93).

In 1952, the Ministry of Social Welfare (υπουργείο κοινωνικής πρόνοιας) created a state executive agency, the National Blood Transfusion Service (Εθνική Υπηρεσία Αιμοδοσίας). The main principle of the blood transfusion program was to provide a single, unified service. Its aims were to apply new scientific methods in blood collection; the up-to-date training of specialized personnel; and to conduct research into transfusion-related problems (Paidousis et al., 1972, pp. 75-76).[1] It was based on voluntary, non-remunerated blood donation and administering units of blood for free. In the same year, four regional blood transfusion centers (περιφερειακά κέντρα αιμοδοσίας) were instituted, two in Athenian hospitals, one in Piraeus and one in Thessaloniki. Over the following years, additional units of varying size began to function in hospital facilities in county capitals (σταθμοί αιμοδοσίας). The legal provisions were codified in legislative acts in 1955; these laws were further amended over the following years (Alexiades & Chamalidou-Alexiadou, 1994).[2]

The national blood transfusion service was not, however, unified, and a mixed system continued to exist. The Red Cross's blood service supplied blood from both paid and non-paid donors. In addition, private blood banks were established, which collected and sold units of blood from paid, "professional" donors (Spanos, 1996, pp. 8-9). In 1965, the National Blood Transfusion

[1] A brief overview of scientific accomplishments related to blood transfusion can be found at Mandalaki-Giannitsioti, 2004, pp. 12-14.

[2] I should note that in this chapter I also refer to the legislative framework but I shall not refer exhaustively to the laws related to the governance of the blood supply. Many separate Acts of law have included provisions for the operation of the blood transfusion service; thus, I shall selectively refer to the legislation.

Service provided about half the total collected blood from non-remunerated donors (see Table 3.1 below). According to an early account of the national service by Paidousis, Politis and Tsevrenis (all three of whom were directors of blood transfusion centers), this "policy resulted in the realization of hundreds of thousands of blood transfusions with a high degree of safety and the training of a great number of physicians and technicians who are strong advocates of the new scientific methods and the principle of the voluntary and free gift of blood" (1972, p. 79). These three haematologists were key actors during the establishment of the national service. For them, in the early 1970s, the crucial problem was to achieve blood sufficiency through constant efforts to raise public awareness about voluntary blood donation. To this end it was necessary to ban any commercialization in the blood supply to enhance voluntary blood donation. In 1968, policies to this end were proposed to the responsible ministry by Professor Alivizatos, President of the Blood Transfusion Committee.

During this period, the voluntary, altruistic donation of blood was debated across many countries and gradually became an integral part of a national and supranational blood policy.[3] Paidousis, Politis, and Tsevrenis (1972) acknowledged these developments, and in particular the work of the Council of Europe. Their argumentation against commercial blood banks was based on both moral issues and issues of safety. They discredited the operation of private, commercial blood banks (it is notable that they always use the term in quotes: private "Blood Banks") as dangerous for public health due to unscientific practice. Moreover, they referred to published research data from international literature showing that the risk of transmitting hepatitis via blood transfusion increased sixfold when the blood came from professional donors rather than from volunteers (Paidousis et al., 1972, p. 77).

Many accounts have characterized the operation of commercial blood banks in Greece as problematic and precarious (Mandalaki et al., 1985; Mandalaki-Giannitsoioti, 2004; Paidousis et al., 1972; Spanos, 1996). T. Mandalaki-Giannitsioti, who succeeded M. Paidousis as director of the second blood transfusion center from 1971 until 1995, recounted that a "fierce fight" began in 1952 for the prevalence of the voluntary blood donation and the termination of any for-profit activities regarding the collection and supply of blood (1989, p. 446). She highlighted the devotion and the extraordinary efforts during this confrontation of the personnel of the national service to reach blood sufficiency based on voluntary donation in the face of all difficulties.

[3] For more see Chapter 1, section 1.2.1; on the European initiatives and policies see the following section 3.2.

Over the next few years, a number of policies were enacted with the aim of increasing the number of volunteer blood donors. From 1958 systematic blood collection began from the Greek armed forces. During the 1970s, organized efforts resulted in the minimization of for-profit activities in blood donation. Some blood transfusion services, from private hospitals and the Social Insurance Organization (Ίδρυμα Κοινωνικών Ασφαλίσεων), became part of the national blood transfusion service. In 1975, the Hellenic Red Cross ended the recruitment of paid donors. During the same period, social insurance funds ceased covering the cost of buying units of blood from private blood banks. Finally, in 1979, the private blood banks ceased operation by a law enacted by the conservative government and promoted by the Minister of Social Services S. Doxiadis, professor of pediatrics (Mandalaki-Giannitsioti, 2004, p. 11).

It is important to take these developments into account in relation to more general issues of the health sector and the public health policy, especially since Greece did not have an established unified national health system until the 1980s. During the 1960s and 1970s the relative high rates of economic growth fostered the development of the private health sector, while public expenditure for health remained low (Traka, 2007, p. 6). Private blood banks were part of the private sector, reimbursed for their services by the social insurance funds. During the dictatorship period (1967–1974) there had been an attempt to legitimize the private blood banks that were functioning unlawfully, but this did not occur (Mandalaki-Giannitsioti, 2004, p. 11).

After the restoration of democracy, as noted above, several actions led to the establishment of a unified blood transfusion service. After years of intense politicization and demand-based struggles, the Greek Socialist Party (PASOK) was elected in 1981. One of the government's major health sector reforms was the creation of the National Health System (ESY) in 1983, the first organized effort to establish a health system providing high-quality healthcare based on the principles of equity and universal coverage of the population (Kouris, Souliotis, & Philalithis, 2007, pp. 51-54; Mossialos & Allin, 2005, pp. 422–425). The Hellenic Red Cross blood services were incorporated in the national blood transfusion service. The health sector in Greece has since been based on a public/private mix comprising of the ESY, the facilities belonging to social security organizations and the private sector.

From the end of the 1970s, the blood services focused on the attraction of blood donors to achieve self-sufficiency. In Table 3.1, I show the amount of the collected blood by type of donation and by year for 1965, 1979 and 1988. In 1965, the national blood transfusion service operated 4 blood transfusion centers and 43 smaller blood transfusion units. After 1979, blood

was provided solely from non-remunerated blood donors. By 1988, the national blood transfusion service included 9 blood transfusion centers and 81 blood transfusion units. The amount of the collected blood gradually increased, but so did the demand for blood. It is important to note that, since 1977, Greece has imported about 50,000 units of blood every year from the Swiss Red Cross for the treatment of people with thalassaemia (see more in section 4.3). In 1988, 61.8% of blood came from replacement donors (from patients' friends and family members); 20.1% came from regular volunteer blood donors; 7% came from the armed forces; and 10.9% was imported from the Swiss Red Cross (Renieri-Livieratou, 1989, pp. 449–450).

Table 3.1 Blood collected in Greece for transfusion (by type of donation/source) and blood supply (per year)

Year	Service	Non-remunerated donors	Paid donors	Total
1965	National service	48,755	2,865	51,720
	Hellenic Red Cross	7,957	23,856	31,793
	Private blood banks	-	20,000	20,000
1979	National service*	234,332	-	234,332
	Private blood banks	-	261	261
1988	National service*	392,580	-	392,580
Blood supply	**(per year)**	**1965:** 103,413	**1979:** 286,085	**1988:** 441,002

Data retrieved from: Paidousis, M., Politis, E. & Tsevrenis, H. (1972). Blood transfusion problems in Greece. *Hellenic Armed Forces Medical Review, 6*, 75–79; Mandalaki-Giannitsioti, T. (1989). Blood banks in Greece. The voyage from the past to the present. *Archives of Hellenic Medicine*, *6*(6), 445–448; Renieri-Livieratou, N. (1989). Blood banks in Greece. The present situation (1979–1988). *Archives of Hellenic Medicine*, *6*(6), 449–451.

**Includes all public blood transfusion services, the Hellenic Red Cross's and private hospitals' services.*

***Includes imports from Swiss Red Cross for 1979 and 1988.*

This short introduction has have presented aspects of the development of the Greek blood transfusion service. During the 1980s, the main goals were to ensure the sufficiency of the blood supply; to improve the organization of non-remunerated blood donation by donor recruitment advertising and campaigns; and to achieve the modernization of the blood transfusion services (Mandalaki et al., 1985; Renieri-Livieratou, 1989). In the following section, I refer to the European setting regarding blood transfusion organization and regulation. I go on to

provide more information about the recent regulation and the institutional setting of blood banking in Greece up to now.

3.2. Historical aspects of blood transfusion regulation in Europe

The aim of this section is to present an outline of European efforts in relation to the governance and the regulation of the blood supply after the Second World War. Such an overview will not be exhaustive due to space limitations, and will concentrate on the developments that have led to more recent European regulatory initiatives. I also refer to the involvement of Greece in these developments. According to Farrell, there has been a "noticeable upsurge in the adoption of norms, standards, guidelines, recommendations and regulation" at the European level over the past two decades following the HIV blood contamination episodes (2012, p. 24).

From its founding in 1949, the Council of Europe promoted cooperation between member states in the field of health.[4] Its work in the field of blood transfusion from the 1950s was based on the principles of promoting voluntary, non-remunerated blood donation, mutual assistance, optimal use of blood and blood components, and protection of donor and recipient (European Directorate for the Quality of Medicines & HealthCare, 2012, p. 3; Hagen, 1993, p. 15). The cooperation of the member states was mainly exercised through the work of an expert committee comprised of national representatives (Bopp, 2001, p. 218).[5]

The first result of this cooperation was the adoption of the *European Agreement on the Exchange of Therapeutic Substances of Human Origin* (European Treaty Series, No. 026) in 1958.[6] This initiative aimed to ensure mutual assistance between the member states in the supply of human blood and its derivatives and the free movement throughout Europe of blood and blood products (Genetet, 1998, p. 5). The work of the Council of Europe in the field of blood transfusion

[4] The Council of Europe is an international organization, founded in 1949, set up to promote democracy and protect human rights and the rule of law in Europe. Greece became member of the Council of Europe in 1949. In 2015 the Council of Europe had 47 member states (28 of which are members of the European Union). For more visit <http://www.coe.int>

[5] Greece has participated in the committee of experts on blood transfusion since 1962. Elias Politis was the first representative from 1962 until 1976, succeeded by Hippocrates Tsevrenis (1976-1981) and Titika Mandalaki-Giannitsioti (1982-1995). The representative of Greece thereafter was Constantina Politis who became president of the expert committee on blood transfusion and immune-haematology (SP-HM) in 2000 (1999, *Hellenic Archives of AIDS*, *7*(2), p. 329).

[6] Greece signed the Treaty in 1958. The European Economic Community (later on European Union), as an international organization, signed the Treaty in 1987. The *European Agreement on the Exchange of Therapeutic Substances of Human Origin* was followed by Agreements on the exchange of blood grouping reagents and tissue-typing reagents in 1962 and 1976 respectively.

over the following years led to the establishment of the European *Blood Bank of Rare Groups* in Amsterdam to ensure the availability of rare blood products (Resolution (68) 32 on the establishment in Amsterdam of a European blood bank of rare groups, 1968). In the field of healthcare, the Council of Europe set up the *European Pharmacopoeia* in 1964 to deal with standards for the quality and safety of medicines, including plasma products and their components (European Treaty Series, No. 50).

From the late 1960s, the Council of Europe engaged in studying the ethical, legal and organizational aspects of blood transfusion in connection to new scientific developments and changes in the field. These efforts were reflected in output of various forms (conventions or agreements, recommendations, and reports). The Health Division of the Council of Europe put forward its activities in the field of transfusion through the expert committee on blood transfusion and immune haematology (SP-HM) and a specialized expert committee on quality assurance in blood transfusion services (SP-GS). Several recommendations were adopted regarding various issues affecting blood supply, for example preventing the transmission of infectious diseases and blood screening; the training of specialists in blood transfusion; and the preparation of plasma and blood products (for a full list of the recommendations see EDQM, 2012). Although the recommendations were not binding on member states, they advanced cooperation and the setting of common standards. Later on, such work and experience on the part of the aforementioned committees fostered cooperation between the Council of Europe and the European Union (EU).

At the beginning of the 1990s, the Council of Europe focused on extending its principles to the new member states joining from Central and Eastern Europe. This effort, aimed at supporting the restructuring of blood transfusion services in the Central and Eastern European countries, continued through the 1990s and 2000s. A report dedicated to this topic was published in 1993 (Heiniger, 1993) as part of a series of reports commissioned by the Council of Europe just after the HIV crisis and the manifestation of blood contamination episodes in many European countries (Hagen, 1993; van Aken, 1993). One such report was entitled *Blood transfusion in Europe: a 'white paper'*. This was an overview of European blood collection and distribution systems, compiled with the intention of informing European citizens and answering their questions regarding blood and blood products safety (Hagen, 1993, pp. 8–12).[7] Another aspect of

[7] The report was reprinted in many national languages in several member states of the Council of Europe. A Greek edition appeared in 1994, translated under the aegis of the Centre for Special Infections Control (Hagen, 1994).

the Council of Europe's focus since 1989 has been to gather data on the collection, testing and use of blood in its member states. The states supply data in response to questionnaires, and, to date, a number of resulting reports have been published (EDQM, 2011, p. 5). The questionnaire has been modified as needed to correspond to the changing regulatory environment in Europe regarding blood supply.

An important recommendation in the field of blood transfusion was issued in 1995: the *Recommendation No. R (95) 15 of the Committee of Ministers to member states on the preparation, use and quality assurance of blood components* (EDQM, 2012, pp. 127–129). This recommendation contained the guidelines on the preparation, use and quality assurance of blood components as a technical appendix, and became the key document for setting technical standards for blood quality and safety in Europe. This technical guide (hereafter referred to as the Guide) stemmed from the work of a select committee of experts on quality assurance in blood transfusion services that started in 1986. The first version was published in 1992. It was considered to be of great use to practitioners in blood banks, legislators, health personnel and all those working in the field, and the select committee prepared a more comprehensive edition in 1995[8]; the Council of Europe suggested that the governments of member states take all necessary measures to ensure that the preparation, use and quality control of blood components were carried out in accordance with the guidelines contained in these Guides. The recommendation also provisioned that the Guide would be regularly updated by a committee of experts. The 17th edition of the Guide was published in 2013 (EDQM, 2013b).

In 1996, the tasks of the Council of Europe in the field of health were transferred to the European Directorate for the Quality of Medicines and HealthCare (EDQM). The EDQM has also been in charge of the European Pharmacopoeia. From 2007, as part of the new organizational landscape of the Council of Europe, the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS – a Steering Committee) has pursued activities in the field of blood transfusion under the aegis of the EDQM (EDQM, 2012, p. 4). An expert working group, deriving from the committee on quality assurance in blood transfusion (GTS) and consisting of members from Europe, Australia, New-Zealand and the US, is responsible for updating the aforementioned *Guide to the Preparation, Use and Quality Assurance of Blood Components*. The EDQM has also issued guidelines regarding organ, tissue and cell transplantation. In 2013, the fifth edition of the

[8] It has been translated into numerous languages, including Greek.

Guide to the quality and safety of organs for transplantation and the first edition of the *Guide to the quality and safety of tissues and cells for human application* were published.

As I move on to the EU's actions, I would like to make a few further comments regarding the work of the Council of Europe.[9] The Council of Europe has concentrated on harmonization activities and setting standards in cooperation with a range of regional and international bodies, for example the EU and the World Health Organization (WHO). Three principles have been central in its work in the field of blood transfusion: the non-commercialization of substances of human origin given on the basis of a voluntary and non-remunerated donation; the goal to achieve self-sufficiency; and protection for both donors and recipients. These ethical principles have had repercussions on the governance of both not-for-profit national blood services and the for-profit plasma industry. Below, I briefly refer to some points regarding the regulation and management of the plasma product.

As Farrell explains, there has been a "tension between the social and the economic in the context of the multi-valuing of blood, which has occurred in the wake of techno-scientific innovation and market expansion involving plasma products" (2012, p. 26). This tension has been apparent in the development of differing subsystems of governance involving not-for-profit national blood services and the for-profit plasma products industry. The Council of Europe has dealt with all products deriving from blood and has actively promoted self-sufficiency through voluntary unpaid blood and plasma donation. To this end, the Council of the European Communities issued Directive 89/381/EEC in 1989 with special provisions for proprietary medicinal products derived from human blood or human plasma (and not for whole blood). This directive regulated plasma derivatives in the Member States with respect to the creation of a single European market that would include pharmaceutical products, and set strict rules on the quality and safety of plasma products.

In the post-HIV period, public concerns about safety were part of the political and regulatory debates. According to a report of the processes that led to this directive, the ethical

[9] The European Union (EU) is currently a political and economic union of 28 Member States in Europe. The European Union took this name in 1993 with Maastricht Treaty. It evolved from the European Coal and Steel Community (ECSC) and the European Economic Community (EEC), and it operates through various institutions and bodies. The three main institutions involved in EU legislation are: the European Parliament, which represents the EU's citizens and is directly elected by them; the Council of the European Union, which represents the governments of the individual member countries; the European Commission, which represents the interests of the Union as a whole. Another institution, the European Council, defines the general political direction and priorities of the European Union. Greece joined the EEC in 1981 (tenth member).

and political objective to promote self-sufficiency could have turned into a regulation that would have been impossible to attain (Valverde, 2006, pp. 25–26). In European countries, a mixed system in the manufacture of plasma products was based on both not-for-profit and commercial sectors; the plasma was sourced from unpaid and paid donors, and a large amount of raw material (sourced from paid donors) was imported. The objective of European self-suffiency through vuluntary non-remunerated blood donation was thus considered unattainable at that point mainly because it might create shortages (Hagen, 1993). The plasma industries were also sceptical about the way this objective would be incorporated in the directive.

In the end, the wording of the Directive 89/381/EEC stated that "Member States shall take the necessary measures to promote Community self-sufficiency in human blood or human plasma. For this purpose, they shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations." The countries were thus given flexibility in choosing their preferred arrangements for the sourcing and supply of plasma products.

Over the following years, the regulation of the plasma products was transferred to an agency of the EU, the European Agency for the Evaluation of Medicinal Products (EMEA, nowdays known as the European Medicines Agency (EMA)). The Committee for Proprietary Medicinal Products (CPMP) of the EMEA was the body responsible for instructing that, as of July 1999, the plasma used for plasma-derived products (regardless of source) should be tested for HCV by NAT (CPMP/BWP/390/97; see also Chapter 2). Later, updated legislation on plasma products was incorporated into the EU regulatory regime for pharmaceuticals in 2001.

Until the mid-1990s, the EU had little involvement in the regulation of blood donation and transfusion other than the adoption in 1987 of the main Council of Europe's agreements (mentioned above). According to Robinson (2007, p. 122), a high-level European Union meeting in 1994 set the agenda to formulate a blood strategy aimed at improving confidence in the safety of the blood transfusion chain and promoting self-sufficiency in the Community. This resulted some years later in the formulation of a recommendation (not legally binding). From 1999, the EU with the Treaty of Amsterdam obtained the authority to initiate legislature in the public health sector. It referred to adopting measures that set "high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent

any Member State from maintaining or introducing more stringent protective measures" (Treaty Establishing the European Community, Article 152).

At that point, a complex legislative process within the institutions of the EU began that lasted more than two years (COM, 2000, 2001; Opinion, 2001). This process led to the adoption of the Directive 2002/98/EC, known as the Blood Directive. The Directive was adopted in early 2003, and Member States had to comply with it by 8 February 2005. Robinson noted that most countries opted to maintain their previous national arrangements for a transitional period of nine months to prepare for full implementation (2007, p. 124). The Commission was responsible to monitor implementation and compliance by Member States. The Blood Directive (referred to as the "mother" or "core" Directive) was supplemented over the following years by three Commission implementation Directives (Directives 2004/33/EC, 2005/61/EC, 2005/62/EC, referred to as "daughter" directives).

The Blood Directive set high standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components in the EU countries. It focused on the quality of these procedures by mostly regulating blood establishments and (to a lesser degree) hospital blood banks. It paid attention to the need for formal licensing, accreditation and inspection processes in blood establishments. It is important to highlight that the Directive specified requirements about the collection and testing of whole blood and plasma (to be further processed); it thus also impacted on the importation of plasma. Moreover, the Directives set requirements for haemovigilance, specifically for the traceability of blood from donor to recipient and vice versa, and for the notification of serious adverse events and reactions. Regarding the technical requirements, it should be remarked that the Directives were largely based on the aforementioned *Guide to the Preparation, Use and Quality Assurance of Blood Components* of the Council of Europe (Faber, 2004; Robinson, 2007). The Blood Directive did not deal with the medical use of blood, which was explicitly excluded.

This last matter has been criticized. Although the Blood Directive regulated blood and blood components at EU level for the first time, its provisions did not cover all parts of the blood transfusion chain. This was a shortcoming of the Directive, since it did not cover a "vein-to-vein" approach that would deal with the clinical practice of transfusion medicine and focus on the patient-recipient (Faber, 2004, pp. 270–271; Farrell, 2012, pp. 207–208). This criticism has merits due to what Faber explains as a focus on the production segment and not on the usage segment of the transfusion chain, since "haemovigilance data from different Member States of the EU

clearly show that most of the problems encountered and the majority of the risks inherent in blood transfusion are located in the usage segment of the blood transfusion chain rather than in the production segment" (2004, p. 271). As Farrell concludes, the political agenda of the EU, formulated in the aftermath of the HIV blood contamination episodes in Member States, prioritized risk management on blood sourcing and supply (2012, pp. 207–208).

Another aspect of debate has been the longstanding issue of the preferred method of blood donation. As I presented before, the objective of self-sufficiency through voluntary, non-remunerated donation has been central in the European area with reference to ethics and safety. The Directive 2002/98/EC stated, in non-legally binding form, that "Member States should take measures to promote community self-sufficiency in human blood or blood components and to encourage voluntary unpaid donations." It indicated that the efforts of the Council of Europe in this domain should be supported, and suggested that the definition of voluntary and unpaid donation of the Council of Europe should be taken into account.

According to this widely accepted definition, "Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his or her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation" (EDQM, 2012, p. 121).[10] For Faber, "a historical chance has been missed in the European Community to render these basic principles governing blood and plasma donations legally binding" (2004, p. 271). Thus, the Directive provided flexibility in blood sourcing that compromised between the various actors in the blood supply and the differing nationally established settings (Mascaretti et al., 2004).

Following the adoption of the Blood Directive, regular meetings of the EU Member States and the Commission monitored their implementation and examined other issues. Greece, as a member of the EU, transposed it in the national law in 2005; I refer to this more in the following chapter. As mentioned above, the Blood Directive set minimum requirements regarding blood collection and testing. Robinson has documented that, among other specific issues raised by national representatives during the meetings, the use of nucleic acid amplification technology (NAT) testing for HIV was brought up: as "a result of a report from Greece about two cases of

[10] This definition can be found at the article 2, Appendix to Recommendation No. R (95) 14 of the Committee of Ministers to member states on the protection of health of donors and recipients in the area of blood transfusion.

transfusion-transmitted HIV infections, the commission was asked to consider the inclusion of HIV NAT into the compulsory testing requirements. The commission consulted experts and the conclusion reached was that due to the heterogeneity of the epidemiological and socioeconomic circumstances among Member States, there is no proof at this stage of the cost-effectiveness of such a test at European level. Feedback on national screening measures will be done at the next (2007) meeting of competent authorities" (2007, p. 127). The report touched on a case of two transfusion-transmitted HIV infections in Greece in 2005. This event was prominent during the policy making process about blood screening in Greece, as I discuss later. Hence, this reference to the EU meetings is very interesting, and to my knowledge it has not been documented in other articles or reports.

I have presented a brief overview of some important developments in the governance of the blood supply at a regional European level by focusing on the work of two important intergovernmental organizations. Of course, more actors have been involved in such processes that impact on the operation of the blood transfusion systems, including the WHO. Among them is the European Blood Alliance (EBA), an association of not-for-profit blood establishments within the EU created in 1998. The primary mission of the EBA has been to contribute to the safety and efficiency of the supply of blood products, cells and tissues by developing an active network of blood establishments in European countries, improving the performance of blood establishments and engaging in regulatory affairs (EBA, 2013).

At a scientific level, in 2002, transfusion medicine societies throughout the EU formed the European Network of Transfusion Medicine Societies (EuroNet-TMS). Professionals from blood transfusion centers in this network aim at promoting medical and scientific developments of blood transfusion in Europe by sharing knowledge and data and develop numerous interfaces with decision-makers, taking into account the diversity of European countries (Rouger, 2004).

Dedicated to the advancement of medical education and specialist teaching of transfusion medicine, the European School of Transfusion Medicine (ESTM) was created in 1992. ESTM is a non-profit association under the Italian law that was established after many years of educational initiatives in the field of transfusion medicine, in conjunction with the Council of Europe and the International Society of Blood Transfusion (ISBT) (Rossi, 2000). The ESTM has organized numerous educational courses in Europe and beyond, in developing countries and in countries facing problems, aiming to raise transfusion medicine practice to a common level of excellence. Its main focus has been the harmonization of the teaching of transfusion medicine within a geographical

Europe wider than the "political" one defined by the EU and the Council of Europe (Rossi, Massaro, Cárdenas & Barbara, 2015).

3.3. Blood banking organization and regulation: institutional setting and national law

Following the outline of the European and supranational efforts on the quality and safety of blood transfusion, I carry on the presentation of the Greek blood transfusion service I began in Section 4.1. Starting with the 1980s, I will refer to legislative actions and institutional efforts, expound on particular issues regarding blood safety and the opinions of transfusion medicine practitioners, and describe specific groups and associations involved in blood supply.

At the beginning of the 1980s, which were characterized as a "new era" in blood transfusion, a unified service was operating in Greece (Mandalaki et al., 1985, p. 383). There were three main objectives in this period: to meet the yearly needs of blood, to better organize the recruitment of volunteer donors, and to modernize the blood transfusion service (Renieri-Livieratou, 1989). During the same decade, the increase in the therapeutic use of blood that had become apparent in the previous years continued, as has been shown in Table 3.1. Thus, the increase in the demand for blood meant an increase in the blood supply (from 220,567 blood units in 1974 to 490,275 in 1990).

Regarding blood distribution and use, 75% of the donated blood has been directed to hospitals and clinics to be used for various medical needs, from scheduled surgery and oncology to emergencies. Approximately 5% of the donated blood has been discarded for various reasons. About 20% of the total blood supply since the mid-1980s has been used for the treatment of people with thalassaemia.

Thalassaemia is a genetic blood disorder that affects the red blood cells function, and more particularly, the formation of the protein haemoglobin that carries the oxygen in blood. Nowadays, it describes a group of genetically inherited blood disorders and syndromes. The disorder is known as thalassaemia or Mediterranean anaemia, a geographical association made due to the high incidence of the disease in coastal areas around the Mediterranean Sea, although it has been identified in people worldwide.[11] Greece has a high prevalence of thalassaemia, mostly

[11] It has been estimated that worldwide about 100.000 people have beta thalassaemia and about 80 million are carriers. In Greece, more than 3.000 people with thalassaemia are estimated. Since the past three decades, preventive prenatal screening in Greece and Cyprus, has eradicated the number of children born with

of the beta type.[12] Gradually, the treatment of thalassaemia has improved through multiple blood transfusions and medication for iron overload; such treatment has led to an impressive increase in the lifespan and quality of life of people with thalassaemia.

Since 1977, Greece has been importing small amounts of blood (about 50,000 units) from the Swiss Red Cross directed toward the treatment of people with thalassaemia. This has been a valuable contribution toward accomplishing blood sufficiency for multi-transfused people; however, it was considered a drawback toward achieving self-sufficiency, a fundamental objective in the European countries. The Greek authorities provided compensation for the testing and the preparation of the blood components to the Swiss Red Cross (Politis & Yfantopoulos, 1993a, p. 10).[13] According to relevant data, in 1974, 28,410 units of blood were used for the treatment of people with thalassaemia; the amount almost quadrupled in 1990 to 101,321 units. In 1984, it was noted that the donated blood was not sufficient for the adequate transfusion therapy of people with thalassaemia (Mandalaki et al., 1985, p. 387).

With the operation of the unified service and the developments in the field of blood transfusion, including the recommendations issued by the Council of Europe, a new, up-to-date Act was passed in 1988 (Law 1820, 1988). The Act of 1988 established the Committee on Blood Transfusion (Επιτροπή Αιμοδοσίας) in the Ministry of Health and Welfare to process and form specific rulings on specialized aspects surrounding the blood supply. The Act banned any for-profit activity regarding blood and its derivatives; thus, the ministry promoted the objectives of self-sufficiency and safety through voluntary blood donation. The organization of the national service was based, as from its founding, on the regionalization of services. The ministry would oversee the service through the Directorate on Blood Transfusion (Διεύθυνση Αιμοδοσίας), the National Blood Center (to be instituted), and the Regional Blood Transfusion Centers. However, the blood

thalassaemia and reduced the incidence (Hatzouli, 2012, pp. 19-21). About 8% of the Greek population has been estimated to be a carrier. Recently, bone marrow transplant procedures have been used for the cure of this genetic disorder.

[12] For an enchanting anthropological study about people with thalassaemia in Greece see Hatzouli, 2012.

[13] The Greek authorities have had further cooperation with the Swiss Red Cross regarding the manufacture of plasma products. During the 1970s the Swiss Red Cross began exporting blood components (red cells) also to other countries (Starr, 1998, p. 261-263). According to Starr, the Swiss Red Cross had established a fractionation center, for the production of plasma products, obtaining plasma from volunteers. The rest of the blood was discarded. In early 1970s, the director of the Swiss Red Cross Central Laboratory and the director of the New York Blood Center considered that "blood should be used in the most intelligent, practical profitable way" (Starr, 1998, p. 261). In 1973 the New York Blood Center started importing blood (red cells discarded in the preparation of plasma products) from the Swiss Red Cross. The program brought money to the Swiss Red Cross which then started shipping blood to Greece and to other counties in North Africa and the Middle East.

center constantly requested by the transfusion medicine practitioners to provide coordination as the national body did not materialize until the mid-2000s and the voting of a new law, harmonized with the European directives.

The national service in the mid-1990s comprised of 14 regional blood transfusion centers and numerous smaller units called blood stations/units (25 Σταθμοί αιμοδοσίας Α' and 55 Σταθμοί αιμοδοσίας Β') functioning within hospitals all over the country (Kyriopoulos, Michail-Merianou, & Gitona, 1995). The blood transfusion centers were located in tertiary hospitals in highly populated areas and were responsible, regionally, for the smaller units. The 14 regional blood transfusion centers were located as follows: six in Attica; two in Thessaloniki; two in Patra; and one each in the cities of Ioannina, Larissa, Herakleion and Alexandoupoli (No. Α8, 1992).

Since the beginning of the 1980s, the identification of blood-associated cases of a new syndrome (later specified as AIDS) has impacted on the issue of blood safety and the organization of the blood supply worldwide. In 1983, when the first transfusion-transmitted cases were identified, various strategies were recommended to minimize the danger of transmitting the disease through blood and blood products by the WHO, the Council of Europe, the International Society of Blood Transfusion (ISBT) and the League of Red Cross and Red Crescent Societies. Strict donor selection was the first response, so that potentially infected people would not donate blood, or would either refrain from or be discarded through the preference for volunteer donors and the exclusion of high-risk groups.

Greece has implemented international and European directives on donor selection since 1983 (Renieri-Livieratou, 1993). In addition, the blood donation facilities provided information about AIDS and developed methods to achieve donor confidential self-exclusion. In 1985, the screening test to detect human antibodies to HIV became compulsory in Greek blood banks as an important safety measure. Several papers provided up-to-dated information and data on the developments regarding HIV/AIDS and transfusion medicine (Kallinikos & Papaevngelou 1985; Mandalaki, 1987; Politis, 1989).

HIV has had repercussions on society since the 1980s, and particularly on the health sector. As noted before, it has been a major issue in transfusion medicine due to the cases of transfusion-transmitted infections. Public awareness of the risk of transmitting infectious diseases through transfusion has risen significantly since then. In Greece, surveys were carried out to investigate the association of possible HIV infection and blood donation to better educate blood donors and the population for better recruitment. From the total sample surveyed, 43% in 1987

and 57.9% in 1994 replied that one cannot get infected by donating blood (Politis & Richardson, 1997). It was important, however, to ensure that regular blood donors did not stop donating, although the rate of growth of regular donors slowed after 1985 (Politis & Yfantopoulos, 1993a, p. 116).

I have already mentioned, more than once, that the topic of voluntary, non-remunerated blood donation in Greece has been central in the operation of the blood transfusion system. This has become a crucial issue because of its connection to blood sufficiency and blood safety, and it is integral to the organization of the service. I shall not refer in detail to the recruitment efforts, but I should mention that, during the 1980s, intense action for the recruitment and the detention of volunteer blood donors took place, often with the assistance of the Hellenic Red Cross. Similar efforts have been apparent since then through recruitment and promotion campains. Specific studies were regularly performed examining the profile of the Greek blood donor to increase the percentage of regular, volunteer donors (Damaskos & Politis, 1999; Marantidou et al., 2007; Politis & Yfantopoulos, 1993a). As can be seen in Table 3.2, the percentage of volunteer donors increased between 1990 and 2005.

Table 3.2 Blood donations in Greece (by type of donorship) and imports

Year	Replacement donors (%)	Volunteer donors (%)	Army recruits (%)	Total blood donations	Imports
1990	278,223 (63.7%)	125,887 (28.8%)	32,512 (7.5%)	436,622	53,653
2005	322,370 (52.8%)	270,534 (44.3%)	17,152 (2.8%)	610,056	24,000

Data retrieved and reconfigured from: Kyriopoulos, J. E., Michail-Merianou, V., & Gitona, M. (1995). Blood transfusion economics in Greece. *Transfusion Clinique Et Biologique, 2*(5), 387–394; Marantidou, O., Loukopoulou, L., Zervou, E., Martinis, G., Egglezou, A., Fountouli, P., . . . Maniatis, A. (2007). Factors that motivate and hinder blood donation in Greece. *Transfusion Medicine, 17*(6), 443–450.

Nonetheless, this increase has not been enough. In 2005, as in previous years, the blood collected in Greece was not sufficient and the country had to rely on imports. Seasonal (usually in summer) and temporal blood shortages did occur. For Marantidou et al., “the effort of the blood donation system in our country has two goals: 1) the overall increase of blood units collected to ensure self-sufficiency in blood supply and 2) the conversion of replacement donors into regular, volunteer donors to increase the safety and facilitate the management of the available blood

supply" (2007, p. 444). It is beyond the scope of this paper to analyze the motives of blood donation. However, in cultural terms, in Greece and other Mediterranean countries, people have responded that they donate mostly for family or friends. Politis comments that in "countries where the family has remained a strong unit, many donors give blood because of the need of a relative or friend" (Politis, 2000, p. 355).

Another major issue regarding the blood supply has been the organization of the national service. As noted before, the structure of the system comprised of 14 regional blood transfusion centers and numerous smaller units functioning within hospitals all over the country. This organizational structure was based on the need to have blood collection sites in many areas where people got hospitalized and blood could be donated as family credit (Kontopoulou-Griva, 1989). The hospital blood banks have great variations in the amount of blood collection and consumption. Still, it should be noted that the modern organization of blood transfusion systems has been directed toward more centralized forms, especially from the 1980s and the reorganization of the blood systems after the HIV crisis. The centralization of the services (of medium or high degree) could offer the possibility of reducing the costs due to economies of scale in a period that the cost of blood was rising. Given the fragmentation of the blood transfusion service, a main objective of the transfusion medicine practitioners has been the establishment of a national blood center, to be responsible for the cooperation of the units, the distribution of blood and to centrally organize actions for donor recruitment, educational activities and other (Kontopoulou-Griva, 1989; Mandalaki, et al., 1985; Michail-Merianou & Malegkanos, 1994).

From the end of the 1980s, the implementation of standards and a focus on quality assurance has been noted in the field of transfusion medicine (as in other sociotechnical systems). In the period following the HIV crisis, emphasis was placed on risk management and quality control. In Greece, there have been no recorded centralized attempts regarding quality management, only individual efforts (Michail-Merianou, 1996, p. 34). Such efforts have been connected with the facilitation of the transfusion medicine practice in areas like the electronic data processing and the integration of information systems within hospitals and blood transfusion services; the use of barcode system for the units of blood; the establishment of good practices and quality control for blood screening technologies; and the interconnection of blood donors databases (Kavallierou-Sioni, 1999; Lazarou, 2000; Michail-Merianou, 1998).

In 2005, a presidential decree (138, 2005) and an Act (3402, 2005) dealt with the reorganization of the blood transfusion system and involved the harmonization of the Greek

legislation with the provisions of the European Directives about blood transfusion I have already discussed above (2002/98 EC & 2004/33 EC). The new law designated the restructuring of the blood transfusion service through the creation of the National Blood Center (ΕΚΕΑ, Εθνικό Κέντρο Αιμοδοσίας), made responsible nationwide for the blood centers and the hospital blood banks. EKEA would also be in charge of setting standards for safety and quality of blood and blood components, traceability of blood and haemovigilance. Its operation did not fulfil its goals, as we will see in the following chapter.

To conclude this section, I briefly describe the main institutions and associations connected to the broad field of transfusion medicine. I have presented opinions of the transfusion medicine practitioners and researchers regarding the operation of the blood transfusion service, and I illustrated certain aspects of its development. At this point, I will present more specifically on public institutions, scientific and academic societies and other relevant social groups, namely donors' associations and patients' groups. As I have already mentioned, the national blood transfusion service operates under the aegis of the Ministry of Health.

The Hellenic Center for Disease Control and Prevention (KEELPNO, Κέντρο Ελέγχου και Πρόληψης Νοσημάτων) was established in 1992 (former name KEEL), supervised and funded by the Ministry of Health.[14] KEELPNO is responsible for protecting public health by developing strategies to prevent disease transmission and performing epidemiological surveillance of infectious diseases. Its purposes include to raise public awareness about infectious diseases and to deal with public health emergencies. In addition, it provides scientific support to health practitioners and reviews and disseminates scientific data. It cooperates with international and European centers for disease prevention and control.

In 1995, the Hellenic Centre for Coordinating Haemovigilance (SKAE, Συντονιστικό Κέντρο Αιμοεπαγρύπνησης) was founded by KEEL.[15] SKAE is the body responsible for developing a haemovigilance system in Greece for all the stages of the chain from donation to transfusion. Its function has been designed in accordance with other similar national bodies in Europe and beyond, and has been supporting the ongoing efforts to establish standards for safety and quality of blood and blood components, traceability of blood and providing information on adverse

[14] It was founded as Centre for Control of Special Infections (KEEL, Κέντρου Ελέγχου Ειδικών Λοιμώξεων) and was renamed to KEELPNO in 2005. To learn more about it visit <http://www.keelpno.gr>

[15] SKAE was founded in 1995, by decision of the board of directors of KEEL. The bylaws governing KEEL/KEELPNO, and SKAE, were published in 2001 in the Government Gazette (No. Υ1/οικ. 5028, 2001). For more visit <http://www.keelpno.gr/el-gr/δομέςλειτουργίες/διοικητικήδιάρθρωση/σκαε.aspx>

reactions of recipients and donors (Politis, 1998b). Its role has been important, especially after 2005 and the harmonization of Greek law with European Blood Directives that set rules for the operation of the haemovigilance systems. In what follows, I refer in more detail to the work of SKAE.

The Hellenic Society of Haematology (EAE, Ελληνική Αιματολογική Εταιρεία) was founded in 1961 and has about 1000 members.[16] From 1998, EAE has published the scientific journal *Haema (Αίμα)*.[17] The society aims to advance the knowledge and professional competence of haemotologists; to provide educational programs in accordance with European standards; and to participate in policy-making processes in the national bodies. It regularly organizes conferences, seminars and workshops and publishes proceedings and other educational material. In 1997, the Hellenic Society of Blood Transfusion (EEM, Ελληνική Εταιρεία Μεταγγισιοθεραπείας) was established.[18] It is a member of the European Network of Transfusion Medicine Societies (EuroNet-TMS). The society was formed to promote research on the field of transfusion medicine and to bring together scientists and researchers from different disciplines (haematologists, biopathologists, surgeons, biologists, technologists, and others). It is active in research and educational programs on the medical act of transfusion and in the development of guidelines and standards for the processing of blood. It co-edits, with the University of Patras Medical School, the journal *Blood donation and transfusion (Αιμοδοσία και Μετάγγιση)*. In 1987, an interdisciplinary association was formed to promote research about HIV/AIDS and its societal impact. The Hellenic Association for the Study and Control of AIDS (EEMAA, Ελληνική Εταιρεία Μελέτης και Αντιμετώπισης του AIDS) has published the quarterly journal *Hellenic Archives of AIDS (Ελληνικά Αρχεία AIDS)* since 1993.

In 1987, the Hellenic Society of Laboratory Haematology and Blood Banking (EEEAA, Ελληνική Εταιρεία Εργαστηριακής Αιματολογίας και Αιμοδοσίας) was founded.[19] The society represents members who are biopathalogists and work in blood banks and haematological laboratories, and cooperates with relevant scientific societies. The society is active in the training of the medical specialty of biopathology in Greece. It organizes various educational activities and provides didactic material. The Hellenic Society of Clinical Chemistry and Clinical Biochemistry

[16] For more visit <http://www.eae.gr>
[17] The journal *Haema* has resumed publication in 2010 in a different format. It is published quarterly, in the Greek language, with each issue dedicated to a special topic.
[18] For more information visit <http://www.hsbt.gr>
[19] For more information visit <http://www.mednet.gr/eeeaa>

(ΕΕΚΧ-ΚΒ, Ελληνική Εταιρεία Κλινικής Χημείας – Κλινικής Βιοχημείας) represents scientists (clinical chemists, biochemists, biologists, physicians, and others) who are professionals in clinical laboratories (private, public and research ones); it was founded in 1989.[20] The society is a member of the International Federation of Clinical Chemistry and Laboratory Medicine and of the European Federation of Clinical Chemistry and Laboratory Medicine. It organizes educational seminars and conferences and publishes educational material, as well as a regular newsletter. In 1987, the PanHellenic Association of Medical Laboratory Technologists (PETIE, Πανελλήνια Ένωση Τεχνολόγων Ιατρικών Εργαστηρίων) was set up.[21] Its members are mostly professionals who graduated from departments of medical laboratory studies at Technological Educational Institutes. PETIE is a member of the International Federation of Biomedical Laboratory Science and of the European Association for Professionals in Biomedical Science.

With respect to the other component of blood donation (donors), in Europe there have been many associations promoting voluntary donor recruitment. In 1935, the International Federation of Voluntary Blood Donation Associations (IFBDO / FIODS) was set up. In Greece, many local associations and unions are engaged with promoting voluntary blood donation. The Panhellenic Federation of Blood Donors Associations (POSEA, Πανελλήνια Ομοσπονδία Συλλόγων Εθελοντών Αιμοδοτών) represents many local associations and manages donor recruitment campaigns, often in association with the Ministry of Health.[22] The Panhellenic Association of Blood Donors of the Ministry of Health (Πανελλήνιος Σύλλογος Εθελοντών Αιμοδοτών του Υπουργείου Υγείας) is another active association with national reach, founded in 1988.[23]

It is of course also necessary to mention the other side of the chain of blood transfusion: the recipients. In Greece, many regional associations represent patients with blood disorders, namely people with thalassaemia, sickle cell anaemia, etc. The Greek Federation of Thalassaemia (EOTHA, Ελληνική Ομοσπονδία Θαλασσαιμίας) was founded in 1991 and represents 24 associations.[24] It is a member of the National Confederation of People with Disabilities (ESAMEA, Εθνική Συνομοσπονδία Ατόμων Με Αναπηρία) and of the Thalassaemia International Federation (TIF). The Panhellenic Association of People with Mediterranean Anaemia (PASPAMA,

[20] For more information visit <http://www.eekx-kb.gr>
[21] For more information visit <http://www.petie.gr>
[22] For more information visit <http://www.posea.gr>
[23] For more information visit <http://www.aimodosia.org>
[24] From its foundation in 1991 and until the mid-2000s, when it renamed to EOTHA, it was known as Panhellenic Federation of Associations of Mediterranean Anaemia (Πανελλήνια Ομοσπονδία Συλλόγων Μεσογειακής Αναιμίας, ΠΟΣΑΜΑ). For more information visit <http://www.eotha.gr>

Πανελλήνιος Σύλλογος Πασχόντων από Μεσογειακή Αναιμία) was established in 1980, internationally the first primary, sociosyndicalist association founded by people with thalassaemia.[25] PASPAMA aims at defending the rights of its members and advancing the quality of their life, and has a long record of societal and medical claims (for a review see Hatzouli, 2012, pp. 286–292). PASPAMA has published the periodical *Mediterranean Anaemia Issues (Θέματα Μεσογειακής Αναιμίας)* since 1990. It organizes conferences and symposia to provide up-to-date information about therapeutic issues, preventive measures and other matters that affect the life of people with thalassaemia. Both EOTHA and PASPAMA have been very active in promoting voluntary blood donation, since multiple transfusions are part of the therapy of people with thalassaemia. They were very energetic during the period after 2006 when the molecular testing of the blood was debated in Greece and demanded the immediate use of the new screening method, as I show later.

A short reference should be made to the production of plasma products in Greece. The regional blood transfusion center of Piraeus (located at the Nikaia General Hospital), under the direction of Elias Politis, became the National Blood Products Preparation Center (Εθνικό Κέντρο Παρασκευής Παραγώγων Αίματος) in 1973.[26] The center had already began the development of blood products at the beginning of the 1960s, for example dry plasma, concentrated factor VIII for the treatment of haemophilia, etc. The center supported the blood transfusion system by various means (Mandalaki-Giannitsioti, 2004, pp. 13–14).

Blood fractionation continued over the following decades, but the further preparation of plasma products proceeded in cooperation with foreign blood centers (the Swiss Red Cross and, after 2000, the Dutch Sanquin Blood Supply Foundation). After the 1990s, the blood products center did not manage to "meet the requirements of the Greek legislation nor to follow the international developments" (Mandalaki-Giannitsioti, 2004, p. 15). As I have mentioned before, plasma products have been regulated as medicinal products, and are thus regulated in a different way than blood components.

[25] For more information visit <http://www.paspama.gr>

[26] The renowned haematologist Elias Politis (1916-1976) contributed greatly to the development of the blood transfusion service and, especially, of the preparation of plasma products (Mandalaki-Giannitsioti, 2004, pp. 13-14). In March 1976 he committed suicide; his act was associated to the earlier event of the death of seven children with thalassaemia after being transfused blood contaminated with bacteria that had been prepared in the blood transfusion center of Piraeus.

Following the 2005 law, the blood products center was incorporated into the EKEA. However, although a new plasma fractionation center had been constructed by 2005, it never operated and had to be reviewed under the current good practices and needs, since it was considered outdated. The decision to create new, industrial-type facilities for the plasma center was made in 1997. Its construction began in 1999, but it was not completed according to its timeframe. When EKEA was established in 2005, it was located in the new facilities of the National Blood Products Preparation Center, which became part of EKEA. According to the opinion of members of EAE in 2011, the review was still pending and a new plan for the plasma center had yet to be developed (EAE, 2011).

3.4. Aspects of blood screening in the Greek blood banks

In this section, I focus on various aspects regarding the use of technologies of blood screening in the blood transfusion system. I analyze the blood transfusion service's approach to blood screening and its associations with the risks of blood transfusion. This is related to the prevention of transfusion-transmitted infections of known viruses. I also discuss particular points about laboratory testing in the Greek blood banks and their operation; in the following chapter, I will specifically address certain points about the prospective usage and the use of NAT testing in the blood service.

In what follows I refer to issues concerning the testing for transmissible diseases in Greece until the end of 2000s.[27] As has been already said, the testing of the collected blood began postwar to deal with the transmission of syphilis by blood transfusion. Routine syphilis testing continues until today, although its effectiveness has been debated (McCullough, 2012, pp. 414–415; Theodossiades & Makris, 2001, p. 30). Over the following decades, the occurrence of post-transfusion hepatitis led to testing for the hepatitis B virus to become standard in blood screening. Serology testing for the detection of the HBV surface antigen (HbsAg) started in the 1970s.[28] The occurrence of cases of post-transfusion hepatitis during the 1980s (then named non-A, non-B hepatitis) contributed to the adoption of an additional serologic test for the detection of the

[27] Recently routine screening for certain viruses can be performed with chemiluminescent assays, a variation of ELISA testing methods.

[28] In 1975, the implementation of third-generation screening tests for the surface antigens of hepatitis B virus (HBV) led to marked reduction in transfusion-transmitted HBV infection. Today, this infection accounts for approximately 10% of all cases of hepatitis after transfusion. Although an acute disease appeared in approximately 35% of infected persons, chronic infection develops in only 1% to 10% of patients.

human antibody to the hepatitis B core antigen (anti-HBc) in the US, although its effectiveness was questioned.[29] However, in Greece, as in many European countries, the anti-HBc screening was not recommended as a surrogate marker of HBV and other possible post-transfusion hepatitis (Koulentaki et al., 1999; Makris, Kouvelis, Drakopoulos, Oikonomou, & Maniatis, 1995; Zervou, Dalekos, Boumba, & Tsianos, 2001). Recently, anti-HBc testing has been used selectively by some blood banks.

Hepatitis B has been considered an important public health problem in Greece. Since 1998, the hepatitis B vaccination has become nationwide as part of the general immunization program, whereas in previous years the vaccination policy only targeted high-risk groups. Recent decades have seen a gradual decline in HBsAg prevalence in Greece (Kyriakis, Foudoulaki, Papoulia, & Sofroniadou, 2000, p. 179; Theodossiades, & Makris, 2001, p. 27; Zervou, Dalekos, Boumba, & Tsianos, 2001, p. 655). The decline has been attributed to a multitude of factors such as improved living conditions, changes in the health behavior (especially in connection to the anti-HIV health campaigns), blood screening and vaccination. Three recent studies have shown low HBsAg seroprevalence (below 1%) in blood donors (Koulentaki et al., 1999; Kyriakis et al., 2000; Zervou et al., 2001). As stated by Kyriakis et al. (2000), the seropositivity rate of regular blood donors was less than half of that of the sporadic donors (p. 178). According to SKAE's data on the epidemiological surveillance of transfusion-transmitted infections between 1996 and 2007, the prevalence of HBV, which represents 70% of all infections, declined each year and dropped from 0.5% to 0.3%, with the exception of an increase in 2005 (SKAE, 2008a). SKAE's data also shows that about 80% of the HBsAg seropositive donors are sporadic, family replacement donors and first-time donors (SKAE, 2008b).

Blood screening is performed with third-generation ELISA testing of high specificity and sensitivity. In accordance to blood testing protocols, the positive HBsAg samples are further tested with confirmatory testing to distinguish truly positive ones from false positives. The window period, the interval between the infection and the detection of HBsAg in the blood sample, has been determined to be 59 days, varying from four to twelve weeks. The residual risk of transfusion-transmitted HBV infection was estimated at 1:68,000 transfusions in Greece in the early 2000s (Diakoumi-Spyropoulou, 2005a, p. 145). According to SKAE's surveillance data, no post-transfusion hepatitis case was confirmed between 1997 and 2011 (SKAE, 2012, p. 19).

[29] Its use as a surrogate test continued though its effectivity was debated.

As I presented previously, at the end of 1980s the study of non-A, non-B hepatitis cases led to the identification through molecular biology methods of a different hepatitis virus, a flavivirus, termed hepatitis C (HCV). A serology donor screening test for detecting the antibody to HCV (anti-HCV) was then introduced. From 1993, a third-generation ELISA screening test was used, with higher sensitivity and specificity, and the risk of post-transfusion hepatitis has been significantly reduced. The window period (the time between infection and the development of detectable antibodies) has been estimated to be an average of 70 days. In the Greek blood banks, ELISA anti-HCV screening has been obligatory since 1992. A positive result is further tested with confirmatory testing. The first-generation ELISA anti-HCV tests were found to be of low sensitivity and specificity for a blood bank environment in research performed in Greek blood banks (Hadziyannis, 1992; Politis, Richardson & Kalantzakis, 1992).

Low rates of anti-HCV seropositivity on blood donors were attested from studies on Greek regions in the late 1990s (Koulentaki et al., 1999; Zervou et al., 2003). Regarding SKAE's epidemiological surveillance data, the prevalence of HCV declined between 1996 and 2007, ranging from 0.19% to 0.05% (SKAE, 2008b). Anti-HCV seropositivity was found to be lower in regular volunteer blood donors than other categories, meaning family replacement and military recruits (Foudoulaki-Paparizos, Kyriakis, Kourendi, & Sofroniadou, 2004). According to SKAE data, the vast majority (83.5%) of seropositive donors are not regular volunteer donors. The residual risk of transfusion-transmitted HCV infection in the early 2000s was estimated at 1:360,000 transfusions (Diakoumi-Spyropoulou, 2005a, p. 145). As I said before, no transfusion-transmitted infection of HCV was confirmed between 1997 and 2011 (SKAE, 2012, p. 19).

Throughout this thesis I have referred to a great detail on the blood screening for HIV. When it was recognized that the new syndrome could be transmitted through blood, several strategies to deal with this matter were discussed, and some were implemented. These involved strict donor selection and possible testing for surrogate markers. The use of the screening test for the detection of the antibody to HIV in 1985 drastically reduced the number of transfusion-transmitted infections. In Greece, anti-HIV screening became obligatory in August/September 1985. At the same time, the blood donation facilities provided information about AIDS and developed methods to achieve donor confidential self-exclusion (Politis & Yfantopoulos, 1993a, p. 123). The screening tests were improved over the following years, providing higher sensitivity and specificity. During the immediate years after 1985, a second-generation ELISA screening test was developed; at the beginning of the 1990s, a third-generation test became available. The aim

of this greater sensitivity in screening tests was to eliminate false negative results. It was known that the anti-HIV screening could miss cases of very early infection, and it was noted that strict donor selection and cautious use of blood were necessary for advancing transfusion safety (Renieri-Livieratou, 1993, p. 123).

At the beginning of the 1990s, testing for HIV type 1 and type 2 became commonly available. The seropositive samples are always tested with further confirmatory testing; the different screening strategies were discussed by transfusion medicine practitioners (Kavallierou, 1995, 1997; Kavallierou, Tsiroyianni & Renieri, 1996; Mandraveli-Hatzikosta, 1995). According to an econometric study, the screening strategy for the prevention of new HIV cases was considered socially beneficial, and anti-HIV 1/2 screening was found to be safe and cost-effective (Politis & Yfantopoulos, 1993b, pp. 125–126).

I will now refer to information about HIV/AIDS cases in Greece and the anti-HIV seroprevalence in blood donors. According to records, a total number of 966 AIDS cases were identified in Greece until June 1994; 52 cases (5.3% of the total) were considered as post-transfusion AIDS (Politis, 1995). A 1993 paper noted that "blood transfusion in Greece can be considered safe since no transfusion-transmitted HIV infection was recognized after the anti-HIV screening began" (Renieri-Livieratou, 1993). Regarding multi-transfused people, before 1986 1% of them were infected with HIV, or 30 cases (Politis, 1998a, p. 138). From 1987 until 1997, one seroconversion of a person with thalassaemia was documented, measured as 1 infected unit in 1,290,000 units of blood (Politis, 1998a, p. 138). From July 1997 to June 1999, a case of transfusion-transmitted HIV infection to two recipients was documented (Politis, 1999). Between 1997 and 2011, a case was confirmed in 2005 of transfusion-transmitted HIV infection to two recipients of blood cells and plasma from the same blood unit (SKAE, 2012, p. 19). I refer more to these cases later.

In the first years after HIV was identified, and until 1990, the prevalence of anti-HIV seropositivity in Greek blood donors was low and was considered indicative of the low prevalence in the general population (Hatzidimitriou et al., 1991). However, during the mid-1990s, the higher prevalence of HIV infection among blood donors was considered disproportionate to the small number of AIDS cases in the country (Politis, 1995, p. 224). SKAE data demonstrated that the prevalence of HIV declined between 1997 and 2002, and tended to increase between 2002 and 2007 (SKAE, 2008b). More specifically, HIV prevalence in blood donors was 0.014% in 1996; 0.005% in 2002; and 0.012% in 2007 (SKAE, 2012, p. 11). Politis notes that seropositivity was

higher among first-time donors than among regular donors, a finding in accordance with international bibliographical data (1995, pp. 224–225). Notably, no positive samples were detected from regular volunteer blood donors between 1989 and 1990 (Hatzidimitriou et al., 1991, p. 216). This trend was also confirmed by research on the HIV epidemic in blood donors for the years 1986–2002. According to the results, the "overall HIV prevalence was 2.15 times in recruits [military donors] and 2.46 in replacement [donors] as compared with regular donors" (Foudoulaki-Paparizos, Kyriakis, Fakitsa, Kourendi, & Sofroniadou, 2004, p. 187). According to SKAE surveillance data, between 1996 and 2007, 25.4% of anti-HIV seropositive donors were regular volunteer blood donors, whereas 74.6% were replacement donors (SKAE, 2008b, p. 26).

The issue of the "window period" in HIV transmission by transfusion (estimated at about 22 days) has been discussed in several articles (for example, see Politis, 1999). There have nevertheless been few published studies that estimate the residual risk for transfusion-transmitted HIV infection in Greece. As I have mentioned above, according to data processed by Politis, the residual risk of HIV in blood transfusion was considered similar to that of the US, or 1:1,290,000 (1998a, pp. 138–139). A similar rate of 1:1,200,000, was estimated for the same period by Michail-Merianou (1999, p. 57). In the early 2000s, the estimated residual risk was reported to be 1:1,830,000 transfusions (Diakoumi-Spyropoulou, 2005a, p. 147).

As I have stated earlier in the introductory chapter, blood components are associated with the transmission of various infectious agents, including viruses, bacteria and parasites. For several of these agents that have been shown to be transmitted by blood, routine screening is not being performed. Nonetheless, other strategies have been applied, mainly through donor deferral. For certain viruses, selected screening policies have also been used, for example for the West Nile virus in the late 2000s. Since the 1980s, more screening tests have been added to the routine laboratory testing of blood. At the beginning of the 1980s, a retrovirus called human T-lymphotropic virus (HTLV) was identified and shown to cause malignancy in humans (McCullough, 2012, p. 425).[30] To avoid the transmission of HTLV by transfusion, screening of donated blood for the antibody to HTLV was initiated in the US in 1988.

[30] HTLV is a virus that infects a type of white blood cell called T-lymphocytes. The great majority of persons infected with HTLV-I remain asymptomatic and about 5% develop a disease. The virus is associated with adult T-cell leukemia/lymphoma, HTLV-I-associated myelopathy and other diseases. It is endemic in Japan, the Caribbean, parts of Africa and Central and South America. The great majority of persons infected with HTLV-II, more than 99%, do not develop any disease due to the infection. HTLV-II infection has been found in Western and Central Africa, North and South America. HTLV can be transmitted vertically from an infected mother to her baby through breastfeeding, by blood transfusion, by intravenous drug use and by sexual contact.

In Greece, as in many European countries, the prevalence of HTLV-I/II needed to be evaluated in connection to the effectiveness of routine screening, as they are non-endemic areas.[31] Prior to the mid-1990s, two studies suggested that routine testing of all donated blood was not required (Dalekos et al., 1995; Politis, Papaevangelou, Sinakos, Trichopoulou, & Roumeliotou, 1989). In contrast, a study on people with thalassaemia indicated an increase of HTLV seroprevalence and justified the initiation of mandatory screening (Politis & Yfantopoulos, 1993a, p. 131). Over the following years, further studies of the anti-HTLV-I/II prevalence in large numbers of volunteer donors identified infected donors (Politis et al., 1999; Tseliou et al., 2003; Zervou et al., 2004). The prevalence ranged from 0.013% to 0.0056%. In Greece, the testing for anti-HTLV-I/II began in 1997 and was not obligatory; it became nationwide from 2000. Regarding SKAE data of epidemiological surveillance of infections, HTLV's prevalence is low at 0.001% (SKAE, 2008b).

I have presented an overview regarding the laboratory screening of the donated blood in Greece, since I will go on to discuss the use of molecular screening technologies. According to Politis (1999), blood screening for HIV and other infectious markers was more uniform despite the high degree of decentralization of the blood services. The findings of the studies performed by SKAE with the voluntary participation of the blood services showed a high degree of uniformity in laboratory testing for transmissible agents and identified cases of non-standard practices regarding the confirmatory testing (Politis et al., 1998, 1999b; SKAE, 2008b). Regarding the transfusion medicine practices on blood preparation, the Greek editions of the technical Guide of the Council of Europe were used as reference material in the services (SKAE 2003, 2008c).

The above historical account of the blood transfusion service in Greece can assist us in approaching the use of screening technologies and the matter of blood safety in the context of its overall operation and in relation to major recurring issues. From the studies of SKAE, transfusion medicine specialists noted that "the number of [blood transfusion] services is high in relation to the population of the country and, consequently, many services are small. This fact, and the high degree of decentralization, lead to problems of communication, training and quality control, which may become more severe as international organizations impose increasing demands on blood services" (Politis et al., 1998, p. 270). Issues regarding the screening of blood cannot, therefore, be addressed without reference to the (re)organization of the services. At the same

[31] For a review of the policies in European countries toward preventing the blood transmission of HTLV in the end of 2000s see Laperche, Worms, and Pillonel (2009).

time, the issue of blood safety should be dealt with in parallel to undertakings for securing the quality of blood and the medical act of transfusion at all levels.

On the other hand, blood safety in the Greek blood supply has been closely connected to the source of blood through the attraction of regular blood donors – a goal that has not been fulfilled, since a great percentage of donors are friends and family replacement donors. It has been noted repeatedly that the prevalence of infectious viral markers has been higher in non-regular blood donors. Thus, the constant review of the practices of donor recruitment and retention is necessary in assuring blood safety and quality (Politis, 2000).

3.5. Concluding remarks

This chapter has presented an overview of the operation of the Greek blood transfusion service. I provided an outline of the establishment of a national blood transfusion service, a critical infrastructure of the overall health system. In this context, I presented the actions undertaken to achieve the operation of a unified service based on voluntary, non-remunerated blood donation, and free provision of blood to the patient. For the first three decades of the postwar period, the system was mixed; private blood banks were established to collect and sell units of blood from paid, "professional' donors". In 1979, however, these private blood banks finally ceased operation by law.

Voluntary altruistic donation of blood gradually became an integral part of national and international/transnational blood policies worldwide. In the second section of this chapter, I presented European transnational efforts to assure blood safety and quality. This account covered recent developments in the context of the EU, which impacted on the organization and the regulation of the Greek service – a point I further elaborate in the following chapter. In the post-HIV era, public concerns about blood safety became part of the political and regulatory debates. The episodes of HIV and HCV transmissions by blood components and products greatly contributed to the transformation of blood banks into highly-geared risk management institutions (Waldby & Mitchell, 2006).

In the early 1980s, the establishment of the ESY provided the first organized effort to establish a system in which the state was to be fully responsible for the provision of health care services based on the principles of equity and universal coverage of the population. At the same time, the operation of a unified service was promoted as the introduction of a "new era" in the field of blood transfusion. For transfusion medicine practitioners, the main objectives were to

achieve blood sufficiency, to enhance regular volunteer donor attraction and retention, and to modernize the blood transfusion service. In 1988, a new law reinforced the expectations for the better organization of the blood supply. However, some of its aspirations did not materialize.

Several attempts were made to reform the ESY. According to critiques, the organizational structure of the ESY (rather centralized and rigid) had contributed to the prevention of health care reforms (Mossialos, Allin, & Davaki, 2005; Tountas, Karnaki, & Pavi, 2002). The levels of public expenditure on health in Greece remained low up to the 1980s. An upsurge in public spending was in fact due to setting up the ESY. In the late 1980s, an increase in both private and public health spending was also connected to large increases in the use of high-level medical technology (Kyriopoulos, Michail-Merianou, & Gitona, 1995). However, between 1996 and 2005, the levels of public expenditure on health appeared to be low in comparison with the government capacity to spend (Thomson, Foubister, & Mossialos, 2009). By the end of the 2000s, Greece only allocated 5.8% of GDP to public health expenditure, one of the lowest proportions among OECD countries.

All the above influenced the operation of the blood transfusion service. The Greek blood transfusion system had faced many challenges. Noticeably, manufacturing blood products had been on hold pending the construction of a new plasma center (approved in 1997). In the late 1990s, an increase of infrastructures (mostly hospitals) took place in the country, assisted by EU convergence policies. The new plasma center was built after some delays, but never functioned as envisaged.

The transfusion medicine practitioners felt the need for institutional changes and "modernization" of the system, but many of their needs would not be addressed before the end of 2000s, as the following chapter will show. An additional point regarding the operation of the blood transfusion service has to do with insights about the strategies employed to deal with transfusion-associated risks. Transfusion safety and blood safety in Greece have been closely connected to advancing volunteer donorship and achieving blood sufficiency, and thus also with efforts to assure the safety and quality of the transfused blood.

Chapter 4

4. The Emergence and Prevalence of Genetic Technologies in Blood Screening in Greece

This chapter deals with introduction of genetic technologies in blood screening in the Greek blood transfusion system. In the first section, I present the discussions among physicians and blood bank practitioners regarding the possible use of NAT in routine screening of the donated blood. The following sections are devoted to the second half of the 2000s and the discussions concerning the use of molecular diagnostics in connection to considerations about blood safety. At the same time, I consider the efforts made to (re)organize the blood transfusion service after 2005. The processes that led to the introduction of NAT are covered in more detail. Finally, I introduce to aspects of the use of molecular screening.

4.1. Considerations about molecular screening and its possible use

Several publications have dealt with the challenges and problems of laboratory screening, especially from the end of the 1980s. The first references to the methods of direct detection of infectious viruses (mainly HIV) with molecular biology techniques date from the mid-1990s (Kavallierou, 1995; Kotsianopoulou & Roumeliotou, 1995; Mandraveli-Hatzikosta, 1995). As for the testing methods that detect the genetic material of the HIV, their use was of particular interest to early HIV diagnosis in neonates and infants, monitoring of HIV/AIDS during antiretroviral therapy, resolving indeterminate testing results, and other research purposes.

From the end of 1990s transfusion medicine practitioners in Greece referred to the international developments about the possible use of molecular diagnostics in addition to routine screening of blood with serology testing as a means to increase blood safety by reducing the diagnostic window of a recent infection. It is nevertheless necessary to remark that the National Blood Products Preparation Center had conformed to the recommendation of the European regulatory agency on medicinal products (CPMP) regarding NAT testing of plasma pools for HCV since July 1999 (Zevgolis, 2010, p. 34). Although this paper does not focus on the production of plasma products, this development should be noted.

Politis discussed blood safety in a comprehensive 1999 paper, paying attention to the strategies of blood screening for HIV (the possible and prospective use of HIV p24 antigen testing and NAT, mainly PCR, as a means to close the diagnostic window). She presented data regarding the HIV prevalence in blood donor population, the residual risk of HIV transmission through blood and blood products in Greece, US, Germany and other countries, the estimated window period reduction and the yield of NAT (Politis, 1999). In addition, Politis talked about the likely use of genetic screening technologies in the future, when technical issues regarding automation and timely throughput of results would be resolved (1999, p. 179).

She also referred to a case of transfusion-transmitted HIV infection in Greece regarding two persons being infected with HIV after being transfused erythrocytes and plasma from the same unit of blood donated by a donor between July 1997 and July 1999 (Politis, 1999, p. 177).[1] The HIV transmission was attributed to the window period since the donated blood was screened with serologic testing and was found to be a false negative. This case of HIV transfusion-transmitted infection was covered by the newspapers in 1999 (see Chapter 5, section 5.3.1). One of the recipients was a premature neonate that tested HIV seropositive four months after it had received transfusion during hospitalization (Papagregoriou-Theodoridou, 1999). In both the aforementioned papers that referred to this event, possible ways to reduce the residual risk of transfusion-transmitted infections due to window period were discussed (Papagregoriou-Theodoridou, 1999; Politis, 1999).

As I have mentioned repeatedly, the use of molecular diagnostics in a blood transfusion service would come with extensive changes in the laboratory practice. In the case of Greece, the analysis of data gathered by SKAE at the end of 1990s indicated that the large number of decentralized blood services could be a problematic factor in performing universal NAT screening as it could generate difficulties in the communication, training and quality assurance (Politis et al., 1999b, p. 294). I should thus note that the operation of the regionalized blood transfusion service permitted the use of NAT at the level of a blood center when it was not yet mandatory in the routine screening of blood; that strategy was noted in other European countries too at the beginning of 2000s (Laperche, 2005).

[1] This case was not been recorded to the SKAE reports (2008a, 2012). It is possible that it was not recorded because of the voluntary participation of the blood banks in the SKAE research, meaning that the particular blood bank did not respond to the SKAE data request in that specific time period.

At the end of 2002, an educational daily workshop (part of the yearly educational seminar series) organized by EAE focused on molecular biology in blood donation practice. In the proceedings of this workshop one can find three papers dedicated to the technologies used in the genetic detection of HBV, HCV and HIV; the papers were prepared by two biologists and one biochemist, all working in blood transfusion services (Gialeraki, 2002; Haikali, 2002; Spyropoulou, 2002). The authors provided up-to-date presentations about the various NAT techniques and other diagnostic methods developed for the detection of each virus in a blood bank setting. However, they did not deal with specific issues in the context of the operation of the Greek blood transfusion service, nor about issues surrounding policy formation.

The same volume encompassed two papers written by two haematologists and directors of hospital-based blood transfusion units. Dadiotis (2002) posed the question: 'Serological screening with the supplement of NAT. Is that the message of Haemovigilance?' He talked about the efforts to reduce the window period of infectivity associated with the need to estimate the potential infectivity of blood donors through the development of mathematical models to measure the residual risk. However, such studies also indicated that the regular blood donors are half of the time less probable to be potentially infectious than other types. Dadiotis further discussed the results from haemovigilance studies in France and UK that showed cases of transfusion-transmitted infections were less common than other transfusion hazards (2002, pp. 81–82).

Thus, to assess the transfusion risks one should consider a) the need to estimate the actual risk in a specific national, social and economic context; b) the implementation of various protection measures from donor selection to the medical decision to transfuse blood; and c) the cost-effectiveness of each strategy with respect to the pursuit of safe blood (Dadiotis, 2002, p. 82). Dadiotis argued that alternative approaches to blood safety should not be seen as in conflict with costly and high-tech approaches like NAT, but could offer the perspective of the expected benefit. Thus, cost–benefit analyses could readjust the focus of the relevant policies since the concentration on reducing the residual risk with the use of biotechnologies has been associated with the profitability of this business sector and, often, the political pressure exerted following exaggerated media reports (Dadiotis, 2002, pp. 83–84). He concluded that transfusion medicine practitioners should give prominence to providing information to the public regarding transfusion risks (Dadiotis, 2002, p. 83).

In the other paper, Mosxou-Parara (2002) discussed whether the goal of zero risk in transfusion medicine would ever be achievable, and gave a negative response. She referred to several developments in the field of transfusion medicine up to the 21st century and the applications of molecular biology, concluding that new screening techniques and inactivation methods needed to be assessed in relation to advancing transfusion safety (Mosxou-Parara, 2002). At the same time, however, she argued in favor of the centrality of constant conformance with good practices through regular training of the personnel (Mosxou-Parara, 2002, p. 107). Neither paper referred directly to the Greek setting, but both raised issues that put options, such as the universal use of NAT, in the context needed to inform the development of public health policy.

The position regarding the need to focus on transfusion safety, rather than only on blood (or component) safety, was expressed in a review article of 2005. The authors, professionals at a blood transfusion service, examined safety from multiple viewpoints, from blood collection to therapy and the follow up of the recipients (Gafou et al., 2005). They concentrated their review on particular international studies based on haemovigilance system reports that proposed solutions to hazards in the transfusion practice, mostly talking about "human error". They agreed with AuBuchon and Kruskall's (1997) influential paper 'Transfusion Safety: Realigning efforts with risks', and argued that "the discussions of blood safety should always reference to the relative magnitudes of the risks and the practicality of their reduction" (Gafou et al., 2005, p. 609). They also concluded that there was a need to adopt a combined approach to improve the overall process of transfusion therapy, in their words to "share resources balancing improvements in the component to the process" (Gafou, et al., 2005, p. 609).

Transfusion medicine professionals recognized, however (as I have shown in the previous chapters), that although many factors contribute to a safe transfusion practice, a lot of attention from the media and political authorities has been paid to the part of blood safety. Stamoulis stated that intense public reactions about blood safety could lead to "decisions or measures which under other conditions would be considered excessive or not efficient" (2005, p. 154). Stamoulis presented an overview of the basic principles of transfusion therapy at an educational seminar on "Haematological Issues" held by EEKX-KB. The development of NAT was presented as a way to reduce the estimated residual risk of infections due to window period; a similar presentation was made at another educational seminar of the same society about the use of molecular biology in laboratory medicine, dedicated to the methods used in diagnosis.

Diakoumi-Spyropoulou presented on NAT techniques, paying special attention to commercially available systems at the appendage in a period when a few blood transfusion centers had (selectively) begun their use (2005a, 2005b). She presented a lot of data about the use of NAT and the estimated reduction of the window period; the estimated residual risk of transfusion-transmitted infections in several countries, including Greece; and the estimated and measured yield of NAT in other countries (Diakoumi-Spyropoulou, 2005a). In conclusion, she contextualized the attempts to advance blood safety in connection to a) the overall transfusion hazards, since only 8% of the post-transfusion complications are related to infections, and b) the global perspective, given that only 43% of the WHO countries test blood for known viruses (Diakoumi-Spyropoulou, 2005a, pp. 153–154).

For Koutsogianni (2007), who heads a blood transfusion service, the use of molecular testing would bring a small added benefit at a great cost. For her, developed countries face the question of whether it was reasonable to allocate resources to reduce the already small risk of transfusion-transmitted infections, or whether it was better to focus on ways to deal with other transfusion risks (Koutsogianni, 2007, p. 24). I should note that the discussions in Greece regarding blood safety and transfusion safety are commonly connected to the overall challenges of the Greek blood transfusion system, which I have pointed out in this chapter. These issues affect the processes of donor selection and the goal of achieving blood sufficiency through non-remunerated, regular blood donors; the overall operation of the services in relation to the adequate staffing and the continuous training of the personnel; and the importance of communicating information on transfusion safety and practice to the public.

To conclude this section, I refer to the research efforts of an academic group based at the Medical School of the University of Athens in the Department of Hygiene, Epidemiology and Medical Statistics (where the National Retrovirus Reference Center and a Laboratory Diagnosis Unit are located).[2] The researchers of the department, under the supervision of professor Aggelos Hatzakis and in cooperation with blood transfusion services and clinical units in Greek hospitals, performed studies to assess the sensitivity and specificity of NAT assays in contact to international developments, particularly of TMA commercial reagents offered by the manufacturer Chiron/Gen Probe corporation (Katsoulidou et al., 2004, 2007).

[2] For more information about the department see <www.ldu.gr/index.php/en/>

To be more specific, the research group evaluated the sensitivity of the assays in detecting viral markers in selected panels with blood samples which included samples with very low viral load. In a study published in 2004, the authors evaluated an HIV-1 and HCV assay (Procleix) which simultaneously detects HIV-1 and HCV RNA. They concluded that the assay "has been shown to have high sensitivity and specificity allowing it to be used in the screening of blood donations" (Katsoulidou et al., 2004, p. 65). In addition, they argued that "the ability of Procleix HIV-1 and HCV assay to significantly reduce the window period underlines the necessity for screening blood donations" (Katsoulidou et al., 2004, p. 64).

Over the following period, the same research group, in collaboration with hospital units, assessed the sensitivity of the Procleix Ultrio multiplex assay, which simultaneously detects HIV-1 RNA, HCV RNA and HBV DNA in individual blood donations (Katsoulidou et al., 2007). Their study was based on testing selected panels that included samples with low viral load to evaluate the performance of the multiplex and the discriminatory assays.[3] The results of the study showed that the multiplex assay "was as sensitive as the Duplex assay indicating that the addition of primers and probe for detection of HBV had not affected the analytical sensitivity for HIV-1 RNA and HCV RNA" (Katsoulidou et al., 2007, p. 12). The study further demonstrated that the "ability of the assay to detect HBV DNA in cases that HBsAg is undetectable may further reduce the risk of transfusion transmitted HBV infection" (Katsoulidou et al., 2007, p. 13). Another finding of the study was the discrepancies observed between multiplex and discriminatory assays testing, which could impact on the routine screening strategy implemented (Katsoulidou et al., 2007, p. 13).

As I have elaborated in Chapter 2, the issue of NAT testing for HBV has been long discussed by transfusion medicine practitioners, mostly because mini-pool testing of HBV DNA was shown to be of poor efficacy when single donation testing was still under development or not widely implemented. In the following sections, I further refer to NAT HBV DNA testing in southern European countries, including Greece, that have had higher HBV prevalence compared to other developed countries and in relation to the study of "occult" HBV (Katsoulidou et al., 2009).

[3] An important aspect of the studies that examine the sensitivity of assays on detecting very low viral loads for blood banks has been whether such units can be infectious. As the authors state: "To mimic a situation that can happen in detecting samples of blood donors with a low viral load, samples of patients that were treated with antiviral therapy were selected and classified deliberately in two categories: samples with undetectable viral load as found in usually less sensitive diagnostic NAT methods and samples with detectable viral load. Although the design of the study is artificial in that patients receiving antiviral therapy are not eligible for blood donation, testing a selection of samples with low virus levels that can potentially give discrepancies between the multiplex and discriminatory assays could be very informative for the practical use of the Ultrio test in blood screening" (Katsoulidou et al., 2007, p.12).

4.2. The (re)organization of the blood transfusion service and the use of NAT: policy, politics and media

In this section, I focus on the planning and the subsequent universal use of NAT in the Greek blood transfusion service. I start by commenting on the efforts regarding the (re)organization of the blood transfusion service by elaborating on the legislative process that took place in the second half of 2005. I outline the main challenges in the blood supply, as analyzed also on the previous chapter: the need to achieve blood sufficiency and to avoid shortages; the enhancement of volunteer donorship; and the coordination of the blood transfusion services. These are issues that are central to the overall operation of the blood transfusion system and impact on the cost of blood to the health service. According to the findings of an analysis about the economics of blood in Greece, "[p]olicy makers and practitioners should encourage the rational use of blood, harness wastage, build on existing policies that lead to an improved system of collection and encourage volunteer donorship" (Kanavos, Yfantopoulos, Vandoros, & Politis, 2006, p. 342). The authors, three scholars of health policy and the head of a blood transfusion center, conclude that blood "may cost less where there are coordinated collection, storage, and distribution activities at national level" (Kanavos et al., 2006, p. 342).

In August 2005, the bill on the "reorganization of the blood transfusion system" (Αναδιοργάνωση του συστήματος αιμοδοσίας και λοιπές διατάξεις) was introduced into parliament by the government (Plenary minutes, 4 August 2005, p. 747).[4] The bill was submitted and debated in the same period as the publication of the presidential decree (138, 2005) transposing the European directives into the Greek legislation – just when the deadline to do so was approaching.[5] The bill incorporated the basic principles ruling the blood transfusion system, as the previous laws had done. The reorganization of the service would be based on 1) the

[4] After the elections held in March 2004 the right-wing, conservative party of Nea Demokratia (Νέα Δημοκρατία) had the majority in the Hellenic Parliament and formed the government. The same party won the early elections of September 2007 and resumed in power until the elections of October 2009. PASOK (Πανελλήνιο Σοσιαλιστικό Κίνημα), the Greek Socialist party, was the governing party from 1993 until the 2004 elections; it also won the majority on the elections of 2009.

[5] The competent ministers introduced the bill with an explanatory report attached, in which they reported the purpose of the proposed legislation on 20/07/2005. They further attached a General Accounting Office's report specifying the amount of the expenditure involved and/or reduction of revenues (3/08/2005), and a special report regarding the coverage of the expenditure by the Minister of Health and Social Solidarity and the Minister of Finance (3/08/2005). Additionally, the bill was transmitted to the Scientific Agency of the Hellenic Parliament which submitted a review on the proposed provisions on 12/09/2005.

establishment of a National Blood Center, the ΕΚΕΑ, the coordinating body, 2) the specification of blood establishments and hospital blood banks, 3) the incorporation of the blood products center in ΕΚΕΑ and 4) the formation of an Advisory Committee on Blood Transfusion (Συμβουλευτική Επιτροπή Αιμοδοσίας) to assist ΕΚΕΑ on "scientific matters" relating to blood donation and transfusion.

During the legislative elaboration and examination of the bill by the Standing Committee on Social Affairs, representatives from the National Federation of People with Thalassaemia, POSEA and EAE were invited to comment on the provisions in addition to the members of parliament and the Minister and Deputy Ministers of Health and Social Solidarity (henceforth referred to as the Minister of Health). The committee met over three sessions between 30 and 31 August 2005. The rapporteurs of Nea Demokratia (the governing party) and PASOK (the major opposition party) were in favor of the bill; the speakers of the minor opposition parties – KKE (the Greek Communist Party) and SYRIZA (a coalition formed by Synaspismos and other pro-European leftish parties) – proposed voting against the bill (Review, 1 September 2005). Following these committee sessions, the bill was debated and voted on the principle and on the articles in plenary sessions.

According to the explanatory report of the Minister of Health Nikitas Kaklamanis, a physician, the bill had a dual purpose: a) the modernization of the blood transfusion system, and b) its harmonization with the imperatives of the EU directives (Explanatory report, 20 July 2005). This dual purpose was highlighted by the speakers of the ruling party in the plenary sessions. In particular, the rapporteur of Nea Demokratia Kostas Markopoulos, also a physician, stated that the bill would resolve the structural problems of the blood supply. In Greece, he said, "we did not have adverse events on transfusions all these years but we understand that the demands [regarding quality of blood], the development of scientific research, of molecular biology, are positioned toward the need to implement it regardless of its high cost, because it offers safety, it should be part of our research in transfusion therapy" (Plenary minutes, 13 September 2005, pp. 1166–1167). This reference to the use of molecular biology technologies by the deputy of Nea Demokratia, most probably to molecular diagnostics, was associated with the need of a new organizational landscape in the blood transfusion system, and was the only relevant remark on this issue in the plenary debates.

During the plenary sessions, several issues regarding the provisions of the bill were discussed. Some were about the ambiguities of the bill regarding the amount and the siting of the

blood establishments (blood centers – Κέντρα Αίματος) and the hospital blood banks (Νοσοκομειακές Υπηρεσίες Αιμοδοσίας); the accreditation process and the quality control inspections; the funding, staffing and responsibilities of the EKEA; and the operation of the plasma center. Some of these issues provoked further legislative initiatives, and I refer more to them later. Hence, the re-establishment of EKEA (which had been projected as a result of the 1988 law, as noted above) was welcomed by the members of parliament. Nonetheless, certain aspects of its planned operation were commented on. The issue of its staffing was noted in association to the sufficiency of the foreseen personnel, the type of the employment status, and the membership in its board of directors.[6] Moreover, clarifications were sought regarding the incorporation of the National Blood Products Preparation Center "Elias Politis" into EKEA.[7]

A great part of the discussion, however, revolved around issues of volunteer donorship, blood sufficiency and blood safety. Several members of parliament belonging to the opposition and the ruling party noted the absence of specific provisions for the enhancement of volunteer donorship. This was also mentioned on the review of the Scientific Agency of the Hellenic Parliament (Review, 12 September 2005). In particular, deputies from the party PASOK asked for a well-rounded, comprehensive, updated national program to contribute to the advancement of the volunteer donorship and the systematic public awareness and blood donor motivation (Plenary minutes, 13 September 2005, pp. 1168, 1173, 1179, 1181, 1187; 20 September 2005, pp. 1395, 1398). The speaker of PASOK, A. Perlepe-Sifounaki, also a physician, claimed the need to institutionalize specific funds for blood donor recruitment actions (Plenary minutes, 20 September 2005, p. 1395). She also noted the lack of a provision regarding specific expenditure for the computerization of the blood transfusion system (Plenary minutes, 13 September 2005, p. 1169). The minister N. Kaklamanis responded that it had been specified in the bill that EKEA was

[6] The board of directors of EKEA, according to the law 3402, consists of: the president, vice-president, and four members, with experience on matters of blood transfusion, selected by the minister of health; a representative of Panhellenic Federation of Blood Donors Associations (POSEA); a representative of the Greek Federation of Thalassaemia (EOTHA); a representative of EKEA's employees.

[7] The Minister N. Kaklamanis stated that a new fractionation center had been programmed in 1998, had begun to be constructed in 2000 and was scheduled to be completed in August 2002. According to his account, the construction was not completed on time and the contractor was not paid (Plenary minutes, 13 September 2005, pp. 1174-1175). When he became minister of health in 2004, the ministry renegotiated the compensation of the contractor and acted toward the completion of the facilities (premises of 6.000 m^2 on a holding of 55.000 m^2). In these facilities the new blood center would be established. In addition, the operation of the new fractionation center would not set but was envisioned in the near future after cautious planning and deliberations with experts.

responsible for carrying out educational activities on donor recruitment, and that the necessary funds were not that high (Plenary minutes, 20 September 2005, p. 1403).

A final remark should be made regarding this parliamentary debate. The deputies from the opposition parties expressed their concerns about the realization of the reorganization of the blood transfusion system as designated, and the timely manner of the compliance to the requirements of the EU directives. The minister assured the audience that specific technical and organizational aspects would be resolved in future bills, but he stated that the reform of the blood transfusion service should be implemented step by step, not only because there were financial constraints, but also because radical shifts could be catastrophic in the field of health (Plenary minutes, 20 September 2005, p. 1404). The bill was passed by a majority in the principle (from Nea Demokratia and PASOK) and on the articles; several articles regarding the blood supply were approved unanimously (Law 3402, 2005).

From 2003, some blood transfusion centers selectively used NAT testing. The services, as part of public hospitals, would individually procure NAT reagents and make the necessary arrangements regarding the facilities, equipment and the specialized personnel; the hospitals assumed the costs. Some blood transfusion centers performed mini-pool PCR NAT, others individual donation testing with TMA NAT. This practice created discrepancies in the quality of the collected blood in Greece. Thus, the introduction of NAT in the Greek blood transfusion services did not happen uniformly, according to a central plan.

Blood safety received extensive media coverage when a newspaper published a front-page article regarding a case of transfusion-transmitted HIV infection on 28 March 2006 (for an elaborate analysis of the press coverage regarding this event, see Chapter 6). The news coverage referred to the transfusion-transmitted HIV infection of a 16-year-old multi-transfused girl with thalassaemia in 2005. The young girl with thalassaemia tested HIV positive in routine testing in January 2006. At the beginning of March 2006, the blood transfusion center in the Ippokrateio General Hospital located in Thessaloniki specified a blood donor who seroconverted and tested HIV positive after he had donated blood. He was described as a 38-year-old male first-time donor who had donated blood on 29 August 2005 for friends or relatives in need of transfusion while being hospitalized in northern Greece. On 29 March 2006 one more patient was reported as having received transfused plasma from the same donor (the patient was described as a 76-year-old male with heart disease from the city of Trikala). The HIV transfusion-transmitted infections were attributed to the window period of the seroconversion of the donor, who had been infected

a few days before he donated blood. The sample was tested with serologic methods and was released as a false negative. It was not tested with molecular diagnostic techniques, as these had not been implemented in blood transfusion centers in Thessaloniki at that time.

As reported, KEELPNO was informed of these details on 15 March 2006, and the Minister of Health a few days later. On 14 February 2006, following a government reshuffle, Dimitrios Avramopoulos (deputy of Nea Demokratia) was appointed Minister of Health, succeeding N. Kaklamanis. When the minister was informed of the event, he issued a ministerial circular (Εγκύκλιος Ε47/24.3.2006) asking for the nationwide use of NAT screening (Plenary minutes, 29 May 2006, p. 6990). On 28 March 2006, the day that the newspaper *To Vima* exposed this story, a press conference was held in the Ministry of Health; present were, among others, the Minister and the Deputy Ministers of Health, the Director of KEELPNO Professor A. Hatzakis, and the Director of SKAE C. Politis. Minister D. Avramopoulos stated that the ministry would pursue rapid implementation of NAT screening nationwide, in all the 14 blood transfusion centers, over the ensuing two months. In the meantime, blood units collected in blood banks not performing NAT testing would be screened with NAT in the eight centers that had already been using it.

The issue was discussed in the Hellenic Parliament after current questions had been addressed by deputies of the opposition parties to the government. On 5 May 2006, a deputy from KKE asked of the Minister of Health about the implementation of NAT following an announcement about using NAT in nine blood transfusion centers nationwide (Plenary minutes, 5 May 2006, p. 6131). She further questioned the immediate actions that would be taken by the ministry for the use of NAT, for the proper staffing of the blood transfusion services and for the enhancement of voluntary blood donation (Plenary minutes, 5 May 2006, p. 6131). The Deputy Minister of Health Athanasios Giannopoulos, a physician, referred to the plan of the ministry to implement NAT screening in nine blood transfusion centers in a centralized manner, as in other countries, and concluded that: “This modern and costly technique does not lead to absolute transfusion safety because the window period does close but a crack remains and an adverse event can occur” (Plenary minutes, 5 May 2006, p. 6132).

A few weeks later, a deputy from SYRIZA asked the Minister of Health why NAT testing was not being performed universally, and what actions would be taken to deal with it (Plenary minutes, 29 May 2006, p. 6990). The Deputy Minister replied that NAT had begun to be used in northern Greece, and it was foreseen that all donated blood would be screened with NAT in nine centers until the end of July 2006 (Plenary minutes, 29 May 2006, p. 6990). He further argued that

"we should not give the wrong impression, the technique that is now legitimately used (ELISA) is not an outdated method," and mentioned that NAT testing was supplementary (Plenary minutes, 29 May 2006, p. 6990). F. Kouvelis from SYRIZA asked again at what point NAT testing would become universal, as the ministerial circular had specified. Deputy Minister A. Giannopoulos replied that the process could not be automated, because the use of NAT required technical knowledge and specialized infrastructure; "it is not about the cost. It is about the know-how" (Plenary minutes, 29 May 2006, p. 6991).

A more elaborate debate took place on 5 June 2006, discussing a question from a group of 29 members of parliament from PASOK about transfusion-associated risks (the question was filed on 4 April 2006, a few days after the aforementioned incident was publicized). The speakers from PASOK questioned the action plan and the timetable of the government regarding the universal use of NAT and other related issues, including overall public health policy, the poor operation of EKEA, the specification and siting of the blood establishments (blood centers), the mode of procurement for NAT, blood sufficiency and national self-sufficiency, and volunteer donorship (Plenary minutes, 5 June 2006). A further aspect discussed by the speakers and the Deputy Minister was the need for appropriate transport of the blood samples from blood transfusion units to a center where they would be tested with NAT (Plenary minutes, 5 June 2006).

In particular, the deputies from PASOK accused the government of delaying the expansion of the use of NAT (which had started in 2003, when PASOK was in power) with the pretext of preparing the new law for the reorganization of the blood transfusion system in 2005. They further indicted the government with trying to cut expenditure on blood screening and medical diagnostics. They also referred to a specific case (which also had appeared in the media) regarding the screening of blood in the blood transfusion center of the General Hospital of Athens "Gennimatas". According to their account, the director of the center, C. Politis, had decided to implement NAT testing, but the hospital management questioned her decision on the grounds of its high cost and not being mandatory; thus no special funds were provisioned, and an intermediate solution was found when the hospital decided to send the blood samples to be tested with NAT to the National Retrovirus Reference Center/Laboratory Diagnosis Unit of the University of Athens.

The Deputy Minister of Health, A. Giannopoulos, responded with the government's plan to adopt NAT screening technology in nine blood centers to conform with the international developments of performing molecular testing in centralized centers, due to the special needs of

personnel and facilities and the high cost (Plenary minutes, 5 June 2006, pp. 7160–7161). He further highlighted the importance of volunteer donors in assuring blood safety apart from laboratory testing. He noted that NAT had a high cost; however, regardless of the cost, the advancement of health services was a government priority (Plenary minutes, 5 June 2006, p. 7161). The speaker of SYRIZA, A. Leventis, a physician, further mentioned that an EKEA report stated that "the cost–benefit ratio from using NAT is low," and that implementation had been based more on political than scientific grounds; for him, such a perspective was not appropriate on issues of public health (Plenary minutes, 5 June 2006, p. 7164). The deputy minister concluded that the commission of NAT would proceed in a legitimate way through an invitation to tender, and the commission agreement would be ratified in the parliament. He repeated that the lack of technical knowledge had contributed to the delays. A month after, he reassured that NAT testing would be nationwide "shortly" (Plenary minutes, 11 July 2006, p. 8211).

Since March 2006, the operation of the blood transfusion system and the actions of the Ministry of Health had come under scrutiny from the media. The following chapters deal thoroughly with this press coverage. The news articles presented the political disputes and the actions taken regarding the commission of NAT in detail, at the same time criticizing and commenting on the delays in the nationwide implementation of molecular screening. In May 2006, there was information that the ministry had signed memoranda of cooperation with the two vendors of NAT systems (Roche's and Chiron's distributors in Greece). In early June, Deputy Minister A. Giannopoulos referred to procurement through a global call for tenders. The whole process was under the close attention of associations of people with thalassaemia, who expressed their views in the press; detailed coverage can be found in *Mediterranean Anaemia Issues* published by PASPAMA. Two editorials of the aforementioned periodical expressing condemnation for the political actions regarding the materialization of the announcement for the use of NAT are indicative ("Της σύνταξης", 2006; "Της σύνταξης", 2007). EOTHA and PASPAMA had been petitioning the health authorities to implement NAT universally since March 2006 ("Μοριακός έλεγχος", 2007).

To proceed with the commission of NAT in a legitimate way, a cross-party parliamentary committee was formed (No. Π1/3006, 2006, pp. 14137-14138),[8] responsible for the procurement

[8] The committee was set up in 10/07/2006 according to regulation for the procurement of goods of high financial or technological value (for procurement exceeding the value of EUR 15 million) by a common decision of the minister of finance, minister for development and minister of health. President of the committee was the minister of health and members were the general secretary of the ministry of finance, the general secretary of commerce

procedure following the specifications set by a scientific committee.[9] It would evaluate the bids and ratify the final agreement. The technical specifications for the procurement were accepted by the committee (with the reservations of the representatives of KKE and SYRIZA) and the call for tenders was approved on 6 November 2006 (Plenary minutes, 13 November 2006, p. 1196). On 15 November, a tender notice with an operating budget EUR 208,250,000 for the commission of nationwide NAT was published -*Αρ. Δ/ξης 10/2006*- (No. ΔΥ6β, 2006, p. 13196).[10] The contract notice referred to the implementation of NAT to nine blood transfusion centers, named Centers of Molecular Blood Testing. The expenditure would be covered by each hospital's budget, depending on the number of blood samples sent from each blood transfusion service to one of the nine centers, with which it would be interconnected.[11]

Shortly after, on 9 January 2007, an *ad hoc* committee was set up by the Ministry of Health to examine the supporting documents and to evaluate the technical and financial offers (No. ΔΥ6β, 2007, pp. 1728–1729).[12] The deadline for placing bids was 9 January 2007, but, according to the newspapers, both companies had filed appeals regarding the open tender (for different reasons), and it was decided that the deadline would be prolonged until 25 January.[13]

I should make two notes regarding the procurement procedure for NAT. First, the tender specified that the commission would include the necessary equipment and its installation and maintenance; the reagents; the training of personnel for the use of NAT; and the transport and handling of the blood samples to blood centers (or Centers of Molecular Blood Testing) for up to five years (No. ΔΥ6β, 2006, p. 13196). Thus, the indications covered many aspects of the use of the new technology. The issue of the transport of biological material, in this case blood samples,

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and the special secretary of privatizations. In addition, members were specified to be S. Ntouni (Councillor of the Court of Audit), T. Papadimitriou (representing Nea Demokratia), M. Katrines (representing PASOK), A. Tzioka (representing KKE), E. Sagkana (representing SYRIZA) and an alternate member for each one.

[9] The minutes of the sessions of the cross-parliamentary committee have not been retrieved.

[10] The number of the tender notice was *Αρ. Δ/ξης 10/2006*. The tender notice was further published on the Supplement to the Official Journal of the European Union dedicated to European public procurement on 21/11/2006, see TED, 2006.

[11] The structure would be similar to the previous one according to which a blood transfusion unit was interconnected to one of the fourteen regional blood transfusion centers. The centers were now designated to be nine and were renamed as Centers of Molecular Blood Testing.

[12] Members of the committee were: M. Parara (haematologist and director of a blood transfusion unit), E. Theodori (haematologist and alternate director of a blood transfusion center), E. Andrioti (biopathologist, director of a blood transfusion center), S. Panagopoulou (head of the General Directorate of Health), E. Kouskouni (microbiologist and university associate professor), G. Pappous (physicist-biomedical engineer and CEO of the Research Center of Biomaterials, EKEVYL), V. Kontozamanis (Vice-President of the National Organization for Medicines, EOF). M. Parara was appointed president of the committee.

[13] See: Η καραμπόλα... (2007, January 3). *Rizospastis*, p.4.

had been discussed in many instances since there was lack of specific provisions. Deputy Minister of Health A. Giannopoulos had noted the need for a process of accreditation of the companies capable of taking on blood delivery (Plenary minutes, 5 May 2006, p. 6133; 29 May 2006, p. 6991; 5 June 2006, p. 7161). A provision regarding the specific licensing for transporting biologic material (blood and plasma) was included in a bill of the Ministry of Transport and Communications at the end of January 2007 (Plenary minutes, 30 January 2007, pp. 3936, 3957; Law 3534, 2007).

Second, with respect to the type of molecular testing, individual donation or mini-pool testing, the testimony of an *ad hoc* committee entitled "Justification for the implementation of molecular testing in individual samples against mini-pool" (Αιτιολόγηση εφαρμογής μοριακού ελέγχου σε μονήρη δείγματα έναντι των μικροδεξαμενών) was given on 31 January 2007 addressed to the General Secretary of the Ministry of Health ("Η επιστημονική ομολογία", 2007). The testimony began with an introductory overview of the development of NAT screening technologies and asserted that, at that point, individual donor testing was feasible and preferable because of its greater sensitivity. Thus, universal individual donor nucleic acid testing (ID-NAT) was "superior". According to the members of the committee, such a decision should be made in reference to local conditions such as a) the prevalence of HIV, HCV and HBV; b) the composition of the blood donor population; c) geography; d) the organizational structure of the blood transfusion service; e) the scientific level of the clinical and laboratory service; and f) the categories of multi-transfused patients ("Η επιστημονική ομολογία", 2007).

The committee advised in favor of individual testing based on the following arguments: a) the fact that more that 50% of the blood donors were sporadic, and thus the incidence of viral markers have been higher compared to regular blood donors; and b) the demonstrated higher sensitivity of single-donor testing in reducing the window period ("Η επιστημονική ομολογία", 2007). The members of the committee paid particular attention to HBV NAT screening, since it had been observed that mini-pool testing reduced the window period only for a few days. Recent research from the first half of the 2000s demonstrated that cases of acute HBV infection and occult HBV infection could be detected with individual donor NAT testing due to low viremia.[14] Moreover, Greece (as is the case for other Mediterranean countries) has a higher HBV prevalence compared to western and northern European countries and the US, Canada and Australia ("H

[14] See more in section 4.4.

επιστημονική ομολογία", 2007). The authors of the report concluded that the high cost of individual donor testing could be covered from the discontinuation of other supplementary screening tests after new guidelines would be set.

The discussion on whether to implement mini-pool or single donation testing had appeared in the news in May 2006. According to newspaper articles, a blood donor had tested positive for HIV, and the retrospective reexamination of a previous blood donation from the same donor was also found to be positive, although at the time it had been considered negative and had been released in the blood banks for transfusion.[15] The former blood sample had been tested in 2005 with NAT PCR method in mini-pools and had been found to be HIV negative; when the sample was retested with individual donation NAT, by SKAE, it was found to be positive. This event was attributed to the window period of a very recent infection. The ΕΚΕΑ testimony made reference to this case to corroborate the superiority of individual donation NAT ("Η επιστημονική ομολογία", 2007).

Regarding the progression of the procurement procedure, the two interested companies (Safe Blood Biotechnology and Roche Hellas Diagnostics) placed their bids in January 2007. The tender was conducted on 24 April. The evaluation committee, which included transfusion medicine specialists as members, checked to ensure the offers contained all the essential items and evaluated them on the basis of the technical specifications set out. According to Minister D. Avramopoulos, while opening the financial offers of the tenders, the evaluation committee noted and the cross-parliamentary committee decided that the offers were not financially beneficial for the state (Plenary minutes, 30 January 2008, p. 4092).[16] It was then decided that the results of the open tender would be aborted. The cross-parliamentary committee decided to follow a negotiated procedure to expedite the conclusion of the tender. The companies were asked to submit new offers and did so on 20 August 2007.[17]

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[15] See articles "Άνοιξαν παράθυρο" στο AIDS!. (2006, May 11). *Ta Nea*, p.14. (Despoina Kouklaki); Ελέγχεται η πιθανότητα νέου κρούσματος AIDS. (2006, May 11). *To Vima*, p.17; Διαπίστωση μόλυνσης σε παλιά μετάγγιση. (2006, May 11). *Rizospastis*, p.21; Πιθανή μετάγγιση HIV σε 85χρονο ασθενή. (2006, May 11). *I Avgi*, p.10; Φόβοι για νέο κρούσμα έιτζ μέσω αιμοδοσίας. (2006, May 11). *I Kathimerini*, p.7; Μολυσμένο αίμα πήρε και 85χρονος. (2006, May 11). *Eleftherotypia*, p.?; Αιμοδότρια με AIDS. (2006, May 11). *Ethnos*, p.?. (Dimitris Karagiorgos).

[16] The minister provided information on the tender when replying to a question asked by a deputy of PASOK regarding the nationwide application of NAT. The question was filed on 5/10/2007 and the minister replied on 20/11/2007; the records appeared on the plenary minutes on 30/01/2008. Since the minutes of the cross-parliamentary committee meetings have not been retrieved I cannot provide more information on the negotiated procedure.

[17] Lawyer P. Demetriades (2008), who was the legal advisor of one of the two companies, documented in a paper a detailed account of the legal aspects of the procurement. According to him, one company's bid was lacking

In the meantime, blood transfusion services could pursue direct commission of NAT systems until the nationwide procurement concluded. This process was not, however, straightforward; on the contrary, it was rather complicated.[18] For more than two years following the announcement of the nationwide use of NAT, a proportion of the blood directed at transfusions was tested with NAT. This was problematic and created discrepancies in the quality and safety of the blood supply (EAE, 2008). The Minister of Health stated that the ministry had decided to announce a call for tenders to achieve "safer blood supply and, thus, the protection of public health"; the task was "complicated" and included the overall provisions for the use of NAT (Plenary minutes, 30 January 2008, p. 4092; 12 May 2008, p. 8781). This description regarding the use of NAT contradicted the announcement of the minister in March 2006 promising nationwide NAT screening of blood in two months.

In early 2007, PASPAMA deployed various means to claim the immediate use of individual donation NAT nationwide and to convey to the officials the problems people with thalassaemia were facing such as blood shortages and the improper function of hospital facilities ("Η παρέμβαση του ΠΑΣΠΑΜΑ", 2007). For instance, EOTHA and PASPAMA particularly asked for the immediate use of NAT screening in the Athenian hospital center "Drakopouleio" (one of the 14 blood transfusion centers operating in a hospital with an effective department for the treatment of people with thalassaemia) for the transitional period until the conclusion of the tender process ("Μοριακός έλεγχος", 2007). In cooperation with the management of the center, they achieved their goal; however, in practice, the decision for the use of NAT did not materialize immediately

essential supporting documents and was rejected; the other company's bid was evaluated as inadequate for four out of the nine blood centers and was considered for the remaining five. The tender was considered financially not beneficial and aborted. Both companies participated in the negotiations and placed new bids.

[18] The process was complicated for various reasons: limited hospital budgets; limitations to the amount allocated for direct commissions; allegations about overpriced equipment; lack of necessary staff and infrastructural challenges. The newspapers covered a few particular cases of direct commissions of molecular testing by hospitals, see Σειρά προβλημάτων στον τρόπο ανάθεσης μοριακών εξετάσεων. (2008, April 21). *Ethnos*, p.?. (Dimitris Karagiorgos). More publicity was given to the case of the general hospital "Amalia Fleming" (one of the 14 blood transfusion centers, located in Attica region) in which the Body of Inspectors for Health and Welfare Services (SEYYP, Σώμα Επιθεωρητών Υπηρεσιών Υγείας και Πρόνοιας) investigated the procedures regarding the commission of NAT system. The newspaper *I Avgi* reported expensively on this case, see: Πώς δύο εταιρείες έκλεβαν το νοσοκομείο "Αμ. Φλέμινγκ". (2008, May 2). *I Avgi*, p.1. The vendor of Chiron screening equipment sent an out-of-court legal notice (εξώδικο) against the newspaper *I Avgi* regarding the aforementioned articles. The newspaper published this document and its journalist replied by referring to the findings from the investigations made by the official body, see Εξώδικη διαμαρτυρία - δήλωση και πρόσκληση. (2008, May 6). *I Avgi*, p.18; Επίθεση της πολυεθνικής "Chiron" στην "Αυγή" για το αίμα!. (2008, May 6). *I Avgi*, p.19. (Vasilis Venizelos); Παρέμβαση Καλογερόπουλου στον διαγωνισμό του "Αμ. Φλέμινγκ"; (2008, May 6). *I Avgi*, p.19. (Vasilis Venizelos); Πλήρης επιβεβαίωση της "Αυγής" για το αίμα στο "Αμ. Φλέμινγκ". (2008, May 9). *I Avgi*, p.32. (Vasilis Venizelos); Για τον μοριακό έλεγχο του αίματος στο "Αμ. Φλέμινγκ". (2008, May 10). *I Avgi*, p.26. (Vasilis Venizelos).

and the PASPAMA members talked about "conscious mockery" on behalf of the officials ("Φάκελος Αίμα", 2007).

According to Minister D. Avramopoulos, the technical parts of the new bids were evaluated on 24 August 2007 (Plenary minutes, 30 January 2008, p. 4092). On 16 September, snap national elections were held in Greece. The political party of Nea Demokratia won the elections and formed a government. D. Avramopoulos resumed his post at the Ministry of Health. PASOK was the major opposition party in the new parliamentary period. Apart from the minor opposition parties KKE and SYRIZA, one other political party was elected to the parliament: LAOS (Λαϊκός Ορθόδοξος Συναγερμός), an ultra-right conservative party. Thus, the cross-parliamentary had to be reformed in the new parliamentary period. The new composition of the cross-parliamentary committee was set up on 3 January 2008 (No. Π1/4821, 2008, pp. 9–10).[19]

From the end of 2007, the newspapers reported extensively on the work of the cross-party parliamentary committee. At different points the coverage referred to an economic scandal regarding the procurement procedure and the two companies involved in it (the vendors of NAT systems). Some newspapers reported that the conflicting interests of the two companies contributed to the delays in the conclusion of the tender process.[20] The newspapers also reported official announcements from the Ministry of Health estimating that about 70% of the collected blood was screened with NAT, while the procedure for the nationwide commission was near completion.[21]

At the beginning of November 2007, E. Oikonomou-Petersen, vice-president of ΕΚΕΑ's board of directors, released a document expressing ΕΚΕΑ's position regarding the procurement process; the document also appeared in the newspaper *To Vima*.[22] According to Oikonomou-Petersen, she identified six challenges faced the supply of blood that needed further assessment: a) about 40% of the collected blood was not screened with NAT; b) although various measures

[19] The representative of PASOK to the committee was changed to P. Kormas and the representative of LAOS was specified to be A. Papamichail. The composition of the committee was further altered: on 28/02/2008, the Councillor of the Court of Audit was replaced, the new member was E. Lykesa (Αριθμ. Π1/563, 2008, pp. 635-636); on 01/07/2008 the representative of the ministry of finance was replaced (Αριθμ. Π1/2240, 2008, pp. 2039-2040).

[20] For example see: Οι εταιρείες και η διαμάχη για τον μοριακό έλεγχο. (2007, November 16). *To Vima*, p. A5; Απαράδεκτες καθυστερήσεις με οδυνηρά αποτελέσματα. (2007, November 16). *Rizospastis*, p. 16;

[21] For example see: Μεταγγίσεις στα τυφλά. (2007, November 16). Ta Nea, p.15; Πόλεμος συμφερόντων για το αίμα. (2007, November 16). *To Vima*, p.A4. (Elena Fyntanidou); Έλεγχος για μετάδοση ηπατίτιδας από μετάγγιση. (2007, November 16). *Eleftherotypia*, p.?; 60χρονη μολύνθηκε με ηπατίτιδα Β' ύστερα από μετάγγιση αίματος. (2007, November 16). *Ethnos*, p.?.

[22] Ανεπαρκής έλεγχος στο αίμα. (2007, November 15). *To Vima*, p. A6. (Elena Fyntanidou)

had been taken, there was an "institutional" gap in NAT testing; c) many hospitals had attempted the supply of NAT on a unit basis; d) the need to clarify the procedures followed by certain hospitals in sending their samples for NAT testing to the National Retrovirus Reference Center at the University of Athens; e) the way the laboratory of the National Retrovirus Reference Center, which did not belong to the blood transfusion service, could take over NAT testing of blood samples, while ΕΚΕΑ could not initiate single-unit testing (ΕΚΕΑ had already been performing mini-pool testing); and f) the fact that NAT testing cost less in many European countries ("Φάκελος Αίμα", 2007, p. 15). For Oikonomou-Petersen, ΕΚΕΑ had a duty to oversee the process of NAT commission, but it did not in practice. Later, I will refer again to the operation of ΕΚΕΑ during this period.

Further to these discussions on the procurement process, and in reaction to the lengthy procedures described above, the newspapers reported in March 2008 that the two companiesinvolved in the procurement scandal had filed applications for interim injunction before the Hellenic Council of State (Συμβούλιο της Επικρατείας).[23] The companies wanted this injunction so that the procurement process would not proceed until a final court judgment could be made on the filed applications for annulment (Demetriades, 2008). On 14 March, three members of the cross-party parliamentary committee (belonging to the opposition parties PASOK, KKE and SYRIZA) addressed a letter to the members of the Council of State who were deliberating on the case ("Φάκελος Αίμα", 2008a, p. 6). The members of the cross-party parliamentary committee proposed to evaluate the financial offers before the court decision on whether the injunction would stand or be canceled.

The stated purpose of their letter was to inform the members of the Council of State of the long procurement process; for them, the two companies had "for three years at least, with urgent processes, managed to supply with reagents and equipment the country not through a public competition but through non-contractual and opaque procedures," resulting in higher prices ("Φάκελος Αίμα", 2008a, p. 6). The companies "were at 'underground' war using judicial means to delay the decision about the tenders" for providing equipment to blood transfusion services, so that at the end of the competition procedure the hospitals would have to commit to

[23] See: Με αναθέσεις προχωρά ο μοριακός έλεγχος του αίματος!. (2008, March 9). *I Avgi*, p. 52; Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos).

one or the other company's NAT system.[24] The members of the cross-parliamentary committee referred to the fact that particular hospitals in Athens assigned NAT testing to a laboratory not belonging to the indicated blood centers to assume NAT after the completion of the procurement ("Φάκελος Αίμα", 2008a, p. 6). The letter did not specify the laboratory, but referred to the National Retrovirus Reference Center at the University of Athens.

PASPAMA replied to this letter by addressing the members of the Court of State in a detailed letter. PASPAMA board members replied to every point raised by the three members of the cross-parliamentary committee ("Φάκελος Αίμα", 2008a, pp. 10–11). According to them, the interim direct commission of NAT by hospitals aimed at the protection of public health from transfusion-transmitted infections, and so did the actions of the National Retrovirus Reference Center. They pledged that the award of the contract would not be based solely on the financial offers of the tenders, but also on compliance to the technical specifications, so as not to compromise the quality of the blood. PASPAMA members questioned the motives of the members of the cross-parliamentary committee in addressing the Court of State, since the latter wanted to evaluate the financial offers before the court decision and the cancellation of the whole procurement process would then be made possible. On 27 March 2008, the board of directors of EAE sent a letter to Minister D. Avramopoulos expressing its worries for the delay on the universal use of NAT, which they attributed to the war between the two companies (EAE, 2008).

At the beginning of April 2008, according to news articles, the Council of State overruled the applications for injunction. Following that, the financial offers of tender were opened and the negotiation began.[25] On 23 April, an article in *To Vima* stated that the price of NAT testing per unit of blood ranged from EUR 38.50 to EUR 45 in the bids, while the price charged at the hospitals ranged from EUR 50 to EUR 57.[26] At the end of May, the newspapers published an announcement

[24] The letter was published on the periodical of PASPAMA. Parts of it were also mentioned on the press: Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos); Χωρίς μοριακό έλεγχο το 30% του συλλεγόμενου αίματος. (2008, March 27). *To Vima*, p. A12. (Elena Fyntanidou). The newspaper *I Avgi* published a letter, sent to its editors, by the company Roche on 27/03/2008. The company replied to the article published on 18/03/2008 regarding the application for an injunction. The representatives of the company denied that Roche provided equipment for molecular screening to hospitals through any type of direct commission and stressed that the co-bidder company first went to court against the procurement process and then Roche followed up in order to protect its rights, see Η Roche για τον μοριακό έλεγχο του αίματος. (2008, March 29). *I Avgi*, p. 10.

[25] See: Ανοίγουν οι προσφορές για τον έλεγχο αίματος. (2008, April 9). *I Avgi*, p. 19; Ύποπτα παιχνίδια σκοπιμότητας στον διαγωνισμό για το αίμα. (2008, April 30). *I Avgi*, p. 6.

[26] Μαίνεται ο πόλεμος για την "πίτα" του αίματος στα δημόσια νοσοκομεία. (2008, April 23). *To Vima*, p. A14. (Elena Fyntanidou)

made by the Ministry of Health stating that the cross-party parliamentary committee, following negotiations with the two companies, had ensued discount by 31.54% from the budget initially allocated to the implementation of NAT.[27] The negotiations would be continued and the adjudication of the agreement would be concluded after the final ruling of the Council of State regarding the applications for annulment filed by the two companies (Plenary minutes, 30 May 2008, p. 10212).

The Council of State rejected the applications by a majority of votes (two to one, Demetriades, 2008). According to the news, the public tender for the nationwide commission of molecular diagnostics was adjudicated at the meeting of the cross-party parliamentary committee held on 9 June.[28] The decision was approved by a majority of the members, whereas the representatives of KKE and SYRIZA disapproved it on the ground that the final bids were still higher than the price offered in other European countries ("Φάκελος Αίμα", 2008b). The commission of NAT in five Centers of Molecular Blood Testing was awarded to the vendor of Chiron NAT system (S.B. Biotechnology Suppliers S.A.) and in the four remaining centers to that of Roche (Roche Diagnostics Hellas S.A. – Katopis Group S.A.).[29] According to the announcement issued by the Ministry of Health, the discount reached 32.19%, and the offer "was considered beneficial and a success of the members who participated in the committee."[30] On 9 August, the newspapers reported that the cross-party parliamentary committee had concluded its task for the procurement of universal NAT testing in the nine Centers of Molecular Blood Testing and the agreement had been validated by the Court of Audit.[31] The signing of the contracts was

[27] Μόνο μια βάρδια με ευθύνη της κυβέρνησης. (2008, May 24). *Rizospastis*, p. 33; Πανηγυρικοί τόνοι από το υπ. Υγείας για το αίμα. (2008, May 24). *I Avgi*, p. 7.

[28] See: Καταψήφισε το ΚΚΕ την κατακύρωση με υψηλές τιμές. (2008, June 11). *Rizospastis*, p.14; Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 11). *I Avgi*, p. 19. (Vasilis Venizelos). Regarding the agreement for the commission of NAT, Roche sent two letters to the newspaper *I Avgi* in which it explained that the cost of NAT testing per unit in Greece did not include only the price of the reagent but also the transport of the blood sample, the configuration of the laboratories and the technicians, thus, it was more expensive that in other countries, as demonstrated in the articles published by *I Avgi*, see: Διευκρινίσεις χωρίς αντίκρισμα από τη "Roche" για το αίμα. (2008, June 20). *I Avgi*, p. 30. (Vasilis Venizelos); Η "Roche" για τον μοριακό έλεγχο του αίματος. (2008, July 1). *I Avgi*, p. 19.

[29] Chiron's vendor would supply the blood centers in ΕΚΕΑ, ΑΧΕΡΑ hospital in Thessaloniki, Alexandoupoli hospital, Douroutis hospital in Ioannina, and Larissa hospital; Roche's vendor would supply two Athenian hospitals (Laiko and G. Gennimatas), Venizeleio hospital in Heraklion, and university hospital of Rio in Patra.

[30] Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 11). *I Avgi*, p. 19. (Vasilis Venizelos)

[31] Πράσινο φως για τον μοριακό έλεγχο του αίματος σε 9 κέντρα. (2008, August 9). *To Vima*, p. A13; Ολοκληρώθηκε σε υψηλές τιμές ο διαγωνισμός. (2008, August 9). *Rizospastis*, p. 12; Απείχε ο ΣΥΡΙΖΑ, υπέρ ψήφισε το ΚΚΕ. (2008, August 9). *I Avgi*, p. 13. (Vasilis Venizelos)

announced by the Minister of Health on 25 August; the minister was said to have stated that the procurement of NAT was "the largest project in the history of the Ministry of Health." [32]

The conclusion of the procurement process did not lead to immediate universal use of NAT screening. The adoption of the complex infrastructure for molecular screening involved specific arrangements in the blood centers and special training of the personnel; some blood centers would also have to rearrange their facilities and laboratory practice, since in the interim period they had been using TMA NAT (Chiron) and would now have to use PCR NAT (Roche) (or vice versa). By all accounts, from the end of October 2008, blood has been screened with single-donation NAT for HIV, HCV and HBV nationwide.

4.3. Further aspects of the (re)organization of the blood transfusion service

In this section, I refer again to the (re)organization of the blood transfusion service as envisaged in legislation passed between 2005 and 2013. The analysis focuses on the organizational aspects of the operation of the blood transfusion service given the challenges from the implementation of the legislation and the European processes on overseeing the application of the Blood Directives. One of the main goals of the European directives, transposed into the national legislation, has been to formalize a tripartite institutional setting in which the designated competent authority (or authorities) would be responsible for specifying and authorizing the blood establishments (which are themselves responsible for activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion) and for licensing and monitoring hospital blood banks (which can store, distribute and perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities).

In Greece, the new organizational landscape designated the Ministry of Health and EKEA as component authorities. The former regional blood transfusion centers would function as blood establishments (called blood centers); an interim period of three years was provided to conform to licensing and accreditation processes. The rest of the blood transfusion units would be hospital

[32] Υπεγράφησαν οι συμβάσεις για τον μοριακό έλεγχο του αίματος. (2008, August 26). *I Avgi*, p.17; Ακόμα δεν τον είδανε... (2008, August 27). *Rizospastis*, p. 4.

blood banks, i.e. responsible for transfusions in the respected hospital, for performing compatibility tests and some screening tests; selected processes (NAT screening and other) would be assumed by the blood center with which each one would be interconnected regionally. In the case of Greece, a hospital blood bank, in cooperation with the blood center, could additionally collect blood and get involved in blood donation procedures at a local level. This organizational scheme bared similarities with the former organization of the blood supply in Greece, but also posed challenges.

An essential facet of this process was the need for EKEA to be set up quickly to coordinate the blood transfusion service. As noted before, EKEA was inaugurated a few months after the approval of the 2005 law. EKEA included the National Blood Products Preparation Center "Elias Politis" (the services and the personnel of the plasma center were transferred to EKEA). According to various sources, EKEA faced many difficulties. To be more specific, the financing of EKEA had not been resolved by the ministry. In February 2007, another Act stipulated that the operating costs of EKEA would be covered for the period from 28 November 2005 to 31 December 2007 by the Nikaia General Hospital "Agios Panteleimon", the public hospital in which the plasma center had been operating before being transferred to EKEA (Law 3527, 2007).

EKEA's board of directors was provisioned with a three-year duty; six out of its nine members were elected after a decision of the Ministry of Health. The first president of EKEA resigned a few months after its inauguration. When D. Avramopoulos became Minister, he appointed another president. In September 2007, Alexandros Giannakakis, then president of EKEA, resigned, claiming that the lack of EKEA financing had created serious problems and that he had not been paid since assuming his duties in a position of full and exclusive employment ("Εθνικό Κέντρο Αιμοδοσίας: Αιμορραγεί", 2007, pp. 12–13). The periodical *Mediterranean Anaemia Issues* published his letter of resignation and a letter sent by the Association of EKEA Employees to the Ministry of Health (3 October 2007). According to the employees (a distinction should be made between the permanent employees of EKEA, those transferred from Nikaia hospital, and the rest who were temporarily employed with eight-month contracts), EKEA did not have its own budget, which hindered its proper operation. By the end of 2007, the issue of remuneration had not been settled, and the contracted employees had not been paid since the initiation of their contracts and had refrained from working since July 2007. EKEA had outstanding bills to public utilities, suppliers and the outsourced company covering cleaning services ("Εθνικό

Κέντρο Αιμοδοσίας: Αιμορραγεί", 2007, p. 14). The understaffing of EKEA was also covered in news articles.[33]

This situation was discussed in parliament, when M. Skoulakis, the PASOK deputy, posed a current question to the Minister of Health (filed on 2 October 2007). Skoulakis described the problems EKEA was facing and asked the minister about his intended actions to ensure its proper operation (Plenary minutes, 8 October 2007, p. 513). D. Avramopoulos replied that the 2005 law "organized, for the first time, the ungoverned, until then, field of blood transfusion" (Plenary minutes, 8 October 2007, p. 513); it was reasonable that EKEA would face some problems during the initial period of its operation, but "from 2008 it would gain full operational autonomy" (Plenary minutes, 8 October 2007, p. 514). An additional point in the parliamentary debates and in the concerns expressed by the employees of EKEA was the fact that the problematic operation of EKEA did not permit the blood products center to function properly; large quantities of recovered plasma remained stored in EKEA instead of being sent to the collaborating Dutch fractionation center.

In March 2008, a letter addressed to the Minister of Health D. Avramopoulos by the board of directors of EAE and other actors (the Hellenic Blood Transfusion Society and patient groups) asked for the universal use of NAT, as noted above, and criticized the limited reorganization of the blood services anticipated in the 2005 law.[34] The actors further specified that EKEA still had to resolve vital aspects regarding its operation (EAE, 2008). In addition to this, while EKEA would be responsible for the blood centers as stated in the 2005 law, a new ruling in 2007 indicated they would be units of the respective hospitals (Law 3527, 2007). Thus, EKEA would have limited authority over them. It was further noted that there were few explanatory rulings regarding the provisions of the 2005 law, as a result of which the blood transfusion services did not know their designation (would they keep their former name or would they be renamed?), while their accreditation was proceeding very slowly (EAE, 2008). The understaffing of the services further generated operational problems.

[33] For example in May 2008, see: Μόνο μια βάρδια με ευθύνη της κυβέρνησης. (2008, May 24). *Rizospastis*, p. 33; Πανηγυρικοί τόνοι από το υπ. Υγείας για το αίμα. (2008, May 24). *I Avgi*, p.7.

[34] The patient groups were EOTHA, SYPPADREMIA (Panhellenic Association for Protection of People with Sickle-cell Anaemia, Πανελλήνιος Σύλλογος Προστασίας Πασχόντων από Δρεπανοκυτταρική & Μικροδρεπανοκυτταρική Αναιμία), and the Association for Protection of Greek Haemophiliacs (Σύλλογος Προστασίας Ελλήνων Αιμορροφιλικών).

The Ministry of Health issued a decision about the specification of blood establishments (blood centers) and hospital blood banks in September 2009 (No. Υ4γ/οικ.121672, 2009). According to this, 9 blood centers and 101 hospital blood banks would operate; their authorization and licensing would be issued by the ministry after a proposal by EKEA; EKEA would be responsible for organizing inspections. Thus, the authority granting the authorization and accreditation would be the same one performing inspections.

Regarding the regulatory framework, following the 2005 legislative initiatives, the Greek State had to transpose the following into national legislation: Directive 2005/61/EC dealing with traceability requirements and notification of serious adverse reactions and events, and Directive 2005/62/EC regarding Community standards and specifications relating to a quality system for blood establishments. Both Directives fleshed out technical and other aspects of the framework Directive 2002/98/EC. Presidential decree 25, harmonizing the national legislation with the two Directives, was published in the government gazette on 24 March 2008.

Since 2005, the European Commission has been regularly monitoring on the transposition and implementation of the European regulatory framework about blood and blood components.[35] From the end of 2005, the designated authority from Greece has been the EKEA, which provided information to the European Commission regarding the implementation of the Directives. As mentioned above, Greece transpose into the national legislation Directives 2002/98/EC and 2004/33/EC in 2005. As for Directives 2005/61/EC and 2005/62/EC, Greece did not adopt these on time; the time-limit for their transposition expired on 31 August 2006, and, thus, Greece failed to fulfil its obligations. Nor was the European Commission notified in timely manner of the adoption of those provisions. In March 2008, the Commission of the European Communities brought action against Greece before the Court of Justice of the EU (Case C-117/08 on 17 March 2008; Case C-121/08 on 19 March 2008).[36] However, the Ministry of Health did

[35] According to Directive 2002/98/EC, Member States have been required to submit to the European Commission, beginning on 31 December 2003 and every three years thereafter, reports on the activities that they have carried out in relation to the implementation of its provisions. The Commission has been required not only to forward these reports to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions but, commencing on 1 July 2004 and every three years thereafter, also to provide them with a report on the implementation of the blood directive's requirements, in particular those relating to inspection and control. The Commission convened a first meeting of representatives of the competent authorities on 26/09/2005 in order to have an exchange on the experiences encountered in the transposition of the directives into their national law (EC, 2005). The first report on the application of the blood directive was issued on 2006 (COM, 2006b).

[36] The cases before the Court of Justice of the European Union were also reported in the periodical of PASPAMA ("Φάκελος Αίμα", 2008a, pp. 5, 10).

transpose the two Directives into national legislation in March 2008 (Presidential decree 25, 2008). In July 2008 the President of the Court ordered that both cases be removed from the register (Order of the President of the Court of 10 July 2008 for Case C-117/08; Order of the President of the Court of 8 July 2008 for Case C-121/08).

The Commission held regular meetings with the competent authorities designated by the Member States to exchange information on the experiences encountered in the course of the implementation of the Directives regarding blood and blood components. During these meetings, the competent authorities provided information about the implementation of the Directives by replying to questionnaires; the responses were published by the Commission (EC, 2005, 2006c, 2008, 2010b). In the case of Greece, up to January 2008 the blood centers and the hospital blood banks had not been designated as such, and had neither been authorized nor inspected by EKEA (EC, 2008). In January 2009, the situation in Greece was described in reference to the anticipated law of 2009 that would specify the operation of the blood centers and the hospital blood banks (EC, 2010b). It was noted that EKEA had performed five inspections (EC, 2010b).

According to the 2010 report of the European Commission on the application of Directive 2002/98/EC and of the additional directives, the implementation was found to be satisfactory (EC, 2010a), but "further efforts and actions by Member States are needed. This concerns the finalization of the accreditation/designation/authorization/licensing process in respect of each individual blood establishment, the carrying out of inspections in all Member States, and the annual report on adverse events and reactions for the Commission" (EC, 2010a, p. 9).

Regarding the last point, it had been a challenge for the European Commission to collect and evaluate data on adverse events and reactions from blood and blood components in a consistent manner.[37] Following reporting exercises and improvements on the reporting tools, the first report on serious adverse events and reactions was published for the year 2010 (EC, 2013a). Since then, yearly reports have been published (EC 2013b, 2014, 2015). The European Commission has also been monitoring the actions taken by the Member States to encourage voluntary unpaid blood donation and planned measures to promote self-sufficiency in the European Community through voluntary unpaid donations (EC, 2006a, 2011).[38]

[37] According to Directive 2005/61/EC1 Member States have had to submit to the Commission every year an annual report on the notification of serious adverse reactions and events received by the competent authority using the formats specified in the directive.

[38] In accordance with Directive 2002/98/EC, Member States have had to submit reports on the practices promoting voluntary and unpaid blood donation to the Commission every three years.

When the Greek authorities commented on the implementation of the directives in January 2009, they specified that a new ruling would be legislated in 2009 regarding the specification of the blood centers and the hospital blood banks (EC, 2010b). However, the representatives of Greece also noted that "Due to geographical reasons and the decentralized scheme in the function of our Blood Transfusion Services it has become difficult to take away from the Hospital Blood Banks activities such as blood collection, blood testing (blood grouping and serological screening of blood for infectious markers) and blood processing" (EC, 2010b, p. 204). As noted above, to ensure blood sufficiency, hospital blood banks would continue to collect blood from non-remunerated blood donors (both regular and replacement volunteer donors).

In addition, SKAE had the responsibility for haemovigilance, i.e. surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions associated with all parts of the donation-transfusion chain since 1996 (EC, 2010b, p. 204). According to the EU directives and the national laws (Law 3402, 2005; Presidential decree 25, 2008), the designated authority was to assume such a role. In early 2011, a new ruling indicated that SKAE, which belongs to KEELPNO, would continue to be responsible for vigilance activities (and other tasks) regarding blood (No. Υ4γ/οικ.11345, 2011). SKAE would be responsible for developing networks among the clinical departments of the hospitals, hospital blood banks, blood centers and EKEA.

A committee of EAE, assigned to develop the society's opinion on the blood transfusion service, criticized this decision as it would transfer responsibilities from EKEA to another body (EAE, 2011).[39] According to EAE, EKEA would be deprived from the capability to coordinate the needed tasks regarding haemovigilance. As noted before, SKAE has been a pioneer in developing a haemovigilance system in Greece on a voluntary basis, and had been closely cooperating with other national and supranational organizations. After the establishment of EKEA, however, the reasons for SKAE not belong to it remained unclear and EAE's criticism seemed reasonable.

The report of the EAE committee in April 2011 dealt with an overall appraisal of the national blood transfusion system, including suggestions for its further reorganization with reference to the 2005 law (EAE, 2011). For EAE, the proper operation of EKEA was of outmost importance. To this end, its proper staffing was an urgent priority. EKEA was the competent authority to coordinate the blood transfusion services and the clinical services and to ensure quality and safety standards; it thus needed to undertake these responsibilities immediately (EAE,

[39] The members of the committee: I. Spiliotopoulou (president), and M. Gkanidou, E. Grouzi, L. Dadiotis, C. Theodosiadis, M. Karakantza, K. Stamoulis (members).

2011). EAE also paid attention to the following aspects: a) of top priority was the uniform computerization of the services and their interconnection under the aegis of EKEA; b) the need for an action plan for attracting and retaining non-remunerated volunteer donors; and c) the need for proper training of personnel in transfusion medicine.

To conclude this section, I will refer to recent developments about the blood transfusion service. The limited reorganization of the service and the operational problems of EKEA were reported by members of parliament, who asked the government to take further actions (Plenary minutes, 30 November 2010, 14 March 2011, 3 February 2011). In October 2009, extraordinary national elections were held in Greece. PASOK formed the government, and Nea Demokratia became the major opposition party. In August 2011, former Deputy Minister of Health, A. Giannopoulos, submitted a question to the Minister of Health A. Loverdos asking about the implementation of the policies for the reorganization of the blood transfusion service (Question 21351/1057, 4 August 2011). Giannopoulos accused the ministry of a lack of comprehensive policies on the field. In particular, he noted that EKEA was incompetent to coordinate the blood transfusion services. The limited reorganization of the service and the poor operation of EKEA under the provisions of the EU directives and the national legislation were also noted by the General Inspector of Public Administration, Leandros Rakintzes (GEDD, 2011, p. 93).

The understaffing of EKEA was depicted in a document of the president of the board of directors in October 2012 (EKEA, 2012).[40] According to this, more than 60% of the established posts projected in EKEA were vacant (only 24 employees were appointed out of 94 established posts). As stated in the document, the board of directors claimed that the established posts were essential to the orderly operation of EKEA. The fact that EKEA continued understaffed in 2012 was indicative of the problems it had faced since its establishment.[41] The lack of governmental actions

[40] In late 2009 Greece faced a government-debt crisis. In April/May 2010 the country, in the face of sovereign default, signed agreements with the European Commission, European Central Bank (ECB) and International Monetary Fund (IMF) for the first bailout program. The Greek economy has been in recession since 2008 (lost about 25% of the GDP) and has had high unemployment rates (reaching about 25%). The bailout programs came with the implementation of austerity measures resulting in cuts of public expenditure. These measures have greatly affected the public health services and the health of the Greek people. The document of the president of the board of directors of EKEA was in response to legislated provisions, associated with the bailout programs, which aimed at cuts in the public sector through the restructuring of public bodies. In addition, strict provisions were implemented with regard to hiring new personnel in the public sector.

[41] The understaffing of EKEA had caused serious difficulties to the operation of the National Blood Products Preparation Center. According to parliamentary questions and the General Inspector of Public Administration, the blood products center experienced problems in processing the collected plasma and, subsequently, in its further handling by the contracted Sanquin Blood Supply Foundation.

to support the operational capabilities of ΕΚΕΑ was a crucial factor hindering the (re)organization of the blood transfusion service.

As I have noted, the transfusion medicine practitioners had requested the development of an integrated, interconnected information system in blood transfusion services. A ministerial decision (co-signed by the Ministries of Health and Education) regarding the development of a central information system to support the operational responsibilities of ΕΚΕΑ was issued in March 2013 (No. Υ4γ/Γ.Π.26176, 2013). The decision referred to the design, implementation, hosting and support of the central information system of ΕΚΕΑ and its interconnection with the blood transfusion services of the country. The development of the system was assigned to GRNET SA (ΕΔΕΤ ΑΕ), a public company.[42] The project was financed by the operational program "Digital Convergence" of the National Strategic Reference Framework (Εθνικό Στρατηγικό Πλαίσιο Αναφοράς, ΕΣΠΑ) for the period 2007-2013, co-funded by the European Regional Development Fund (ERDF). In 2015 a unified blood donors' registry was created and became available to the blood transfusion services and the blood donors (Ministry of Health, 2015).[43]

The aforementioned developments are essential in the analysis regarding the operation of the Greek blood transfusion service. The use of molecular screening in Greece has to be seen in connection to the overall needs of the Greek health care system and, specifically, the situation of the blood transfusion system. Law 3402 in 2005, and the founding of ΕΚΕΑ a few months later, appeared to be a great opportunity for reorganizing the blood transfusion service in accordance with the claims and auspices of the transfusion medicine practitioners. I have presented their opinions from the 1980s, asking for coordination and modernization of the services, but this reorganization was limited and slow; nor was the issue of the proper staffing of the blood transfusion services resolved.

In October 2012, the Advisory Committee on Blood Transfusion, after deliberation with the president of ΕΚΕΑ, issued a recommendation on "cost savings in blood transfusion service and improving safety and quality of blood" (Advisory Committee, 2012).[44] The committee delivered short- and medium-term proposals based on three pillars: the safety and quality of blood; the

[42] GRNET operates under the auspices of the Greek Secretariat for Research and Technology / Ministry of Education, Research and Religious Affairs. GRNET develops and operates the Greek Research & Technology Network.

[43] For more visit <https://www.blooddonorregistry.gr/>.

[44] At that time the president of the board of directors of ΕΚΕΑ was Leonidas Anomeritis. The Advisory Committee on Blood Transfusion consisted of: C. Politis (president), E. Zervou, A. Karafoulidou, O. Marantidou, M. Parara, G. Martinis, G. Kavallierou-Sioni (members).

organization of the service; and cost reduction through economies of scale. The short-term strategy recommended the concentration of blood testing (molecular and serologic) in the nine blood centers. This strategy would permit economies of scale because serologic blood testing would be performed only in the blood centers. In addition, it would give impetus to reassuring quality in blood screening through internal and external quality control. The medium-term strategy, after two years, would include a comprehensive plan to further concentrate blood testing in fewer than nine blood centers, as in other European countries.

The advisory committee remarked that any attempt to promote a more centralized blood supply had as prerequisites the uniform and universal computerization of the services, the safe transport of blood samples and the “rational management” of the personnel (Advisory Committee, 2012). The recommendations were based on studies of the cost of blood made by C. Politis, president of the committee, and colleagues, for example see Kanavos et al. (2006). According to the data presented for 2008, the yearly cost for blood screening was estimated: EUR 22 million for NAT, EUR 12 million for serologic testing and EUR 6.5 million for immunohaematology control (Advisory committee, 2012). The committee further advised on the planning for the public procurement process for blood screening since the contracts for NAT testing would end in August 2013. For the members of the committee the planning had to begin on time, since an 18-month period was envisaged for the conclusion of the process.

It is beyond the scope of this dissertation to provide a detailed account of the developments after 2013, but I should note that the operation of the blood transfusion service (and, in particular, issues related to blood safety) once again attracted public attention in the media. Since 2010, the detection of cases of West Nile virus (WNV) infections in Greece had posed challenges to the public health and to the safety of the blood supply. The authorities decided to screen the donated blood from the affected areas with NAT testing for WNV. The procurement process for WNV testing was accounted in news stories as “scandalous”. A central public procurement through a call for tenders was decided on at the end of 2012. At the end of 2013, however, it was annulled, since it was decided that the procurement would be included in the central commission of NAT testing for the period after August 2013, when the previous contracts ended (Ministry of Health, 4 December 2013).

At the end of 2012, the Minister of Health decided on the suggestion of EKEA to approve the planning for the supply of NAT systems in four blood centers, namely EKEA, "Venizelio-Pananio” hospital in Heraklion, the university hospital of Rio in Patra, and AXEPA hospital in

Thessaloniki (Ministry of Health, 10 December 2012a). The annual cost was estimated at EUR 13.5 million, and the contracts would last four years at a total cost of EUR 54 million. The implementation of the commission would be held in accordance with the procurement provisions of the Health Procurement Committee (Επιτροπή Προμηθειών Υγείας). The call for tenders was approved in May 2013 and was made public; the deadline for placing bids was on 21 June 2013 (Ministry of Health, 2013).[45]

For the period after 2013, it was decided that NAT would be performed in fewer blood centers for the centralization of blood screening, leading also to cost savings due to economies of scale.[46] The procurement did not include blood transport; another call for tenders dealt with that (Ministry of Health, 10 December 2012b). The decisions on both these procurements indicated that the estimated cost would be covered by the allocated budget in EKEA and not from the respective hospitals (Ministry of Health, 10 December 2012a; 10 December 2012b). The total cost per annum was estimated at EUR 13.5 million for NAT systems and EUR 4 million for blood transport; in total, it was significantly less than the cost of the previous contracts for 2008–2013. The same two vendors of NAT systems placed their bids in June 2013.

The process was not, however, completed before the end of the previous contracts. At the end of August 2013, the media reported extensively on the discontinuation of NAT testing because of the lack of new agreements for the commission of reagents. These news were alarming to the people with thalassaemia who expressed their anguish to the media. The Ministry of Health reassured the nation that NAT testing would continue through temporary procurements or extension of the contracts until the signing of the new agreements.

4.4. The use of NAT in the Greek blood transfusion service

From the research I have presented up to this point, it should be obvious that there had not been a long debate regarding the universal adoption of NAT in Greece in connection to both organizational and economic factors, or to local characteristics. As I have argued above, the introduction of NAT in the Greek blood transfusion services did not happen uniformly, since some blood centers had been selectively using NAT before 2006 when it became mandatory. Although

[45] The process would be through an e-procurement platform. The call for tenders was published on the Supplement to the Official Journal of the EU, dedicated to European public procurement, on 08/05/2013 (TED, 2013).

[46] The plan for the centralization of blood testing was continued in 2015; apart from NAT testing, serologic testing would be also performed in the centralized blood centers.

the Minister of Health had promised the rapid implementation of NAT testing nationwide, this did not happen until the end of 2008.

The use of NAT testing on the designated blood transfusion centers, renamed blood centers (or Centers of Molecular Blood Testing), proceeded slowly from 2006. According to the published testing results on the report of SKAE in 2008, the NAT positive and serological negative tested blood units for 2007 were: 2 units HIV-RNA (+); 2 units HCV-RNA (+) out of 355,214 blood units; and 48 units HBV-DNA (+) out of 332,138 blood units (SKAE, 2008a). According to the data SKAE recorded for 2007–2011, the NAT yield in 2,698,154 tested blood units was 6 units HIV-RNA (+), at a rate of 1:449,692; 12 units HCV-RNA (+), at a rate of 1:224,846; and 283 units HBV-DNA (+), at a rate of 1:9,534 (SKAE, 2012, p. 15).[47]

SKAE has also been collecting and analyzing data regarding adverse reactions associated with the transfusion of blood and blood components. As noted before, SKAE recorded the case of two HIV transfusion-transmitted infections in 2005, while possible cases of HCV and HBV transfusion-transmitted infections were not confirmed (SKAE, 2012, p. 19). For 1997–2011, in 7,506,583 blood components, 8,158 adverse reactions were reported. Of those, 562 reactions (6.89%) were characterized as serious, and three deaths were reported (SKAE, 2012, p. 20).[48]

Transfusion medicine practitioners and professionals in blood transfusion services reported on the results from NAT testing in conferences and journals. In a research paper published in 2008, the research group presented the results from TMA NAT testing of blood donors in the University Hospital of Patra (Sgourou et al., 2008). The paper aimed to assess the impact of NAT in blood screening. They examined 38,264 units of blood between January 2005 and the end of March 2007. The yield of NAT testing was 7 for HBV and 0 for HIV and HCV. The authors further discussed the impact of individual donation NAT testing in the detection of HBV DNA, and concluded that "universal implementation of ID NAT for HBV requires further assessmenet", an issue to which I refer to below (Sgourou et al., 2008, p. 110). They also noted that the main disadvantage of ID testing was the high cost.

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[47] From the year 2006, more than 80% of the nationwide blood transfusion services participated on the haemovigilance network set up by SKAE and the data collected concerned more than 90% of the collected blood (SKAE, 2012, p. 10). The yearly amount of the collected blood units has been about 600.000. I do not include the data on the results from the seasonal testing for WNV in north Greece that began in the summer of 2010.

[48] SKAE has been recording data on the adverse reactions associated with the transfusion of blood and blood components in accordance with the guidelines of the Directive 2005/61/EC, the relevant recommendations of the Council of Europe and the European Haemovigilance Network. The serious adverse reactions could of different type, like: incompatibility of blood type ABO; incompatibility due to other alloantibody; haemolysis related to transfusion of platelets; anaphylactic; TRALI; infectious.

In another reasearch paper, professionals from the Center of Molecular Blood Testing in Ioannina and the blood transfusion units connected to it reported the results from the use of TMA NAT in blood screening (Zervou et al., 2008a). In their introduction, the authors noted that blood tranfusion "today has been safer than ever," but the public demand for zero risk has led to the introduction of new technologies like NAT (Zervou et al., 2008a, p. 269). They further mentioned that the Ministry of Health had decided on the adoption of NAT after the report about the two HIV tranfsusion-transmitted infections. They presented the testing results of 31,102 blood samples between April 2006 and May 2008.The NAT yield was 1 HIV positive (infection in window period) and 8 HBV positive (one acute infection in window period and 7 occult HBV infection).[49]

Other blood centers also published the results of testing blood units with molecular methods after 2008. In what follows, I briefly present these as retrieved mainly from conference proceedings and books of abstracts (papers and posters). The testing results in the blood center at the Hospital in Alexandroupoli indicated that the NAT yield in 17,358 blood units was 7 HBV positive, or 1:2,473 (0 for HIV and HCV in 39,303 tested units) (Kasmeridou et al., 2008, p. 89). The blood center of Ippokrateio Hospital reported that blood screening for HCV with NAT in 35,000 units did not detect any only NAT positive donors (Sinanidou, Alemagexou, Stagia, Mitousi, & Papagiannis, 2008, p. 90). The NAT yield in 17,257 blood units tested in the blood transfusion service in the hospital of Volos resulted in 1 HCV and 3 HBV positive (Kateris et al., 2009, p. 64).

In the Center of Molecular Blood Testing in Laiko hospital in Athens, 63,794 blood units were tested over the first nine months of 2009. The NAT yield was reported to be 1 HCV positive (in the window period) and 32 HBV positive (2 window period cases and 30 occult HBV cases) (Kikakis et al., 2010, p. 101). Between December 2008 and January 2010, 60,895 were tested in the Center of Molecular Blood Testing of the University Hospital of Patra. The NAT yield was 8 occult HBV cases (Theodorou et al., 2010, p. 103).

Regarding the NAT testing results announced, most papers noted that molecular screening was advancing blood safety and reducing the risk of viral transmissions. The yield of NAT testing indicated several cases of HBV infection in blood donors, not reactive with serological screening. In the case of Greece, the adoption of ID NAT for HIV, HCV and HBV was associated with the prevalence of HBV in the population of the country. NAT testing of individual donations

[49] In a poster in a conference of the Hellenic Society of Blood Transfusion the research group further examined and specified the profile of the blood donors who tested NAT positive in NAT for HIV and HBV during the window period of seroconversion (Zervou et al., 2008b).

has greater sensitivity in detecting blood samples with low viremia, i.e. low levels of HBV DNA. As I have mentioned before, the routine use NAT HBV testing has been a point of debate in the international transfusion medicine community since the late 1990s.

The detection of HBV in blood donors has been achieved by screening for hepatitis B surface antigen (HBsAg) as of the early 1970s. To further reduce the risk of HBV transmission, NAT HBV DNA testing has been shown to detect pre-seroconversion window period infections likely to transmit HBV.[50] HBV NAT testing in single samples has a higher sensitivity in detecting window period infections than pooled-sample NAT (Busch, 2004). Besides window period transmissions, a second source of post-transfusion HBV risk has been associated with the units donated by HBV carriers who lack detectable HBsAg but whose prior HBV infection is indicated by positive antibodies to hepatitis B core antigen (anti-HBc) test. However, in moderate and high endemicity regions, anti-HBc screening has been considered impractical due to the high loss of donors, as in the case of Greece (Zervou et al., 2001). The use of sensitive PCR methods led to the identification of an increasing number of individuals carrying HBV DNA as the only marker of active infection, a status named occult HBV (Allain, 2004). Occult HBV infection (OBI) is characterized by the presence of HBV DNA in blood or tissues without detectable HBsAg, with or without antibodies to hepatitis B core antigen (anti-HBc) or hepatitis B surface antigen (anti-HBs).[51]

The identification of occult HBV raised concerns regarding the possibility of transfusion-associated OBI and the risk of transmission. Reports on the infectivity of occult HBV by transfusion suggest that is rare (Katsoulidou et al., 2009). The significance of the cases identified as OBI for blood safety has been debated in the scientific community as more studies are being published. For Allain, the infectivity of occult HBV by transfusion according to the origin of the condition and to the susceptibility of the potential recipients with various levels of immunocompetence should be further explored (2004, p. 23). From a blood safety point of view, to deal with the transfusion risk of occult HBV two main screening methods have been implemented: anti-HBc tests and HBV NAT; NAT has the potential to detect only HBV DNA cases and window period infections. Allain

[50] Estimating the residual risk of transfusion-transmission of HBV has been more complex that for HCV and HIV according to Kleinman and Busch (2006). Such estimations are connected to the endemicity of HBV in a region and the measurement of HBV incidence in the donor population. The introduction of HBV NAT testing in pooled samples in the US, since US had already implemented mini-pool NAT for HIC and HCV, in addition to HBsAg and anti-HBc screening of blood donors was debated during the 2000s (Busch, 2004).

[51] For a recent review of studies regarding occult HBV and its implications on blood transfusion see Hollinger (2008).

(2004) argued that NAT would be the preferable strategy for countries in which anti-HBc was not performed; especially ID NAT that has higher sensitivity in detecting cases with very low viral load.

In Greece, between July 2004 and January 2007, a total of 231,027 blood units were tested with NAT and 38 cases were positive for HBV-DNA and negative with HBsAg, a prevalence of 1 per 6080 units (Politis et al., 2007). According to Politis and colleagues, a high prevalence of occult hepatitis B was identified in areas where NAT screening was implemented, suggesting that "NAT screening of the total blood supply and new preventive strategies for the transmission of HBV infection through blood transfusion are essential" (2007, p. 134).

As noted before, several studies regarding the yield of NAT indicated cases of occult HBV. Thus, it becomes more complicated to evaluate the impact of ID NAT screening in reducing the residual risk of HBV transmission. Moreover, as noted before, post-transfusion hepatitis cases have not been recorded in recent years. Further studies would be needed to further evaluate the clinical significance and the infectivity of the cases indicated as occult HBV (for example see Katsoulidou et al., 2009). As the universal use of NAT progressed, transfusion medicine practitioners discussed specific aspects in their papers regarding the preferred screening strategy, for example the testing algorithm for NAT to discriminate false positive results (Diaz Tapias et al., 2010; Hatzitaki et al., 2010).

It is worth mentioning the opinion of a medical laboratory technologist as depicted in his contribution to the first conference organized by PETIE (Πανελλήνια Ένωση Τεχνολόγων Ιατρικών Εργαστηρίων). According to Iliopoulos, it was known that "enormous dangers are related to the insufficient blood screening. The approval and the establishment of the technology of nucleic acids as routine screening tests is due to its capability to reduce and eliminate such problems [transmission of viral infections]" (2009, p. 31). Iliopoulos noted that the use of molecular screening was a "revolution" in the field of transfusion therapy, reducing the period until the detection of the viral agents. To him, this was the reason that it was preferred, and in some cases it was "legally enforced" against other serological methods (Iliopoulos, 2009, p. 32).

As discussed in Chapter 2, the debates regarding the development of NAT brought about competing approaches regarding the advancement of transfusion safety in the context of finite resources. Thus, the argumentation regarding the higher sensitivity of molecular screening techniques is not to be considered in an abstract way but as socially influenced as any of the other options. The episode regarding the development and use NAT is paradigmatic to similar debates

about the cost and the benefit of new medical technologies. In other words, in these cases the trade-offs associated with the use of new technologies should be further explored.

As remarked by Stamoulis (2013a), then scientific director of EKEA, the transmission of HIV and HCV in blood and blood products recipients in the 1980s and 1990s brought up a "fear" that guided the decision-making in the field. For him, today the dangers in decision-making are on the one hand due to "dramatization" and on the other hand due to "underestimation" of transfusion-associated risks. Stamoulis noted that both can lead to "an additional inexcusable danger: investing in excessively costly technologies which lead to the absorption of the available resources, in an effort to be in line with wealthy countries believing that this is the way to achieve safe blood" (2013, p. 1). He further argued that this approach could result in the loss of necessary funds otherwise invested on: donor attraction, retention and education; training of the physicians; the organization of the services. These are necessary prerequisites for a safe blood supply (Stamoulis, 2013a, p. 1).

To conclude this section, the decision about the use of molecular screening in blood transfusion services ought to be considered regarding the cost-benefit analyses and with respect to the overall risks to transfusion safety in a specific sociopolitical setting (Dadiotis, 2011; Stamoulis, 2013b). Despite this, Dadiotis (2011) and Stamoulis (2013b) further commented that recent decisions have been made under political and media pressure. This has been apparent in the case of Greece.

4.5. Concluding remarks

This chapter has presented on the introduction and use of molecular screening technologies in the Greek blood transfusion service. I paid attention to the discussions of the physicians regarding the use of NAT in the country and provided a detailed account regarding the policy-making about its implementation. Since the use of NAT took place when the reorganization of the blood transfusion system was occurring, I also reported on this. In the last section, I introduced issues concerning the use of NAT in the testing of blood units.

The adoption of NAT in Greece, first selectively at some blood centers and then, after 2006, as mandatory routine screening, happened after some European countries had already introduced it and others planned to do so. From the late 1990s, reports demonstrated the poor cost–benefit ratio of using NAT and the incremental effect it had on increasing blood safety. These reports were connected to suggestions to reorient the efforts to advance transfusion safety to

deal with transfusion risks beyond post-transfusion viral infections. Similar arguments were advanced by some physicians in Greece in the context of pointing to alternative measures and their expected benefit. These arguments did not exercise any great influence.

The discussions about the estimation of the residual risk of transfusion-transmitted infections were not key in the specialist literature, at least not before 2006. What was indicated by the haemovigilance data was the fact that the incidence of viral infections was higher in first-time blood donors that in regular volunteer donors. As we have seen, this was connected to a constant challenge facing the blood transfusion system: the need to attract and retain regular, volunteer blood donors. Donor selection is a pillar of blood safety. In 2006, when a case of transfusion-transmitted HIV infections was exposed, the risk of viral infections overwhelmed the public discussions and the policy-making processes. Again, the issue of the residual risk did not enter the discussion as a factor to be discussed. Rather, the fact that post-transfusion infections occurred, and more importantly HIV infections, challenged assertions of a safe blood supply.

To recapitulate, the use of NAT in the Greek blood transfusion services did not happen uniformly. NAT testing became compulsory in March 2006 by ministerial circular. It was presented as an act to restore political accountability when a case of transfusion-transmitted HIV infections was making media headlines. These media headlines proved crucial in the formation of relevant public health policies. The Minister of Health had promised the rapid implementation of NAT testing nationwide and the political parties uniformly advocated the use of genetic technologies in blood screening. The role of the press was also crucial into pushing for the universal use of NAT (see Chapters 5 and 6). In addition, patient groups (especially associations of people with thalassaemia) were very active in pushing for the immediate and universal use of molecular screening technology.

This chapter has presented many important episodes of the lengthy and complex process of implementing NAT. Following the rising public concerns after the exposition of the transfusion-transmitted HIV infections, the government committed to the quick use of NAT nationwide. However, this commitment was not reflected on a well-grounded plan. In parliamentary debates it was noted, more than once, that such a plan was indispensable and required special technical knowledge, including a rearrangement of the facilities.

The complex process of the procurement of NAT was concluded in August of 2008 and was described as the largest single procurement of the Ministry of Health. In the interim period, the reported delays on the process were discussed on the parliament and were recorded in the

newspapers, which were also meticulous in covering the procurement processes for the nationwide commission of NAT through a call for tenders, talking about “economic scandals” and vested interests.

At the end of 2005 a new law was voted regarding the reorganization of the blood transfusion system. This new law transpose European directives about the quality and safety of blood into the national law. The establishment of EKEA as the competent authority ruling the blood supply was unanimously welcomed, but the problems facing it, including the constant understaffing of the blood transfusion services and the delays in enacting other provisions of the 2005 law, showed that the reform was not pursued in a structured manner. Given the low public expenditure on health, the recurring claims of the transfusion medicine practitioners were not adequately addressed. The position of EAE in 2011 further exposed the limited reorganization of the blood services, anticipated by the voting of the 2005 law.

I argue that there was a shift in health policy priorities over 2005 and 2006. The 2005 legislation was loaded with expectations of modernizing the blood services and investing in this process, but a large part of the investment was directed at the use of a biomedical technology. This case shows the discontinuity in carrying out an integrated health policy in Greece. The reorganization of the blood transfusion service could enhance volunteer donorship, interconnect the services, ensure blood sufficiency, and promote quality assurance throughout the whole process, from blood collection to patient care.

The political agenda in 2006 nevertheless prioritized the use of an innovative technology as part of a policy of adopting all measures to increase blood safety. This decision was influenced by media and political pressure. It is important to note that NAT, which contributed to incremental improvement in blood safety and has been used in many developed countries despite debates about its poor cost–benefit ratio, was not introduced in the Greek health system via informed policy-making processes and long-term planning. The endeavor to modernize the blood transfusion service became connected to, and reinforced by, the use of biomedical technology. This decision should be viewed with caution in the context of finite public health resources and the anticipated benefits of alternative medical interventions (Farrell, 2012, p. 195).

Chapter 5

5. The Public Image of Blood Safety: Initial Issues

This chapter will introduce the formation of the public image(s) of blood screening technologies and blood safety in the Greek press.[1] At the beginning of this chapter, I refer to certain theoretical trends that have influenced and informed my research. I then consider particular issues about the specific research I have undertaken, and present how I have made certain decisions regarding the collection of my primary sources. I then present my findings and I arrive at my concluding remarks. The chapter focuses on the way the Greek press presented the biotechnology of genetic/molecular screening and the issues surrounding its introduction in the Greek blood transfusion service. The research questions addressed here focus on reporting the topic of blood safety as connected to the technologies used in blood screening (regardless of its appearance in the special scientific news). This chapter and the one that follows aim to contribute to a more comprehensive understanding of newspaper coverage of a biomedical technology and its use in a certain country, in other words in a specific sociopolitical, economic, legal, and cultural context.

5.1. Theoretical framework

5.1.1. Science and the media

I focus on the analysis of the public image of molecular diagnostics in the Greek press, and thus do not attempt to talk about the public reaction to the media reporting. I do accept that the media coverage of scientific, technological and medical issues influences the relevant public discourse on the national level, especially regarding the emergence and problematization of risks in the public sphere; but one should not assume, as Dorothy Nelkin (1996) argues, that automatically understands the way it influences audiences. Nelkin further suggests that the effect

[1] For the research methods I employed to study the newspapers see 5.2. I would like to note that especially for chapters 5 and 6 I have reconfigured the referencing style. I use the APA referencing throughout this dissertation with the exception of sections 5.3, 6.1 and 6.2. For these sections, due to the large number of references to primary material I avoid in-text citation in order to facilitate reading. I chose to post citations (full reference) in footnotes. I decided to repeat the full reference of each newspaper article (if needed) because I believe that it will help the reader to better assess them. Of course, this decision has been to the detriment of redundancy.

of a specific journalistic coverage on the publics opinion is difficult to evaluate, since it pervades the social context within which the messages from the media are accepted (1996, p. 1603). It is recognized, however, that the media constitute a legitimate alternative space for public dialogue (Kitzinger, 1999; Weingart, Salzmann, & Wörmann, 2008). This study thus focuses on the media discourse about technology and risk.

At this point I shall briefly refer to certain historiographical developments that have affected the broader field of science, technology and medicine and the media. In the discipline of the history of science there has been considerable historiographical discussion regarding science in the public sphere, and more importantly about issues surrounding "popularization" and "popular science".[2] Roger Cooter and Stephen Pumfrey (1994), historians of science, have suggested the need for more research on the communicative processes of science (p. 239). Since then, fruitful historiographical approaches and new research have emerged and provided more pluralistic ways of dealing with science in the public sphere.[3]

In recent studies, historians of science have examined the role of science in the society and the relationship among science and the public(s) by paying particular attention to power relations, cultural aspects, issues of scientific authority and various modes of scientific practice. Such approaches focus on the intricate ways through which society gets in touch with science and the culture of science (Gavroglu, 2014, p. 99). These perspectives have generated a renewed interest in examining various types of mass media as archival sources for studying the public image of science and technology. In particular, newspapers have been studied as a meaningful primary material that can address the question of how the political, social and mental features of a period can influence the public discourse about science (Papanelopoulou & Kjaegaard, 2009).

Historians of science, like Cooter and Pumfrey (1994), have criticized the emphasis on a passive procedure of reception of scientific knowledge. Such aspirations from the discipline of the history of science have been accompanied by the work of sociologists of science. A very influential article was published in 1992 by the sociologist Stephen Hilgartner in which he reconsidered the "dominant view of popularization". Hilgartner criticized the so called "diffusionist model", simply described as a two stage process during which scientists develop genuine scientific knowledge

[2] For a broad overview and critical discussion of the issues surrounding "popularization" of science and "popular science" see Mergoupi-Savaidou (2011). In her doctoral dissertation, Eirini Mergoupi-Savaidou examines public discourse about science in empirical material from the late 19th century in Greece.

[3] For a recent discussion, see ISIS Focus: Historicizing "Popular Science" (Bensaude-Vincent, 2009; Daum, 2009; O'Connor, 2009; Pandora, 2009; Topham, 2009).

and then those designated as populizers disseminate simplified accounts to the public (1992, p. 519). Such a model cannot clearly distinguish between scientific and popularized knowledge. At the same time, scientific knowledge is considered inaccessible by the public. For Hilgartner (1992, p. 530), this process assists scientists and scientific experts to pursue the political goal of having a privileged position on public discourse deriving from scientific authority. Critique of the diffusionist model has since been expressed by scholars in additional fields.

5.1.2. Communication of science and technology

Over the past two decades, similar insights rejecting simplified explanations based on the premise of a gap between expert and lay knowledge have been drawn from numerous studies coming from the field of STS and in particular from scholars focusing on Science Communication. Such areas of studies have grown in size and scholarly outcome, publish their own journals and are interrelated. In these research fields one can find different types of studies, methodological perspectives and theoretical approaches regarding media and science.[4] It is important to highlight that the broader field of science communication encompasses various modes and institutions related to science, technology and medicine, and their positioning in the society.

A related key point in approaching public debates on science and technology has been the criticism of the "deficit model" in the so called "public understanding of science" scheme (Bauer, Allum & Miller, 2007; Wynne, 1992). In its simple form, the deficit model attributed public reaction (usually negative and skeptical) to scientific and technological developments to the lack of appropriate knowledge. This scheme encompassed the deficit explanation for public deficient awareness linked to the formation of unfavorable attitudes toward science and technology. The basic critique to these approaches has been related to the methodological foundations of measuring pubic knowledge and attitudes, and has been supported with efforts to contextualize empirical data. In the same time, it has raised considerations about the decision-making and the policy formation regarding science and technology.

Despite the criticism of the "deficit model" and its normative perspective, recent efforts have been directed at developing complimentary approaches in which "scientific

[4] According to the findings of a meta-analysis of the research published regarding media coverage of science: a) researchers are using a mixture of methods (almost half are quantitative and less than half qualitative); b) the natural sciences are mostly analyzed (with an emphasis on biology/biotechnology); c) research is mainly about the media coverage in the Western world; d) the studies mostly analyze print media (Schäfer, 2010).

knowledge"/"scientific literacy" is one of the factors in the studies aiming to understand public attitudes toward science (Sturgis & Allum, 2004). Such efforts consider that the concerns of those in favor of contextualist approaches might no longer be applicable to refined studies that "veer from a narrow focus on science literacy, and explore the interactions between social context, forms of knowledge, and/or media use in shaping public views of science" (Nisbet & Goidel, 2007, p. 423).

I should note that these fields of studies are overwhelmed with terms and concepts that need further exploration (like "public", "lay public", "audience", "popular science", "science journalism" and "science mediator"), but at this point I shall not analyze them further. Stemming from the recent effort by Burns, O'Connor, and Stocklmayer (2003, p. 191) to define science communication as "the use of appropriate skills, media, activities, and dialogue to produce one or more of the following personal responses to science: awareness, enjoyment, interest, opinions, understanding", I concentrate on the media factor. The analysis of media coverage provides us with insights about the positioning of science and technology in the public sphere in relation to specific debates and events.

I should, however, make an additional point. Recent research has led to considerations regarding more participatory procedures about decision-making affecting science and technology research. These considerations and research orientations have been known, the recent years, as public engagement models.[5] Again, I shall not directly address aspects regarding the participatory modes of scientific governance; yet, I believe that studies examining the public image of specific scientific and technological developments related often with policy developments, provide interesting insights on the multifaceted aspects of their positioning in the public domain affecting policy agendas. Furthermore, they can assist in considering ways to democratize scientific and technological research decision-making. At the same time, the media discourse is connected to the policy-making procedures and forms part of the public discussion about research and development and the use of technologies. The media discourse can act toward the legitimization

[5] Alan Irwin (2008) specifically addressed the issue of science communication and risk management by distinguishing 1)first-order approaches, that entail the "deficit" models by promoting more communication and providing information, 2)second-order, which include public dialogue and engagement that aim to societal consensus, and 3)third-order thinking in risk communication. The proposal for a third-order thinking "suggests that science-public relations need to be placed in wider context, and that critical evaluation is required of current approaches to scientific governance and science communication, whether of first- or second-order variety, or any unstable compound thereof" (Irwin, 2008, p. 209). Such a proposal focuses on the neglected questions of the direction, quality and need for sociotechnical change.

of science and technology (Weingart, Salzmann, & Wörmann, 2008). Such considerations are also interrelated with the funding of scientific and technological research, especially after the Second World War, which marked a grand change on the private funding (Bauer & Gregory, 2007; Nelkin, 1989, p. 108).

Some studies connect the journalistic coverage of issues regarding science, technology, and medicine with its impact on the public regarding these specific issues. STS and science communication researchers have developed sophisticated models that approach the media impact on the public (for an example see Nisbet et al., 2002). I shall not deal with merely quantitative and/or qualitative approaches that examine the reception and the formation of public perception of science and technology related news. These approaches have a different focus than the one of this research; therefore they cannot contribute to the examination of the press coverage of molecular diagnostics.

Scientific and technological issues in the Greek press have been studied, among others, by Kostas Dimopoulos and Vasilis Koulaidis (2002). They focused on the ways methodological elements and social organization of techno-scientific work have been presented or framed in the Greek press (Dimopoulos & Koulaidis, 2002, p. 226). Their approach has been based on content analysis of multiple variables on selected news articles. Dimopoulos and Koulaidis (2002) found that the science and technology articles have been presented also in non-specialized columns in the newspapers they examined, something that also came up in the results of my study. They also suggested that the press attributes to science and technology a mainly instrumental role as a tool of legitimizing (or more rarely de-legitimizing) political decisions, something also apparent in my research findings (Dimopoulos & Koulaidis, 2002, p. 236).

I am dealing with the public image(s) of the technologies used in blood screening, and the public discussion about risk in Greece, as this is portrayed in the Greek press. For this endeavor, I follow the proposal made by Eirini Mergoupi-Savaidou, Faidra Papanelopoulou and Spyros Tzokas (2010; 2012) who consider the daily press as a valuable source for researching the shaping of the public image(s) of science and technology and the public perception of their role in the society. As I am going to examine the way the blood screening technologies were portrayed in Greek newspapers, I focus, on the one hand, on the media accounting of this particular biomedical technology and, on the other hand, on the discussions produced regarding issues of risk. To do so my attempt has also relied on perspectives and research findings that deal with media accounts

of issues about health and medicine. In addition, I have also examined relevant scholarly work that analyzes media coverage of risk.

5.1.3. Media, risk, and health

Deborah Lupton (1992) has emphasized the importance of research to news media and other communication sources in understanding ideologies of health and illness. In recent years, the analysis of media discourse has been acknowledged as significant in sociological studies of health and illness. Such studies aim for deeper understandings of the mass mediated medical knowledge and its influence on perceptions of medical issues, and the role of media representations in experiences of health and illness (Prosser, 2010; Seale, 2004). For example, Helen Prosser examined newspaper articles in the UK to investigate dominant discourses and frames of meaning that have been used in the coverage of medicines to enrich public understandings of the construction of health beliefs and healthcare behavior (2010, p. 54).

The media comprise an arena within which scientific controversies come to the attention of the public and of various groups such as decision makers and interest groups. Needless to say, controversies and risk disputes are attracting media coverage (Nelkin, 1996, p. 1603; Kitzinger, 1999, p. 63). The media influence the attention of competing political actors and the public, but, can also "powerfully shape how policy issues related to science and technology controversies are defined, symbolized, and ultimately resolved" (Nisbet, Brossard, & Kroepsch, 2003, p. 38).

There have been studies devoted on the way media coverage deals with issues of risk. The media can be crucial players in the construction of, and communication about, risk (Kitzinger, 1999, 54). As Nelkin noted, media tend to emphasize "risky" medical technologies and risk disputes (1996). An early study made by Allan Mazur (1981) examined the positive correlation among the quantity of coverage of a technical controversy and the public interest on that issue, more particularly by a rise in negative opinions. He noticed, however, that risky technical issues have not been covered in relation to how "risky" they have been considered regarding their effect in fatalities (Mazur 1981, p. 114).

Taking a sociological approach, Robert Stallings (1990) examined the media discourse in the aftermath of a dramatic event (a bridge collapse in the US) by paying particular attention to the causal explanation of such an event by the news accounts. Stallings showed that during the different time phases of the media reporting, the same event could be framed as a public policy issue and an economic issue (1990, p. 92). In his case, study emphasis was given on the selection

of news sources and its impact on the formation of those news accounts that prevailed over others. The role of power struggles of news sources has been considered an important factor to be taken into account when attempting to explain the appearance and disappearance of a selective range of risks in news media (Wilkinson, 1999, p. 28).

Besides that, for Stallings, the prevailing accounts managed to place an event in context through linking it to similar events (as part of a pattern) and by providing a credible explanation (1990, pp. 88–89). A related point about risk coverage that I consider important is that he invited us to think in media discourse not only the causal accounts apparent in the news but also those absent, considering the multifaceted characteristics of risk (Stallings, 1990, p. 86). The type of reporting of a story is affected by the prevailing risk characteristics (Kitzinger, 1999, p. 64). Therefore, risk reporting is very much interested in answering questions of causation, accountability and blame; the ability to position blame can affect media interest in a story (Kitzinger, 1999, p. 63).

In a more recent review of the research regarding media and risk Emma Hughes, Jenny Kitzinger and Graham Murdock considered it essential to examine the following three major issues: the role of journalists and institutions in making the news, the interaction between the imagery informing media messages and the reality being communicated, and the role of audiences in actively contributing to the interpretation of media output (2006, p. 252). I consider it important to refer to particular findings regarding media reporting on risk issues mainly by focusing on the creation of the news and the issue of newsworthiness. Such findings are not exhaustive but are selectively presented as corroborative to the analysis that follows.

Regarding particular findings from previous studies suggesting patterns in media coverage that have informed the research performed, I would like to refer to the following. An important finding is that reporting tends to be event-oriented than issue-oriented. An event is defined as a crisis that attracts media coverage (Kitzinger, 1999; Hughes et al., 2006; Spencer & Triche, 1994). Media accounts of risk are connected to official processes, regulatory decisions, and bureaucratic procedures (Kitzinger, 1999, p. 63). A lack of policy events can often lead to lack of media interest (Hughes et al., 2006, p. 254). Hence, the policy context matters in the coverage of a risk dispute about science and technology, as in the coverage of a scientific controversy. When policy development is restricted mainly to administrative arenas the coverage is usually modest; media attention peak as policies are about to be enacted (Nisbet et al., 2003).

In addition, media focus on cases where appears to be conflict between stakeholders and vested interests (Kitzinger, 1999, p. 63; Hughes et al., 2006, p. 258). The media tend to privilege official sources by covering press releases and press conferences regarding stories about risk (Stallings, 1990, p. 87; Hughes et al., 2006, p. 254). Nelkin further suggests that while covering risk disputes journalists create polarities; "a medical technology is either very risky or totally safe" (1994, p. 1602). While I present my research findings, I shall refer again to these.

5.2. Methodological issues

5.2.1. Selecting primary sources

In this subsection, I will present how I selected the primary material and the ways in which I analyzed it. I present my findings in the following section and in Chapter 6. My primary material consists of newspaper articles. Two issues are of importance regarding the selection of my sources. The first concerns the time frame of the research performed. The time span of my research has been in newspapers published between 1995 and 2010. I chose 1995 as the first year for my research because the first relevant articles were published in this year. It was a year during which the implementation of molecular diagnostics was considered in other countries (as mentioned in previous chapters). I decided to end my research in 2010 because, by then, molecular testing was used widely in the Greek health system.[6]

The second issue concerns the selection of the newspapers to be examined. I have chosen to examine seven newspapers: *Ta Nea (Τα Νέα)* and *To Vima (Το Βήμα)* (both belong to the Lambrakis Press Group SA), *I Kathimerini (Η Καθημερινή), Eleftherotypia (Ελευθεροτυπία), Ethnos (Έθνος), Rizospatis (Ριζοσπάστης)* and *I Avgi (Η Αυγή).* These newspapers were selected based on two parameters. The first is the circulation figures. As depicted in the data (see Appendix 1) from the Athens Daily Newspaper Publishers Association (Ένωση Ιδιοκτητών Ημερήσιων Εφημερίδων Αθηνών), most of the selected newspapers had high circulation numbers during the period under study.[7] However, a few newspapers (namely *Rizospastis* and *I Avgi*) had a lower circulation and were included to embrace different political views in connection with the representation of

[6] Additionally, during the preparation of this dissertation, this research occurred in two periods. First, during the spring of 2011, therefore, the year 2010 seemed appropriate as an end date in order to gather relevant material. I concluded this research, by adding more newspapers' articles, and by performing additional search attempts, in order to validate my results, during March and April 2013.

[7] In the Appendix I present indicative data from daily average circulation numbers for three years (1999, 2006 and 2008) as retrieved from < http://www.eihea.com.gr>.

political parties to the Hellenic Parliament during that period. Therefore, the second parameter is associated with the inclusion of different political views and readership. [8]

To Vima has been a daily, morning newspaper considered to belong to the political center. It was published daily from 1945–1984 and 1999–2010. It has also been published on Sundays (and currently is still published). *Ta Nea* is a daily evening newspaper positioned toward the political center, and for many years has had the largest circulations numbers in Greece (it issues a Saturday edition but is not published on Sundays). *I Kathimerini* is a daily morning newspaper with a Sunday edition, and includes an elaborate inset with financial news. It belongs to the center-right of the political spectrum. The newspaper *Eleftherotypia* was a daily evening newspaper with a Sunday edition, which ceased publishing in December 2011. It was considered to express center-left positions. *Ethnos* is considered a center-left newspaper, close to the positions of the Greek populist socialist party PASOK. It is a daily evening newspaper, and has a Sunday edition. The daily morning newspaper *Rizospastis* is a body of the Central Committee of the anti-west Greek Communist Party (KKE) and issues a Sunday edition. *I Avgi* is a daily morning newspaper with a Sunday edition, and is close to the opinions of the left-wing, pro-European political party Synaspismos (after 2004 this belonged to SYRIZA, a coalition of leftish parties).

Specifically for 29 and 30 March 2006 (dates when the topic I study was very much reported on front-pages, editorials, feature articles and large headlines because of a case of HIV transfusion-transmitted infections), I have included some additional newspapers in my research. These are *Eleftheros Typos (Ελεύθερος Τύπος), Adesmeftos Typos (Αδέσμευτος Τύπος)* and *Espresso (Εσπρέσσο)*; all belong to the center and center-right of the political spectrum.

To locate the news articles relevant to my research, I have used several digital archives provided by the newspapers' publishing houses.[9] In addition, I have visited the newspapers'

[8]I should mention that I would have liked to include two more newspapers, namely *Eleftheros Typos (Ελεύθερος Τύπος)* and *Apogevmatini (Απογευματινή)*. These newspapers have been considered conservative and more close to the views of the right-wing political party of Nea Demokratia. However, due to the economic crisis and the general problems in the press industry, in the 2000s, both newspapers have ceased publishing for good or have been sold and resumed editions, but, in both cases it was not possible to gain access to their digital archive.

[9] For the newspapers *Ta Nea (Τα Νέα)* and *To Vima (Το Βήμα)* I have used the digital archive of the Lambrakis Press Group SA <http://premiumarchives.dolnet.gr≥ (available with subscription). For the newspaper *I Kathimerini (Η Καθημερινή)* I have used the digital archive located in the newspaper's website, <www.kathimerini.gr>. I have also contacted the editors and the manager of the archive in order to retrieve some full issues in electronic format. For the newspaper *Eleftherotypia (Ελευθεροτυπία)* I have used a combination of the two electronic archives available at <www.enet.gr>, which include the archive of the newspaper's editions divided by the old and the new version of its website. For the newspaper *Ethnos (Έθνος)* I have used the online archive <www.ethnos.gr>. For the newspaper *Rizospatis (Ριζοσπάστης)* I have used the online archive <www.rizospastis.gr>. For the newspaper *I Avgi (Η Αυγή)* I have used a combination of archives. Since the

physical archives and I had personal contact with the publishing houses to retrieve specific issues. For certain newspapers, I have encountered some limitations on the time span of my research due to limited availability of digital archives. For *Ethnos,* I have retrieved relevant articles from 2006 until 2010. For *Eleftherotypia* and *I Kathimerini,* I have retrieved relevant articles from 2001 until 2010.[10] During the analysis of the relevant articles, I have not distinguished them according to daily or Sunday editions. In the cases of *I Kathimerini*, *Ethnos* and *Eleftherotypia,* the digital archives did not provide the articles "as printed" and the page number is missing (unless otherwise stated).

Since I have used digital archives of several newspapers (which, in most cases, are located on the website of the newspaper) I should mention that I am aware of the fact that online newspaper editions pose new difficulties to historians and sociologists. Hauke Riesch (2011, p. 772) noted several such challenges connected to the fluidity of online news reporting compared to the rigid printed editions.[11] To avoid confusion arising from possible multiple versions of online articles, I decided to gather only articles published in print and to omit those that appeared only online.

To locate all relevant articles, I performed multiple search attempts using a variety of keywords. I used many combinations of keywords and other tools provided by the search engines. First, I searched using the keywords "molecular testing" (μοριακός έλεγχος) and combinations

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newspaper's archive was not available through the website due to upgrading (March and April 2013), I visited the offices of the newspaper and examined the digital archive available to the editors. In addition, I examined and photographed the printed editions of the newspaper on the archive (by looking on the specific dates I had already specified in the digital archive). For the additional newspapers on the dates 29 and 30 March 2006 I bought the corresponding issues from a private archive of the Greek Daily and Periodical Press.

[10] The online archive of the newspaper *I Kathimerini* supported searching with keywords only after 2001. I have retrieved the relevant articles for some dates in January 1999 that a case of transfusion-transmitted infection was reported in the media by searching the editions by date.

[11] Hauke Riesch (2011) suggested that there has been a shift with online newspaper editions that brought changes in journalism and a rise of alternative forms of communication, such as the blogs. This shift brought challenges to traditional journalism while adapting to the newspapers' move online. He recognized important problems that a researcher can face while analyzing the press. With the online editions it becomes difficult to recognize what constitutes an "original article", since archived and/or printed versions may differ from the version that was seen by most of the readership online. Other issues concern the use (or disappearance) of images and the positioning of an article on the printed version or the website. For these reasons, Riesch posed the following questions. Due to the fact of disappearing news and many versions of online articles how can we understand who has read which version and when? Since a news story can change, which version did people read and how were the stories used to inform opinions on the topic? This uncertainty over what the paper actually did say makes the social and historical reconstruction and analysis of a debate difficult. For these reasons, methodological concerns are raised in newspaper analysis. These practices also challenge us to re-consider the maintenance of the archives of newspapers (and the possibility for archives of their websites). Riesch concluded that it is social science's responsibility to change its methodologies to keep up with developments in the media (2011, p. 776).

such as “molecular testing AND blood” (μοριακός έλεγχος ΚΑΙ αίμα) and “molecular testing of blood” (μοριακός έλεγχος αίματος). I then reviewed all results to save all the relevant ones. I also searched by using the keywords “blood safety” (ασφάλεια αίματος), with the words being located nearby in the articles or by both words appearing in an article. Additionally, I performed search attempts with the keywords “blood AND transfusion” (αίμα ΚΑΙ μετάγγιση), “blood AND PCR” (αίμα ΚΑΙ PCR), “blood AND risk” (αίμα ΚΑΙ διακινδύνευση), “blood screening AND aids” (έλεγχος αίματος ΚΑΙ aids) and “blood screening AND HIV” (έλεγχος αίματος ΚΑΙ HIV). In all these attempts I examined the results to locate relevant articles that would refer to the technologies used in blood screening, cases of transfusion-transmitted infections and other issues regarding blood safety and transfusion safety. In many instances, the results included duplicate articles. Table 5.1 presents the number of relevant articles from each newspaper (titles and short stories on the front-page of a newspaper are counted as separate articles). The Appendix provides a full list of the articles (including selected articles beyond this time frame, and the selected articles from the additional newspapers for 29–30 March 2006).

Table 5.1 Number of articles

Newspapers / **Years**	*Τα Νεα (Τα Νέα)*	*To Vima (Το Βήμα)*	*I Kathimerini (Η Καθημερινή)*	*Elefthero-typia (Ελευθεροτυπία)*	*Ethnos (Έθνος)*	*Rizospastis (Ριζοσπάστης)*	*I Avgi (Η Αυγή)*	***Total***
1995–2005	16	26	19	8	-	17	26	**112**
2006	30	40	19	31	22	26	26	**194**
2007–2010	14	23	6	17	18	33	43	**154**
Total	**60**	**89**	**44**	**56**	**40**	**76**	**95**	
Total number of articles: 460								

5.2.2. Analyzing the primary sources

In the analysis of the primary sources I found the proposal of Lupton (1992, p. 146) useful. Lupton stated that discourse analysis of the media coverage of medical issues has the potential to reveal valuable insights into the social and political contexts in which varied discourses about health take place. In Lupton’s methodological aspirations of the analysis, discourse is defined as a “patterned system of texts, messages, talk, dialogue or conversation which can both be identified in these communications and located in social structures” (1992, p. 145).

While in broader terms this means a critical examination of media texts, as for the research concerned here, I am aware that nuanced approaches to discourse analysis have

emerged (Fairclough, 2003; Glynos, Howarth, Norval, & Speed, 2009). Discourse analysis is composed of two main dimensions: textual and contextual. Textual dimensions account for the structures of discourses and are concerned with the use of the language, grammar, rhetorical devices, syntax, sound forms and the overt meaning and content mater of words and sentences. Additionally, attention is paid to macro structures as the selection of topics and themes. The contextual dimension examines the production and reception processes of discourse, with particular attention to the production of ideology and hegemony in such processes, and the links between discourse structures and social interaction and situations (Lupton, 1992, p. 146). For Fairclough, "different texts within the same chain of events or which are located in relation to the same (network of) social practices, and which represent broadly the same aspects of the world, differ in the discourses upon which they draw" (2003, p. 127); thus, discourses are ways of representing the world which can be identified and differentiated at different levels of abstraction (2003, p. 133).

To give an illustration, Prosser (2010) applied discourse analysis to study the construction of the meaning and function of prescription medicines and to analyze the underlying meanings and assumptions that news stories exhibited. She specifically utilized discourse analysis because it permitted the systematic examination of how texts and their language construct reality and guide the ideological and possible understandings of the reader (Prosser, 2010, p. 56). Savaidou et al. (2009) studied the public image(s) of science and technology by analyzing articles in newspapers at the beginning of the 20th century in Greece to understand the multifaceted discourse of journalists on these topics.

This type of media discourse analysis is qualitative, and therefore it does not focus on quantitative aspects of journalistic coverage (for example, counting the number of times an issue or wording is appearing and the length of each article, or the statistically measured size of an article in a newspaper). Although the positioning of an article in a newspaper is important and I consider it while analyzing my material, I do not provide relevant statistical data. The goal of my analysis is not to evaluate to correctness and credibility of the news accounts, especially when they refer to scientific and technological issues. Therefore, I will look at the media reporting without commenting systematically on the contents validity.

To further analyze the news items, I considered expedient to utilize framing analysis.[12] Pan and Kosicki (1993) suggested ways in which the theoretical perspective of framing analysis can be helpful in a qualitative study as a constructivist approach to examine news discourse. Framing in the process of news discourse encompasses the participating members (news sources, journalists and active audiences) who engage in the process based on their socially defined roles (Pan & Kosicki, 1993). According to Entman, framing involves selection and salience (1993, 52). Thus, in a news story, frames call attention to some aspects and obscure other. Frames in news discourse manifest though various framing devices, giving meaning to an issue.[13] For Entman (1993), frames define problems, make causal interpretations, share judgements and evaluations on the causes, and propose treatments. Statements about the effects and the causes of an issue in media discourse are essential to a frame (Gamson & Modigliani, 1989; Van Gorp, 2007). Since news discourse associates with public policy making, framing can have policy implications. Frames make statements, implicitly or explicitly, about policy options; thus, framing analysis provides insights about the construction of public discourse on policy issues.

In the following section, I present the analysis of the news articles for the period from 1995 until 2005. In the following chapter, I carry on the analysis with 2006 onwards, when the use of molecular screening was on the spotlight. I believe such an analysis can contribute to a better understanding of the construction of the public discourse regarding public health policy, and more specifically about safety and risk in transfusion medicine. Besides that, I pay attention to the discourses about the use of specific technologies and the ways they are represented by the journalists. The main issues studied will be presented by chronological order of the printed articles and by informal taxonomies arranged by relevance according to their main topic and theme. I have translated all quotations from the newspapers from Greek into English. Besides, continuing from Chapters 3 and 4, I refer to "blood transfusion" centers/system as a translation of the

[12] In sociological theory, Erving Goffman aimed to "try to isolate some of the basic frameworks of understanding available in our society for making sense out of events and to analyze the special vulnerabilities to which these frames of reference are subject" (1974/1986, p 10). He proposed frame analysis in which a frame relates to the definitions of a situation which "are built up in accordance with principles of organization which govern events-at least social ones-and our subjective involvement in them" (Goffman, 1974/1986, pp. 10-11).

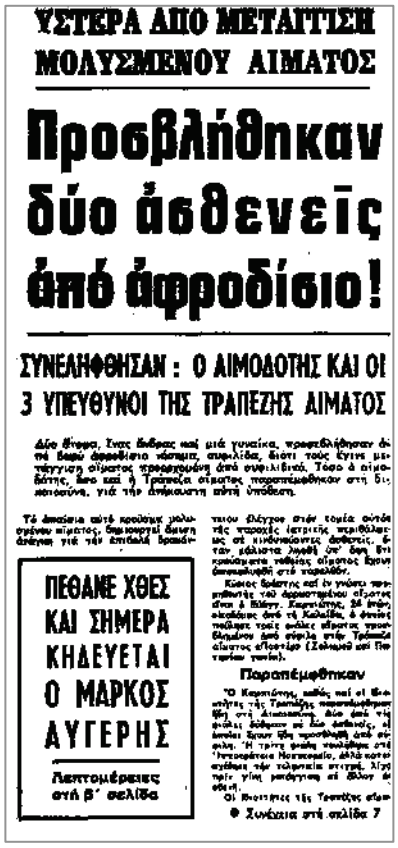
[13] Framing devices can be the word choice, metaphors, exemplars, descriptions, arguments, depictions. Pan and Kosicki (1993) proposed four categories of framing devices representing structural dimensions of news discourse: syntactical structure (related to news writing), script structure (related to story-telling), thematic structure (choice of theme and type of argumentation), and rhetorical structure (the stylistic choices made by journalists in relation to their intended effects).

"κέντρα/σύστημα αιμοδοσίας". Of course, when the topic is about blood donation, I distinguish this.

5.3. Blood safety in the Greek press (1995–2005): "Are you afraid of blood transfusions?"[14]

5.3.1. The early years

While performing research for the technology of molecular diagnostics in transfusion medicine I came across some interesting articles from earlier periods, and I shall refer to a few indicative stories. I believe it is worth mentioning an article of 1973 regarding a case of transfusion-transmitted syphilis that appeared on the front-page of the newspaper *Ta Nea*.[15] The context of blood donation was different in 1973, since it was based on a mixed system of remunerated and non-remunerated blood donors. The article stated that the donor and the doctors at the blood bank would be prosecuted (the blood bank personnel was considered responsible for not performing screening tests).[16] The case was characterized "unheard of" and "hideous" (see Image 5.1).


ΥΣΤΕΡΑ ΑΠΟ ΜΕΤΑΓΓΙΣΗ ΜΟΛΥΣΜΕΝΟΥ ΑΙΜΑΤΟΣ

Προσβλήθηκαν δύο ἀσθενεῖς ἀπό ἀφροδίσιο!

ΣΥΝΕΛΗΦΘΗΣΑΝ : Ο ΑΙΜΟΔΟΤΗΣ ΚΑΙ ΟΙ 3 ΥΠΕΥΘΥΝΟΙ ΤΗΣ ΤΡΑΠΕΖΗΣ ΑΙΜΑΤΟΣ

ΠΕΘΑΝΕ ΧΘΕΣ ΚΑΙ ΣΗΜΕΡΑ ΚΗΔΕΥΕΤΑΙ Ο ΜΑΡΚΟΣ ΑΥΓΕΡΗΣ

Παραπέμφθηκαν

Image 5.1 ***Ta Nea*****, June 9 1973, p. 1**

In November 1993, *Ta Nea* published (over three consecutive days) feature articles reporting on the safety of transfusions.[17] The articles mentioned transfusion methods and procedures; referred to the window period and the residual risk of transfusion-transmitted infections; dealt with the cost of blood in the Greek health system; and compared the safety of blood products in Greece with that in other countries. Furthermore, the articles focused on the operation of the blood transfusion service and discussed its possible reform in reference to the accompanying short historical

[14] Η ερώτηση της ημέρας: Φοβάστε τις μεταγγίσεις αίματος;. (2000, August 12). *To Vima*, p. A32.
[15] Προσβλήθηκαν δύο ασθενείς από αφροδίσιο. (1973, June 9). *Ta Nea*, p. 1.
[16] Προσβλήθηκαν δύο ασθενείς από αφροδίσιο. (1973, June 9). *Ta Nea*, p. 7.
[17] Πόσο ασφαλείς είναι οι μεταγγίσεις αίματος. (1993, November 8). *Ta Nea*, p. 20-21; Επάρκεια ίσον ασφάλεια. (1993, November 9). *Ta Nea*, p. 18; Αποθήκευση-ανακύκλωση. (1993, November 10). *Ta Nea*, p. 33.

review of blood transfusion. Attention was paid to the lack of attempts to promote voluntary blood donation; to methods to advance transfusion safety; and to alternatives to allogeneic blood transfusion, with a focus on autologous transfusion.[18]

In an article published in June 1995, a new screening test for the HIV virus was presented in connection with the decision of the Food and Drug Administration (FDA) to approve its use in the US.[19] This article referred to the p24 antigen test (see Chapter 2) that could be used to detect an antigen of HIV a few days earlier than the detection of the presence of the antibody to the virus, although in the article the exact test was only roughly described and not named.[20] At the end of 1995, the newspaper *Ta Nea* (in a short article in the *Health* section) covered the publication of a scientific paper in the *New England Journal of Medicine* about the estimated risk of HIV transfusion-transmitted infections in the US.[21] The article mentioned the results of the US study about HIV infectious donations that remained available for transfusion (due to the window period) and concluded by quoting from the paper that "the dangers of transmitting the virus of AIDS by the transfusion of screened blood are minimal", using in Greek the word "dangers" (κίνδυνοι) instead of "risk" (διακινδύνευση) that is mostly used in such scientific papers in this context, and was used also in the quoted scientific paper. During the same period, articles in a two-page feature in the special section *Health* were dedicated to news regarding the disease of AIDS, reprinted from the *Los Angeles Times*. A short article reported a news story from France regarding the development of a new screening test for the detection of antibodies to HIV 1/2 of higher sensitivity compared to tests already in use, thus reducing the window period and improving blood safety.[22]

On 10 April 1996, two newspapers published the announcement made by the Ministry of Health regarding the withdrawal of screening assays (by Abbott Company) for the detection of anti-HIV from Greek blood banks due to the possibility of diagnostic malfunction, referring also to

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[18] These articles could be connected to the news coverage by Greek newspapers of a story regarding older cases of transfusion-transmitted HIV infections in Germany that were published and discussed in the German media during October 1993. Σιωπούσαν για το μολυσμένο αίμα. (1993, October 9). *Ta Nea*, p. 65.

[19] Θα εντοπίζεται γρηγορότερα ο ιός του AIDS. (1995, August 12). *Ta Nea*, p. 20.

[20] According to estimations, the window period of HIV detection was going to be shortened by about six days comparted to anti-HIV tests, and not "to six days" as written in the aforementioned newspaper article. For more on the p24 antigen test see sections 1.2 and 2.2.

[21] Μεταγγίσεις. (1995, December 29). *Ta Nea*, p. 39. This article referred to the following published, scientific paper: Lackritz, E. M., Satten, G. A., Aberle-Grasse, J., Dodd, R. Y., Raimondi, V. P., Janssen, R. S., . . . Petersen, L. R. (1995). Estimated Risk of Transmission of the Human Immunodeficiency Virus by Screened Blood in the United States. *New England Journal of Medicine, 333*(26), 1721-1725.

[22] Εντοπισμός μολυσμένων με γρήγορο τεστ. (1995, November 28). *Ta Nea*, p. 43.

similar practices in other countries.[23] *Rizospastis* associated this event with the planned shutdown of a laboratory for testing plasma (responsible also for quality control) in the National Blood Products Preparation Center operating at the Nikaia Public Hospital.[24] In many articles, this decision by the Ministry of Health was questioned and the issue of transfusion safety was discussed; the articles also reported on the related current questions posed by deputies of the political party of KKE in the Hellenic Parliament.[25] This specialized laboratory could perform quality control in screening tests, and, as reported, was necessary in the blood transfusion service to assure quality and safety as the case with the defective screening assays had demonstrated.[26] One article was entitled "Danger for the safety of transfusions"; it presented the opinions of transfusion medicine professionals, who claimed the immediate re-operation of the laboratory for quality control.[27]

From the research I performed, the first article I identified that referred to molecular diagnostics was a general article about genetic engineering in a two-page feature entitled "Searching for the secret of life" in *To Vima* in 1995. According to the article, one of the advancements of genetic engineering was the development of diagnostic tests that could detect viruses or other pathogens in the blood like the PCR test.[28] In 1996, I came across a reference to PCR testing in two articles of *Rizospastis*, mentioned above, regarding its planned use to test plasma in the laboratory of the National Blood Products Preparation Center. According to the authors of the articles, the laboratory closed when it was ready to make one more scientific step by implementing new tests (PCR) to detect HIV and other viruses.[29] In the same year, *Ta Nea* ran

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[23] Κάλλιον το προλαμβάνειν... (1996, April 10). *Rizospastis*, p. 19; Ειδική Επιτροπή: Δεν χρειάζεται επανεξέταση των αιμοδοτών ή αυτών που χρησιμοποίησαν το αίμα, οι ευρωπαίοι σπεύδουν για επανεξέταση. (1996, April 10). *I Avgi*, p. ?

[24] Το κλειστό εργαστήριο και τα "κλειστά" αυτιά. (1996, April 30). *Rizospastis*, p. 40.

[25] Ο ΕΟΦ ζητά την επαναλειτουργία. (1996, March 16). *Rizospastis,* p. 16. (Panagiotis Theodoropoulos); Κάλλιον το προλαμβάνειν... (1996, April 10). *Rizospastis,* p. 19; Αναγκαία η επανεξέταση μεθόδων και κανονισμών αιμοδοσίας. (1996, April 19). *Rizospastis,* p. 19; Το κλειστό εργαστήριο και τα "κλειστά" αυτιά. (1996, April 30). *Rizospastis,* p. 40; Ερώτηση για το Κέντρο Αιμοδοσίας Νίκαιας. (1996, June 12). *Rizospastis,* p. 16; Κίνδυνος για την ασφάλεια των μεταγγίσεων. (1996, June 18). *Rizospastis,* p. 25.

[26] Το κλειστό εργαστήριο και τα "κλειστά" αυτιά. (1996, April 30). *Rizospastis*, p. 40.

[27] Κίνδυνος για την ασφάλεια των μεταγγίσεων. (1996, June 18). *Rizospastis*, p. 25. The shutdown of the laboratory for quality control and plasma testing was also connected to the fact that it undermined the fulfillment of the agreement Greece had with the Swiss Red Cross for the production of blood products from plasma exported to Switzerland (the terms involved exporting plasma and getting back selected blood products).

[28] Θεραπεία με όπλο τα γονίδια. (1995, June 4). *To Vima*, p. A50-51(62-63).

[29] Κάλλιον το προλαμβάνειν... (1996, April 10). *Rizospastis,* p. 19; Αναγκαία η επανεξέταση μεθόδων και κανονισμών αιμοδοσίας. (1996, April 19). *Rizospastis,* p. 19; Το κλειστό εργαστήριο και τα "κλειστά" αυτιά. (1996, April 30). *Rizospastis,* p. 40

a two-page module in the section *Health* labeled "War on AIDS and infectious diseases".[30] In an interview with Dr. Robin A. Weiss (Director of Research at the Chester Beatty Laboratories of the Institute of Cancer Research in London) the new molecular techniques were mentioned as they could detect the "genetic code" of HIV, but its potential future use in blood bank setting was not discussed.[31]

I identified some recurring themes with a connection to issues of transfusion and blood safety. One category of articles consisted of those dedicated to specific viruses and the possibility of transfusion-transmitted infections. Another article of the module "War on AIDS and infectious diseases" in the *Health* section of *Ta Nea* was entitled "All we need to know about AIDS".[32] The article included a part about transfusion and AIDS, which mentioned that "nowadays it is extremely unlikely, as British experts point out, in most developed countries that a transfusion of infectious blood would occur […] since blood is tested for antibodies to HIV and the risk of being infected is almost zero."[33] In another short article dedicated to autologous transfusion, data was presented regarding the risk of transfusion-transmitted infections.[34] An article in the newspaper *I Avgi* reported on the presentation of a national epidemiological research conducted by the Ministry of Health and SKAE.[35] According to the article, the findings of the research showed the prevalence of infectious markers on blood donors and pointed out the reduction of the relevant rates.[36] In a two-page article about the virus of hepatitis C, it was noted that the disease could be transmitted through transfusion, but over the past few years the thorough screening of blood had further reduced the risk of transmitting the virus.[37]

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[30] Για 10 χρόνια ακόμα θα σκοτώνει ανθρώπους το AIDS. (1996, July 30). *Ta Nea*, p. 28-29 (Health 2-3). (Mairi Katsanapoulou). This article referred mostly to therapeutic prospects about AIDS.

[31] Για 10 χρόνια ακόμα θα σκοτώνει ανθρώπους το AIDS. (1996, July 30). *Ta Nea*, p. 28-29 (Health 2-3). (Mairi Katsanapoulou).

[32] Όλα όσα πρέπει να γνωρίζουμε για το AIDS. (1996, July 30). *Ta Nea*, p. 29 (Health 3).

[33] Όλα όσα πρέπει να γνωρίζουμε για το AIDS. (1996, July 30). *Ta Nea*, p. 29 (Health 3).

[34] Αν χρειαστείτε αίμα, ας έχετε παρακαταθέσει το δικό σας. (1996, August 13). *Ta Nea*, p. 26 (Health 2).

[35] SKAE is the Hellenic Centre for Coordinating Haemovigilance (Συντονιστικό Κέντρο Αιμοεπαγρύπνησης). For more see chapters 3 and 4.

[36] Μειώθηκαν οι λοιμώξεις που μεταδίδονται από το αίμα. (1997, December 13). *I Avgi*, p. 9.

[37] Πώς "θερίζει" η ηπατίτιδα C. (1998, June 28). *To Vima*, p. A58-59. (Ioanna Soufleri).

5.3.2. The potential use of molecular diagnostics

The first articles I encountered regarding the use of molecular diagnostics in the Greek blood transfusion service were published at the beginning of 1999.[38] The possibility of the early adoption of these techniques in Greece was discussed. The discussion was associated with the reporting of a case of transfusion-transmitted infections of HIV that occurred during the second half of 1998 and was exposed in January 1999 (see Image 5.2). This case, according to several newspaper articles, was revealed when a baby, born prematurely in August 1998, received blood components several times and later (due to health problems) tested positive for the HIV virus. Its parents tested negative to HIV and, after retrospective control, one of the blood donors was found to be seropositive. From the donated unit of blood collected from this donor, two more patients were identified to have been transfused (one patient eventually died a few days after the transfusion, and a second patient was described as a 71-year-old lady).[39]


ΣΑΒΒΑΤΟ 16 ΙΑΝΟΥΑΡΙΟΥ 1999 — Η ΚΑΘΗΜΕΡΙΝΗ 7

Ενα πρόωρο νεογέννητο στο μαιευτήριο «Ελενα» και δύο ηλικιωμένες γυναίκες μολύνθηκαν από τον ιό του έιτζ κατά τη διάρκεια μετάγγισης.

ΕΠΙΚΑΙΡΟΤΗΤΑ

Το «σιωπηλό παράθυρο», αιτία τριών μολύνσεων

Ο ιός του έιτζ δεν ήταν ανιχνεύσιμος στη μοιραία φιάλη αίματος

Μια μολυσμένη φιάλη αίματος, που προσέφερε το καλοκαίρι νεαρός αιμοδότης, έγινε αιτία να μολυνθούν τρεις άνθρωποι από τον ιό του έιτζ. Ενα νεογέννητο βρέφος που γεννήθηκε πρόωρα τον Αύγουστο στο μαιευτήριο «Ελενα» και δυο ηλικιωμένες γυναίκες. Η μια από αυτές πέθανε τρεις ημέρες μετά την εγχείριση στο «Ελενα» -καθώς έπασχε από ανίατη νόσο- και η άλλη αναζητείται από την κοινωνική υπηρεσία μεγάλου νοσοκομείου της Αθήνας, για να υποβληθεί σε εξετάσεις και εάν χρειαστεί σε αντιρετροϊκή θεραπεία.

Η συγκίνηση που προκάλεσε η είδηση για τη μόλυνση του νεογέννητου στο πανελλήνιο, συνοδεύτηκε για μια ακόμη φορά από ένα ατόπημα. Η μητέρα συνειδητοποίησε το πρόβλημα του παιδιού της από την τηλεόραση καθώς δεν είχε ακόμη ενημερωθεί...

Παράλληλα, έρχεται για μια ακόμη φορά στο προσκήνιο το θέμα της ασφάλειας των μεταγγίσεων και καθίσταται σαφές ότι και με τις καλύτερες συνθήκες -που δεν υπάρχουν πάντα στα 93 διάσπαρτα κέντρα αιμοδοσίας της χώρας- είναι δυνατόν να μεταδοθούν σοβαρές παθήσεις, όπως το έιτζ και η ηπατίτιδα. Το λεγόμενο σιωπηλό «παράθυρο», όταν δηλαδή κατά τη διάρκεια του χρόνου επώασης, ο ιός δεν μπορεί να ανιχνευθεί στο αίμα, δείχνει ότι και η επιστήμη έχει τα όριά της.

Σύμφωνα με τη διευθύντρια Αιμοδοσίας, κ. Ντ. Πολίτου, οι πιθανότητες είναι πολύ μικρές και στη χώρα μας είναι 1:1.200.000 μεταγγίσεις. Η κ. Πολίτου υποστήριξε ότι από τότε που άρχισε ο έλεγχος του αίματος έχει συμβεί μόνο μια ακόμη μόλυνση από μετάγγιση. Σίγουρα όμως κανείς δεν μπορεί να αποκλείσει το ενδεχόμενο να έχουν συμβεί και άλλες μολύνσεις (αφού κάθε χρόνο γίνονται χιλιάδες μεταγγίσεις), οι οποίες να μην είναι γνωστές ή να αποδόθηκαν σε άλλες αιτίες.

Η πιθανότητα αυτή, βεβαίως, όπως επισήμανε χθες μετά τη συνεδρίαση της επιτροπής Επιδημιολογίας του υπουργείου Υγείας η διευθύντρια Αιμοδοσίας, κ. Τ. Μανδαλάκη, δεν υποβαθμίζει την αξία των μεταγγίσεων, που σώζουν χιλιάδες ζωές. «Η μετάγγιση», είπε η κ. Μανδαλάκη, «είναι ένα πολύ σοβαρό όπλο και επομένως δεν πρέπει να το στερηθούμε. Να μη βάλουμε σε δίλημμα τους γιατρούς και να μην τρομοκρατήσουμε τον κόσμο».

Της ΓΑΛΗΝΗΣ ΦΟΥΡΑ

Οπως διευκρίνισαν ο καθηγητής και πρόεδρος του ΚΕΕΛ κ. Ι. Στρατηγός και η διευθύντρια Αιμοδοσίας κ. Ντ. Πολίτου μετά τη χθεσινή συνεδρίαση της Επιτροπής Επιδημιολογίας του ΚΕΕΛ, ο νεαρός αιμοδότης μολύνθηκε περί τα τέλη του περασμένου Ιουλίου. Στις 12 Αυγούστου έδωσε αίμα (μία μονάδα) ένα μικρό μέρος του οποίου δόθηκε λίγες ημέρες αργότερα στο νεογνό. Το πλάσμα από αυτή τη μονάδα δόθηκε πάλι στο ίδιο νοσοκομείο, σε μια πολύ ηλικιωμένη γυναίκα, η οποία μεταγγίστηκε στο χειρουργείο και μετά από λίγες ημέρες πέθανε επειδή ήταν στο τελικό στάδιο καρκίνου του τραχήλου της μήτρας. Το υπόλοιπο αίμα, δόθηκε σε άλλη ασθενή, 71 ετών, σε μεγάλο νοσοκομείο της Αθήνας.

Το βρέφος γεννήθηκε στις 5 Αυγούστου και είχε πολλά προβλήματα υγείας, αφού ζύγιζε μόλις 660 γραμμάρια. Στο πλαίσιο των θεραπευτικών παρεμβάσεων έγιναν και μικρομεταγγίσεις από 15 μονάδες αίματος.

Το παιδάκι, έπειτα από μια δίμηνη νοσηλεία στο μαιευτήριο πήγε στο σπίτι του, καθώς ήταν και παραμένει ασυμπτωματικό. Στη συνέχεια, όμως, διαπιστώθηκε ότι εμφάνιζε μια διόγκωση του ήπατος και παραπέμφθηκε για περαιτέρω διερεύνηση στο νοσοκομείο Παίδων Αγία Σοφία. Αυτό έγινε λίγο πριν από τις γιορτές, ενώ ο κλινικοεργαστηριακός έλεγχος ολοκληρώθηκε στις 5 Ιανουαρίου και διαπιστώθηκε ότι ήταν θετικό στη λοίμωξη HIV.

«Πρώτη ενέργεια που έγινε», ανέφερε ο κ. Πολίτου, «ήταν να ελεγχθούν οι γονείς, που βρέθηκαν οροαρνητικοί. Ετσι, ξεκίνησε η προσπάθεια των αρμοδίων υπηρεσιών να εντοπισθεί η πηγή μόλυνσης. Υπάρχουν τα αρχεία των δοτών, ενώ στην κατάψυξη είχαν διατηρηθεί οροί από τις μονάδες αίματος που είχαν χορηγηθεί στο παιδάκι.

Στην πρώτη φάση του ελέγχου εξετάστηκαν οι οροί και βρέθηκαν αρνητικοί. Ετσι, αναζητήθηκαν οι 15 αιμοδότες, από τους οποίους ελήφθη και δεύτερο δείγμα αίματος. Τότε διαπιστώθηκε ότι ένας από αυτούς είχε κάνει ορομετατροπή, είχε δηλαδή γίνει θετικός στον ιό του Aids. Επομένως, ήταν βέβαιο ότι η μετάδοση του ιού έγινε κατά τη διάρκεια της περιόδου επώασης ή, όπως λέγεται, του ορολογικά σιωπηλού παραθύρου».

Αυτή η περίοδος επώασης του ιού, κατά την οποία δεν μπορεί να ανιχνευθεί στο αίμα, διαρκεί από τρεις εβδομάδες έως έξι μήνες από την στιγμή που θα μολυνθεί κάποιος από έιτζ, διευκρίνισε η κ. Πολίτου.

Μετά τη συνεδρίαση της επιτροπής Επιδημιολογίας τονίστηκε ότι μέχρι στιγμής έχουν γίνει όλες οι αναγκαίες ενέργειες για τη θεραπευτική αντιμετώπιση του βρέφους και του αιμοδότη, καθώς και για την κοινωνική στήριξη της οικογένειας.

«Το παιδάκι βρίσκεται στα καλύτερα χέρια», υπογράμμισε ο καθηγητής κ. Γιάννης Κοσμίδης. «Στη μονάδα Ειδικών Λοιμώξεων του νοσοκομείου Παίδων Αγία Σοφία, η οποία είναι πρότυπη σε διεθνές επίπεδο, και έχει πολλές πιθανότητες με τα νέα φάρμακα να πάει καλά.

Το ίδιο ισχύει και για τον αιμοδότη, ο οποίος θα μπορέσει να αρχίσει θεραπεία πριν εξελιχθεί η λοίμωξη, στην αρχή της».

Δηλωθέντα κρούσματα παιδιών με AIDS (ηλικίας ≤ 12 ετών) στην Ελλάδα μέχρι τις 30 Σεπτεμβρίου 1998

ΟΜΑΔΕΣ ΗΛΙΚΙΩΝ	ΑΓΟΡΙΑ		ΚΟΡΙΤΣΙΑ		ΣΥΝΟΛΟ	
	Αρ.	%	Αρ.	%	Αρ.	%
0 - 11 μηνών	1	7,1	1	8,3	2	7,7
1 - 4 ετών	6	35,7	8	66,7	13	50,0
5 - 9 ετών	1	7,1	3	25,0	4	15,4
10 - 12 ετών	7	50,0	0	0,0	7	26,9
ΣΥΝΟΛΟ	**14**	**100,0**	**12**	**100,0**	**26**	**100,0**

ΚΑΤΗΓΟΡΙΑ ΜΕΤΑΔΟΣΗΣ	ΑΓΟΡΙΑ		ΚΟΡΙΤΣΙΑ		ΣΥΝΟΛΟ	
	Αρ.	%	Αρ.	%	Αρ.	%
Πολυμεταγγισμένα παιδιά	8	57,1	0	0,0	8	30,8
Μεταγγισμένα παιδιά	0	0,0	2	16,7	2	7,7
Ακαθόριστα	0	0,0	0	0,0	0	0,0
[illegible]						
Χρήστες ενδοφλέβιων ναρκωτικών	0	0,0	0	0,0	0	0,0
Μεταγγισμένες	1	7,1	1	8,3	2	7,7
Ετεροφυλόφιλες	2	14,3	3	25,0	5	19,2
Καταγωγή από χώρα με συχνή ετεροφ. μετάδοση	1	7,1	2	16,7	3	11,5
Ακαθόριστος	2	14,3	4	33,3	6	23,1
ΣΥΝΟΛΟ	**14**	**100,0**	**12**	**100,0**	**26**	**100,0**

Εκσυγχρονισμός των ελέγχων

«Εάν αυτό το παιδάκι δεν είχε υποβληθεί σε μεταγγίσεις, δεν επρόκειτο να ζήσει», υπογράμμισε η καθηγήτρια της Αιματολογίας κ. Τίτικα Μανδαλάκη.

«Πρέπει να εξασφαλίσουμε, ότι με τα δεδομένα της επιστήμης και τις δυνατότητες που έχουμε αυτή τη στιγμή, κάνουμε αυτό που επιβάλλεται από τους διεθνείς οργανισμούς και από την ελληνική νομοθεσία. Και αυτό γίνεται».

Η κ. Μανδαλάκη επισήμανε ότι οι μεταγγίσεις, όπως και τα φάρμακα, δεν είναι απολύτως ασφαλείς. Ο κίνδυνος είναι μικρότερος για το έιτζ και μεγαλύτερος για τη μετάδοση ηπατίτιδας και δεν έχει έως σήμερα τελείως αποκλειστεί διεθνώς. «Οι γιατροί το ξέρουν αυτό και οι μεταγγίσεις γίνονται, πάντα, ύστερα από αυστηρή επιλογή της ένδειξης», είπε.

Σε παρατήρηση της «Κ» ότι στην εποχή της βιοτεχνολογίας, όταν σε άλλες υπηρεσίες και προϊόντα -όπως τα φάρμακα- υπάρχουν αυστηρές απαιτήσεις για ποιοτικούς ελέγχους, δεν είναι δυνατόν η ευθύνη για τον έλεγχο του αίματος να ανατίθεται σε 93 μικρές διάσπαρτες μονάδες Αιμοδοσίας σε όλη τη χώρα, απάντησε: «Δυσκολίες υπάρχουν. Εχετε πολύ δίκιο. Αλλά αυτό το είχε προτείνει η Εθνική Επιτροπή Αιμοδοσίας από το 1992.

Χρειάζεται συγκέντρωση των υπηρεσιών, όχι μόνο για να είναι οικονομικότερη η όλη επεξεργασία του αίματος, αλλά να είναι και ασφαλέστερη. Δυστυχώς δεν έγινε τίποτε από τις εκάστοτε ηγεσίες του υπουργείου, για πολλούς και διάφορους λόγους.

Αυτό δεν σημαίνει ότι δεν γίνεται προσπάθεια. Σημαίνει ότι δεν έχουμε έναν συγκεντρωτικό κατάλογο των εθελοντών αιμοδοτών, ώστε να ελέγχονται κάθε τρίμηνο-τετράμηνο. Κάτι που θα βοηθήσει ουσιαστικά ώστε να γίνει ασφαλέστερο το αίμα».

ΑΚΙΣ

Σύγχυση

Κοίταζα τα παιδιά που διαδήλωναν στο κέντρο και σκεφτόμουν κάποια περασμένα χρόνια, όταν κι εμείς, μαθητές ή λίγο μεγαλύτεροι, ακολουθούσαμε τις δικές μας σημαίες και υψώναμε τις δικές μας γροθιές. Μόνο να, που αυτή τη φορά τα οράματα έχουν κάπως ξεφύγει. Δεν είχαν οι μαθητικές κινητοποιήσεις τα στοιχεία της βίας που διακρίνει αυτές που βρίσκονται σε εξέλιξη. Δεν θα μπορούσαν να διανοηθούν ακόμη και οι νέοι της περασμένης δεκαετίας να χειροδικήσουν κατά πολιτών. Δεν θα τολμούσαν να σκεφθούν ότι θα εξύβριζαν χυδαία «on camera». Δεν θα μπορούσαν να φαντασθούν ότι θα υπήρχε μαθητής που θα ξυλοκοπούσε μητέρα συμμαθητή του. Κι όταν πια η πορεία έφτασε στην κορύφωση κι έπεσαν οι Μολότοφ κατά των αστυνομικών, κάποιος από την ομήγυρη, παλιός και δυναμικός αριστερός, θυμήθηκε τα λόγια του Παζολίνι. «Οταν βλέπω τα παιδιά των αστών να κάνουν φασαρίες και να στρέφονται κατά των αστυνομικών που βγάζουν το μεροκάματό τους, τότε είμαι με τους αστυνομικούς»! Πώς και με ποιον τρόπο να «καταπιείς» την ωμή βία των «καλόπαιδων»; Πώς και γιατί να σιωπήσεις μπροστά στις εγκληματικές τους ενέργειες; Τι δουλειά έχει η αντίθεση στην εκπαιδευτική μεταρρύθμιση με τους εμπρησμούς και τις απόπειρες δολοφονίας; Η σύλληψη και παραδειγματική τιμωρία των αλητών που «τη χώθηκαν» σε άλλη μια πορεία για «να κάνουν τα δικά τους», είναι καθήκον της Πολιτείας. Ας μην το ξεχνούν αυτό οι αλαφιασμένοι και πανικόβλητοι «καθ' ύλην αρμόδιοι»...

ΔΗΜΗΤΡΗΣ ΚΑΠΡΑΝΟΣ

Image 5.2 ***I Kathimerini*, January 16 1999, p. 7**

[38] Θα εντοπίζουν άμεσα τον ιό. (1999, January 18). *Ta Nea*, p. 38; Λείπει η υποδομή για σύγχρονες μεθόδους ελέγχου του αίματος. (1999, January 19). *I Avgi*, p. 8. (Maria Koukoumpeti).

[39] Βρέφος φορέας από μετάγγιση. (1999, January 15). *Ta Nea*, p. 21. (Roula Tsoulea); Πρωτοφανής περίπτωση μόλυνσης βρέφους από AIDS. (1999, January 16). *I Avgi*, p. 7. (Maria Koukoumpeti); Ελπίδα ζωής για το βρέφος

The case was characterized as an extremely rare event due to the window period; a period in a recent infection with HIV during which antibodies to the virus cannot be detected in the donated blood.[40] According to the journalist of *I Kathimerini,* "the so-called silent 'window', when during the time of the incubation the virus cannot be detected in the blood, shows that science has its limitations."[41] In *I Avgi,* one could read that "a case, like the one recorded regarding the newborn baby, is considered extremely unlikely and the possibility of it occurring is statistically insignificant compared to the benefits of blood donation."[42]

A further article in *I Kathimerini* focused on the many blood transfusion services operating in the Greek Health System (93 were mentioned).[43] According to this article, a more centralized blood transfusion system was needed in connection with the changes brought by the biotechnology era and the need for quality control to advance blood screening. Over the following days, more relevant articles were published. On 18 January 1999, the title of a short article in *Ta Nea* was "A new method of directly diagnosing AIDS: they will directly detect the virus" (see Image 5.3).[44] The following day, an article in *I Avgi* appeared, entitled "The infrastructure for modern methods of blood screening is missing," and the new method was labeled as "advanced".[45] Both articles described the new method as leading to the direct detection of the virus, and the possibility of it being implemented in Greece until July 1999 was mentioned explicitly for the first time.[46] Another article in *Ta Nea* followed up on the story by referring to the plans of the blood transfusion committee of the Ministry of Health to implement the "more advanced" blood screening


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ΚΟΙΝΩΝΙΑ

ΝΕΑ ΜΕΘΟΔΟΣ ΑΜΕΣΗΣ ΔΙΑΓΝΩΣΗΣ ΤΟΥ AIDS

Θα εντοπίζουν άμεσα τον ιό

Image 5.3 ***Ta Nea*****, January 18 1999, p. 38**

με έιτζ. (1999, January 16). *I Kathimerini*, p. 1; Το «σιωπηλό παράθυρο» αιτία τριών μολύνσεων. (1999, January 16). *I Kathimerini*, p. 7. (Galini Foura).

[40] Βρέφος φορέας από μετάγγιση. (1999, January 15). *Ta Nea*, p. 21. (Roula Tsoulea); Πρωτοφανής περίπτωση μόλυνσης βρέφους από AIDS. (1999, January 16). *I Avgi*, p. 7. (Maria Koukoumpeti).

[41] Το «σιωπηλό παράθυρο» αιτία τριών μολύνσεων. (1999, January 16). *I Kathimerini*, p. 7. (Galini Foura).

[42] Πρωτοφανής περίπτωση μόλυνσης βρέφους από AIDS. (1999, January 16). *I Avgi*, p. 7. (Maria Koukoumpeti).

[43] Το «σιωπηλό παράθυρο» αιτία τριών μολύνσεων. (1999, January 16). *I Kathimerini*, p. 7. (Galini Foura).

[44] Θα εντοπίζουν άμεσα τον ιό. (1999, January 18). *Ta Nea*, p. 38.

[45] Λείπει η υποδομή για σύγχρονες μεθόδους ελέγχου του αίματος. (1999, January 19). *I Avgi*, p. 8. (Maria Koukoumpeti).

[46] As noted in Chapter 3, molecular screening of plasma for HCV started in July 1999, following a European instruction.

method which is based on the principles of molecular biology.[47] It is worth mentioning that, in this article, the screening method was described as the PCR test, which could detect the genetic material of the virus, but the article also mentioned that it could detect the p24 antigen. This could only be detected by a different test, a serologic one that detects the presence of the p24 antigen of HIV a few days before the antibody is detectable on the blood.

The same article referred to the fact that the technique of PCR could already be used in the Nikaia hospital (however, this was about implementing PCR tests for screening plasma for further preparation of blood products, and not for whole blood). The shutdown of the laboratory for quality control of blood and blood products in the National Blood Products Preparation Center (which, according to the articles, owned equipment for PCR testing) was discussed in many articles in connection with this case of transfusion-transmitted infections, raising concerns about transfusion safety.[48] The author of an article in *Rizospastis* contested the residual risk of HIV transfusion-transmitted infection with the political decision not to implement molecular testing in blood products (and not in blood components directed at transfusions) in the aforementioned laboratory, and characterized the latter as an outrageous decision which "obeys the logic of cutbacks and every sort of petty politics."[49]

At a political level, according to the news, the blood transfusion committee of the Ministry of Health advised the establishment of a National Blood Center.[50] In addition, *Rizospastis* reported that a KKE deputy had put a question in parliament to the Minister of Health regarding the government's plans to "make universal in Greece the implementation of molecular screening of blood and blood products with the technique of molecular biology (PCR)."[51] Another aspect

[47] Πιο αυστηρός ο έλεγχος αίματος για ασφαλείς μεταγγίσεις. (1999, January 19). *Ta Nea*, p. 21.

[48] Πιο αυστηρός ο έλεγχος αίματος για ασφαλείς μεταγγίσεις. (1999, January 19). *Ta Nea*, p. 21; Παράγωγα μιας παράλογης πολιτικής. (1999, January 19). *Rizospastis*, p. 22; Τεράστιες ευθύνες για τη συρρίκνωση υπηρεσιών. (1999, January 21). *Rizospastis*, p. 25; Περί στήριξης. (1999, January 23). *Rizospastis*, p. 19; Θύμα των περικοπών στις κοινωνικές δαπάνες. (1999, January 26). *Rizospastis*, p. 6; Λείπει η υποδομή για σύγχρονες μεθόδους ελέγχου του αίματος. (1999, January 19). *I Avgi*, p. 8. (Maria Koukoumpeti); Ερώτηση βουλευτών για το αίμα. (1999, January 19). *I Kathimerini*, p. 7.

[49] Παράγωγα μιας παράλογης πολιτικής. (1999, January 19). *Rizospastis*, p. 22.

[50] Πιο αυστηρός ο έλεγχος αίματος για ασφαλείς μεταγγίσεις. (1999, January 19); Παράγωγα μιας παράλογης πολιτικής. (1999, January 19). *Rizospastis*, p. 22; Ερώτηση βουλευτών για το αίμα. (1999, January 19). *I Kathimerini*, p. 7; Περί στήριξης. (1999, January 23). *Rizospastis*, p. 19.

[51] Τεράστιες ευθύνες για τη συρρίκνωση υπηρεσιών. (1999, January 21). *Rizospastis*, p. 25; Θύμα των περικοπών στις κοινωνικές δαπάνες. (1999, January 26). *Rizospastis*, p. 6.

highlighted in these articles was the large number of decentralized blood banks as part of the blood transfusion system, which should have been reorganized.[52]

The newspapers also reported on the case when it reached the courts. On 4 May 1999, an article was published about the compensation application made by the family of the baby infected with HIV, and the incident was described as a case of transfusion-transmitted infection due to the window period in which the blood donor had not seroconverted.[53] The title of this article was "AIDS: the lethal 'silent window'".[54] The same edition reported that the method of PCR could detect an early infection, but that it was not used in blood banks and only in research centers.[55] The assistant director of the blood transfusion unit of Elena Hospital (the maternity hospital where the baby had been hospitalized) mentioned that it was "medically impossible" to diagnose the donor with HIV, since both the antibody and antigen tests had been negative, and only the PCR testing performed in retrospect was positive.[56] According to these articles, the transfusion medicine practitioners had urged the Ministry of Health to proceed with the allocation of the huge funds necessary to implement this technique.[57] The lawyer of the family was quoted stating that "…there is no liability, because the method that is applied worldwide involves this risk; it is minimal, but it exists."[58]

The second patient infected with HIV after a transfusion from the same donor (described as a 71-year-old woman) also took legal action and claimed compensation from the hospital in which she had been nursed (the biggest compensation ever to have been claimed from a public hospital, according to a newspaper).[59] This lawsuit brought again into the spotlight the issue of efficacy of blood screening in transfusion medicine. According to an article in *Ta Nea*, the case was characterized as a "medical error".[60] In the same article, the seropositive woman was quoted

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[52] Το "σιωπηλό παράθυρο" αιτία τριών μολύνσεων. (1999, January 16). *I Kathimerini*, p. 7. (Galini Foura); Ερώτηση βουλευτών για το αίμα. (1999, January 19). *I Kathimerini*, p. 7; Λείπει η υποδομή για σύγχρονες μεθόδους ελέγχου του αίματος. (1999, January 19). *I Avgi*, p. 8. (Maria Koukoumpeti).

[53] AIDS: το φονικό "σιωπηλό παράθυρο". (1999, May 4). *To Vima*, p. A21. (Despoina Mprousali).

[54] AIDS: το φονικό "σιωπηλό παράθυρο". (1999, May 4). *To Vima*, p. A21. (Despoina Mprousali).

[55] AIDS: το φονικό "σιωπηλό παράθυρο". (1999, May 4). *To Vima*, p. A21. (Despoina Mprousali); Σπάνια η περίπτωση να μην είναι ανιχνεύσιμος ο ιός. (1999, May 4). *To Vima*, p. A21.

[56] AIDS: το φονικό "σιωπηλό παράθυρο". (1999, May 4). *To Vima*, p. A21. (Despoina Mprousali).

[57] AIDS: το φονικό "σιωπηλό παράθυρο". (1999, May 4). *To Vima*, p. A21. (Despoina Mprousali); Σπάνια η περίπτωση να μην είναι ανιχνεύσιμος ο ιός. (1999, May 4). *To Vima*, p. A21.

[58] Έντονη η διαφωνία γιατρών και δικηγόρων. (1999, May 4). *To Vima*, p. A21. (Sofia Giavridou).

[59] 2ο θύμα από μετάγγιση ζητεί μισό δισ. (1999, October 4). *Ta Nea*, p. 1; Και 2ο θύμα από μετάγγιση. (1999, October 4). *Ta Nea*, p. 22. (Dionysis Nasopoulos).

[60] Και 2ο θύμα από μετάγγιση. (1999, October 4). *Ta Nea*, p. 22. (Dionysis Nasopoulos).

stating that "all the citizens risk their life when they are being transfused" because the modern screening method (PCR) was not implemented.[61]

The following day, 5 October 1999, the same newspaper ran a half-page commentary, signed by two reporters, dedicated to molecular screening. It was asserted that transfusion safety could have been "absolute" with a special laboratory screening test (PCR) that could "annihilate the 'silent window'" responsible for the recent case of HIV transfusion-transmitted infections.[62] The opinion of a director of a blood transfusion unit was presented, stating that "this method is infallible when it is applied correctly and could be used for blood screening. However, it has three important disadvantages that currently prohibit its massive use, not only in our country but worldwide."[63] The main reasons this new technique was not implemented were: a) it was considered time-consuming and needed specially trained staff; b) the cost was extremely high; and c) due to the amount of blood samples in a blood bank setting (daily throughput), it was not possible with currently available techniques to screen all of them one by one in a timely manner.[64] Apart from the blood bank director, Aggelos Hatzakis, professor of epidemiology, was consulted regarding the use of PCR. He stated that the PCR test was not used worldwide "because of the cost and the technological difficulties in its application." He also mentioned that as "the technology progresses," blood transfusion services in European countries discussed the possibility of using PCR over the following two years, not in single donations but in pools. The legal adviser of KEEL (the Centre for Control of Special Infections) stated that the possibility of transfusion-associated transmission of AIDS to a patient "is inherent in all medical therapeutic methods."[65] For him, this was the reason for the two HIV infections mentioned above; they were not due to a mistake in the overall process regarding the transfusions.

In 2000, the case reappeared in the press as the judicial process moved on. According to the articles, the Prosecutor, after the inquiry was complete, accused three doctors and the blood

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[61] Και 2ο θύμα από μετάγγιση. (1999, October 4). *Ta Nea*, p. 22. (Dionysis Nasopoulos). Again, in this article, the PCR testing was confused with the p24 antigen test.

[62] Εξέταση που ανιχνεύει το AIDS στις αιμοληψίες δε γίνεται λόγω κόστους. (1999, October 5). *Ta Nea*, p. 10. (Nana Ntaountaki-Roula Tsoulea).

[63] Εξέταση που ανιχνεύει το AIDS στις αιμοληψίες δε γίνεται λόγω κόστους. (1999, October 5). *Ta Nea*, p. 10. (Nana Ntaountaki-Roula Tsoulea).

[64] Εξέταση που ανιχνεύει το AIDS στις αιμοληψίες δε γίνεται λόγω κόστους. (1999, October 5). *Ta Nea*, p. 10. (Nana Ntaountaki-Roula Tsoulea).

[65] KEEL was the Centre for Control of Special Infections (Κέντρο Ελέγχου Ειδικών Λοιμώξεων); in 2005 it was renamed to KEELPNO. Εξέταση που ανιχνεύει το AIDS στις αιμοληψίες δε γίνεται λόγω κόστους. (1999, October 5). *Ta Nea*, p. 10. (Nana Ntaountaki-Roula Tsoulea).

donor of a felony because the doctors had not performed the necessary screening tests, and the donor donated blood although he knew he was HIV seropositive.[66] The case would need to be further investigated, since the doctors and the representatives of the hospital blood transfusion unit had stated in 1999 that this was a case of transfusion-transmitted infections due to the window period (because the donor had not seroconverted).[67] In *Rizospastis,* the president and the assistant secretary of the Greek Movement for Thalassaemia expressed their concerns about blood safety due to this case, and paid a lot of attention to whether the donor knew whether he had been infected with HIV.[68] The family of the baby was awarded a monthly compensation by the court.

The issue seems to have raised public concern. It is worth noticing that, on 12 August 2000, the *Question of the Day* for citizens in *To Vima* was: "Are you afraid of blood transfusions?"[69] The same day, an article reported on the judicial process entitled "Questions about the safety and the testing of transfused blood" (see Image 5.4). The case was exposed in detail, and the opinions of the baby's family lawyer and the vice president of the maternity hospital were presented. An announcement made by KEEL aimed to reassure the public regarding the adequacy of blood screening procedures in Greece.[70] The journalist noted that "it is worth mentioning that the phenomenon of 'silent window', although extremely rare, nevertheless makes very possible the transmission of the virus."[71] The article further made reference to the residual risk, estimated at 1 in 600,000–1,000,000 blood units. An associate professor at a pediatrician clinic in charge of a

[66] Άσκηση αυτεπάγγελτης δίωξης (για κακούργημα) σε τρεις γιατρούς και στον αιμοδότη-φορέα του AIDS. (2000, August 11). *To Vima*, p. A27/47. (Maria Tsoli); Σε τρεις γιατρούς και έναν αιμοδότη, Δίωξη για τη μόλυνση με AIDS. (2000, August 11). *I Avgi*, p. 15; «Απαιτούμε απαντήσεις με το δικαίωμα υπεράσπισης της ζωής μας». (2000, August 19). *Rizospastis*, p. 18.

[67] Άσκηση αυτεπάγγελτης δίωξης (για κακούργημα) σε τρεις γιατρούς και στον αιμοδότη-φορέα του AIDS. (2000, August 11). *To Vima*, p. A27/47. (Maria Tsoli); Σε τρεις γιατρούς και έναν αιμοδότη, Δίωξη για τη μόλυνση με AIDS. (2000, August 11). *I Avgi*, p. 15; Ερωτήματα για την ασφάλεια και τον έλεγχο του μεταγγιζόμενου αίματος. (2000, August 12). *To Vima*, p. A14. (Marina Petropoulou).

[68] «Απαιτούμε απαντήσεις με το δικαίωμα υπεράσπισης της ζωής μας». (2000, August 19). *Rizospastis*, p. 18. The representatives of the Greek Movement for Thalassaemia (Πανελλήνια Κίνηση για τη Μεσογειακή Αναιμία) questioned the information that led the Prosecutor to place criminal charges against the doctors and the donor. They mentioned that if the donor was tested seropositive and diagnosed with AIDS then the Centre for the Control of Special Infections should have been informed, and consequently more people were responsible for the case. If the donor had not tested positive before and therefore did not know he was infected, then the doctors were innocent and the case should not have reached the court.

[69] Η ερώτηση της ημέρας: Φοβάστε τις μεταγγίσεις αίματος;. (2000, August 12). *To Vima*, p. A32.

[70] Ερωτήματα για την ασφάλεια και τον έλεγχο του μεταγγιζόμενου αίματος. (2000, August 12). *To Vima*, p. A14. (Marina Petropoulou).

[71] Ερωτήματα για την ασφάλεια και τον έλεγχο του μεταγγιζόμενου αίματος. (2000, August 12). *To Vima*, p. A14. (Marina Petropoulou).

unit of special infections was quoted explaining that the "risk of 'silent window' is repealed only with the use of the method of polymerase chain reaction, which detects the genome of the virus."[72] For her, PCR "is a very costly method, and for this reason in our country it is used only in individual (special) cases."[73]

A14 ΡΕΠΟΡΤΑΖ ΤΟ ΒΗΜΑ

Εντοπίστηκε μοριακός διακόπτης παχυσαρκίας

Ελέγχει τη δημιουργία των κυττάρων του λιπώδους ιστού κατά την εμβρυϊκή ανάπτυξη – Ανοίγει ο δρόμος για κατασκευή **φαρμάκου**

Ερωτήματα για την ασφάλεια και τον έλεγχο του μεταγγιζόμενου αίματος

Προβληματισμός μετά την υπόθεση μόλυνσης με τον ιό του AIDS βρέφους έξι μηνών και 70χρονης από αιμοδόση που γνώριζε ότι ήταν φορέας

Μάνυμα για τη Διεθνή Ημέρα Νέων

Ξέφυγαν δύο αδήγαντοι έμποροι ναρκωτικών

Οσοι γυναστές προσέθετε...

Ζητεί αποζημίωση ύψους 267 εκατ. δρχ. γιατί έμεινε ανάπηρος κατά τη διάρκεια της θητείας του

Image 5.4 ***To Vima*****, August 12 2000, p. A14**

A month later, an article in *Rizospastis* reported on the outcome of the investigation on the above mentioned case of transfusion-transmitted infections by the blood transfusion committee of the Ministry of Health: "it was an extremely rare case of administering blood from an infected donor in the phase of the serological silent 'window' (i.e. the infection by the virus of AIDS of the donor without the ability to detect the antibody to the virus)."[74] The same article indicated that the issue of blood safety was affected by many factors, such as the selection of appropriate donors and laboratory blood screening.[75] The new method of blood screening (PCR) was also mentioned, regarding attempts to apply it to screen plasma.[76] On 24 April 2001, an article in *I Avgi* followed up on the case regarding the compensation application discussed in the court; the parents of the baby were referred to declaring that the

[72] Ερωτήματα για την ασφάλεια και τον έλεγχο του μεταγγιζόμενου αίματος. (2000, August 12). *To Vima*, p. A14. (Marina Petropoulou).

[73] Ερωτήματα για την ασφάλεια και τον έλεγχο του μεταγγιζόμενου αίματος. (2000, August 12). *To Vima*, p. A14. (Marina Petropoulou).

[74] Εξαιρετικά σπάνια περίπτωση. (2000, September 14). *Rizospastis*, p. 28.

[75] Εξαιρετικά σπάνια περίπτωση. (2000, September 14). *Rizospastis*, p. 28.

[76] Εξαιρετικά σπάνια περίπτωση. (2000, September 14). *Rizospastis*, p. 28.

blood transfused to the baby had not been screened for HIV, although it had been obligatory in the Greek blood banks to do so since 1985.[77]

Various other articles were published in the newspapers dealing with different issues surrounding blood safety and transfusion safety. I have decided to group them by topic and date of publication. On 7 April 2000, World Health Day was dedicated to blood donation under the aspirations of WHO. Two articles referred to data presented by WHO regarding the inequality, on a worldwide scale, to access to screened blood for transfusion (according to these, 20% of transfused blood was not screened in developing countries) and corresponding data on transfusion-transmitted infections.[78] It was pointed out that, in Greece, the contribution of the regular voluntary blood donation to the yearly needs of blood was small (about 40%).[79] It was highlighted that regular blood donors, according to scientific data, were less likely to be infected by transmissible diseases than sporadic donors (who were usually patients' relatives and friends).

The relevant commentary in the *Health* section of *Ta Nea* presented the views of representatives of the Hellenic Society of Blood Transfusion who highlighted the benefits of voluntary blood donation and explained the window period of the seroconversion of a virus.[80] The focus of the article was on the method of autologous transfusion; a director of a hospital blood bank was quoted stating that one strategy to cope with transfusion-transmitted infections due to window period was to collect blood from regular donor, and that another strategy was to promote programs of autologous transfusion.[81] The second part of the commentary presented general information about transfusion from the WHO.[82] In these articles, I did not come across any reference to the molecular diagnostics; however, it was mentioned that blood was relatively safer, although not 100% safe.[83] Other sporadic articles referred to the need for blood sufficiency in the Greek health system by promoting regular blood donation.[84]

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[77] Αποζημίωση για το κοριτσάκι που μολύνθηκε με AIDS. (2001, April 24). *I Avgi*, p. 4.

[78] Μεταγγίσεις που σκορπούν το θάνατο. (2000, April 7). *To Vima*, p. A27/47; Παγκόσμια Οργάνωση Υγείας, Κώδωνας κινδύνου για τις μεταγγίσεις μολυσμένου αίματος. (2000, April 8). *I Avgi*, p. 13.

[79] Αυτομετάγγιση, η απόλυτη ασφάλεια. (2000, April 6). *Ta Nea*, p. 32; Μεταγγίσεις που σκορπούν το θάνατο. (2000, April 7). *To Vima*, p. A27/47; Παγκόσμια Οργάνωση Υγείας, Κώδωνας κινδύνου για τις μεταγγίσεις μολυσμένου αίματος. (2000, April 8). *I Avgi*, p. 13.

[80] Αυτομετάγγιση, η απόλυτη ασφάλεια. (2000, April 6). *Ta Nea*, p. 32.

[81] Αυτομετάγγιση, η απόλυτη ασφάλεια. (2000, April 6). *Ta Nea*, p. 32.

[82] Όλα όσα θα θέλατε να ξέρετε για το αίμα. (2000, April 6). *Ta Nea*, p. 45.

[83] Αυτομετάγγιση, η απόλυτη ασφάλεια. (2000, April 6). *Ta Nea*, p. 32.

[84] Ανάγκη διεύρυνσης των εθελοντών. (2000, May 11). *Rizospastis*, p. 38; Αυξάνεται η έλλειψη αίματος. (2001, July 13). *I Kathimerini*, p. ?; Επάρκεια αίματος και ασφαλέστερες οι μεταγγίσεις... (2001, November 22). *I Kathimerini*, p. ?; Γιατί λείπει το αίμα από νοσοκομεία της περιφέρειας. (2003, August 8). *I Avgi*, p. 6; Αίμα για το

I located several articles on the production of blood products from plasma.[85] In 2001, some newspapers reported on the suspension of the operation of the National Blood Products Preparation Center at the Nikaia Public Hospital, and the non-renewal of the memorandum of cooperation with the Swiss Red Cross, since the center did not comply with the new European Regulation regarding the safety of blood products.[86] The needs for blood products in Greece would be covered with imported products from other countries, while the new center for blood products would be instituted, conjointly with the National Blood Center.[87]

On 13 November 2002, the newspapers covered the announcement made by the Ministry of Health about the detection of HCV (hepatitis C virus) in units of recovered plasma sent from Greece to Sanquin Blood Supply Foundation (the Dutch plasma center with which Greece had signed an agreement for the processing of blood products). According to the articles, the blood was tested in the Netherlands using the method of molecular biology PCR, and HCV had been detected (in Greece the virus was not detected due to the window period); the units of blood had subsequently been destroyed.[88] The ministry launched an investigation to examine in retrospect whether patients nursed in Greek hospitals had been infected with HCV after the transfusion of red blood cells from the infected units of blood (the other possibility was that were thrown away due to the short expiration date).[89] According to the Minister of Health K. Stefanis and the Deputy Minister E. Nasiokas, although PCR screening was not obligatory, it had been used in a pilot

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2004. (2004, February 11). *Eleftherotypia*, p. ?; Λείπει ο «δεσμός» με τον αιμοδότη. (2004, June 20). *Rizospastis*, p. 20. (Natasa Panopoulou); Ζητούνται επειγόντως εθελοντές αιμοδότες. (2005, May 19). *To Vima*, p. A16/16.

[85] As I presented in Chapter 1, the production of plasma products has been based, mainly, on the for-profit pharmaceutical industry. In Europe, not-for-profit organizations also have been involved in the preparation of plasma products mostly with recovered plasma coming from non-remunerated blood donors. This field was been regulated by authorities regulating medicinal products. The implementation of molecular diagnostics for plasma pre-dated in most European countries the use in blood banks. More specifically, since July 1999 plasma directed at the preparation of plasma products had to be tested with NAT for HCV.

[86] Απ' την εγκατάλειψη στην αναστολή λειτουργίας. (2001, March 13). *Rizospastis*, p. 18; «Προσωρινή αναστολή» μετά τη διαρκή αδιαφορία. (2001, March 20). *Rizospastis*, p. 18; Στη Βουλή τα παράγωγα αίματος. (2001, August 4). *I Avgi*, p. 5. (Vasilis Venizelos).

[87] «Προσωρινή αναστολή» μετά τη διαρκή αδιαφορία. (2001, March 20). *Rizospastis*, p. 18. For more on the establishment of the National Blood Center, conjoint with the plasma center, see chapters 3 and 4.

[88] Επιβεβαίωση για το μολυσμένο αίμα με τον ιό της ηπατίτιδας C. (2002, November 13). *To Vima*, p. A23; Μοιραία κατάληξη των περιορισμών. (2002, November 13). *Rizospastis*, p. 28; Μολυσμένο αίμα. (2002, November 13). *I Kathimerini*, p. 1; Μόλυνση με ηπατίτιδα C από μετάγγιση αίματος. (2002, November 13). *I Kathimerini*, p. 7.

[89] Επιβεβαίωση για το μολυσμένο αίμα με τον ιό της ηπατίτιδας C. (2002, November 13). *To Vima*, p. A23; Μοιραία κατάληξη των περιορισμών. (2002, November 13). *Rizospastis*, p. 28; Μόλυνση με ηπατίτιδα C από μετάγγιση αίματος. (2002, November 13). *I Kathimerini*, p. 7; Μία στις 103.000 μεταγγίσεις, η πιθανότητα μόλυνσης από ηπατίτιδα C. (2002, November 16). *Eleftherotypia*, p. ?.

scheme in the National Blood Products Preparation Center since March 2002, and from the beginning of 2003 it would be used to test all units of collected plasma.[90]

On 16 November 2002, the newspapers reported the announcement of EAE claiming that the probability of getting infected with HCV after a transfusion was 1:103,000 (estimated residual risk of HCV transmission in the US), characterized as "small" and "minimal".[91] In addition, it was mentioned that the use of the molecular technique PCR could shorten the window period, but that it was not obligatory worldwide for screening whole blood.[92] Interestingly, this event raised general concerns about transfusion safety in Greece, as noticed in some articles. In *Rizospastis,* the detection of HCV infected units of blood was reported as a direct outcome of the policies implemented by the governments, which had led to the deterrence of the implementation of the "modern screening method (PCR)" in the Nikaia hospital.[93]

The need to reorganize the Greek blood transfusion service was also reported again. It was noted that the blood supply lacked central control due to the fragmentation of the many scattered units; this raised questions about the efficacy of the service, and dramatically raised its operating cost.[94] An article in *To Vima* further reported on the possible adoption of the methods of molecular biology in blood screening which, although not mandatory, were used in most EU Member States.[95] However, their use had the prerequisite of a new infrastructure and adequately trained personnel; in Greece, the operation of more than 90 blood transfusion services was presented as a factor prohibiting the adequate use of molecular diagnostics. It was also considered impossible to accomplish quality control in the many laboratories performing screening tests.[96]

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[90] Επιβεβαίωση για το μολυσμένο αίμα με τον ιό της ηπατίτιδας C. (2002, November 13). *To Vima*, p. A23. It should be noted, as mentioned before, that EU had regulated as mandatory since July 1999 to screen plasma for HCV with molecular diagnostics.

[91] Μία στις 103.000 μεταγγίσεις, η πιθανότητα μόλυνσης από ηπατίτιδα C. (2002, November 16). *Eleftherotypia*, p. ?; Δεν εγκυμονεί κινδύνους μόλυνσης με ηπατίτιδα C η μετάγγιση αίματος. (2002, November 16). *To Vima*, p. A15.

[92] Μία στις 103.000 μεταγγίσεις, η πιθανότητα μόλυνσης από ηπατίτιδα C. (2002, November 16). *Eleftherotypia*, p. ?; Δεν εγκυμονεί κινδύνους μόλυνσης με ηπατίτιδα C η μετάγγιση αίματος. (2002, November 16). *To Vima*, p. A15.

[93] Μοιραία κατάληξη των περιορισμών. (2002, November 13). *Rizospastis*, p. 28.

[94] Μετ' εμποδίων οι έλεγχοι ποιότητας στο σύστημα αιμοδοσίας στη χώρα μας. (2002, November 14). *To Vima*, p. A22. (Ioanna Soufleri-Theodora Tsoli).

[95] Μετ' εμποδίων οι έλεγχοι ποιότητας στο σύστημα αιμοδοσίας στη χώρα μας. (2002, November 14). *To Vima*, p. A22. (Ioanna Soufleri-Theodora Tsoli).

[96] Μετ' εμποδίων οι έλεγχοι ποιότητας στο σύστημα αιμοδοσίας στη χώρα μας. (2002, November 14). *To Vima*, p. A22. (Ioanna Soufleri-Theodora Tsoli); Επάρκεια αίματος και ασφαλέστερες οι μεταγγίσεις... (2001, November 22). *I Kathimerini*, p. ?.

As mentioned above, the newspapers reported on the governmental actions regarding the establishment of the National Blood Center (envisaged in a 1988 Act of law) and the modernization of the National Blood Products Preparation Center. In May 2005, a draft bill was made public and available for deliberation regarding the reorganization of the blood transfusion service and the foundation of a national center, i.e. a central supervising authority for coordinating the blood transfusion services.[97] According to the articles, the bill would transpose the European Directive on blood and blood components into Greek legislation.[98] The bill was debated in the Hellenic Parliament in August 2005.[99] The National Blood Center (EKEA) was inaugurated on 3 February 2006 by the Minister of Health and Social Solidarity (hereafter the Minister of Health) Nikitas Kaklamanis.[100] According to *Rizospastis*, EKEA was understaffed and could operate fully only in the future.[101]

In addition to the case of the HIV transfusion-transmitted infections presented above, other cases that reached the courts were reported in newspaper articles. Similar cases of transfusion-transmitted infection did not result in the prosecution of somebody official, since it was stated that the infection could not have been detected on the blood units, whereas in another case the plaintiffs were awarded compensation because the doctors were found not to have screened the blood properly.[102] In another case of transfusion-transmitted infection with HIV (a multi-transfused thalassaemic girl who had died in 1996), the three-member District Court (Τριμελές Πρωτοδικείο Αθηνών) awarded compensation to the parents for the hospital's not testing (or poorly testing) of the blood by the hospital blood bank.[103] After the hospital filed an appeal, the Court of Appeals again considered the family to be due compensation, but after the demand of the hospital representative, the case reached the Supreme Court.[104] Finally, in 2003, the Supreme Court ratified the compensation to the family.[105] I have also located more general

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[97] Αιμοδοσία με αυστηρούς κανόνες. (2005, May 19). *I Kathimerini*, p. ?. (Penny Mpouloutza); Συγκροτείται Εθνικό Κέντρο Αιμοδοσίας. (2005, May 19). *I Avgi*, p. 24. (Vasilis Venizelos)

[98] For more on the Greek and the European regulations see chapters 3 and 4.

[99] Βαριές ποινές και πρόστιμα στους εμπόρους αίματος. (2005, August 5). *To Vima*, p. A10/10. The law 3402/2005 was voted for in September 2005. It legislated the institutionalization of the National Blood Center, EKEA (Εθνικό Κέντρο Αιμοδοσίας).

[100] Τα εγκαίνια... (2006, February 4). *Rizospastis*, p. 4.

[101] Τα εγκαίνια... (2006, February 4). *Rizospastis*, p. 4.

[102] Στο αρχείο οι μηνύσεις για το μολυσμένο αίμα. (1995, May 12). *Ta Nea*, p. 11; Αποζημιώσεις σε ασθενείς που μολύνθηκαν από AIDS, με τη δικαστική κρίση στην περίπτωση της 11χρονης. (1998, June 11). *I Avgi*, p. 8.

[103] Αποζημίωση 60 εκατ. δρχ. για μετάγγιση αίματος με AIDS (2000, March 18). *To Vima*, p. A16.

[104] Αποζημίωση για το θάνατο από AIDS λόγω μολυσμένου αίματος. (2001, August 1). *I Avgi*, p. 4.

[105] «Δικαίωση» 7 χρόνια μετά. Αποζημίωση σε γονείς για θάνατο από έιτζ. (2003, December 5). *I Kathimerini*, p. ?.

articles about “medical errors”, in which cases of transfusion-transmitted infections were mentioned.[106]

During the years I examined for this section, news stories regarding bovine spongiform encephalopathy (BSE), commonly known as *mad cow disease*, were in the spotlight. The UK was very much affected by this disease after the middle of the 1980s. The disease could be transmitted to humans and cause a variant of Creutzfeldt–Jakob disease (vCJD). I have located articles reporting the possibility of vCJD being transmitted by blood transfusion from infected donors (who developed the disease the following years).[107] A front-page news story in the UK *Guardian* reported that blood products (produced from blood collected from donors who later developed vCJD) were sold by the British Bio-Products Laboratory to 11 countries.[108] Between 2002 and 2004, several articles covered announcements regarding the possibility of transmitting vCJD by blood transfusion, the precautionary measures implemented in the UK and other countries (to control donors and test patients who were transfused blood from carriers of vCJD), and donor deferral strategies to avoid donors who might be affected by the disease.[109]

In the newspapers carrying world news sections, I also noted a number of articles regarding transfusion safety. The French judicial case regarding the scandal of transmitting HIV to people with haemophilia in 1984–1985 (when the HIV virus was being analyzed and attempts to create a screening test for blood banks were being made) was covered in the newspapers.[110] In February 1999, a trial began in Paris against the former French Prime Minister Laurent Fabius and two former ministers. The charge was manslaughter due to negligence. It was claimed that they had delayed the introduction of blood screening for HIV and had released blood products to be

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[106] Το Δημόσιο έχει υποχρεωθεί να καταβάλει ήδη 340 εκατ. (2001, September 26). *Eleftherotypia*, p. ?; Αγωγές πάνω από 1 δισ. για ιατρικά λάθη. (2001, September 26). *Eleftherotypia*, p. ?; Γιατροί που σκοτώνουν και δεν πληρώνουν. (2005, October 16). *To Vima,* p. A44/72.

[107] Και μέσω αίματος η "Κρόιτσφελντ Γιάκομπ". (1997, March 28). *I Avgi*, p. 10; Το αίμα μπορεί να μεταδίδει την ασθένεια Κρόιτσφελντ – Γιάκομπ. (2001, January 19). *I Avgi*, p. 19; Επικίνδυνοι οι αιμοδότες με Κρόιτσφελντ Γιάκομπ. (2002, January 30). *I Kathimerini*, p. ?.

[108] Σε 11 χώρες δόθηκε αίμα με τη νόσο των τρελών αγελάδων. (2001, February 5). *Ta Nea*, p. 37; Προϊόντα αίματος με σπογγώδη εγκεφαλοπάθεια! (2001, February 11). *I Avgi*, p. 19. (Christina Koukounara).

[109] Επικίνδυνοι οι αιμοδότες με Κρόιτσφελντ Γιάκομπ. (2002, January 30). *I Kathimerini*, p. ?; Πρώτος θάνατος από την ασθένεια Κρόιτσφελντ - Γιάκομπ από μετάγγιση αίματος. (2003, December 18). *I Avgi*, p. 10. (Dimitris Stoumpos); Βρετανία - τρελές αγελάδες: Πρώτη μετάδοση του ιού από μετάγγιση αίματος. (2003, December 18). *Eleftherotypia*, p. ?; Μέτρα ελέγχου στη χώρα μας και στην Ε.Ε. (2004, January 4). *I Kathimerini*, p. 17. (Tania Georgiopoulou); Χιλιάδες Βρετανοί πιθανοί φορείς του Κρόιτσφελντ-Γιάκομπς. (2004, September 22). *To Vima*, p. A17/25; Πανικός λόγω «τρελών αγελάδων». (2004, September 22). *I Kathimerini*, p. ?; Μολυσμένο αίμα εξήγαγε η Βρετανία... (2004, September 28). *I Avgi*, p. 10. (Dimitris Stoumpos).

[110] For more on this case see Chapter 1 and Saul (2006).

used in haemophilia treatments, knowing that they might possibly be HIV infectious.[111] *I Avgi* mentioned that the documents from that period demonstrated the "uncertainty" of the scientific community regarding HIV infectivity from seropositive donors (who had not developed the disease of AIDS). The journalist wrote: "What is today considered fact, was then contested…"[112] According to the same journalist, this case was an example of the criminalization of politics; the judicature gained uncontrolled power to judge on every topic.[113] This case was also mentioned in other articles dealing with Greek cases of transfusion-transmitted infections.[114] Another world news story referred to the illegal trading of collected blood by companies producing plasma products in China that were associated with HIV transmissions.[115]

I have also gathered relevant articles elaborating on scientific news regarding transfusion medicine (mostly located in the *Science* sections of the newspapers). One of the topics covered referred to pathogen inactivation methods for treating blood products.[116] In a 2000 article, these methods were described as "blood cleansing methods" and were contrasted with the blood screening methods for known viruses.[117] It was mentioned that the occurrence of a new epidemic in the future could not be excluded (similar to what had happened at the beginning of 1980s and the cases of HIV transfusion-transmitted infections before the virus was identified as such); inactivation methods could therefore prove promising (a specific method by an American company was described in this article).[118] The possibility of the manifestation of new viral infections transmitted through blood was presented as an advantage of the further development of virus and pathogen inactivation methods to eliminate these unknown viruses and pathogens.[119] The detailed description of the new methods was followed by a discussion about its controversial

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[111] Άρχισε η δίκη για το μολυσμένο αίμα. (1999, February 10). *I Avgi*, p. 13. (E. Tserezole); Ο Λοράν Φάμπιους στο εδώλιο. (1999, February 14). *To Vima*, p. A30; Η δίκη του αίματος και η ποινικοποίηση της πολιτικής... (1999, February 14). *I Avgi*, p. 50. (E. Tserezole).

[112] Η δίκη του αίματος και η ποινικοποίηση της πολιτικής... (1999, February 14). *I Avgi*, p. 50. (E. Tserezole).

[113] Η δίκη του αίματος και η ποινικοποίηση της πολιτικής... (1999, February 14). *I Avgi*, p. 50. (E. Tserezole).

[114] Shorter references to the French case can be found in articles about Greek cases that reached the court (I have mentioned them above). In addition, references to the case in France have been located in articles during 2006, as other cases of transfusion-transmitted infections occurred (I present them on the following chpter).

[115] Ανταγωνιστικό πλάσμα του AIDS. (2001, June 18). *Eleftherotypia*, p. ?. (Perikles Korovesis); Επιδημία έιτζ απειλεί τώρα και την Κίνα. (2001, August 25). *I Kathimerini*, p. ?; Βασική αιτία της επιδημίας AIDS, Το εμπόριο αίματος στην Κίνα. (2004, August 20). *I Avgi*, p. 14. (Dimitris Stoumpos).

[116] These methods aim at inactivating existing or unknown pathogens (viruses, bacteria, parasites and other pathogens, as well as potentially harmful white blood cells).

[117] Καθαρότερο αίμα. (2000, April 16). *To Vima*, p. 32/56 (*To allo Vima*).

[118] Καθαρότερο αίμα. (2000, April 16). *To Vima*, p. 32/56 (*To allo Vima*).

[119] Ασφαλείς μεταγγίσεις. (2003, September 14). *To Vima*, p. 66 (*Vima Science* p. 8); Πιο ασφαλές αίμα για μεταγγίσεις. (2004, January 11). *I Kathimerini*, p. ?.

aspects by specialists in this scientific field, and the very high cost of their implementation, which would overwhelm the blood transfusion services.[120] An additional scientific development regarding blood transfusions presented in the news was about the creation of artificial blood; this has been a recurring topic, because artificial blood might be "risk-free" and has been associated with the promises of molecular biology. In such articles, the experimental development of artificial blood was presented as a solution to blood shortages.[121]

5.4. Concluding remarks

This chapter focused on the public image of the blood screening technologies by analyzing articles in Greek newspapers published between 1995 and 2005. In the first section, I briefly presented the main theoretical perspectives that have influenced my analysis. In the second section, I explored methodological issues by expounding on how I chose my primary material and the ways in which I approached it. The third section presented in detail the findings of the analysis of the selected newspaper articles for the period up to 2005, before the universal adoption of NAT. I continue my analysis for 2006–2010 on the chapter that follows.

In the previous section, I presented the findings from the media coverage of issues regarding the technologies used in blood screening between 1995 and 2005 by grouping them into two subsections. During this period, the newspapers reported accounts regarding issues of blood safety and transfusion safety. The emphasis on some articles was also placed on blood shortages and blood sufficiency, a more general theme apparent in all the periods I have studied. Regarding the technologies used in blood screening, reporting was connected to specific events. In particular, the development of molecular diagnostics was covered due to media attention paid to a case of HIV transfusion-transmitted infections (even though this was not published on the front pages, nor was it covered in multi-page investigative articles). In addition, the interest in presenting the new technology was accompanied with possible policy initiatives toward its adoption. When relevant judicial cases appeared on the news, the issue of attributing responsibility and blame were also connected to the screening technologies used.

[120] Πιο ασφαλές αίμα για μεταγγίσεις. (2004, January 11). *I Kathimerini*, p. ?.

[121] Επιστήμονες δημιουργούν τεχνητό αίμα στα εργαστήρια. (2001, June 20). *To Vima*, p. A29/49; Το τεχνητό αίμα διχάζει. (2004, March 30). *Eleftherotypia*, p. ?; Δημιούργησαν αίμα στο εργαστήριο. (2004, December 28). *To Vima*, p. A39/63.

To be more specific, the genetic screening technologies were presented as "newer" and more "advanced". These characterizations were connected with the fact that the new screening technologies were based on advances of molecular biology that would signify a move toward the "era of biotechnology". The molecular diagnostics were linked to the PCR testing and were described as having the potential to minimize the risk of transfusion-associated infections. The techniques previously used were automatically assumed to be more "risky", "scientifically limited" and susceptible to produce "medical errors". At the same time, while in general articles the risk of transfusion-transmitted infections was presented as minimal, there was (sometimes implicit and sometimes explicit) reference to the possibility of achieving zero risk when the possible adoption of new screening technology was discussed.

The new screening technology was not described in detail. The first claim to universalize the use of PCR in the blood transfusion service was recorded in *Rizospastis* in 1999, although it was not analyzed thoroughly. Hence, since there were no policy developments regarding the use of new technology, the coverage was not extensive. The lack of policy developments was further examined in an article in *to Vima*, in 2001, in which transfusion medicine "experts" were quoted as asserting that molecular screening was not routinely possible at that time. The policy initiatives were also at the focus of different articles pointing out the need to reorganize the Greek blood transfusion service. *I Kathimerini* and *Ta Nea* associated the adoption of molecular diagnostics with the need to reform the blood transfusion system in Greece due to the lack of central control of the many operating units, but the legislative initiatives in 2005, which aimed at just such a reorganization of the blood transfusion service in accordance with EU directives, did not attract media attention.

Regarding the news sources mentioned in the articles, it has been noted that official sources were privileged. At the same time, patient groups could also access the news. Some topics did attract the interest of particular newspapers; for example, *Rizospastis* published many articles regarding the Blood National Blood Products Preparation Center of the Nikaia Public Hospital and its laboratories, since the political position of the newspaper was clearly against the shutdown of the center as expressed by the deputies of KKE. This specific decision was contextualized against the overall liberal and reformatory governmental health policy. *Rizospastis* also carried frequent accounts of the need to advance voluntary blood donation.

Chapter 6

6. The Public Image of Blood Safety: Genetic Technologies in Blood Screening

This chapter continues the study of the public image(s) of blood screening technologies in the Greek press begun in Chapter 5.[1] The chapter includes an analysis of newspaper articles between 2006 and 2010. During these years, molecular diagnostic technologies were introduced into the routine laboratory screening of donated blood. I argue that media coverage was crucial in pushing for the use of this technology. In what follows, I present my research findings and arrive at my concluding remarks. The main issues analyzed will be presented according to chronological order of the printed articles and by informal taxonomies by relevance of their main topic and theme. I have translated all the quotations from the newspapers from Greek into English. As noted in the previous chapters, I refer to "blood transfusion" centers/system as a translation for the "κέντρα/σύστημα αιμοδοσίας"; in cases where the topic is blood donation, I distinguish it.

6.1. Blood safety and screening technologies: "everything under *(molecular)* control"[2]

6.1.1. Exposing the case of HIV transfusion-transmitted infections in March 2006

In 2006, the issue of blood safety received extensive media coverage when *To Vima* published a front-page article regarding a case of transfusion-transmitted infection of HIV on 28 March 2006.[3] The headline on the front-page was: "Death transfusion to a 16-year-old girl!" (see

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[1] For the theoretical framework and the methodological issues related to this research see Chapter 5. In continuation from section 5.3, due to the large number of references to primary material I avoid in-text citation in order to facilitate reading. I chose to post citations (full reference) in footnotes. I decided to repeat the full reference of each newspaper article (where needed) because I believe that it will help the reader to better assess them.

[2] Title of a front-page article in a newspaper [in Greek: Όλα υπό *(μοριακό)* έλεγχο]; Όλα υπό (*μοριακό*) έλεγχο. (2006, March 30). *Eleftheros Typos*, p. 1.

[3] The case was covered extensively by all media, and was on the spotlight for many days. In this paper, as stated before, I analyze newspapers' articles. I have spotted commentaries regarding the alarming coverage of the event

Image 6.1).[4] Before I present the newspaper coverage of this event, I shall provide some information, as I have reconstructed the story from the numerous publications. When *To Vima* first published the story, it referred to the HIV transfusion-transmitted infection of a 16-year-old multi-transfused girl with thalassaemia, as well as the possibility that more transfused patients might have been infected. Over the following days, the patient was mentioned as a 17-year-old girl who had received the infectious blood components during programmed transfusion in autumn 2005 at the Ippokrateio General Hospital located in Thessaloniki.[5]

ΤΟ ΒΗΜΑ

ΤΡΙΤΗ 28 ΜΑΡΤΙΟΥ 2006

ΔΙΑΒΑΣΤΕ

Παιχνίδια συγκάλυψης και απειλές για τις υποκλοπές

Κοινή ευρωπαϊκή άδεια οδήγησης ως το 2012

Αποκλείουν σήμερα τα Τέμπη οι εργαζόμενοι στα Λιπάσματα

«Το Βήμα» αποκαλύπτει έγκλημα σε νοσοκομείο της Θεσσαλονίκης

Μετάγγιση θανάτου σε δεκαεξάχρονο κορίτσι!

Του έδωσαν αίμα μολυσμένο με AIDS

Πώς αντέδρασε ο υπουργός μόλις το έμαθε

«Το απίστευτο ιατρικό λάθος πιστοποιήθηκε στις 18 Ιανουαρίου του 2006 και ο αρμόδιος υπουργός ενημερώθηκε μόλις την περασμένη Παρασκευή 24 Μαρτίου 2006»

«Το μολυσμένο με τον ιό HIV αίμα είχε προέλθει από άνδρα αιμοδότη ο οποίος το είχε προσφέρει για να βοηθήσει μοναδικό του παιδί που νοσηλεύονταν σε νοσοκομείο της Χαλκιδικής»

ΤΟ ΣΥΣΤΗΜΑ

Είναι ασφαλώς εγκληματική πράξη η μετάγγιση αίματος μολυσμένου με AIDS σε ένα 16χρονο κορίτσι σε δημόσιο νοσοκομείο της Θεσσαλονίκης. «Δικαιολογείται» προφανώς από το σύστημα ελέγχου του αίματος που εφάρμοσαν παρά το ότι έπρεπε το σύστημα αυτό να έχει αλλάξει.

Ποιο σύστημα, άραγε, δικαιολογεί το γεγονός ότι και αυτό το έγκλημα απεκρύβη επί τόσους μήνες; Ποιοι και γιατί κράτησαν επιτυχώς στο μυστικό ένα έγκλημα που θα μπορούσε να επαναληφθεί (αν δεν έχει ήδη επαναληφθεί!) με άλλα θύματα;

Ας ελπίσουμε ότι στη συγκεκριμένη περίπτωση δεν θα φροντίσει η κυβέρνηση να συσπάσει σιδηρά μέτρα... μυστικότητα. Και ότι αυτοί, τουλάχιστον, οι ένοχοι θα βρεθούν...

ΤΟ ΒΗΜΑ

Η αιρνιδιαστική τροπολογία για το Ασφαλιστικό των τραπεζών οξύνει την πολιτική αντιπαράθεση

«Πολιτικός αυταρχισμός και ανομία»

Το ΠαΣοΚ καταγγέλλει – τα συνδικάτα συσπειρώνονται

ΔΕΚΑΠΕΝΘΗΜΕΡΟ ΕΚΛΟΓΩΝ ΑΝΑΜΕΤΡΗΣΕΩΝ

Η ωραία Γιούλια ρυθμιστής στην Ουκρανία

Πρώτος ο εκλεκτός της Μόσχας Γιανούκοβιτς – Κάλπες σήμερα στο Ισραήλ

ΙΤΑΛΙΑ

Παραλήρημα Μπερλουσκόνι με ύβρεις κατά πάντων

Image 6.1 ***To Vima*****, March 28 2006, p. 1**

The girl tested positive for HIV on 18 January 2006, and the test was confirmed positive on 8 February 2006 by the National Reference Center for AIDS of North Greece. The previous scheduled testing of the girl was negative to HIV (17 August 2006). According to the news accounts, 24 blood donors, whose blood had been transfused to the girl in the meantime of the two tests, were informed they had to be retested. From the 21 blood donors who were retested, one was found to be seropositive to HIV on 3 March 2006. The newspapers reported that it was a 38-year-old male first-time donor who had donated blood on 29 August 2005 for friends or relatives who needed blood transfusion while being nursed in northern Greece. More information

from television news broadcast: On Air. (2006, March 30). *To Vima*, p. 8. (Kosmas Vidos); Ρατσισμός χωρίς προφυλάξεις. (2006, April 15). *Eleftherotypia*, p. ?. (Ios Press).

[4] Μετάγγιση θανάτου σε δεκαεξάχρονο κορίτσι! (2006, March 28). *To Vima*, p. 1.

[5] Thessaloniki is the second larger city of Greece (after the capital Athens).

about the donor was released in the press, and we were informed that his wife was pregnant (and she tested negative to HIV). In addition, on 29 March 2006, it was reported that one more patient had been transfused blood components (plasma) from the same donor and that he was also infected with HIV (the patient was described as a 76-year-old male with heart disease from the city of Trikala).

KEELPNO was informed on 15 March 2006, and the Minister of Health on 24 March (or 23 March, according to other articles).[6] The transfusion-transmitted infections were attributed to the window period of the seroconversion of the virus to the blood of the donor, who had been infected a few days before he donated blood. The unit of blood was reported to have been tested with the serologic methods (detection of antibodies) and was released to the hospital blood transfusion center as a 'false negative'. It was not tested with molecular diagnostic techniques, which had not yet been implemented in blood transfusion centers in Thessaloniki but were used in other blood centers in Greece. According to the articles, the molecular diagnostic techniques were implemented on 8 out of the 14 blood transfusion centers that performed blood screening to units collected from regional blood transfusion units in various locations in Greece. It was estimated that the 20% of the country's donated blood was screened with NAT.

As stated before, *To Vima* published the exclusive news about this case, which led to the public disclosure of the event. It was labeled as a "crime", a "medical error" and "criminal medical negligence".[7] The editorial political commentary on the front page emphasized the fact that the blood screening system should have changed, but this did not explain why the incident was not revealed earlier.[8] It was hoped that the judicial authorities would find the individuals responsible and that the government would not intervene. The main article presented a timeline of the event.[9] While the headlines proclaimed that "[they] transfused AIDS at the 16-year-old", the main story elaborated that "she was given blood infected with the HIV virus that causes the disease of

[6] The Hellenic Center for Disease Control and Prevention (KEELPNO, Κέντρο Ελέγχου και Πρόληψης Νοσημάτων) is a private law entity, supervised and funded directly by the Ministry of Health and Social Solidarity, formerly known as Centre for the Control of Special Infections (KEEL, Κέντρο Ελέγχου Ειδικών Λοιμώξεων), for more see chapters 3 and 4. When the case was published the Minister of Health was Dimitrios Avramopoulos (member of the political party of Nea Demokratia, a right-wing conservative party that formed the government since the elections of March 2004). He was appointed minister of health on 14/02/2006 after a government reshuffle (the previous minister, since March 2004, was Nikitas Kaklamanis). From 1993 until 2004 the political party PASOK, the Greek socialist party, was in power.

[7] Μετάγγιση θανάτου σε δεκαεξάχρονο κορίτσι! (2006, March 28). *To Vima*, p. 1; Μετάγγισαν AIDS σε δεκαεξάχρονη! (2006, March 28). *To Vima*, p. 3. (Ioanna Soufleri).

[8] Το σύστημα. (2006, March 28). *To Vima*, p. 1.

[9] Η εξέταση, το δείγμα και ο δότης. (2006, March 28). *To Vima*, p. 3.

AIDS."[10] In the articles, the methods used to screen the donated blood were described, and the incident was pointed out as having occurred due to the window period. The molecular diagnostics were named as NAT for the first time.[11] It was reported that, on the same day that the Minister of Health D. Avramopoulos was informed of the case (24 March), he issued a ministerial circular regarding the nationwide implementation of the "much more valid molecular technique of nucleic acids."[12] In addition, the Body of Inspectors of the Ministry of Health and the Prosecutor of Thessaloniki were asked to investigate the event.

The same day that *To Vima* published this news story, a press conference was held at the ministry. Present were, among others, the Minister of Health D. Avramopoulos, the Deputy Ministers A. Giannopoulos and G. Konstantopoulos, the president of KEELPNO professor Aggelos Hatzakis and the director of SKAE Dr. Constantina Politis. Three main interrelated issues dominated in the news stories over the following days: a) issues regarding blood screening techniques and the blood transfusion system; b) the political repercussions regarding the responsibilities, the response of the Ministry of Health and the measures to be implemented; and c) news about the infected patients and the blood donor, as well as about the legal case and the actions of the public prosecutor.

On 29 March, the incident appeared on the front page of most of the newspapers I examined.[13] The most extensive coverage of the incident was in *Ta Nea* and *To Vima.* The front page of *Ta Nea* (see Image 6.2) was entitled "For 30 Euros, the 16-year-old was infected!", juxtaposing the cost of serologic screening per unit of blood (EUR 10) to the cost of NAT testing per unit of blood (EUR 30) and the possibility of infection with HIV by each screening method.[14] The same issue dedicated four pages to this story, entitled "Scandal with blood."[15] *To Vima* devoted three pages to this story under the label "Crime".[16]

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[10] Μετάγγιση θανάτου σε δεκαεξάχρονο κορίτσι! (2006, March 28). *To Vima*, p. 1; Μετάγγισαν AIDS σε δεκαεξάχρονη! (2006, March 28). *To Vima*, p. 3. (Ioanna Soufleri).

[11] Νέα τεχνική για τον έλεγχο της ποιότητας του αίματος. (2006, March 28). *To Vima*, p. 3.

[12] Νέα τεχνική για τον έλεγχο της ποιότητας του αίματος. (2006, March 28). *To Vima*, p. 3.

[13] Για 30 ευρώ μολύνθηκε η 16χρονη!. (2006, March 29). *Ta Nea*, p. 1; Ο φόβος του αίματος. (2006, March 29). *To Vima*, p. 1; Μηχανήματα ελέγχου έιτζ μετά το σοκ. (2006, March 29). *I Kathimerini*, p. 1; Αθωράκιστοι στο AIDS. (2006, March 29). *Eleftherotypia*, p. 1; Παράθυρο στο AIDS αφήνει το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 1; «Παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 1; Κυκλοφορεί ελεύθερη η γυναίκα-θάνατος. (2006, March 29). *Espresso*, p. 1; Στη Δικαιοσύνη η «εγκληματική» μετάγγιση αίματος σε 17χρονη από φορέα του AIDS. (2006, March 29). *Adesmeftos Typos*, p. 1.

[14] Για 30 ευρώ μολύνθηκε η 16χρονη!. (2006, March 29). *Ta Nea*, p. 1.

[15] (2006, March 29). *Ta Nea*, pp. 10-14.

[16] (2006, March 29). *To* Vima, pp. 3-5.

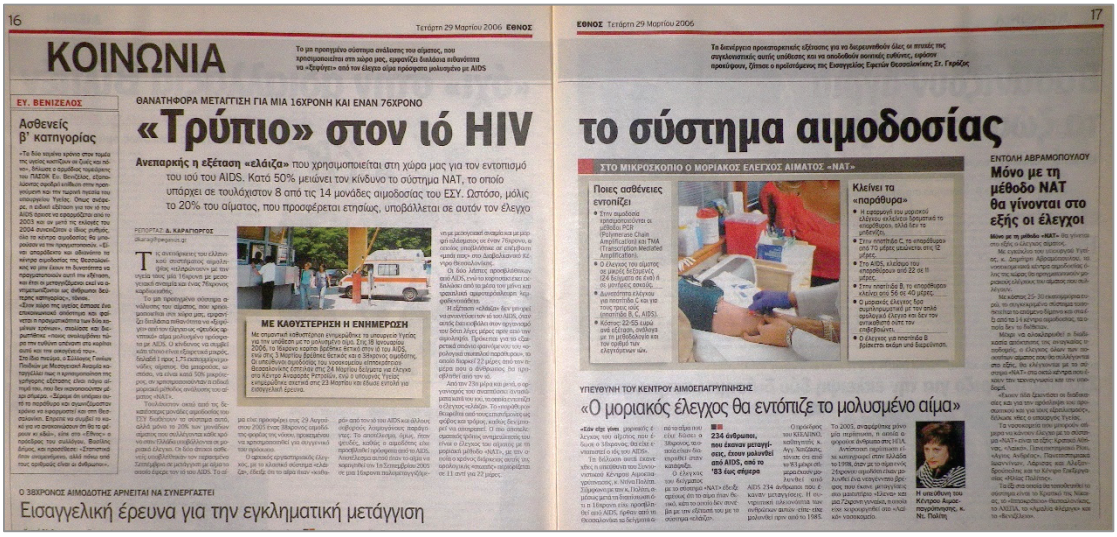
Image 6.2 ***Ta Nea*****, March 29 2006, p. 1**

All the newspapers reported a timeline of the events that led to the transfusion-transmitted infections and paid special attention to the screening methods implemented in the blood transfusion service. The molecular screening method NAT was characterized as "modern", "new", "advanced", "sophisticated" and "detailed". The journalists provided elaborated descriptions of the screening methods. More particularly, *Ethnos* wrote that the screening test Elisa was "inefficient", explaining further that the "not advanced system of blood screening used in our country has a twofold likelihood that blood infected recently with AIDS will 'slip through' as a 'false negative'."[17] In the same issue, an accompanying table described NAT technology (see Image 6.3). A similar table contrasting the technologies used in blood screening (ELISA and NAT) was published in *Eleftherotypia* (see Image 6.4).[18] Likewise, another article presenting the screening techniques stated that the reliable technique ELISA "carries an endogenous disadvantage that renders it inefficient for the detection of recent infections."[19]

Thereafter, presentation of NAT techniques reported that "the progress of molecular biology has recently permitted the application of other methods, which detect the virus itself and do not infer its presence from the reaction of the organism to it."[20] Similarly, another newspaper article reported that the infection was attributed to the "gap which is based mainly on the inability

[17] «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, pp. 16-17. (Dimitris Karagiorgos).
[18] AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos)
[19] Οι τεχνικές, τα μειονεκτήματα και η αξιοπιστία. (2006, March 29). *To Vima*, p. 4.
[20] Οι τεχνικές, τα μειονεκτήματα και η αξιοπιστία. (2006, March 29). *To Vima*, p. 4.

of science to detect the virus of AIDS immediately after the infection of the organism, known as the silent window."[21]



16 Τετάρτη 29 Μαρτίου 2006 ΕΘΝΟΣ

ΚΟΙΝΩΝΙΑ

Το μη προηγμένο σύστημα ανάλυσης του αίματος, που χρησιμοποιείται στη χώρα μας, εμφανίζει διπλάσια πιθανότητα να «ξεφύγει» από τον έλεγχο αίμα πρόσφατα μολυσμένο με AIDS

ΕΥ. ΒΕΝΙΖΕΛΟΣ

Ασθενείς β' κατηγορίας

ΘΑΝΑΤΗΦΟΡΑ ΜΕΤΑΓΓΙΣΗ ΓΙΑ ΜΙΑ 16ΧΡΟΝΗ ΚΑΙ ΕΝΑΝ 76ΧΡΟΝΟ

«Τρύπιο» στον ιό HIV

Ανεπαρκής η εξέταση «ελάιζα» που χρησιμοποιείται στη χώρα μας για τον εντοπισμό του ιού του AIDS. Κατά 50% μειώνει τον κίνδυνο το σύστημα ΝΑΤ, το οποίο υπάρχει σε τουλάχιστον 8 από τις 14 μονάδες αιμοδοσίας του ΕΣΥ. Ωστόσο, μόλις το 20% του αίματος, που προσφέρεται ετησίως, υποβάλλεται σε αυτόν τον έλεγχο

ΡΕΠΟΡΤΑΖ Δ. ΚΑΡΑΓΙΩΡΓΟΣ

ΜΕ ΚΑΘΥΣΤΕΡΗΣΗ Η ΕΝΗΜΕΡΩΣΗ

Ο ΘΕΤΡΟΝΟΣ ΑΙΜΟΔΟΤΗΣ ΑΡΝΕΙΤΑΙ ΝΑ ΣΥΝΕΡΓΑΤΕΙ

Εισαγγελική έρευνα για την εγκληματική μετάγγιση

ΕΘΝΟΣ Τετάρτη 29 Μαρτίου 2006 17

Τα διευρύνεται προληπτικές εξέτασης για να διερευνηθούν όλες οι πτυχές της συγκλονιστικής αυτής υπόθεσης και να αποδοθούν ακριβείς ευθύνες, ώρισε προχθες, ζήτησε ο πρόεδρος της Εισαγγελίας Εφετών Θεσσαλονίκης Στ. Γιαρένης

το σύστημα αιμοδοσίας

ΣΤΟ ΜΙΚΡΟΣΚΟΠΙΟ Ο ΜΟΡΙΑΚΟΣ ΕΛΕΓΧΟΣ ΑΙΜΑΤΟΣ «ΝΑΤ»

ΕΝΤΟΛΗ ΑΒΡΑΜΟΠΟΥΛΟΥ

Μόνο με τη μέθοδο ΝΑΤ θα γίνονται στο εξής οι έλεγχοι

Ποιες ασθένειες εντοπίζει

Κλείνει τα «παράθυρα»

ΥΠΕΥΘΥΝΗ ΤΟΥ ΚΕΝΤΡΟΥ ΑΙΜΟΕΠΑΓΡΥΠΝΗΣΗΣ

«Ο μοριακός έλεγχος θα εντόπιζε το μολυσμένο αίμα»

234 άνθρωποι, που έλαναν μεταγγίσεις, έχουν μολυνθεί από AIDS, από το '83 έως σήμερα

Image 6.3 *Ethnos*, March 29 2006, pp. 16-17

As one can understand from the above, the newspaper articles provided detailed accounts of the technologies used in blood screening. They referred to the window period and explained what it meant. It is interesting to note that the expression appeared figuratively in many headlines and articles, mostly as "silent window", for example: "Tragedy in the transfusion due to 'window' of irresponsibility"; "Window to AIDS allowd in the blood transfusion system"; "AIDS: Death window in the screening of blood"; and "'Silent window' into ostentatious deficiencies".[22] Another metaphor I encountered was "dark window".[23]

Data was also provided in many articles regarding estimations of the risk of transfusion-transmitted infections. The residual risk of transfusion-transmitted HIV, due to the window period of serologic screening, was mostly stated to be 1 case in 1,750,000 units of blood. This information was conveyed during the press conference on 28 March 2006.[24] It was also mentioned that, after

[21] Όλα υπό έλεγχο. (2006, March 30). *Eleftheros Typos,* p. 9. (Nina Komninou).

[22] Τραγωδία στη μετάγγιση από «παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 10-11. (Nina Komninou); Παράθυρο στο AIDS αφήνει το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 1; AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos); «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10.

[23] "Τα δύο χαμένα χρόνια στον τομέα Υγείας κοστίζουν σε ζωές και πόνο". (2006, March 29). *To Vima*, p. 3; Στο κενό οι κραυγές για το AIDS. (2006, March 30). *Ethnos*, p. 5. (Vasilis Ignatiades).

[24] "Ίσως μολύνθηκαν περισσότεροι". (2006, March 29). *To Vima*, p. 3. (Elena Fyntanidou); Δράμα που αφύπνισε Πολιτεία και όλους μας. (2006, March 29). *I Kathimerini*, p. 7. (Penny Mpouloutza); AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos); «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 16-17. (Dimitris Karagiorgos); «Σιωπηλό παράθυρο» σε κραυγαλέες

18 Ελλάδα

ΕΛΕΥΘΕΡΟΤΥΠΙΑ ΤΕΤΑΡΤΗ 29 ΜΑΡΤΙΟΥ

16χρονη και 75χρονος μολύνθηκαν από μετάγγιση

Κίνδυνοι από τον έλεγχο ρουτίνας (ELISA)

ΠΑΣΟΚ: Κόστισαν τα δύο χαμένα χρόνια

NAT και ασφάλεια αίματος

AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος

ΤΟ ΠΡΟΤΟ ΘΥΜΑ

Image 6.4 ***Eleftherotypia*****, March 29 2006, p. 18**

the implementation of molecular diagnostics, the risk would be minimized by 50%. *Ta Nea* featured a table in which the residual risk after Elisa screening was recorded as 1:930,000 and the risk after NAT screening was recorded as 1:1,576,000 (sources were cited from the European Centre for Disease Prevention and Control, ECDC, and KEELPNO).[25] In an article in *I Avgi*, a professor of pathology and immunology, Maria Raptopoulou, provided information regarding the case and stated that the risk for transfusion-transmitted infections for multi-transfused patients was 1.4 in 1,000,0000 transfusions.[26]

The description of screening technologies was accompanied with figures about the expected shortening of the window period after the use of NAT. The window period, after

ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Τι είναι το «σιωπηλό παράθυρο». (2006, March 29). *Eleftheros Typos*, p. 11; Στη Δικαιοσύνη η «εγκληματική» μετάγγιση αίματος σε 17χρονη από φορέα του AIDS. (2006, March 29). *Adesmeftos Typos*, p. 10.

[25] Καταδίκη για μια εξέταση. (2006, March 29). *Ta Nea*, p. 10. (Nana Ntaountaki, Roula Tsoulea, Despoina Kouklaki, Foteini Stefanopoulou).

[26] "Η δημοσιότητα θα είναι εις βάρος της 16χρονης". (2006, March 30). *I Avgi*, p. 7. (Maroula Plika).

serologic screening, was identified in the articles with a variety of numbers, from 20 days to 4 weeks or longer. The period in which the HIV virus could not be detected with NAT screening was specified to be 11 days subsequent to the infection in most newspapers, and 6–10 days in *Ta Nea*. Interestingly, in other pieces in the same editions, this period was also quoted to be 5 days, from the statement made by the director of the blood transfusion service of the Ippokrateio General Hospital Leonidas Papagiannis. To achieve zero risk, Papagiannis said he would initiate retesting of the blood donors at the blood bank for which he was responsible, 10 days after the initial donation.[27]

The presentation of the screening technologies was in some cases accompanied by additional details. In the accompanying table in the central article of *Ethnos,* two methods were mentioned as being available for NAT blood screening: PCR and TMA (see Image 6.3).[28] However, the following day, the same newspaper mentioned that the Ippokrateio hospital had previously requested the initiation of molecular testing, first using PCR and then with NAT, to reduce the window period further.[29] In another article, NAT was presented as equivalent to PCR.[30] Other articles referred specifically to NAT-TMA as the "modern" detection method.[31] Another element regarding the NAT method, which appeared in some articles, had to do with the possibility of screening many samples at the same time (mini-pool testing) and single-unit testing.[32] In addition, the two tables (Images 6.3 and 6.4) stated that although NAT was complementary to the "simple" serologic screening, it did not replace it or confirm it.[33]

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[27] Στη Δικαιοσύνη η «εγκληματική» μετάγγιση αίματος σε 17χρονη από φορέα του AIDS. (2006, March 29). *Adesmeftos Typos*, p. 10; «Κινούμενη βόμβα» η γυναίκα που μετέδωσε τον ιό. (2006, March 29). *Eleftheros Typos*, p. 11. (Vaggelis Moisis); Εισαγγελική έρευνα για την εγκληματική μετάγγιση. (2006, March 29). *Ethnos*, p. 16; Ο δότης είχε μολυνθεί λίγες μέρες πριν. (2006, March 29). *I Avgi*, p. 8; Εισαγγελική έρευνα και αγωνία ασθενών. (2006, March 29). *I Kathimerini*, p. 7. (Giota Myrtsioti); Ψυχολογική στήριξη για τη 16χρονη φορέα του ιού. (2006, March 30). *Eleftherotypia*, p. 19. (Sakis Apostolakis); Μετά 10ήμερο έλεγχο θα δίνεται αίμα για μεταγγίσεις.(2006, March 30). *Ta Nea*, p. 10. (Foteini Stefanopoulou); Ψυχολογική υποστήριξη στη 17χρονη που μολύνθηκε. (2006, March 30). *Eleftheros Typos*, p. 9. (Vaggelis Moisis).

[28] «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 16-17. (Dimitris Karagiorgos)

[29] Στο κενό οι κραυγές για το AIDS. (2006, March 30). *Ethnos*, p. 5. (Vasilis Ignatiades)

[30] Μέσα σε 6 μέρες θα εντόπιζαν τον ιό. (2006, March 29). *Ta Nea*, p. 10.

[31] «Κινούμενη βόμβα» η γυναίκα που μετέδωσε τον ιό. (2006, March 29). *Eleftheros Typos*, p. 11. (Vaggelis Moisis); Ο δότης είχε μολυνθεί λίγες μέρες πριν. (2006, March 29). *I Avgi*, p. 8.

[32] Καταδίκη για μια εξέταση. (2006, March 29). *Ta Nea*, p. 10. (Nana Ntaountaki, Roula Tsoulea, Despoina Kouklaki, Foteini Stefanopoulou); Μέσα σε 6 μέρες θα εντόπιζαν τον ιό. (2006, March 29). *Ta Nea*, p. 10; «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 16-17. (Dimitris Karagiorgos); Τι ελέγχουν, τι δεν ελέγχουν στο αίμα. (2006, March 30). *Eleftherotypia*, p. 18. (Nikos Stasinos-Sofia Neta).

[33] AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos); «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 16-17. (Dimitris Karagiorgos)

Regarding the particular case of HIV transmissions, two statements made by the director of SKAE Dr. C. Politis during the press conference were quoted in most articles. The first statement was that "if the unit of the donated blood had been screened with NAT, it would have been found positive to HIV." The second was that "zero risk does not exist in medical practice."[34] In most accounts, the case was framed as a *tragedy* and a *scandal*. In this context, I have paid attention to some phrases encountered in the articles that referred to the risk of transfusion-transmitted infections. To be more specific, the case was said to be "improbable but possible", "a very rare incident", and the risk was characterized "extremely low" and "minimal but existing".[35] Gogo Papaioannou, a haematologist in a hospital in Thessaloniki, described the event as an "unfortunate coincidence".[36] The Deputy Minister of Health A. Giannopoulos, a physician, characterized the case as an "accidental event".[37] I shall refer more extensively to the political issues raised by this event in the following paragraphs.

By way of concluding the presentation of the press coverage of the screening technologies during this case, I focus on one more issue. In certain articles, I noticed some expressions referring to the technologies more directly by highlighting the role of the machinery and the equipment in blood screening. Such a reference to the technologies gives an impression of their autonomous function and assigns them agency. Two front-page headlines read "Machines for screening aids after the shock" and "The molecular method NAT finds AIDS and hepatitides."[38] An article in *I Avgi* attributed the case to the "lack of the machine for the implementation of the modern method NAT-TMA."[39]

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[34] Άρον άρον στη νέα μέθοδο.(2006, March 29). *Ta Nea*, p. 12; "Ίσως μολύνθηκαν περισσότεροι". (2006, March 29). *To Vima*, p. 3. (Elena Fyntanidou); 620.000 μονάδες οι ετήσιες ανάγκες. (2006, March 29). *I Kathimerini*, p. 7; AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos); «Ο μοριακός έλεγχος θα εντόπιζε το μολυσμένο αίμα». (2006, March 29). *Ethnos*, p. 17; Από το 2001 καθυστερεί ο λεπτομερέστερος έλεγχος του αίματος! (2006, March 29). *I Avgi*, p. 8. (Vasilis Venizelos); Τραγωδία στη μετάγγιση από «παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 10-11. (Nina Komninou); Εγκληματικές παραλείψεις που οδήγησαν στην τραγωδία. (2006, March 29). *Espresso*, p. 8. (V. Karatzaferi)

[35] Στη Δικαιοσύνη η «εγκληματική» μετάγγιση αίματος σε 17χρονη από φορέα του AIDS. (2006, March 29). *Adesmeftos Typos*, p. 10; Εισαγγελική έρευνα και αγωνία ασθενών. (2006, March 29). *I Kathimerini*, p. 7. (Giota Myrtsioti); «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 16-17. (Dimitris Karagiorgos); Τι είναι το «σιωπηλό παράθυρο». (2006, March 29). *Eleftheros Typos*, p. 11.

[36] Θέλω να τον ρωτήσω "γιατί";.(2006, March 29). *Ta Nea*, p. 11.

[37] "Τυχαίο συμβάν" η μοιραία μετάγγιση. (2006, March 30). *To Vima*, p. 3. (Elena Fyntanidou)

[38] Μηχανήματα ελέγχου έιτζ μετά το σοκ. (2006, March 29). *I Kathimerini*, p. 1; Βρίσκει AIDS και ηπατίτιδες. (2006, March 30). *Eleftherotypia*, p. 1.

[39] Ο δότης είχε μολυνθεί λίγες μέρες πριν. (2006, March 29). *I Avgi*, p. 8.

The newspapers also covered announcements regarding the "quick" nationwide implementation of the molecular diagnostics in the country's blood transfusion service and the accompanying political discussions. The national law for the reorganization of the Greek blood supply was voted in 2005, and incorporated the European directives about blood safety. In subsection 5.3.2 I mentioned the newspaper coverage of the establishment of EKEA. According to the relevant articles, the molecular diagnostics were introduced on a trial basis to the Greek blood transfusion services in 2003. The newspapers reported that NAT screening was performed in 8 out of 14 blood transfusion centers. The Minister of Health D. Avramopoulos stated during the press conference that the ministry would pursue rapid implementation of NAT screening nationwide in all 14 centers over the following two months. Until then, the blood collected from the local blood transfusion units would be screened with NAT in the eight centers already equipped to perform it.[40] The minister's policies were characterized in some articles "as lacking a plan" and "without proper planning".[41] Most articles focused on the "delayed" implementation of the "new" screening technology. The minister was quoted to have stated in response that the country would be now "shielded" from such events and that the citizens should feel secure.[42]

To universally implement NAT, the Minister of Health also announced the allocation of about EUR 25–30 million. The cost of the screening technologies was discussed in some articles. *Ta Nea* reported that the cost of NAT per unit of blood was EUR 30, and therefore a total of EUR 18 million would be required per year; the total cost would not exceed the EUR 25–30 million,

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[40] Νέα τεχνική για τον έλεγχο της ποιότητας του αίματος. (2006, March 28). *To Vima*, p. 3; Πού εφαρμόζεται η τεχνική νουκλεϊκών οξέων. (2006, March 29). *To Vima*, p. 3; "Ίσως μολύνθηκαν περισσότεροι". (2006, March 29). To Vima, p. 3. (Elena Fyntanidou); Άρον άρον στη νέα μέθοδο.(2006, March 29). *Ta Nea*, p. 12; «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Από το 2001 καθυστερεί ο λεπτομερέστερος έλεγχος του αίματος! (2006, March 29). *I Avgi*, p. 8. (Vasilis Venizelos); Δράμα που αφύπνισε Πολιτεία και όλους μας. (2006, March 29). *I Kathimerini*, p. 7. (Penny Mpouloutza); AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos); Μόνο με τη μέθοδο ΝΑΤ θα γίνονται στο εξής οι έλεγχοι. (2006, March 29). *Ethnos*, p. 17; Τραγωδία στη μετάγγιση από «παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 10-11. (Nina Komninou); Οι εγκληματικές παραλείψεις που οδήγησαν στην τραγωδία. (2006, March 29). *Espresso*, p. 8. (V. Karatzaferi); Στη Δικαιοσύνη η «εγκληματική» μετάγγιση αίματος σε 17χρονη από φορέα του AIDS. (2006, March 29). *Adesmeftos Typos*, p. 10. Όλα υπό έλεγχο. (2006, March 30). *Eleftheros Typos*, p. 9. (Nina Komninou)

[41] Ολιγωρία. (2006, March 29). *Ta Nea*, p. 3; «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Άρον άρον στη νέα μέθοδο. (2006, March 29). *Ta Nea*, p. 12.

[42] Δράμα που αφύπνισε Πολιτεία και όλους μας. (2006, March 29). *I Kathimerini*, p. 7. (Penny Mpouloutza); Τραγωδία στη μετάγγιση από «παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 10-11. (Nina Komninou); Τι ελέγχουν, τι δεν ελέγχουν στο αίμα. (2006, March 30). *Eleftherotypia*, p. 18. (Nikos Stasinos-Sofia Neta)

including the recruiting and training of necessary personnel.[43] The cost per screening test was identified to be EUR 22–55 in *Ethnos*.[44] An article in *Espresso* remarked that this technique was "extremely expensive".[45] At the same time, *Eleftherotypia* reported that NAT screening cost three times more than the method already in use, as stated by a molecular biologist, representative of a company that sold NAT equipment.[46] He added that the benefit was the minimizing of the window period. This was the only reference to the companies that sold NAT equipment in Greece. Another comment regarding the cost of the screening technologies was encountered in *Rizospastis*. The author of the article questioned the statement of the minister about the foreseen cost and added "the minister made these promises when EUR 250 million per year are needed only for the reagents of EKEA – according to his predecessor – and when a 50% increase in the personnel is needed – specifically for nursing staff – in the blood transfusion units to function rudimentarily."[47] This was the only article that challenged the announcement made by the officials regarding the implementation and cost of NAT.

The issue was also discussed in relation to the overall situation in the Greek blood supply. On 28 March 2006, an article in *To Vima* attributed the failure to implement the molecular diagnostics to the scattered blood transfusion system due to the operation of numerous local units.[48] This issue was also mentioned in other articles. Sporadic, shorter, general references were also recorded; thus, this aspect was not covered in detail by all the newspapers. More specific news coverage dealt with the severe lack of staff and infrastructure in the blood transfusion services.[49] The absence of data processing and information systems was pointed out.[50] An article in *Espresso* mentioned that, according to experts, the hospitals did not have the "technical knowledge" to implement NAT.[51] Another issue, highlighted in some articles, referred to the transport of blood between the smaller units and the blood transfusion centers that performed

[43] Καταδίκη για μια εξέταση. (2006, March 29). *Ta Nea*, p. 10. (Nana Ntaountaki, Roula Tsoulea, Despoina Kouklaki, Foteini Stefanopoulou)
[44] «Τρύπιο» στον ιό HIV το σύστημα αιμοδοσίας. (2006, March 29). *Ethnos*, p. 16-17. (Dimitris Karagiorgos)
[45] Οι εγκληματικές παραλείψεις που οδήγησαν στην τραγωδία. (2006, March 29). *Espresso*, p. 8. (V. Karatzaferi)
[46] Ψυχολογική στήριξη για τη 16χρονη φορέα του ιού. (2006, March 30). *Eleftherotypia*, p. 19. (Sakis Apostolakis)
[47] «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10.
[48] Μετάγγισαν AIDS σε δεκαεξάχρονη! (2006, March 28). *To Vima*, p. 3. (Ioanna Soufleri)
[49] «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Στο 60% φθάνουν οι ελλείψεις προσωπικού στα τμήματα αιμοδοσίας.(2006, March 30). *Ta Nea*, p. 10; Τραγικές ελλείψεις στην αιμοδοσία. (2006, March 31). *Rizospastis*, p. 20.
[50] Στο 60% φθάνουν οι ελλείψεις προσωπικού στα τμήματα αιμοδοσίας.(2006, March 30). *Ta Nea*, p. 10.
[51] Οι εγκληματικές παραλείψεις που οδήγησαν στην τραγωδία. (2006, March 29). *Espresso*, p. 8. (V. Karatzaferi)

NAT screening.[52] According to the Deputy Minister of Health, the ministry would have shortly mandated accredited transport processes "to eliminate phenomena like the transport of blood with buses or patients' relatives' personal cars."[53]

The coverage of this case brought into the discussion issues surrounding voluntary blood donation and blood sufficiency. According to some articles, Politis, the director of SKAE, reportedly stated during the press conference on 28 March that, regardless of the screening methods, blood safety would have been greater if sufficiency in blood supply was to be achieved through voluntary unpaid blood donation instead of irregular, last-minute donors.[54] *To Vima* reported that many questions regarding blood safety were raised after the disclosure of the transfusion-transmitted infections, which might not have been raised "if the movement of voluntary blood donation was forcible enough to cover the country's needs in blood without having to resort to occasional blood donors from necessity…."[55] Another article in the same issue pointed out that the enhancement of the voluntary donation would be the best solution to the problems of the blood transfusion service.[56] The opinion of Aliki Maniati, professor of haematology and president of the Hellenic Blood Transfusion Society, was presented stating that voluntary donation could maximize blood safety and this approach would not cost much.[57] The same newspaper published an investigative article about the needs of blood and the mismanagement of the donated blood by the services.[58] It is worth noting that the president of the Hellenic Federation of the Associations of Voluntary Blood Donors, when consulted by the journalist, explained the weaknesses of the blood transfusion system as experienced by the

[52] Ολιγωρία. (2006, March 29*). Ta Nea*, p. 3; Νέα τεχνική για τον έλεγχο της ποιότητας του αίματος. (2006, March 28). *To Vima*, p. 3; Φιάλες αίματος στα σκουπίδια!. (2006, March 30). *To Vima*, p. 3. (V. Nedos); Ο διορατικός κ. Σούρλας. (2006, March 30). *Adesmeftos Typos*, p. 4; Όλα υπό έλεγχο. (2006, March 30). *Eleftheros Typos*, p. 9. (Nina Komninou). This aspect regarding the transport of units of blood was connected by the journalists to a previous denotation of this problem by a deputy of Nea Demokratia, Georgios Sourlas, during 1999. A similar case was also covered by the news in 2010. On the regulation see Chapter 4.

[53] Νέα τεχνική για τον έλεγχο της ποιότητας του αίματος. (2006, March 28). *To Vima*, p. 3.

[54] Άρον άρον στη νέα μέθοδο.(2006, March 29). *Ta Nea*, p. 12; "Ίσως μολύνθηκαν περισσότεροι". (2006, March 29). *To Vima*, p. 3. (Elena Fyntanidou); 620.000 μονάδες οι ετήσιες ανάγκες. (2006, March 29). *I Kathimerini*, p. 7; Οι εγκληματικές παραλείψεις που οδήγησαν στην τραγωδία. (2006, March 29). *Espresso*, p. 8. (V.Karatzaferi)

[55] "Ίσως μολύνθηκαν περισσότεροι". (2006, March 29). *To Vima*, p. 3. (Elena Fyntanidou)

[56] Νοσεί το σύστημα αιμοδοσίας στη χώρα μας. (2006, March 29). *To Vima*, p. 5. (Ioanna Soufleri)

[57] Νοσεί το σύστημα αιμοδοσίας στη χώρα μας. (2006, March 29). *To Vima*, p. 5. (Ioanna Soufleri)

[58] Φιάλες αίματος στα σκουπίδια!. (2006, March 30). *To Vima*, p. 3. (V. Nedos)

donors.[59] The selection of appropriate volunteer blood donors was presented as the key measure for achieving blood safety in another article focusing on the screening methods.[60]

The need for systematic voluntary blood donation and the promotion of blood donating were highlighted by representatives of groups of people with thalassaemia. The opinion of Odysseas Platis, president of EOTHA, was presented in two articles. Platis acknowledged that the implementation of molecular diagnostics, as announced by the minister, would minimize the window period but would not eliminate it. He reportedly said: "100% safe blood does not exist. We will have safe blood only when we get conscious, regular donors."[61] He also stated that "the citizens should realize that the risk of infection during a transfusion is small but it concerns everybody."[62] A representative of a local association of parents of children with thalassaemia and people with thalassaemia in Thessaloniki, Vasilis Dimos, said that the association had in the past requested the implementation of NAT in a local hospital.[63] Another article presented the views of two people with thalassaemia. They noted that NAT screening was necessary; the risk was the same for people with thalassaemia and other patients in need of transfusion.[64] During the coverage of this case over 29 and 30 March 2006, I also encountered two general articles about the disease of AIDS, which could be connected to transfusion-transmitted infections.[65] In one of them, data was presented to indicate an increase in new HIV infections in Greece between 2002 and 2005.[66]

Regarding the political discussion evoked from this case, I shall first refer to the statement made by Professor Maniati about the difficulties in the Greek blood transfusion centers and the alleged implementation of NAT. She said the allocation of the necessary funds for infrastructure and recruiting of specialized personnel was one side of the problem, and the lack of political will was the other.[67] The political discussion triggered by the disclosure of this case concentrated on

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[59] Φιάλες αίματος στα σκουπίδια!. (2006, March 30). *To Vima*, p. 3. (V. Nedos)
[60] Τι ελέγχουν, τι δεν ελέγχουν στο αίμα. (2006, March 30). *Eleftherotypia*, p. 18. (Nikos Stasinos-Sofia Neta)
[61] "Δεν υπάρχει εκατό τοις εκατό ασφαλές αίμα".(2006, March 29). *Ta Nea*, p. 11.
[62] Οι μεταγγίσεις απειλούν με κοινωνική απομόνωση τους ασθενείς. (2006, March 30). *Ethnos*, p. 5.
[63] Ο δότης είχε μολυνθεί λίγες μέρες πριν. (2006, March 29). *I Avgi*, p. 8; Ψυχολογική στήριξη για τη 16χρονη φορέα του ιού. (2006, March 30). *Eleftherotypia*, p. 19. (Sakis Apostolakis); 6 δισ. δρχ. τον χρόνο για έλεγχο με NAT. (2006, April 4). *Eleftherotypia*, p. ?. (Sakis Apostolakis)
[64] Ανάστατοι οι πάσχοντες από μεσογειακή αναιμία. (2006, March 30). *Espresso*, p. 9. (Thanos Makrogamvrakis)
[65] 3 εκατ. οι νεκροί κάθε χρόνο. (2006, March 29). *Eleftherotypia*, p. 19; Σιωπηλή έκρηξη στο AIDS.(2006, March 30). *Ta Nea*, p. 10. (Despoina Kouklaki)
[66] Σιωπηλή έκρηξη στο AIDS.(2006, March 30). *Ta Nea*, p. 10. (Despoina Kouklaki)
[67] Νοσεί το σύστημα αιμοδοσίας στη χώρα μας. (2006, March 29). *To Vima*, p. 5. (Ioanna Soufleri)

the attribution of political responsibility for this event. One issue of debate regarded the actions taken by the accountable ministry.

The Minister of Health, Dimitrios Avramopoulos, was appointed a month before the public disclosure of the case; the discussion thus also involved the preceding minister, Nikitas Kaklamanis.[68] Kaklamanis was also questioned by the media about this case, and stated that there had been no delay during his time at the ministry in the implementation of molecular diagnostics. More specifically, regarding the provisions for the adoption of NAT, Kaklamanis noted that "it involves investments, establishment of infrastructure and training of the personnel"; it was therefore time-consuming to modernize the blood transfusion centers.[69] He highlighted that even molecular screening did not fully safeguard patients from transfusion-transmitted infections.[70] Regarding the liability for the case, the political commentaries in some newspapers referred to disputes of petty politics among the two politicians of the same political party (and government).[71] Some political analysts criticized Kaklamanis, who at the time was running as candidate mayor for the city of Athens, for his performance during his two-year service at the Ministry of Health, and questioned his future efficacy as a mayor.[72]

The newspapers covered also the reaction of the political parties of the opposition. Evaggelos Venizelos, the spokesperson about health matters from the major opposition party, PASOK (which had been in power until 2004, and under which NAT had begun to be implemented), stated that "the two lost years on the sector of health cost in lives and pain."[73] In his view, "Greece had started to implement the special screening test, which excludes the so-

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[68] Αρνείται ότι υπήρξε καθυστέρηση ο Κακλαμάνης.(2006, March 29). *Ta Nea*, p. 12; Έντονη δυσαρέσκεια στο Μέγαρο Μαξίμου για τα "πυρά" Αβραμόπουλου κατά Κακλαμάνη. (2006, March 29). *To Vima*, p. 4; ΠΑΣΟΚ: Κόστισαν τα δύο χαμένα χρόνια. (2006, March 29). *Eleftherotypia*, p. 18; Από το 2001 καθυστερεί ο λεπτομερέστερος έλεγχος του αίματος! (2006, March 29). *I Avgi*, p. 8. (Vasilis Venizelos); «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Όλα υπό έλεγχο. (2006, March 30). *Eleftheros Typos*, p. 9. (Nina Komninou)

[69] Αρνείται ότι υπήρξε καθυστέρηση ο Κακλαμάνης.(2006, March 29). *Ta Nea*, p. 12; Όλα υπό έλεγχο. (2006, March 30). *Eleftheros Typos*, p. 9. (Nina Komninou)

[70] Αρνείται ότι υπήρξε καθυστέρηση ο Κακλαμάνης.(2006, March 29). *Ta Nea*, p. 12.

[71] Έντονη δυσαρέσκεια στο Μέγαρο Μαξίμου για τα "πυρά" Αβραμόπουλου κατά Κακλαμάνη. (2006, March 29). *To Vima*, p. 4; Αίμα. (2006, March 30). *Ta Nea*, p. 10. (Kostas Botopoulos)

[72] Φούσκα.(2006, March 29). *Ta Nea*, p. 11. (Giorgos Papachristos); Έντονη δυσαρέσκεια στο Μέγαρο Μαξίμου για τα "πυρά" Αβραμόπουλου κατά Κακλαμάνη. (2006, March 29). *To Vima*, p. 4; 3η σελίδα. (2006, March 29). *Ethnos*, p. 3.

[73] «Τα δύο χαμένα χρόνια στον τομέα Υγείας κοστίζουν σε ζωές και πόνο». (2006, March 29). T*o Vima*, p. 3; Ασθενείς β' κατηγορίας. (2006, March 29). *Ethnos*, p. 16; ΠΑΣΟΚ: Κόστισαν τα δύο χαμένα χρόνια. (2006, March 29). *Eleftherotypia*, p. 18; Τραγωδία στη μετάγγιση από «παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 10-11. (Nina Komninou)

called 'dark window' in cases of blood donors infected with the virus of AIDS" in 2003; if the pace had been kept up after the 2004 elections, then by 2006 all the blood transfusion centers would have been capable of performing the test.[74] Alekos Alavanos, the president of Synaspismos, a left-wing party of the minor opposition, also criticized the government and said that officials presented a distorted image of the situation in the sector of health.[75] Alavanos argued that it was inconceivable for hospitals to not have the infrastructure to perform molecular screening.[76]

The responsibility regarding the case of the transfusions-transmitted infections was attributed to the delay of the implementation of NAT screening technology and to the non-compliance with the regulations regarding the reorganization of the blood transfusion service, as argued in the political commentaries. It was characterized as an outcome of "negligence" and "laxity" on the management of blood supply (the Greek word used in some articles was 'ολιγωρία').[77] In *Ta Nea,* the secondary head-line of one of the main articles was "Behind the lack of infrastructure for the molecular screening method of the virus of AIDS 'NAT' are barricaded the officials of the Ippokrateio Hospital of Thessaloniki, indicating at the same time – implicitly but definitely – the 38-year-old blood donor as the sole responsible for the infections."[78] *Ethnos* published an article dedicated to the fact that the hospital where the infection of the thalassaemic girl occurred had in the past requested the implementation of NAT, by sending six relevant memoranda to the ministry.[79] It was highlighted that the public officials did not assume responsibility for the infection of the two patients.[80]

In a short opinion article about the lack of comprehensive preventive policy-making in Greece, Lykourgos Liaropoulos, professor of health economics, stated that "we hear that EUR 30 million are needed to prevent one (more) case of transfusion-transmitted infection of AIDS."[81] He

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[74] «Τα δύο χαμένα χρόνια στον τομέα Υγείας κοστίζουν σε ζωές και πόνο». (2006, March 29). T*o Vima*, p. 3; Κόντρες... (2006, March 29). *Ta Nea*, p. 12.

[75] Κόντρες... (2006, March 29). *Ta Nea*, p. 12; ΠΑΣΟΚ: Κόστισαν τα δύο χαμένα χρόνια. (2006, March 29). *Eleftherotypia*, p. 18; Τραγωδία στη μετάγγιση από «παράθυρο» ανευθυνότητας. (2006, March 29). *Eleftheros Typos*, p. 10-11. (Nina Komninou); «Η κυβέρνηση παρουσιάζει ψευδή εικόνα για την Υγεία». (2006, March 29). *I Avgi*, p. 8.

[76] «Η κυβέρνηση παρουσιάζει ψευδή εικόνα για την Υγεία». (2006, March 29). *I Avgi*, p. 8.

[77] Ολιγωρία. (2006, March 29). *Ta Nea*, p. 3; Δράμα που αφύπνισε Πολιτεία και όλους μας. (2006, March 29). *I Kathimerini*, p. 7. (Penny Mpouloutza)

[78] Θέλω να τον ρωτήσω "γιατί";.(2006, March 29). *Ta Nea*, p. 11.

[79] Στο κενό οι κραυγές για το AIDS. (2006, March 30). *Ethnos*, p. 5. (Vasilis Ignatiades)

[80] Ολιγωρία. (2006, March 29). *Ta Nea*, p. 3; Η ευθύνη. (2006, March 29). *Ta Nea*, p. 12. (Panagis Galiatsatos); Αίμα. (2006, March 30). *Ta Nea*, p. 10. (Kostas Botopoulos); "Τυχαίο συμβάν" η μοιραία μετάγγιση. (2006, March 30). *To Vima*, p. 3. (Elena Fyntanidou); Σοκ και ανασφάλεια. (2006, March 30). *Adesmeftos Typos*, p. 4. (M. Dimiriou)

[81] Η χαμένη "τιμή" της πρόληψης.(2006, March 30). *Ta Nea*, p. 10. (Lycourgos Liaropoulos)

juxtaposed this with: “hundreds of lives that are lost every year in a country where thousands of people drive every night in a state of inebriation, but alcohol tests take place only on the eve of government reshuffle or evaluations on the police force.”[82] He further added that Greece did not deal consistently with preventive policies for obesity and smoking, and he concluded: “are we going to find EUR 30 more million and 30 grams of brain to cope with these [issues]?”[83] This was the only commentary I have encountered in the media accounts which contrasted the implementation of NAT with other health care interventions, and especially with preventive policies.

The framing of the story as a scandal was complemented by elaborate information regarding the “delays” in the procedure of reporting of the HIV infection of the thalassaemic girl. This issue was covered in many articles.[84] The responsible individuals from SKAE, KEELPNO and the Ministry of Health were involved in the discussion, since, during the press conference held on 28 March 2006, they provided conflicting information about the timeline after the girl tested HIV seropositive. The reported delays were attributed to the lack of protocols for the reporting of adverse effects in transfusions. Politis, director of SKAE, announced that action was needed by the haemovigilance center to institute official reporting procedures.

Regarding the two persons infected with HIV, more attention was given to the girl with thalassaemia. The news covered the reaction of the officials extensively regarding the support and the protection of the girl.[85] At the same time, another social issue covered by the news involved the blood donor who was detected with HIV. An aspect discussed by some newspapers

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[82] Η χαμένη "τιμή" της πρόληψης.(2006, March 30). *Ta Nea*, p. 10. (Lycourgos Liaropoulos)

[83] Η χαμένη "τιμή" της πρόληψης.(2006, March 30). *Ta Nea*, p. 10. (Lycourgos Liaropoulos)

[84] Το σύστημα. (2006, March 28). *To Vima*, p. 1; Μετάγγισαν AIDS σε δεκαεξάχρονη! (2006, March 28). *To Vima*, p. 3. (Ioanna Soufleri); Θέλω να τον ρωτήσω "γιατί";.(2006, March 29). *Ta Nea*, p. 11; Τείχος στην ενημέρωση. (2006, March 29). *Ta Nea*, p. 12; "'Ισως μολύνθηκαν περισσότεροι". (2006, March 29). *To Vima*, p. 3. (Elena Fyntanidou); AIDS: Παράθυρο θανάτου στον έλεγχο του αίματος. (2006, March 29). *Eleftherotypia*, p. 18. (Nikos Stasinos); «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Από το 2001 καθυστερεί ο λεπτομερέστερος έλεγχος του αίματος! (2006, March 29). *I Avgi*, p. 8. (Vasilis Venizelos); «Μπαλάκι» οι ευθύνες μεταξύ των αρμοδίων. (2006, March 29). *Espresso*, p. 9; Στο κενό οι κραυγές για το AIDS. (2006, March 30). *Ethnos*, p. 5. (Vasilis Ignatiades)

[85] Θέλω να τον ρωτήσω "γιατί";.(2006, March 29). *Ta Nea*, p. 11; Ο δότης και τα πρόσωπα της τραγωδίας. (2006, March 29). *To Vima*, p. 4; «Θέλω να τον ρωτήσω γιατί μου το έκανε αυτό». (2006, March 29). *Eleftherotypia*, p. 19. (Sakis Apostolakis); Άλλαξε η ζωή τους από τη μια στιγμή στην άλλη. (2006, March 29). *Espresso*, p. 9. (V. Karatzaferi); Ψυχολογική στήριξη για τη 16χρονη φορέα του ιού. (2006, March 30). *Eleftherotypia*, p. 19. (Sakis Apostolakis) "Η δημοσιότητα θα είναι εις βάρος της 16χρονης". (2006, March 30). *I Avgi*, p. 7. (Maroula Plika); Στον εισαγγελέα και ο αιμοδότης- φορέας του έιτζ. (2006, March 30). *I Kathimerini*, p. 7; Οι μεταγγίσεις απειλούν με κοινωνική απομόνωση τους ασθενείς. (2006, March 30). *Ethnos*, p. 5; Μετάγγισαν μολυσμένο αίμα σε 3χρονη το 1988. (2006, March 30). *Ethnos*, p. 5; Ψυχολογική υποστήριξη στη 17χρονη που μολύνθηκε. (2006, March 30). *Eleftheros Typos*, p. 9. (Vaggelis Moisis)

involved the scenarios regarding his infection with HIV; articles recorded that he was married and his pregnant wife was HIV negative. According to the articles, he stated at the officials of the blood bank of the Ippokrateio hospital that he had had extramarital sexual relations a few days prior to the donation, with two women whom he did not specify.[86]

Some newspapers focused on this issue. *Espresso,* the only tabloid newspaper in Greece at the time, had front pages dedicated to this on 28 and 29 March (see Image 6.5).[87] The coverage of this issue was connected to the actions taken by the Public Prosecutor (Εισαγγελία Πρωτοδικών) in Thessaloniki. According to some articles, the blood donor did not reveal the women, who were prostitutes, but he specified that they were Greek in origin.[88] According to other articles, the prostitute infected with HIV was probably foreign, and was characterized as a "moving bomb" who "could have spread the HIV virus" to other males.[89] This scenario was elaborated by articles in the newspaper *Espresso*. The female prostitute was described as "deadly woman" in headlines.[90]

Image 6.5 *Espresso*, March 29 2006, p. 1

[86] Θέλω να τον ρωτήσω "γιατί";.(2006, March 29). *Ta Nea*, p. 11; Ο δότης και τα πρόσωπα της τραγωδίας. (2006, March 29). *To Vima*, p. 4; Ο δότης είχε μολυνθεί λίγες μέρες πριν. (2006, March 29). *I Avgi*, p. 8; Εισαγγελική έρευνα και αγωνία ασθενών. (2006, March 29). *I Kathimerini*, p. 7. (Giota Myrtsioti); «Θέλω να τον ρωτήσω γιατί μου το έκανε αυτό». (2006, March 29). *Eleftherotypia*, p. 19. (Sakis Apostolakis); Εισαγγελική έρευνα για την εγκληματική μετάγγιση. (2006, March 29). *Ethnos*, p. 16; Δεν γνώριζε ότι ήταν φορέας. (2006, March 29). Eleftheros Typos, p. 10; Ελεύθερη η γυναίκα-θάνατος. (2006, March 29); Καλούν τον αιμοδότη. (2006, March 30). *Eleftherotypia*, p. 19; *Espresso*, p. 8-9. (Kostas Zafiriou); Ψυχολογική υποστήριξη στη 17χρονη που μολύνθηκε. (2006, March 30). *Eleftheros Typos*, p. 9. (Vaggelis Moisis); «Call girls πολυτελείας σπέρνουν τον ιό του AIDS». (2006, March 30). *Espresso*, p. 8-9. (G. Makri - S. Tzanetatos); Ψάχνουν ακόμη την Ουκρανή που μόλυνε τον 38χρονο. (2006, March 30). *Espresso*, p. 8-9. (Kostas Zafiriou)

[87] Κυκλοφορεί ελεύθερη η γυναίκα-θάνατος. (2006, March 29). *Espresso*, p. 1; «Call girls πολυτελείας σπέρνουν τον ιό του AIDS». (2006, March 30). *Espresso*, p. 1.

[88] «Θέλω να τον ρωτήσω γιατί μου το έκανε αυτό». (2006, March 29). *Eleftherotypia*, p. 19. (Sakis Apostolakis); "Η δημοσιότητα θα είναι εις βάρος της 16χρονης". (2006, March 30). *I Avgi*, p. 7. (Maroula Plika); Καλούν τον αιμοδότη. (2006, March 30). *Eleftherotypia*, p. 19.

[89] «Θέλω να τον ρωτήσω γιατί μου το έκανε αυτό». (2006, March 29). *Eleftherotypia*, p. 19. (Sakis Apostolakis); «Κινούμενη βόμβα» η γυναίκα που μετέδωσε τον ιό. (2006, March 29). *Eleftheros Typos*, p. 11. (Vaggelis Moisis); Ψάχνουν ακόμη την Ουκρανή που μόλυνε τον 38χρονο. (2006, March 30). *Espresso*, p. 8-9. (Kostas Zafiriou).

[90] Κυκλοφορεί ελεύθερη η γυναίκα-θάνατος. (2006, March 29). *Espresso*, p. 1; Ελεύθερη η γυναίκα-θάνατος. (2006, March 29). *Espresso*, p. 8-9. (Kostas Zafiriou); «Call girls πολυτελείας σπέρνουν τον ιό του AIDS». (2006, March 30). *Espresso*, p. 1; «Call girls πολυτελείας σπέρνουν τον ιό του AIDS». (2006, March 30). *Espresso*, p. 8-9. (G. Makri - S. Tzanetatos). The way part of the media dealt with this case, by focusing on the possibility of the

Regarding the actions taken by the prosecutor and the ongoing public inquiry, the newspapers reported relevant news. According to the articles, the prosecutor would inspect if the instituted provisions for blood screening had been followed and consider possible criminal liabilities.[91] Some articles mentioned that the prosecutor would investigate whether the donor knew he was infected with HIV when he donated the blood, and additionally would inspect the source of his infection.[92]

During the newspapers' coverage of this case, I located articles that referred to older cases of transfusion-transmitted infections and the corresponding legal cases.[93] Such articles mentioned that the families of those infected by a transfusion were usually awarded compensations when the cases reached the court. An article in *Ta Nea* remarked that "the hospitals pay compensations, but nobody gets punished."[94] On the same page of the newspaper, another article focused on international cases (scandals during the decades of 1980s and 1990s) regarding HIV infected blood that "led most of the governments to implement strict measures to safeguard the quality of blood."[95] In addition, during the reporting of this case, data was provided in many articles regarding cases of transfusion-associated HIV transmissions that occurred in Greece after 1985 when testing for HIV began.[96]

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donor to had been infected by a foreign prostitute, was criticized in another article in which one can read that "a scape goat was found for the scandal with the infected blood", in Ρατσισμός χωρίς προφυλάξεις. (2006, April 15). *Eleftherotypia*, p. ?. (Ios Press).

[91] Μετά 10ήμερο έλεγχο θα δίνεται αίμα για μεταγγίσεις.(2006, March 30). *Ta Nea*, p. 10. (Foteini Stefanopoulou); Εισαγγελική παρέμβαση για το μολυσμένο αίμα. (2006, March 30). *To Vima*, p. 3; «Θέλω να τον ρωτήσω γιατί μου το έκανε αυτό». (2006, March 29). *Eleftherotypia*, p. 19. (Sakis Apostolakis); Ο δότης είχε μολυνθεί λίγες μέρες πριν. (2006, March 29). *I Avgi*, p. 8; Εισαγγελική έρευνα για την εγκληματική μετάγγιση. (2006, March 29). *Ethnos*, p. 16; «Κινούμενη βόμβα» η γυναίκα που μετέδωσε τον ιό. (2006, March 29). *Eleftheros Typos*, p. 11. (Vaggelis Moisis); "Η δημοσιότητα θα είναι εις βάρος της 16χρονης". (2006, March 30). *I Avgi*, p. 7. (Maroula Plika); Στο κενό οι κραυγές για το AIDS. (2006, March 30). *Ethnos*, p. 5. (Vasilis Ignatiades); Στη Δικαιοσύνη η «εγκληματική» μετάγγιση αίματος σε 17χρονη από φορέα του AIDS. (2006, March 29). *Adesmeftos Typos*, p. 10.

[92] Εισαγγελική έρευνα για την εγκληματική μετάγγιση. (2006, March 29). *Ethnos*, p. 16; Καλούν τον αιμοδότη. (2006, March 30). *Eleftherotypia*, p. 19; "Η δημοσιότητα θα είναι εις βάρος της 16χρονης". (2006, March 30). *I Avgi*, p. 7. (Maroula Plika); Ψυχολογική υποστήριξη στη 17χρονη που μολύνθηκε. (2006, March 30). *Eleftheros Typos*, p. 9. (Vaggelis Moisis); Ψάχνουν ακόμη την Ουκρανή που μόλυνε τον 38χρονο. (2006, March 30). *Espresso*, p. 8-9. (Kostas Zafiriou)

[93] Τα νοσοκομεία πληρώνουν αποζημιώσεις, αλλά κανείς δεν τιμωρείται.(2006, March 29). *Ta Nea*, p. 14; Ιατρικά λάθη και αποζημιώσεις. (2006, March 29). *To Vima*, p. 5. (P. Tsimpoukis); Το πρώτο θύμα. (2006, March 29). *Eleftherotypia*, p. 18; Αποζημίωση-«μαμούθ» μετά το θάνατο 12χρονης από τη Ρόδο. (2006, March 30). *Espresso*, p. 9.

[94] Τα νοσοκομεία πληρώνουν αποζημιώσεις, αλλά κανείς δεν τιμωρείται.(2006, March 29). *Ta Nea*, p. 14.

[95] Γαλλία: Πρωθυπουργός στο σκαμνί.(2006, March 29). *Ta Nea*, p. 14. (Giorgos Aggelopoulos).

[96] Πάνω από 300 Έλληνες μολύνθηκαν με AIDS από μεταγγίσεις.(2006, March 29). *Ta Nea*, p. 10; Δράμα που αφύπνισε Πολιτεία και όλους μας. (2006, March 29). *I Kathimerini*, p. 7. (Penny Mpouloutza); «Σιωπηλό παράθυρο» σε κραυγαλέες ελλείψεις. (2006, March 29). *Rizospastis*, p. 10; Τι είναι το «σιωπηλό παράθυρο».

6.1.2. Press coverage during the rest of 2006

Over the following period, the newspapers frequently reported on the adoption of NAT all over the country. They also followed up on the specific case described in the previous subsection. It was reported that the 38-year-old male donor would be prosecuted for "transmission of disease due to conscious negligence" since he was considered to have lied in the donor questionnaire he filled in.[97] The preliminary inquiry did not fix liability on the doctors of the blood transfusion service.[98] Deputies of the major opposition political party, PASOK, posed a parliamentary question to the Minister of Health in which they charged the ministry with political and criminal responsibilities for not implementing NAT screening universally after 2004.[99] I also encountered two articles referring to the alleged ongoing dispute between Avramopoulos, Minister of Health, and Kaklamanis, his predecessor, regarding their relative responsibility for the limited use of NAT.[100]

In the Sunday edition, *To Vima* published on 2 April 2006 a module titled "the fear of blood", which also appeared on the front page of the newspaper.[101] The feature article noted that the tragic story of the HIV transfusion-transmitted infections demonstrated the significant shortcomings in the blood transfusion system (a timeline of the events was also recorded).[102] It was highlighted that large quantities of donated blood were discarded and that the EKEA was not yet fully operational.[103] Attention was also paid to the problem of the transport of the blood units because the procurements were not yet validated due to high costs.[104] These issues were also discussed in an article in the Sunday edition of *Eleftherotypia*.[105] The other two pages of the

(2006, March 29). *Eleftheros Typos*, p. 11; Ογδόντα πέντε περιστατικά από το 1985. (2006, March 29). *Espresso*, p. 8. (V.Karatzaferi).

[97] Ο εισαγγελέας καλεί τον 38χρονο φορέα. (2006, April 1). *Eleftherotypia*, p. ?; Διώκεται ο 38χρονος για "μετάδοση του AIDS από αμέλεια". (2006, April 3). *Ta Nea*, p. 13; Δίωξη κατά του αιμοδότη που μόλυνε τη 16χρονη. (2006, April 3). *Eleftherotypia*, p. ?; Δίωξη στο δότη και μπαλάκι οι ευθύνες. (2006, April 4). *Rizospastis*, p. 10.

[98] Διώκεται ο 38χρονος για "μετάδοση του AIDS από αμέλεια". (2006, April 3). *Ta Nea*, p. 13.

[99] Δίωξη κατά του αιμοδότη που μόλυνε τη 16χρονη. (2006, April 3). *Eleftherotypia*, p. ?; Πολιτικές και ποινικές ευθύνες. (2006, April 4). *To Vima*, p. 9; ΠΑΣΟΚ: Πολιτικές ευθύνες για την αιμοδοσία. (2006, April 6). *I Avgi*, p. 10.

[100] Τέλος -για την ώρα- στην αντιπαράθεση Αβραμόπουλου-Κακλαμάνη. (2006, April 2). *I Avgi*, p. 10. (Vasilis Venizelos); Στο παρασκήνιο συνεχίζεται ο καυγάς Αβραμόπουλου-Κακλαμάνη. (2006, April 4). *To Vima*, p. 9.

[101] Ο φόβος του αίματος. (2006, April 2). To Vima, pp. A12-15/12-15; Οι αιμοληψίες, οι μεταγγίσεις, οι έλεγχοι και η ασφάλεια. (2006, April 2). *To Vima*, p. 1.

[102] Γιατί πετάμε πολύτιμο αίμα. (2006, April 2). *To Vima*, p. A12/12. (V. Nedos)

[103] Γιατί πετάμε πολύτιμο αίμα. (2006, April 2). *To Vima*, p. A12/12. (V. Nedos)

[104] Γιατί πετάμε πολύτιμο αίμα. (2006, April 2). *To Vima*, p. A12/12. (V. Nedos)

[105] Ανοργανωσιά που στοιχίζει ζωές. (2006, April 2). *Eleftherotypia*, p. ?. (Marina Petropoulou)

module were dedicated to 20 questions and answers regarding blood donation and transfusion. The journalist interviewed Maniati, professor of haematology and president of the Hellenic Blood Transfusion Society, regarding various aspects of transfusion medicine, because many readers had expressed relevant queries.[106] The technologies of blood screening were presented and the interviewee noted there was no technique with a "zero window"; NAT should therefore not be considered a panacea. She emphasized, once again, the importance of regular non-remunerated blood donors for achieving blood safety.[107]

The organization and the promotion of voluntary blood donation and the problems in the Greek blood transfusion services were also reported in other articles in connection with the implementation of NAT screening.[108] It was noted that confusion and unrest had decreased the number of blood donors since the news coverage of the case of the transfusion-transmitted infections, and blood sufficiency was endangered.[109] In some articles, data was also presented that showed that about 45% of the yearly needs in units of blood were provided by regular voluntary donors, a percentage that could be increased to advance blood safety.[110] A more specific comment appeared in *Rizospastis,* which connected the health policy of the Ministry of Health (for the implementation of NAT screening and the transport of blood to be handled by private companies) to the devaluation of voluntary blood donation.[111] The government was accused for "consciously marginalizing the organization of voluntary blood donation that would safeguard the sufficiency – and quality – of blood."[112]

A particular case regarding the intermediate use of NAT was covered by some newspapers. The director of the blood transfusion service of the General Hospital of Athens "Gennimatas", C. Politis (also the director of SKAE as mentioned above), accused the manager of

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[106] 20 ερωτήσεις-απαντήσεις, οι αιμοληψίες, οι μεταγγίσεις, οι έλεγχοι και η ασφάλεια. (2006, April 2). *To Vima*, p. A14/14-A15/15. (Ioanna Soufleri)

[107] 20 ερωτήσεις-απαντήσεις, οι αιμοληψίες, οι μεταγγίσεις, οι έλεγχοι και η ασφάλεια. (2006, April 2). *To Vima*, p. A14/14-A15/15. (Ioanna Soufleri)

[108] Παράθυρο θανάτου 11 ημερών. (2006, April 1). *Eleftherotypia*, p. ?. (Dani Vergou); 6 δισ. δρχ. τον χρόνο για έλεγχο με ΝΑΤ. (2006, April 4). *Eleftherotypia*, p. ?. (Sakis Apostolakis); Οι αιμοδότες "χάθηκαν" από τα νοσοκομεία. (2006, April 9). *To Vima*, p. A45/81. (Elena Fyntanidou); Περικοπές και στις εξαγγελίες!. (2006, April 19). *Rizospastis*, p. 18.

[109] Οι αιμοδότες "χάθηκαν" από τα νοσοκομεία. (2006, April 9). *To Vima*, p. A45/81. (Elena Fyntanidou)

[110] Παράθυρο θανάτου 11 ημερών. (2006, April 1). *Eleftherotypia*, p. ?. (Dani Vergou); Γιατί πετάμε πολύτιμο αίμα. (2006, April 2). *To Vima*, p. A12/12. (V. Nedos); Ανοργανωσιά που στοιχίζει ζωές. (2006, April 2). *Eleftherotypia*, p. ?. (Marina Petropoulou); Μειώνεται με την αύξηση της αιμοδοσίας. (2006, May 18). *Rizospastis*, p. 14.

[111] Περικοπές και στις εξαγγελίες!. (2006, April 19). *Rizospastis*, p. 18.

[112] Περικοπές και στις εξαγγελίες!. (2006, April 19). *Rizospastis*, p. 18.

the hospital of budget cuts that led to the interruption of NAT screening for more than a month.[113] According to the articles, there was a conflict among the aforementioned officials of the hospital that led to the publication of personal accusations from both sides (however the story did not appear again on the news). Another issue covered by some articles referred to an infection with hepatitis C of a new-born baby.[114] The infection was not attributed to the transfusions received by the baby but the news articles associated the story with the case of the HIV transfusion-transmitted infections.

At this point, I shall mention the news coverage of the implementation of the NAT screening method following the plans made by the Ministry of Health. According to several articles, the scheduling of the nationwide implementation of NAT screening in two months was questioned.[115] It was reported that the procedure would be concluded in four months, i.e. by August 2006, and during this period the blood centers would assume the necessary provisions (including infrastructural arrangements, equipment, personnel hiring and training). In addition, the blood centers would have to follow procedures for certification and accreditation.[116] In the middle of April 2006, Avramopoulos gave a press conference regarding the "upgrade of the hospitals", in which a new plan was presented for the implementation of NAT.[117] The creation of a National Network of Molecular Screening Blood Centers was foreseen, to comprise of 9 blood centers (instead of 14 pronounced in the end of March) and to be fully operational in October 2006.

At the same time, the safety of the transport of blood would be taken care of through new accreditation processes. The political party of KKE, as reported in *Rizospastis*, criticized the decisions made by the minister about the formation of less centers, the high costs, and the outsourcing of blood transport to private companies.[118] A particular issue was raised regarding

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[113] "58 ημέρες χωρίς μοριακό έλεγχο για το AIDS". (2006, April 3). *Ta Nea*, p. 13. (Roula Tsoulea); "Πόλεμος" για το μολυσμένο αίμα. (2006, April 4). *To Vima*, p. 9. (Elena Fyntanidou); Δίωξη στο δότη και μπαλάκι οι ευθύνες. (2006, April 4). *Rizospastis*, p. 10; Διαμάχη στο Γενικό Κρατικό Αθήνας για τον έλεγχο του αίματος. (2006, April 4). *I Avgi*, p. 8. (Vasilis Venizelos)

[114] Ψάχνουν πώς κόλλησε ηπατίτιδα C το βρέφος. (2006, April 7). *Eleftherotypia*, p. ?. (Sakis Apostolakis); Έρευνα για τη μόλυνση βρέφους από ηπατίτιδα C. (2006, April 7). *I Kathimerini*, p. 7. (Giota Myrtsioti); Άγνωστη η αιτία μόλυνσης βρέφους με ηπατίτιδα. (2006, April 7). *I Avgi*, p. 23. (Maroula Plika).

[115] Παράθυρο θανάτου 11 ημερών. (2006, April 1). *Eleftherotypia*, p. ?. (Dani Vergou); Μοριακοί έλεγχοι σε όλα τα Κέντρα. (2006, April 4). *Ethnos*, p. ?; Επιμηκύνεται η καθυστέρηση του μοριακού ελέγχου. (2006, April 5). *Rizospastis*, p. 12; Μοριακός πλέον ο έλεγχος αίματος. (2006, April 5). *I Kathimerini*, p. ?.

[116] Μοριακοί έλεγχοι σε όλα τα Κέντρα. (2006, April 4). *Ethnos*, p. ?; Επιμηκύνεται η καθυστέρηση του μοριακού ελέγχου. (2006, April 5). *Rizospastis*, p. 12; Μοριακός πλέον ο έλεγχος αίματος. (2006, April 5). *I Kathimerini*, p. ?.

[117] Χρονοδιάγραμμα για αναβάθμιση στα νοσοκομεία. (2006, April 19). *I Kathimerini*, p. ?. (Penny Mpouloutza)

[118] Περικοπές και στις εξαγγελίες!. (2006, April 19). *Rizospastis*, p. 18.

the siting of the nine blood centers, none of which would be located in the island of Lesvos.[119] According to *Rizospastis*, a deputy of KKE further questioned the actions taken by the ministry for the immediate implementation of NAT in connection to the full functionality of EKEA and the public character of the blood transfusion procedures.[120]

At the beginning of May 2006, the newspapers covered a story about a blood donor who was detected positive to HIV. According to the announcement made by the KEELPNO, the donor had donated blood on 17 February 2006, and the unit of blood had been transfused to two patients (one of them tested negative to HIV).[121] The remaining sample of the donated blood would be further tested by molecular screening for HIV. According to the articles, the molecular test on the blood sample was negative and the transfusions were "clear", as mentioned in a headline.[122] During the coverage of this story, NAT screening was presented as the test that would show whether the donated blood was infected. In an article published in *Eleftherotypia* about this case, the implementation of NAT was discussed, and it was mentioned that the minister had signed agreements with the two companies that provide NAT equipment (Roche and Chiron), so the screening centers would operate until the end of July.[123]

Over the following days, another possible transfusion-transmitted infection was reported in the news. According to the articles, the case was disclosed after the announcement made by KEELPNO.[124] A blood donor tested positive to HIV in a donation performed during March 2006. The authorities, SKAE, retested the sample of the previous donation (June 2005) of the same donor (a 62-year-old female) which also tested positive; however, at that time it was considered negative and had been released for transfusions. One patient had been transfused with that unit

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[119] Περικοπές και στις εξαγγελίες!. (2006, April 19). *Rizospastis*, p. 18; Ανάγκη για κέντρο ελέγχου αίματος στη Μυτιλήνη. (2006, April 29). *I Avgi*, p. 7. (Vasilis Venizelos)

[120] Σοβαρά ερωτηματικά από τον περιορισμό της εφαρμογής του. (2006, May 3). *Rizospastis*, p. 18; Κυβερνητική εμμονή στον περιορισμό. (2006, May 6). *Rizospastis*, p. 10.

[121] Συναγερμός μετά τον εντοπισμό αιμοδότη φορέα του ιού του AIDS. (2006, May 6). *To Vima*, p. 17; Θρίλερ στο «Ελπίς», με αίμα από φορέα του AIDS. (2006, May 06). *Eleftherotypia*, p. ?; Αιμοδότης βρέθηκε θετικός στον ιό του AIDS. (2006, May 5). *Ethnos*, p. ?; Υποψίες μόλυνσης σε μετάγγιση αίματος. (2006, May 6). *Rizospastis*, p. 21.

[122] Μολύνθηκε από AIDS αφού έδωσε αίμα για τη μητέρα του. (2006, May 8). *Ta Nea*, p. 13; Λήξη συναγερμού μετά τον μοριακό έλεγχο. (2006, May 9). *I Kathimerini*, p. ?; «Καθαρή» η μετάγγιση. (2006, May 08). *Eleftherotypia*, p. ?.

[123] «Καθαρή» η μετάγγιση. (2006, May 08). *Eleftherotypia*, p. ?.

[124] "Άνοιξαν παράθυρο" στο AIDS!. (2006, May 11). *Ta Nea*, p. 14. (Despoina Kouklaki); Ελέγχεται η πιθανότητα νέου κρούσματος AIDS. (2006, May 11). *To Vima*, p. 17; Διαπίστωση μόλυνσης σε παλιά μετάγγιση. (2006, May 11). *Rizospastis*, p. 21; Πιθανή μετάγγιση HIV σε 85χρονο ασθενή. (2006, May 11). *I Avgi*, p. 10; Φόβοι για νέο κρούσμα έιτζ μέσω αιμοδοσίας. (2006, May 11). *I Kathimerini*, p. 7; Μολυσμένο αίμα πήρε και 85χρονος. (2006, May 11). *Eleftherotypia*, p. ?; Αιμοδότρια με AIDS. (2006, May 11). *Ethnos*, p. ?. (Dimitris Karagiorgos)

of blood after an operation, and the authorities had not found him to test him (he was described as an 85-year-old male). What was considered notable in this case was the fact that the donated blood had been screened with the NAT method in 2005, but had been found to be HIV negative. The news articles further elaborated that the NAT method used in 2005 was the PCR testing in mini-pools of four samples. When the blood was retested by SKAE, NAT single-unit testing was performed and the HIV virus was detected. The case was attributed to the window period of a very recent infection.

Ta Nea reported that "due to cost saving, many blood samples are tested together and, as a result, in a cocktail of four samples, the deadly virus cannot be detected."[125] In other articles, A. Hatzakis, the director of KEELPNO, was quoted as saying the "the molecular testing of blood in single units is going to be implemented, which is the most modern and efficient method to screen the blood."[126] An article in *Rizospastis* commented that this case "confirms the main objective of transfusions: that even with the application of molecular screening (NAT) the risk of infection would become zero only if it is combined with an organized system of voluntary blood donation, that would provide sufficient blood and better terms for screening."[127] According to *Ethnos,* the consecutive cases of contaminated blood revealed, on the one hand, the imperfections on the blood screening system and, on the other hand, the "outbreak" of AIDS infections in Greece.[128]

Notably, this story was not followed up by the news. It was not covered on front pages, and information regarding the blood donor or public inquiries about the event were not reported. Apart from the reference to the announcement made by KEELPNO for the adoption of single-unit NAT testing, no politicians or officials were questioned about it. The news articles provided many details regarding molecular testing and, more specifically, about the differences between single-unit testing and mini-pool testing. In these articles, molecular testing was not contrasted with serology testing, but the journalists adopted the information in the announcement made by KEELPNO and presented single-unit testing as the "safest" method to screen blood, regardless of other parameters.

At the end of May 2006, the news covered the inauguration of the Center of Molecular Screening of Blood (as the nine blood transfusion centers were named in the articles at that time)

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[125] "Άνοιξαν παράθυρο" στο AIDS!. (2006, May 11). *Ta Nea*, p. 14. (Despoina Kouklaki)
[126] Ελέγχεται η πιθανότητα νέου κρούσματος AIDS. (2006, May 11). *To Vima*, p. 17; Αιμοδότρια με AIDS. (2006, May 11). *Ethnos*, p. ?. (Dimitris Karagiorgos)
[127] Διαπίστωση μόλυνσης σε παλιά μετάγγιση. (2006, May 11). *Rizospastis*, p. 21.
[128] Αιμοδότρια με AIDS. (2006, May 11). *Ethnos*, p. ?. (Dimitris Karagiorgos)

in AHEPA General Hospital in Thessaloniki by the Minister of Health, Avramopoulos, who confirmed that all the nine centers would operate until the end of July.[129] The same was asserted by the deputy minister in the Hellenic Parliament after a current question posed by a deputy of the political party of SYRIZA, as noted in an article in *I Avgi*.[130]

During the summer, the newspapers reported on a temporary blood shortage, an issue condemned by associations of people with thalassaemia.[131] The blood shortage was connected to problems in the operation of the blood transfusion services due to understaffing. It was reported that some services could not accept blood donors in the evening shift, and thus possible units of donated blood were not collected during the summer.[132] *Rizospastis* covered the subfunction of EKEA, as criticized also by its employees.[133] It was highlighted that the personnel needed for the full operation of EKEA had not been employed yet, and this could endanger the safety of the current employees and the safety of blood.[134] In addition, it was noted that the subfunction of the center did not allow the shipment of plasma to the Netherlands for further preparation of plasma derived products.[135]

The delay in the implementation of NAT was also pointed out in two articles, which noted that the deadline of July set by the minister for the full operation of the Centers of Molecular Screening of Blood had passed, and the promise had not been realized.[136] *I Avgi* characterized the public commitment of the minister as "overweening" and "inapplicable".[137] At the beginning of

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[129] Κουβαρντάς στη... δημαγωγία ο υπουργός Υγείας. (2006, May 26). *Rizospastis*, p. 14; Άρχισε ο μοριακός έλεγχος του αίματος στη Θεσσαλονίκη. (2006, May 26). *I Avgi*, p. 6; Έφυγε άρον άρον ο Αβραμόπουλος. (2006, May 26). *Eleftherotypia*, p. ?.

[130] Ελλιπής ο έλεγχος του μεταγγιζόμενου αίματος. (2006, May 31). *I Avgi*, p. 56.

[131] Έμειναν μόνον οι μπαταριές. (2006, July 20). *Rizospastis*, p. 5; Προβλήματα από την καλοκαιρινή έλλειψη αίματος. (2006, July 20). *I Avgi*, p. 8. (Vasilis Venizelos); Μεγάλες και εφέτος οι ελλείψεις σε αίμα. (2006, July 27). *To Vima*, p. 13. (Elena Fyntanidou); Επί Ισοις Οροις. (2006, August 14). *Eleftherotypia*, p. ?.

[132] Προβλήματα από την καλοκαιρινή έλλειψη αίματος. (2006, July 20). *I Avgi*, p. 8. (Vasilis Venizelos); Μεγάλες και εφέτος οι ελλείψεις σε αίμα. (2006, July 27). *To Vima*, p. 13. (Elena Fyntanidou); Αδικαιολόγητη καθυστέρηση στην εφαρμογή. (2006, August 9). *Rizospastis*, p. 15; «Ρώσικη ρουλέτα» οι μεταγγίσεις. (2006, September 13). *Rizospastis*, p. 25; Καθυστερεί ο μοριακός έλεγχος στις μονάδες αιμοδοσίας. (2006, September 13). *I Kathimerini*, p. ?. (Penny Mpouloutza); Καθυστερεί η εφαρμογή μοριακού ελέγχου στις μονάδες αιμοδοσίας. (2006, September 13). *Ethnos*, p. ?.

[133] Σταθερά σε υπολειτουργία. (2006, June 21). *Rizospastis*, p. 20; Μειώνεται δραματικά το προσωπικό. (2006, July 13). *Rizospastis*, p. 12.

[134] Μειώνεται δραματικά το προσωπικό. (2006, July 13). *Rizospastis*, p. 12.

[135] Μειώνεται δραματικά το προσωπικό. (2006, July 13). *Rizospastis*, p. 12; Μεγάλες και εφέτος οι ελλείψεις σε αίμα. (2006, July 27). *To Vima*, p. 13. (Elena Fyntanidou).

[136] Αγωνία για τον έλεγχο αίματος. (2006, July 31). *Eleftherotypia*, p. ?. (Sofia Neta); Καθυστερεί ακόμη ο μοριακός έλεγχος του αίματος. (2006, August 9). *I Avgi*, p. 10. (Vasilis Venizelos).

[137] Καθυστερεί ακόμη ο μοριακός έλεγχος του αίματος. (2006, August 9). *I Avgi*, p. 10. (Vasilis Venizelos).

September 2006, representatives of associations of people with thalassaemia gave a press conference focusing on the delay in the implementation of NAT screening method after the promises made by the Minister of Health in the aftermath of the case of the transfusion-transmitted infections in the end of March. According to the representative of EOTHA, about 30–40% of the donated blood was being screened nationwide with NAT.[138] He was quoted as saying that every time people with thalassaemia were transfused, they "played Russian roulette with their life."[139] The representative of the federation requested from the ministry a full briefing regarding the programming and the realization of the implementation of NAT screening. In addition, they demanded the advancement of the blood transfusion centers and their proper staffing.

The procurement procedure for the commission of the molecular testing received a lot of publicity from August 2006 until its conclusion in August 2008. On 8 October 2006, *Eleftherotypia* (Sunday edition) published an investigative regarding the embroilments in the implementation of NAT screening.[140] It was noted that the foreseen budget for molecular screening would reach 208 million euros, and it would be the largest amount ever invested in consumables by the Ministry of Health. The process for the implementation of NAT screening was proceeding through memoranda of cooperation signed among the ministry and the two companies that could provide it, Chiron and Roche.[141] However, according to the article, one of the two companies (Roche Hellas) had had a judicial conflict with its distributor in Greece and the memorandum was canceled. The General Secretary of the Ministry of Health, A. Kalogeropoulos, was quoted having said that the memoranda were canceled because the pricing was not reasonable. According to Kalogeropoulos, the procurement process of NAT would involve negotiations instead of an open

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138 «Ρώσικη ρουλέτα» οι μεταγγίσεις. (2006, September 13). *Rizospastis*, p. 25; Καθυστερεί επικίνδυνα ο μοριακός έλεγχος του αίματος. (2006, September 13). *I Avgi*, p. 16. (Vasilis Venizelos); Καθυστερεί ο μοριακός έλεγχος στις μονάδες αιμοδοσίας. (2006, September 13). *I Kathimerini*, p. ?. (Penny Mpouloutza); «Χάθηκε» ο μοριακός έλεγχος. (2006, September 13). *Eleftherotypia*, p. ?; Καθυστερεί η εφαρμογή μοριακού ελέγχου στις μονάδες αιμοδοσίας. (2006, September 13). *Ethnos*, p. ?.

139 «Ρώσικη ρουλέτα» οι μεταγγίσεις. (2006, September 13). *Rizospastis*, p. 25; Καθυστερεί επικίνδυνα ο μοριακός έλεγχος του αίματος. (2006, September 13). *I Avgi*, p. 16. (Vasilis Venizelos); Καθυστερεί ο μοριακός έλεγχος στις μονάδες αιμοδοσίας. (2006, September 13). *I Kathimerini*, p. ?. (Penny Mpouloutza); Καθυστερεί η εφαρμογή μοριακού ελέγχου στις μονάδες αιμοδοσίας. (2006, September 13). *Ethnos*, p. ?. The Panhellenic Federation of Associations of Mediterranean Anaemia, founded in 1991, was renamed to Greek Federation of Thalassaemia, EOTHA (Ελληνική Ομοσπονδία Θαλασσαιμίας). It brings together local associations and represents 5,000 patients and their families.

140 Εμπλοκή με τον μοριακό έλεγχο στο αίμα. (2006, October 8). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou)

141 Αγωνία για τον έλεγχο αίματος. (2006, July 31). *Eleftherotypia*, p. ?. (Sofia Neta); Εμπλοκή με τον μοριακό έλεγχο στο αίμα. (2006, October 8). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou)

tender that would be time-consuming. A cross-party parliamentary committee would determine the final agreement, following the recommendations set by a scientific committee of the National Committee on Blood Transfusion. The cross-party parliamentary committee would be asked to safeguard the transparency of the procurement.[142]

The same article focused on the two companies (Chiron and Roche) that could supply the NAT screening method. As noted earlier, the officials had expressed their preference toward single-unit testing instead of mini-pool testing, which, according to the journalist, had "proved to be unreliable".[143] The representative of Chiron stated that Roche could not supply equipment for single-unit testing and it was in the interest of Roche to delay the procurement to produce it. The representative of Roche stated that the company's test was accredited both for mini-pool testing and single-unit testing. Additionally, the article was accompanied by two pictures, one depicting reagents for blood screening by Chiron company and the other showing a brochure from Roche. In this article I encountered explicit references related to financial interests in the commission of the molecular diagnostics.

A few days later, the newspapers reported a new incident of possible transfusion-transmitted infection, according to the announcement of SKAE and the ministry.[144] The articles reported that a 39-year-old blood donor was found to be HIV seropositive after a blood donation on 29 September 2006. The previous donation from the same donor (on 29 March 2006) was found seronegative after Elisa screening; a blood sample from this donation was retrospectively tested with NAT screening and was found positive to HIV. The whole blood from that donation had been transfused to a 63-year-old lady, who died a few days later (April 2006). According to the announcement of SKAE, the death of the transfused patient was not attributed to the possible HIV infection.[145] The incident did not attract extensive coverage in the newspapers. *Ethnos*

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[142] Εμπλοκή με τον μοριακό έλεγχο στο αίμα. (2006, October 8). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou).

[143] Εμπλοκή με τον μοριακό έλεγχο στο αίμα. (2006, October 8). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou). This point referred to the case of transfusion-transmitted infection published in the newspapers during May 2006, in which the HIV virus was not detected by PCR mini-pool testing.

[144] Μολυσμένο αίμα με τον ιό του AIDS μεταγγίστηκε σε 63χρονη. (2006, October 10). *Ta Nea*, p. 16; Και τρίτο κρούσμα με μολυσμένο αίμα. (2006, October 10). *To Vima*, p. A14. (Elena Fyntanidou); Νέα μόλυνση σε μετάγγιση αίματος. (2006, October 10). *Rizospastis*, p. 27; Κι άλλο κρούσμα μετάγγισης μολυσμένου αίματος!. (2006, October 10). *I Avgi*, p. 10. (Vasilis Venizelos); Μετάγγιση αίματος μολυσμένου από έιτζ. (2006, October 10). *I Kathimerini*, p. ?; Αίμα: Έλεγχος μηδέν. (2006, October 10). *Eleftherotypia*, p. ?; Διάτρητο το σύστημα των μεταγγίσεων. (2006, October 10). *Ethnos*, p. ?. (Dimitris Karagiorgos)

[145] Μολυσμένο αίμα με τον ιό του AIDS μεταγγίστηκε σε 63χρονη. (2006, October 10). *Ta Nea*, p. 16; Και τρίτο κρούσμα με μολυσμένο αίμα. (2006, October 10). *To Vima*, p. A14. (Elena Fyntanidou); Νέα μόλυνση σε μετάγγιση αίματος. (2006, October 10). *Rizospastis*, p. 27; Κι άλλο κρούσμα μετάγγισης μολυσμένου αίματος!. (2006, October 10). *I Avgi*, p. 10. (Vasilis Venizelos); Μετάγγιση αίματος μολυσμένου από έιτζ. (2006, October 10). *I Kathimerini*,

published an elaborate article in which the table presenting the differences between serologic testing and NAT testing was reprinted (see Image 6.3).[146] Again, Elisa screening was characterized as "traditional", "simple" and "conventional".[147] The case was not followed up in the news, apart from an article in *To Vima*, which interviewed the family of the transfused patient who had died.[148]

The story was associated with the delays in the nationwide implementation of NAT screening. Some articles quoted the director of the SKAE, Politis, to have stated that "as the nationwide molecular testing lingers so the incidents will augment."[149] According to the representative of EOTHA the delays were associated with technical barriers to the installation of the NAT equipment and the financial interests of the two companies distributing NAT screening technology.[150] The newspaper *Eleftherotypia* further reported that the memoranda of cooperation among the ministry and the two companies were canceled and only one Center of Molecular Screening of Blood was formed.[151] *Ethnos* ran an article in which the three cases of HIV transfusion-transmitted infections, which occurred during 2006, were characterized by scientists as "very rare" and were associated with the rise of HIV infections in Greece.[152] In *Rizospastis,* the cases were related to the lack of organized voluntary blood donation.[153]

On 11 October 2006, *To Vima* had a front-page headline entitled "The war of the companies for the molecular screening of blood."[154] It was accompanied by a front-page editorial political commentary in which one could read that "Six months after [the March 2006 case], a new case of infection with the virus of AIDS revealed that the modern and safer blood tests continue to divide the ones responsible and, at the same time, provide an opportunity to the pharmaceutical companies for predatory bargaining."[155] In the main article, the situation was

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p. ?; Αίμα: Έλεγχος μηδέν. (2006, October 10). *Eleftherotypia*, p. ?; Διάτρητο το σύστημα των μεταγγίσεων. (2006, October 10). *Ethnos*, p. ?. (Dimitris Karagiorgos)

[146] Διάτρητο το σύστημα των μεταγγίσεων. (2006, October 10). *Ethnos*, p. ?. (Dimitris Karagiorgos)

[147] Μολυσμένο αίμα με τον ιό του AIDS μεταγγίστηκε σε 63χρονη. (2006, October 10). *Ta Nea*, p. 16; Μετάγγιση αίματος μολυσμένου από έιτζ. (2006, October 10). *I Kathimerini*, p. ?.

[148] Θλιβερές ιστορίες αιμοδοσίας ζητούν απαντήσεις. (2006, October 19). To Vima, p. A14. (Ioanna Soufleri)

[149] Μολυσμένο αίμα με τον ιό του AIDS μεταγγίστηκε σε 63χρονη. (2006, October 10). *Ta Nea*, p. 16; Διάτρητο το σύστημα των μεταγγίσεων. (2006, October 10). *Ethnos*, p. ?. (Dimitris Karagiorgos)

[150] Διάτρητο το σύστημα των μεταγγίσεων. (2006, October 10). *Ethnos*, p. ?. (Dimitris Karagiorgos)

[151] Αίμα: Έλεγχος μηδέν. (2006, October 10). *Eleftherotypia*, p. ?.

[152] Αιτία και η αύξηση των κρουσμάτων AIDS. (2006, October 10). *Ethnos*, p. ?.

[153] Νέα μόλυνση σε μετάγγιση αίματος. (2006, October 10). *Rizospastis*, p. 27; Υποκρισία και στρουθοκαμηλισμός. (2006, October 12). *Rizospastis*, p. 5.

[154] Ο πόλεμος των εταιρειών για τον μοριακό έλεγχο του αίματος. (2006, October 11). *To Vima*, p. 1.

[155] Η αρπαγή. (2006, October 11). *To Vima*, p. 1.

described as a "drama" in the field of blood transfusion.[156] The main actors of this drama were the multi-transfused patients who repeatedly requested safe blood; the ministry that had reacted erratically; the two companies feuding over the "huge pie" of blood transfusion investments; and the cross-party parliamentary committee that had to decide on the procurement. According to the journalist, the memoranda of cooperation had established the price of EUR 50 per unit of blood for five years, a price five times higher than the one paid for NAT screening in Poland. The distributor of Chiron was questioned about this, and responded that the price mentioned included transport and quality control apart from testing. However, the memoranda were no longer effective. The nationwide implementation of NAT was still pending and the procedure, as mentioned above, involved the specifications set by a scientific committee and the evaluation to be made by the cross-party parliamentary committee.[157]

Over the following period, the newspapers covered the political debate regarding the commission of NAT screening technology, which was framed as a "scandal" but for different reasons. Minister of Health D. Avramopoulos stated that "the Greek citizens should feel secure with the implementation of the molecular screening system" since the last case occurred before his proclamation for nationwide implementation in the end of March 2006.[158] At the same time, the major opposition party PASOK, according to the newspaper articles, referred to unacceptable delay on the implementation and blamed the ministry.[159] In addition, deputies of PASOK asked for an invitation to tender instead of a direct award for the procurement of NAT. According to the news articles, one company appealed to the Hellenic Competition Commission claiming that the specifications set for the molecular screening were promoting the acquisition of the equipment only from one company (its competitor).[160] The articles condemned the fact that the

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156 Υπόγειος πόλεμος εταιρειών για την "πίτα του αίματος". (2006, October 11). *To Vima*, p. A6. (Ioanna Soufleri)

157 Υπόγειος πόλεμος εταιρειών για την "πίτα του αίματος". (2006, October 11). *To Vima*, p. A6. (Ioanna Soufleri)

158 Καθυστερεί η εφαρμογή της μοριακής μεθόδου. (2006, October 11). *To Vima*, p. A6; Υποκρισία και στρουθοκαμηλισμός. (2006, October 12). *Rizospastis*, p. 5; Μεταγγίσεις υψηλού κινδύνου. (2006, October 15). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou)

159 Καθυστερεί η εφαρμογή της μοριακής μεθόδου. (2006, October 11). *To Vima*, p. A6; Υποκρισία και στρουθοκαμηλισμός. (2006, October 12). *Rizospastis*, p. 5.

160 Ξέσπασε πόλεμος για τον μοριακό έλεγχο του αίματος. (2006, October 19). *Ta Nea*, p. 12. (Despoina Kouklaki); «Κόλλησαν» τα 9 κέντρα για τον έλεγχο του AIDS. (2006, October 21). *Ethnos*, p. ?. (Giannis Kritikos). In these articles the companies were not named, but it was known that Roche made the appeal so that the NAT system it could provide would not be excluded from the single-unit testing specifications set. Another article the following month specifically referred to Roche's announcement regarding possible exclusion of the company's NAT system from the tender, see Εταιρεία καταγγέλλει εκβιασμούς για τον έλεγχο του αίματος. (2006, November 22). *I Avgi*, p. 9. (Vasilis Venizelos).

implementation of NAT was not completed on time, i.e. by the end of July, in accordance with the proclamation of the minister.[161]

The issue was further complicated when the sector of health of the political party of the opposition Synaspismos (member of the SYRIZA coalition) denounced the decision of the ministry to sign memoranda of cooperation with the two companies at a fixed price for five years as illegal, and asked for an invitation to tender.[162] Following the announcement of Synaspismos, the Ministry of Health replied with another announcement in which it was stated that the memoranda were no longer effective. In addition, the minister questioned the personal opinion of the representative of Synaspismos in the cross-party parliamentary committee that had led the political party to false and inaccurate statements about the procedure of the commission of NAT screening.[163] The sector of health of Synaspismos further replied by asking official information regarding the cost of NAT screening and an open tender in the immediate future instead of a direct award at high pricing.[164] For Synaspismos, the procedure of negotiation and the signing of memoranda were unacceptable, considering they had resulted in so great cost and were sustained by the supposedly absolute and immediate need.[165] The Greek Federation of Thalassaemia complained about the decision of Synaspismos to ask for an invitation to tender, because it would further delay the implementation of NAT for more than six months; they reiterated that SYRIZA deputies had condemned the delays over the past months.[166] The federation had repeatedly asked for the immediate nationwide use of NAT. The sector of health of Synaspismos replied that the lack of political will had hindered the implementation of NAT and their actions targeted the citizens' benefit by controlling the political power and the allocation of public funds.[167]

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[161] Καθυστερεί η εφαρμογή της μοριακής μεθόδου. (2006, October 11). *To Vima*, p. A6; Ξέσπασε πόλεμος για τον μοριακό έλεγχο του αίματος. (2006, October 19). *Ta Nea*, p. 12. (Despoina Kouklaki); «Κόλλησαν» τα 9 κέντρα για τον έλεγχο του AIDS. (2006, October 21). *Ethnos*, p. ?. (Giannis Kritikos).

[162] ΣΥΝ κατά Αβραμόπουλου. (2006, October 25). *Ta Nea*, p. 16; Παράνομη υπογραφή για το αίμα. (2006, October 25). *I Avgi*, p. 17; Αναδίπλωση με επίθεση κατά του ΣΥΝ από τον Δ. Αβραμόπουλο για το αίμα. (2006, October 25). *I Avgi*, p. 17; Αλλού βρίσκεται η ουσία. (2006, October 25). *Rizospastis*, p. 12.

[163] ΣΥΝ κατά Αβραμόπουλου. (2006, October 25). *Ta Nea*, p. 16; Αναδίπλωση με επίθεση κατά του ΣΥΝ από τον Δ. Αβραμόπουλο για το αίμα. (2006, October 25). *I Avgi*, p. 17.

[164] Τέσσερα ερωτήματα στον Δ. Αβραμόπουλο για το αίμα. (2006, October 26). *I Avgi*, p. 14.

[165] Τέσσερα ερωτήματα στον Δ. Αβραμόπουλο για το αίμα. (2006, October 26). *I Avgi*, p. 14.

[166] Η Ομοσπονδία θαλασσαιμικών καλύπτει τον υπουργό Υγείας για το αίμα. (2006, October 27). *I Avgi*, p. 7.

[167] Η Ομοσπονδία θαλασσαιμικών καλύπτει τον υπουργό Υγείας για το αίμα. (2006, October 27). *I Avgi*, p. 7. The following period (February 2007) the president of Synaspismos, A. Alavanos, met with representatives of thalassaemic organizations to inform them about the procedure for the nationwide implementation of NAT and

According to the news articles, the cross-party parliamentary committee decided to proceed through an invitation to tender for the procurement of the NAT.[168] I have located the tender notice published in the relevant section in *to Vima* on 17 November 2006.[169] The technical specifications for the procurement, as proposed by the advisory scientific committee of the EKEA, were accepted by the cross-party parliamentary committee (with the reservations of the representatives of KKE and SYRIZA).[170] The positions of the political party KKE were elaborated in articles in the newspaper *Rizospastis*. As mentioned before, EKEA was favoring the implementation of single-unit NAT testing instead of mini-pool testing. According to an article in *Rizospastis*: "both screening methods are correct and are used simultaneously in countries implementing molecular screening of blood. On the choice and the range of the application of one or the other method it is of great importance the opinion of the scientists. But the issue of the alternative coverage – meaning by both methods – is a political issue and for that only the Minister of Health can decide. Not implementing both methods, at least in EKEA, would be inconceivable."[171] Moreover, it was noted that the implementation only of single-unit testing, apart from the fact that it was more expensive, would not permit alternative solutions in case of paucity or other problems with the distributor.[172] Especially for EKEA, the representative of KKE pointed out that it would subvert its function since it was already using mini-pool testing.[173]

The newspapers followed up the story about the implementation of NAT. According to an article in *I Avgi,* the company Roche had sent a letter to the Minister of Health, condemning the fact that the open tender was excluding the company's NAT equipment.[174] Avramopoulos gave a press conference on 27 November 2006 regarding the national AIDS strategy (the 1st of December is the World AIDS Day). When questioned about the implementation of molecular diagnostics in Greece, Avramopoulos responded that the tender notice was published and the deadline was on

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to discuss relevant issues, Συνάντηση Αλαβάνου με πάσχοντες από μεσογειακή αναιμία. (2007, February 9). *I Avgi*, p. 9.

[168] Προωθείται η εξάρτηση από μια μόνο επιστημονική μέθοδο. (2006, October 31). *Rizospastis*, p. 12; Μοριακός έλεγχος σε μεταγγίσεις αίματος. (2006, October 31). *I Kathimerini*, p. ?; Διεθνή διαγωνισμό για το αίμα απεδέχθη τελικά ο Δ. Αβραμόπουλος. (2006, October 31). *I Avgi*, p. 13. (Vasilis Venizelos)

[169] Ανακοίνωση Ανοικτού Διαγωνισμού. (2006, November 17). *To Vima*, p. B10.

[170] Θα ήταν αδιανόητη. (2006, October 24). *Rizospastis*, p. 5; Αλλού βρίσκεται η ουσία. (2006, October 25). *Rizospastis*, p. 12; Προωθείται η εξάρτηση από μια μόνο επιστημονική μέθοδο. (2006, October 31). *Rizospastis*, p. 12.

[171] Θα ήταν αδιανόητη. (2006, October 24). *Rizospastis*, p. 5.

[172] Προωθείται η εξάρτηση από μια μόνο επιστημονική μέθοδο. (2006, October 31). *Rizospastis*, p. 12.

[173] Προωθείται η εξάρτηση από μια μόνο επιστημονική μέθοδο. (2006, October 31). *Rizospastis*, p. 12.

[174] Εταιρεία καταγγέλλει εκβιασμούς για τον έλεγχο του αίματος. (2006, November 22). *I Avgi*, p. 9. (Vasilis Venizelos).

9 January 2007.[175] He also emphasized that the procedure chosen would safeguard transparency and exclude private interests. According to the articles, at that point about 40–45% of the annually donated blood was screened with NAT.[176] The articles were alarming regarding the delay in the use of NAT and the non-compliance to the previous timetables.[177] It is also worth noting that some articles during this period presented data according to which every year six people would be infected with HIV after a transfusion without NAT screening of the donated blood.[178] In an article published in *Ta Nea,* this was attributed to the fact that "in 400,000 units of blood, the classical screening method is applied, which leaves room for error."[179]

Rizospastis further covered the procurement process and the meetings of the cross-party parliamentary committee. According to the coverage, both companies had filed appeals regarding the invitation to tender (for different reasons).[180] It was decided that the deadline would be prolonged until 25 January 2007.

6.1.3. Summing up the findings for 2006

During 2006, the newspapers reported extensively on issues regarding the technologies used in blood screening (I gathered 194 relevant articles). This coverage focused on specific events. The central event was the case of transfusion-transmitted infections that was published in the end of March 2006. This event was framed as a "scandal", a "crime" and a "tragedy". The causes of the event were located in different spaces. The prevailing discourse in the newspapers identified the lack of the use of NAT screening technology as the cause of this case. This was manifested with the use of metaphors regarding the window period (which supposedly would be

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175 Επικίνδυνη καθυστέρηση στον μοριακό έλεγχο του αίματος. (2006, November 28). *Ta Nea*, p. 47; Η δράση στις εθελοντικές οργανώσεις!. (2006, November 28). *Rizospastis*, p. 27; Επιτροπή Σοφών κατά του έιτζ. (2006, November 28). *I Kathimerini*, p. ?. (Penny Mpouloutza); Ούτε στο μισό οι έλεγχοι. (2006, November 28). *Ethnos*, p. ?. (Dimitris Karagiorgos); Χωρίς ασπίδα πρόληψης. (2006, December 1). *Rizospastis*, p. 20.

176 Επικίνδυνη καθυστέρηση στον μοριακό έλεγχο του αίματος. (2006, November 28). *Ta Nea*, p. 47; Η δράση στις εθελοντικές οργανώσεις!. (2006, November 28). *Rizospastis*, p. 27; Ούτε στο μισό οι έλεγχοι. (2006, November 28). *Ethnos*, p. ?. (Dimitris Karagiorgos).

177 Επικίνδυνη καθυστέρηση στον μοριακό έλεγχο του αίματος. (2006, November 28). *Ta Nea*, p. 47; Ούτε στο μισό οι έλεγχοι. (2006, November 28). *Ethnos*, p. ?. (Dimitris Karagiorgos).

178 Μεταγγίσεις υψηλού κινδύνου. (2006, October 15). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou); Ξέσπασε πόλεμος για τον μοριακό έλεγχο του αίματος. (2006, October 19). *Ta Nea*, p. 12. (Despoina Kouklaki); Επικίνδυνη καθυστέρηση στον μοριακό έλεγχο του αίματος. (2006, November 28). *Ta Nea*, p. 47.

179 Ξέσπασε πόλεμος για τον μοριακό έλεγχο του αίματος. (2006, October 19). *Ta Nea*, p. 12. (Despoina Kouklaki)

180 Χωρίς ετοιμότητα. (2006, December 28). *Rizospastis*, p. 5; Η καραμπόλα... (2007, January 3). *Rizospastis*, p. 4; ...και το «σβάρνισμα». (2007, January 3). *Rizospastis*, p. 4.

eliminated with the use of NAT) such as “window of irresponsibility”, “window to AIDS”, “death window”, “silent window” and “dark window”.

Not using the technology thus evoked policy developments regarding its mandatory adoption, by proclaiming its universal use in the immediate future. The policy initiatives somehow obscured the discussion regarding political blame. On 30 March 2006, *Eleftheros Typos*, a newspaper with views friendly to the governing party of Nea Demokratia, shifted the framing of the story by supporting the minister’s policy option for the immediate use of NAT by using the catchy headline “everything under (molecular) control”. Regarding the causality, has been noted that after the first days of the reporting, a possible causal link to the physicians’ actions and the practice of transfusion medicine did not persist in news stories.

At the same time, some news stories encompassed alternative causal links. For example, mainly in tabloid newspaper *Espresso* and in *Eleftheros Typos,* the coverage located the source of the risk and the causality of the event to a “foreign prostitute with HIV”, meaning it was portrayed as originating elsewhere and crossing the national borders through immigration (Hughes et al., 2006, p. 257). The story-telling in the tabloid newspaper had a sensationalist character and concentrated on “foreign dangers”.

During the coverage of the case of transfusion-transmitted infections, the newspapers relied heavily on the official sources (the information conveyed through the press conferences and press releases). Scientists, professionals in blood banks, physicians, patient groups and blood donors’ associations also expressed their opinions. In addition, personal accounts of those involved in the events were part of the media coverage. The story-telling focused on the “victims”; I presented in detail the coverage about this theme. The news stories also often reported on the judicial cases.

From the analysis of the articles, it becomes obvious that the newspapers provided extensive accounts regarding the technologies used in blood screening. At the end of March, when the case was reported, NAT was presented as superior to the previously used techniques, regardless of the prerequisites of its implementation. The new technology was considered more advanced in the context of the ideology of the superiority of the biotechnologies and biomedical technologies in general. NAT screening was presented as an advanced technology of molecular biology. In these accounts the two screening technologies were presented in such a way that a polarizing effect was created: serologic testing was presented as more “risky” and the cause of “medical error” whereas NAT was considered to be the technology that would have averted the

case since it was “safer”. Many of the articles even presented the possibility of “zero risk” in transfusion medicine after the use of the molecular screening of blood.

The news stories described the way blood screening was performed by the two methods, serologic and molecular. On the one hand, molecular screening technology was described “modern”, “advanced”, “sophisticated” and “detailed”. On the other hand, ELISA was characterized as “inefficient” and having an “endogenous disadvantage”. Although some articles referred to the fact that the two methods are complementary and the additional cost of using NAT was high, these issues were not associated with the descriptions of the technologies. Thus, a “technical solution” was the key to remedy the problem.

Two other specific cases were reported in the media during 2006. In the (much more limited) newspaper coverage of the case in May 2006, the main theme presented was regarding the preference between the two methods of NAT screening implemented in various countries. The “technical issue” prevailed on the news accounts and the official opinion (through a press release) was privileged. In these accounts, single-unit NAT screening was presented as “safer” compared with mini-pool testing. However, alternative causal explanations were also presented since *Ethnos* connected the case to the rise of new HIV infections in Greece, and *Rizospastis* associated the event with the devaluation of voluntary blood donation. When another case of HIV transfusion-associated infection was published during October 2006, the relevant coverage was limited.

The policy initiatives were, as noted above, a main theme addressed in the news accounts. When the Minister of Health announced the quick nationwide implementation of NAT, his political decision was welcomed. It should be noted that all the political parties of the opposition supported and claimed the immediate use of NAT. At the same time, representatives of the parties of the opposition criticized the governmental actions for not being pro-active. The newspaper accounts, in late March, presented the plan of the ministry to extend NAT testing to all the blood transfusion centers in two months. In the beginning of April, the news reported on the planning of the ministry to do so in four months.

Since May 2006, the focus of the newspapers coverage about NAT implementation in Greece shifted to the political debate regarding the preferred type of the procurement process for the screening technology and the timetable. The news stories often criticized the process for delays. From that period, the bureaucratic procedures and the possibility of vested interests to be involved came to the forefront (for more on this issue, see subsection 6.2.1). Especially from

October 2006, the processes were framed as a scandal of economic/political type. The story-telling in *To Vima*, reporting on this process as a drama, is indicative.

During the policy discussions, *Rizospastis* explicitly addressed the political decisions regarding the adoption of new medical technologies. In an article published on 24 October 2006, the journalist, in referring to the positions the political party KKE, stated that regardless of the scientific advice the ministry should proceed with the implementation of both types of NAT screening as this was purely a political question, connected to a future dependence in one distributor of a technology.

Throughout this period, the newspaper accounts discussed more themes of blood safety in the context of transfusion safety. For example, several articles emphasized the need to advance blood donation with a comprehensive plan for attraction and retention of volunteer donors. The contribution of volunteer donorship to a safer blood supply was directly associated in stories about the cases of transfusion-transmitted infections. Hence, the association was not compelling in terms of policy development as it was with the use of NAT screening. The theme of blood donation is a familiar one in journalistic coverage and was encountered in all the years of this research,

In addition, the newspapers, specifically *To Vima* and *Rizospastis,* frequently published stories regarding the knotty organizational aspects of the blood transfusion service in Greece. *Rizospastis* consistently reported on the problems facing the operation of the services and EKEA, from employee concerns to overall health care policy. Again, although the need for reorganizing the blood transfusion service was noted, policy initiatives were not explored. I find this interesting, because a process for the reorganization of the service had begun at the end of 2005. In particular, at the end of March 2006, the former Minister, N. Kaklamanis, defended his work at the ministry by stating that the modernization of the system was time-consuming. According to him, the difficulties in the use of NAT were associated with the cost, the necessary infrastructure and the training of personnel. More news stories mentioned the demanding prerequisites for the use of NAT, and only one story referred to the lack of technical knowledge. In this case, the prevailing framing obscured parts of the process of implementing NAT, regarding the cost, the preferred allocation of resources and the complex process of the adoption of a new medical technology.

6.2. Discussing the implementation and use of molecular screening between 2007–2010: "the largest project in the history of the Ministry of Health"[181]

6.2.1. The procurement process (2007–2008)

In March 2007, a year after the publicizing of the case of HIV transfusion-transmitted infections in Thessaloniki, *Ethnos* reported on NAT screening performed at the AHEPA hospital (where a Center of Molecular Screening of Blood inaugurated in June 2006).[182] According to this article, during a daily conference about blood safety at which the Minister of Health was present, it was announced that "the molecular screening of blood, implemented since last summer, prevented the infection with hepatitis B and C of at least 12 people, in central and western Macedonia."[183] An article in *Rizospastis* reported that a year had gone by since the announcement made by the ministry regarding the nationwide use of NAT (planned by the end of July 2006).[184] The article mentioned that, at that point, only the 45% of the donated blood was being screened with molecular diagnostics while the tender process had not yet been concluded. In addition, articles pointed out that the EKEA continued to subfunction, while there had recently been blood shortages in certain hospitals.[185]

At the beginning of May 2007, the newspapers covered a press conference regarding the Hellenic Conference "Thalassaemia 2007". According to the articles, both the representative of EOTHA and Politis referred to the time-consuming processes for the implementation of NAT in Greece, which had resulted in screening of only 50% of the donated blood.[186] Stoumpiadis, president of EOTHA, also stressed the lack of personnel and infrastructure in blood transfusion services.[187] In the following period, the newspapers reported "delays" in the procurement process

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[181] This phrase is part of the announcement made by the ministry of health regarding the introduction of NAT, Ακόμα δεν τον είδανε... (2008, August 27). *Rizospastis*, p. 4.

[182] Σωτήριος ο μοριακός έλεγχος στο αίμα. (2007, March 19). *Ethnos*, p. ?. (Vasilis Ignatiades)

[183] Σωτήριος ο μοριακός έλεγχος στο αίμα. (2007, March 19). *Ethnos*, p. ?. (Vasilis Ignatiades)

[184] «Σάρκα και οστά»... (2007, March 23). *Rizospastis*, p. 5.

[185] Έλλειψη αίματος σε μεγάλα νοσοκομεία. (2007, February 15). *I Avgi*, p. 17; «Σάρκα και οστά»... (2007, March 23). *Rizospastis*, p. 5.

[186] Μόνο μία στις δύο φιάλες ελέγχεται μοριακά. (2007, May 4). *To Vima*, p. A15; Παραμένουν οι επικίνδυνες ελλείψεις. (2007, May 4). *Rizospastis*, p. 19; Ο μοριακός έλεγχος στο αίμα μεταγγίσεων. (2007, May 4). *I Kathimerini*, p. ?; Αίμα «δύο ταχυτήτων». (2007, May 4). *Eleftherotypia*, p. ?. (Sofia Neta)

[187] Μόνο μία στις δύο φιάλες ελέγχεται μοριακά. (2007, May 4). *To Vima*, p. A15; Ο μοριακός έλεγχος στο αίμα μεταγγίσεων. (2007, May 4). *I Kathimerini*, p. ?.

for the nationwide implementation of NAT until the autumn of 2007, when snap elections were held in Greece.[188]

In the meantime, until the decision for the central commission of NAT though the procurement process described, the blood transfusion centers could pursue direct commission of NAT equipment. However, this process was not straightforward; on the contrary, it was rather complicated. According to a news article in *Eleftherotypia* (Sunday edition), molecular testing was discontinued in a hospital of Athens; however the officials promised that it would be performed again.[189] In two articles in *Rizospastis,* specific issues were raised regarding privatization practices in the public sector of health. More specifically, one article mentioned that certain services would be privatized, including the transport of blood and blood products.[190] The other article referred explicitly to the open tender for the implementation of molecular screening. According to that, the planning approved by the ministry led to "the molecular screening of blood, after the collection of the sample and up to the testing result, to be confined to private companies, even at a high pricing paid by the Greek people, instead of being performed in the corresponding services of the Greek hospitals."[191]

On 15 November 2007, the issue of blood safety in transfusion medicine was again in the spotlight and featured on the front page of *To Vima* under the title "Danger. Problem with the blood: without complete screening 4 out of 10 units. Two new hepatitis infections due to transfusion."[192] The front-page editorial political commentary explained that "In March 2006, Greek society had been shocked by the cases of infections of patients with the virus of AIDS after blood transfusions in hospitals of the country. At that point, it had been demonstrated that the existing screening of blood was not complete and does not prevent the patients who receive blood from being subject to unpleasant 'accidents'."[193] The feature article focused on the delays in the implementation of NAT by referring to the past announcements of the Minister of Health

[188] ... με ασυνέπεια. (2007, June 14). *Rizospastis*, p. 4; Ελλείψεις και άγρια εκμετάλλευση. (2007, June 21). *Rizospastis*, p. 20; Αδικαιολόγητη καθυστέρηση. (2007, July 17). *Rizospastis*, p. 12; Μοριακός έλεγχος. (2007, July 28). *Eleftherotypia*, p. ?; Έμεινε στα χαρτιά ο μοριακός έλεγχος του αίματος. (2007, August 16). *Τa Nea*, p. 12; Κενό γράμμα οι κυβερνητικές εξαγγελίες. (2007, August 17). *Rizospastis*, p. 14.
[189] Διέκοψαν τον μοριακό έλεγχο. (2007, July 1). *Eleftherotypia*, p. ?.
[190] «Εξειδικευμένες» ιδιωτικοποιήσεις στα νοσοκομεία. (2007, May 19). *Rizospastis*, p. 14.
[191] Σκανδαλώδης παράδοση στους ιδιώτες. (2007, August 22). *Rizospastis*, p. 21.
[192] Πρόβλημα με το αίμα: χωρίς πλήρη έλεγχο 4 στις 10 φιάλες. (2007, November 15). *To Vima*, p. 1.
[193] Το αίμα. (2007, November 15). *To Vima*, p. 1.

that had not been realized.[194] According to the article, two patients had been infected with hepatitis B after blood transfusions in different hospitals of Athens.

The article also paid special attention to the functioning of EKEA by publicizing a memo sent by the vice president of the Board of Directors of the center, Efrosuni Oikonomou-Petersen (dated 5 November 2007).[195] The vice president of EKEA condemned the delay in the institutionalization of the Centers of Molecular Screening of Blood. According to the memo, she had questioned the subfunctioning of the EKEA, especially the fact that mini-pool NAT screening was implemented, but single-unit testing was not. The article concluded that the central commission of NAT was near to completion, after the delays caused by the re-formation of the cross-party parliamentary committee following the national elections of September 2007.[196]

After *To Vima* exposed the case of HBV transfusion-transmitted infections, these were reported by all the newspapers. According to the articles, one HBV infection was confirmed by the Ministry of Health and SKAE.[197] The news articles referred to the announcement made by the ministry, according to which 70% of the collected blood was screened with NAT, while the procedure for the commission of the technology was in the last stage before completion.[198] In addition, it was reported that the formation of the cross-party parliamentary committee was proceeding at a quick pace.[199] *To Vima* dedicated a front-page headline to this issue, but with a

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194 Ανεπαρκής έλεγχος στο αίμα. (2007, November 15). *To Vima*, p. A6. (Elena Fyntanidou)

195 Ανεπαρκής έλεγχος στο αίμα. (2007, November 15). *To Vima*, p. A6. (Elena Fyntanidou)

196 In 16/09/2007 extraordinary national elections were conducted in Greece. The political party of Nea Demokratia won the elections and resumed being at the government. Dimitrios Avramopoulos continued his duty at the Ministry of Health and Social Solidarity. PASOK was the second party in votes and major opposition in the new parliamentary period. Apart from KKE and SYRIZA (a coalition formed by Synaspismos and other leftish pro-European parties), one more political party was elected to the parliament, named LAOS (Λαϊκός Ορθόδοξος Συναγερμός), a right-wing conservative party.

197 Μεταγγίσεις στα τυφλά. (2007, November 16). Ta Nea, p. 15; Πόλεμος συμφερόντων για το αίμα. (2007, November 16). *To Vima*, p. A4. (Elena Fyntanidou); Απαράδεκτες καθυστερήσεις με οδυνηρά αποτελέσματα. (2007, November 16). *Rizospastis*, p. 16; Έλεγχος για μετάδοση ηπατίτιδας από μετάγγιση. (2007, November 16). *Eleftherotypia*, p. ?; 60χρονη μολύνθηκε με ηπατίτιδα Β' ύστερα από μετάγγιση αίματος. (2007, November 16). *Ethnos*, p. ?.

198 Μεταγγίσεις στα τυφλά. (2007, November 16). Ta Nea, p. 15; Πόλεμος συμφερόντων για το αίμα. (2007, November 16). *To Vima*, p. A4. (Elena Fyntanidou); Απαράδεκτες καθυστερήσεις με οδυνηρά αποτελέσματα. (2007, November 16). *Rizospastis*, p. 16; Έλεγχος για μετάδοση ηπατίτιδας από μετάγγιση. (2007, November 16). *Eleftherotypia*, p. ?; 60χρονη μολύνθηκε με ηπατίτιδα Β' ύστερα από μετάγγιση αίματος. (2007, November 16). *Ethnos*, p. ?.

199 Οι εταιρείες και η διαμάχη για τον μοριακό έλεγχο. (2007, November 16). *To Vima*, p. A5.; Απαράδεκτες καθυστερήσεις με οδυνηρά αποτελέσματα. (2007, November 16). *Rizospastis*, p. 16; Έλεγχος για μετάδοση ηπατίτιδας από μετάγγιση. (2007, November 16). *Eleftherotypia*, p. ?.

different emphasis, indicated in the title: “The scandal of transfusions. Conflicts of interest linger in the screening of blood” (see Image 6.6).[200] According to the newspaper, the financial interests of the two companies that distributed NAT technology resulted in delays in its nationwide implementation.[201] The article mentioned that the decision of the cross-party parliamentary committee would be leaning toward a sharing between the two NAT technology providers.[202]


ΤΟ ΒΗΜΑ

ΠΡΟΕΔΡΟΣ Α.Σ.: ΧΡΗΣΤΟΣ Δ. ΛΑΜΠΡΑΚΗΣ ΕΚΔΟΤΗΣ - ΔΙΕΥΘΥΝΤΗΣ: ΣΤΑΥΡΟΣ Π. ΨΥΧΑΡΗΣ

ΙΔΡΥΤΗΣ: ΔΗΜΗΤΡΙΟΣ ΛΑΜΠΡΑΚΗΣ Έτος ιδρύσεως 1922 • Έτος ΠΣΤ' - Αριθ. 15217 • Τιμή: € 2,00 • ΠΑΡΑΣΚΕΥΗ 16 ΝΟΕΜΒΡΙΟΥ 2007 •

Το σκάνδαλο των μεταγγίσεων

Σύγκρουση συμφερόντων καθυστερεί τους ελέγχους του αίματος

■ Πόλεμος δύο πολυεθνικών για τις προμήθειες ■ Στη Διακομματική Επιτροπή της Βουλής παραπέμπει ο υπουργός Υγείας

ΣΤΗΝ ΕΛΛΑΔΑ

Πάνω από 560 θάνατοι ετησίως από

Πίσω από το πρόβλημα με το αίμα κρύβεται η μεγάλη σύγκρουση συμφερόντων δύο πολυεθνικών εταιρειών. Μετά τις αποκαλύψεις του «Βήματος» για το σκάνδαλο με τις μεταγγίσεις, ο υπουργός Υγείας παραπέμπει το θέμα στη Διακομματική Επιτροπή της Βουλής. ΣΕΛΙΔΕΣ Α4-5

Φυτοφάγος δεινόσαυρος μ

Image 6.6 *To Vima*, November 16 2007, p. 1

The following day, another article in the newspaper *To Vima* followed the story by presenting more information regarding the devaluation of the operation of ΕΚΕΑ.[203] The case regarding the transfusion-transmitted HBV infection did not raise a political debate. The only comment reported was from the sector of health of Synaspismos which condemned the governmental actions as responsible for the delays.[204] The relevant article in *Rizospastis* once again accused the government for obstruction both to the implementation of NAT and to the promotion and organization of voluntary blood donation.[205] The need for a comprehensive plan for the blood donation system was stressed also

[200] Σύγκρουση συμφερόντων καθυστερεί τους ελέγχους του αίματος. (2007, November 16). *To Vima*, p. 1.
[201] Πόλεμος συμφερόντων για το αίμα. (2007, November 16). *To Vima*, p. A4. (Elena Fyntanidou); Οι εταιρείες και η διαμάχη για τον μοριακό έλεγχο. (2007, November 16). *To Vima*, p. A5.
[202] Οι εταιρείες και η διαμάχη για τον μοριακό έλεγχο. (2007, November 16). *To Vima*, p. A5.
[203] Ανησυχία για τις μεταγγίσεις. (2007, November 17). *To Vima*, p. A15. (Elena Fyntanidou)
[204] Ανησυχία για τις μεταγγίσεις. (2007, November 17). *To Vima*, p. A15. (Elena Fyntanidou)
[205] Απαράδεκτες καθυστερήσεις με οδυνηρά αποτελέσματα. (2007, November 16). *Rizospastis*, p. 16.

in an opinion article written by Evmorfia Sagkana, the representative of SYRIZA to the cross-party parliamentary committee.[206]

The newspapers continued to report extensively about the work of the cross-party parliamentary committee. After the latter half of 2007, the coverage of the "scandal" focused on the procurement process and the two companies involved in it. According to *I Avgi*, which reported comprehensively about this issue, one of the problems in the procurement process was related to the legitimacy of the shareholders' lists of the two companies that participated in the tender.[207] The Court of Audit (Ελεγκτικό Συνέδριο) advised the continuation of the negotiations regarding the procurement and the cross-party parliamentary committee continued its meetings (end of January 2008).

In March 2008, *To Vima* and *I Avgi* reported that the two companies, Roche and Chiron, had applied for injunctions against the Hellenic Council of State (Συμβούλιο της Επικρατείας) about the tender.[208] Three members of the cross-party parliamentary committee (belonging to the opposition parties PASOK, KKE and SYRIZA) addressed a letter to the Council of State arguing that the two companies "for three years at least, with urgent processes, managed to supply with reagents and equipment the country not through a public competition but through non-contractual and opaque procedures."[209] The members of the committee specified that the companies were charging higher prices during the direct commission of reagents to the hospitals compared to the prices offered in other European countries' blood transfusion centers or in individual procurements through competitions made by hospitals.[210]

According to the news articles, the companies were "blocking" the public procurement process to provide equipment to blood transfusion centers, so that at the end of the central procurement process the hospitals would have already been committed to using one or the other

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[206] Απόψεις: "Μόνη λύση οι εθελοντές αιμοδότες". (2007, November 16). *To Vima*, p. A4. (Evmorfia Sagkana)

[207] Κρύβουν τα μετοχολόγιά τους. (2008, January 24). *I Avgi*, p. 28; Προχωράει κανονικά ο διαγωνισμός για το αίμα. (2008, January 30). *I Avgi*, p. 15. (Vasilis Venizelos); Ανοίγουν οι προσφορές για το αίμα. (2008, January 31). *I Avgi*, p. 15. (Vasilis Venizelos)

[208] Με αναθέσεις προχωρά ο μοριακός έλεγχος του αίματος!. (2008, March 9). *I Avgi*, p. 52; Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos); Χωρίς μοριακό έλεγχο το 30% του συλλεγόμενου αίματος. (2008, March 27). *To Vima*, p. A12. (Elena Fyntanidou)

[209] Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos); Χωρίς μοριακό έλεγχο το 30% του συλλεγόμενου αίματος. (2008, March 27). *To Vima*, p. A12. (Elena Fyntanidou)

[210] Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos); Χωρίς μοριακό έλεγχο το 30% του συλλεγόμενου αίματος. (2008, March 27). *To Vima*, p. A12. (Elena Fyntanidou)

company's NAT system.[211] Another issue raised in the articles concerned the fact that certain hospitals in Athens paid for NAT reagents to screen the donated blood in the laboratory of the National Retrovirus Reference Center (located in the Department of Hygiene, Epidemiology and Medical Statistics at the Athens University Medical School) which, however, did not belong to the 9 Centers of Molecular Screening of Blood planned.[212] This was also highlighted in the letter sent by the members of the cross-party parliamentary committee, though the laboratory was not specified.[213]

On 27 March 2008, *I Avgi* published a letter by Roche addressed to its editors, in which the company replied to the article I mentioned above (published on 18 March 2008). The representatives of the company denied that Roche had provided molecular screening products through any type of direct commission to hospitals and stressed that the co-bidder company first appealed against the tender and then Roche followed up to protect its rights.[214] Additionally, the letter emphasized that Roche had supported the decision made by the Ministry of Health for an open invitation to tender.[215]

At the beginning of April 2008, according to the news articles, the Council of State ruled out the injunction made by one of the companies and the process proceeded through the opening of the bids.[216] *To Vima* emphasized that the companies charged the hospitals with excessive amounts for the molecular screening through direct commissions.[217] The short text on the front page is indicative: "In 'gold' assess the pharmaceutical companies the molecular screening of blood in the Greek hospitals, as this is shown by the opening of the (dramatically cheaper) bids."[218] According to the feature article, as reported in reference to the bids made by the companies, the

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[211] Οι εταιρείες και η διαμάχη για τον μοριακό έλεγχο. (2007, November 16). *To Vima*, p. A5; Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos); Χωρίς μοριακό έλεγχο το 30% του συλλεγόμενου αίματος. (2008, March 27). *To Vima*, p. A12. (Elena Fyntanidou)

[212] Ανεπαρκής έλεγχος στο αίμα. (2007, November 15). *To Vima*, p. A6. (Elena Fyntanidou)

[213] Οι εταιρείες μπλοκάρουν τον διαγωνισμό για τον μοριακό έλεγχο του αίματος. (2008, March 18). *I Avgi*, p. 18. (Vasilis Venizelos); Χωρίς μοριακό έλεγχο το 30% του συλλεγόμενου αίματος. (2008, March 27). *To Vima*, p. A12. (Elena Fyntanidou)

[214] Η Roche για τον μοριακό έλεγχο του αίματος. (2008, March 29). *I Avgi*, p. 10.

[215] Η Roche για τον μοριακό έλεγχο του αίματος. (2008, March 29). *I Avgi*, p. 10.

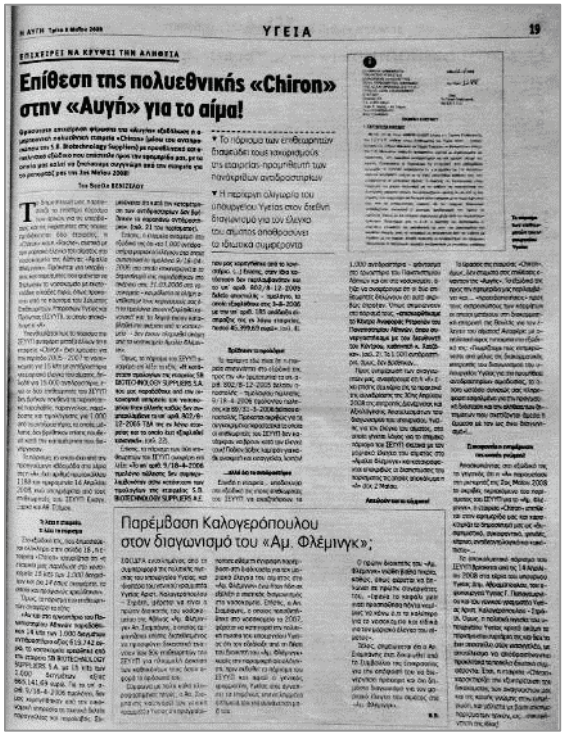
[216] Ανοίγουν οι προσφορές για τον έλεγχο αίματος. (2008, April 9). *I Avgi*, p. 19; Μαίνεται ο πόλεμος για την "πίτα" του αίματος στα δημόσια νοσοκομεία. (2008, April 23). To Vima, p. A14. (Elena Fyntanidou); Ύποπτα παιχνίδια σκοπιμότητας στον διαγωνισμό για το αίμα. (2008, April 30). *I Avgi*, p. 6.

[217] Μαίνεται ο πόλεμος για την "πίτα" του αίματος στα δημόσια νοσοκομεία. (2008, April 23). *To Vima*, p. A14. (Elena Fyntanidou)

[218] Ο κούκος, αηδόνι. (2008, April 23). *To Vima*, p. A1.

price of testing per unit of blood ranged from EUR 38.5 to EUR 45, while at the same time, the prices charged to the hospitals ranged from EUR 50–57.[219]

The newspapers covered a few representative cases regarding the direct commission of molecular testing in hospitals. Special publicity was given to the case of the hospital "Amalia Fleming" in Athens. The Body of Inspectors for Health and Welfare Services (Σώμα Επιθεωρητών Υπηρεσιών Υγείας και Πρόνοιας) had investigated the procedures regarding the commission of NAT testing at this hospital.[220] The newspaper *I Avgi* reported in detailed accounts this case and had short headlines on two front-pages about it.[221] In response, Chiron sent an out-of-court legal notice (εξώδικο) against the newspaper regarding its articles about the "Amalia Fleming" case.[222] The newspaper published this notice and its journalist replied by referring to the findings from the investigations made by the official body, see Image 6.7.[223] In addition, the newspaper published the replies of the inspector who had investigated the case, and, also, of the former manager of the hospital.[224]


ΥΓΕΙΑ 19

ΕΠΙΧΕΙΡΕΙ ΝΑ ΚΡΥΨΕΙ ΤΗΝ ΑΛΗΘΕΙΑ

Επίθεση της πολυεθνικής «Chiron» στην «Αυγή» για το αίμα!

Παρέμβαση Καλογερόπουλου στον διαγωνισμό του «Αμ. Φλέμινγκ»;

Image 6.7 *I Avgi*, May 6 2008, p. 19

Articles in *Rizospastis* and *I Avgi* were critical of the handling of the procurement

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219 Μαίνεται ο πόλεμος για την "πίτα" του αίματος στα δημόσια νοσοκομεία. (2008, April 23). *To Vima*, p. A14. (Elena Fyntanidou)

220 Σειρά προβλημάτων στον τρόπο ανάθεσης μοριακών εξετάσεων. (2008, April 21). *Ethnos*, p. ?. (Dimitris Karagiorgos); Πώς δύο εταιρείες έκλεβαν το νοσοκομείο "Αμ. Φλέμινγκ". (2008, May 2). *I Avgi*, p. 1; Πώς δύο εταιρείες έκλεβαν το νοσοκομείο "Αμ. Φλέμινγκ". (2008, May 2). *I Avgi*, p. 8. (Vasilis Venizelos; Επίθεση της πολυεθνικής "Chiron" στην "Αυγή" για το αίμα!. (2008, May 6). *I Avgi*, p. 19. (Vasilis Venizelos); Πλήρης επιβεβαίωση της "Αυγής" για το αίμα στο "Αμ. Φλέμινγκ". (2008, May 9). *I Avgi*, p. 32. (Vasilis Venizelos); Για τον μοριακό έλεγχο του αίματος στο "Αμ. Φλέμινγκ". (2008, May 10). *I Avgi*, p. 26. (Vasilis Venizelos)

221 Πώς δύο εταιρείες έκλεβαν το νοσοκομείο "Αμ. Φλέμινγκ". (2008, May 2). *I Avgi*, p. 1; Επίθεση της πολυεθνικής "Chiron" στην "Αυγή" για το αίμα!. (2008, May 6). *I Avgi*, p. 1.

222 Επίθεση της πολυεθνικής "Chiron" στην "Αυγή" για το αίμα!. (2008, May 6). *I Avgi*, p. 19. (Vasilis Venizelos);

223 Εξώδικη διαμαρτυρία - δήλωση και πρόσκληση. (2008, May 6). *I Avgi*, p. 18; Επίθεση της πολυεθνικής "Chiron" στην "Αυγή" για το αίμα!. (2008, May 6). *I Avgi*, p. 19. (Vasilis Venizelos); Παρέμβαση Καλογερόπουλου στον διαγωνισμό του "Αμ. Φλέμινγκ";. (2008, May 6). *I Avgi*, p. 19. (Vasilis Venizelos)

224 Πλήρης επιβεβαίωση της "Αυγής" για το αίμα στο "Αμ. Φλέμινγκ". (2008, May 9). *I Avgi*, p. 32. (Vasilis Venizelos); Για τον μοριακό έλεγχο του αίματος στο "Αμ. Φλέμινγκ". (2008, May 10). *I Avgi*, p. 26. (Vasilis Venizelos)

process by the ministry.[225] One could read that "the Ministry of Health has many tools to put pressure on the two companies to comply with and contribute to the completion of the tender as they owe to; however it shows, interestingly, special tolerance to the strategies of the two companies and enhances the procrastination."[226] Also, "in practice, the government seems to be submissive to the deadly competition of the multinational [companies] – unless it proves, urgently, the opposite…"[227] As reported, the prices for the nationwide commission of NAT would be further negotiated, after the opening of the financial part of the offers, in the cross-party parliamentary committee.

Both left-wingish newspapers *Rizospastis* and *I Avgi* meticulously covered the progress of the procurement process. During May 2008, the coverage was associated with the reporting on the press conference organized by EOTHA, held on 14 May 2008, regarding the conference "Thalassaemia 2008".[228] As reported, during the press conference the president of the federation expressed complaints about the procrastination in the implementation of NAT. *Rizospastis* published detailed articles listing the problems that people with thalassaemia were facing due to the lack of medical and nursing staff, the recurring periods of blood shortage, the unorganized voluntary blood donation system and the risks of transfusion-transmitted infections, connected to the pending of the nationwide NAT screening.[229] Both newspapers referred to the operational problems ΕΚΕΑ was facing. According to the employees of ΕΚΕΑ, the center would operate only in the morning shift (i.e. it would cease being functional 24 hours a day) because the employees would stop working overtime due to the delays in the payment of accrued earnings for overtime shifts and the constant understaffing of the center.[230]

In the same articles, on 24 May 2008, the two newspapers reported the announcement made by the Ministry of Health according to which the cross-party parliamentary committee, after

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[225] Ύποπτα παιχνίδια σκοπιμότητας στον διαγωνισμό για το αίμα. (2008, April 30). *I Avgi*, p. 6; Υποταγή στο θανάσιμο ανταγωνισμό. (2008, May 2). *Rizospastis*, p. 5; Το Σάββατο η συνέχεια στη διαπραγμάτευση. (2008, May 8). *Rizospastis*, p. 15; Νέα ύποπτη εμπλοκή στον διαγωνισμό για το αίμα!. (2008, May 13). *I Avgi*, p. 11. (Vasilis Venizelos); "Όλα καλά στον διαγωνισμό για το αίμα"!. (2008, May 15). *I Avgi*, p. 26.

[226] Νέα ύποπτη εμπλοκή στον διαγωνισμό για το αίμα!. (2008, May 13). *I Avgi*, p. 11. (Vasilis Venizelos)

[227] Υποταγή στο θανάσιμο ανταγωνισμό. (2008, May 2). *Rizospastis*, p. 5.

[228] Στοιβαγμένοι ασθενείς και χωρίς γιατρούς. (2008, May 14). *Rizospastis*, p. 29; Μεγάλη καθυστέρηση στον διαγωνισμό για το αίμα. (2008, May 14). *I Avgi*, p. 19.

[229] Τεράστιες ελλείψεις και πριμοδότηση των ιδιωτών. (2008, April 5). *Rizospastis*, p. 3; Στοιβαγμένοι ασθενείς και χωρίς γιατρούς. (2008, May 14). *Rizospastis*, p. 29; Παρέμβαση για την εθελοντική αιμοδοσία. (2008, May 20). *Rizospastis*, p. 20; Απαράδεκτη η κατάσταση στις Μονάδες Μεσογειακής Αναιμίας. (2008, May 21). *Rizospastis*, p. 18.

[230] Μόνο μια βάρδια με ευθύνη της κυβέρνησης. (2008, May 24). *Rizospastis*, p. 33; Πανηγυρικοί τόνοι από το υπ. Υγείας για το αίμα. (2008, May 24). *I Avgi*, p. 7.

negotiations with the two companies, had secured discount of 31.54% from the original budget for the implementation of NAT (the budget allocated for the five-year contract was EUR 208,250,000).[231] The negotiations would be further continued and the adjudication of the agreement would be concluded after the final ruling of the Council of State on the applications for annulment of the call for tenders filed by the companies.[232] The Council of State rejected the applications made by the companies seeking to protect their interests during the process.[233] The contract award about the nationwide commission of molecular diagnostics was adjudicated in the meeting of the cross-party parliamentary committee held on 9 June 2008.[234] Five Centers of Molecular Screening of Blood were awarded to the distributor of Chiron (S.B. Biotechnology Suppliers S.A.) and four centers to Roche (Roche Diagnostics Hellas S.A. – Katopis Group S.A.).

According to the announcement issued by the Ministry of Health, the discount reached 32.19% and "was considered beneficial and a success for all the members which participated in the committee."[235] The decision was approved by the majority of the members whereas the representatives of KKE and SYRIZA disapproved it on the ground that the final bids were still higher than the pricing offered at other European countries.[236] Regarding the contract award, Roche sent two letters to *I Avgi*, in which it argued that the cost of NAT testing per unit in Greece did not include only the price of the reagent but also the transport of the blood sample, the configuration of the laboratories and the technicians.[237] The company responded to the articles, published by the newspaper, which stated that the cost was higher than in other countries.

On 9 August 2008, the newspapers reported that the cross-party parliamentary committee had concluded its task on the procurement of NAT in the nine Molecular Screening

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[231] Μόνο μια βάρδια με ευθύνη της κυβέρνησης. (2008, May 24). *Rizospastis*, p. 33; Πανηγυρικοί τόνοι από το υπ. Υγείας για το αίμα. (2008, May 24). *I Avgi*, p. 7.

[232] Διαγκωνισμοί για τον Μοριακό Έλεγχο. (2008, May 31). *Rizospastis*, p. 36; Στον αέρα ο έλεγχος του αίματος. (2008, June 4). *Eleftherotypia*, p. ?; Συνεχίζονται οι διαπραγματεύσεις. (2008, June 5). *Rizospastis*, p. 16.

[233] «Πράσινο» για τον μοριακό έλεγχο του αίματος. (2008, June 6). *Ethnos*, p. ?.

[234] Καταψήφισε το ΚΚΕ την κατακύρωση με υψηλές τιμές. (2008, June 11). *Rizospastis*, p. 14; Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 11). *I Avgi*, p. 19. (Vasilis Venizelos); Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 15). *I Avgi*, p. 17. (Vasilis Venizelos)

[235] Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 11). *I Avgi*, p. 19. (Vasilis Venizelos)

[236] Καταψήφισε το ΚΚΕ την κατακύρωση με υψηλές τιμές. (2008, June 11). *Rizospastis*, p. 14; Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 11). *H Avgi*, p. 19. (Vasilis Venizelos); Ολοκληρώθηκε ο διαγωνισμός για το αίμα. (2008, June 15). *I Avgi*, p. 17. (Vasilis Venizelos)

[237] Διευκρινίσεις χωρίς αντίκρισμα από τη "Roche" για το αίμα. (2008, June 20). *I Avgi*, p. 30. (Vasilis Venizelos); Η "Roche" για τον μοριακό έλεγχο του αίματος. (2008, July 1). *I Avgi*, p. 19.

Blood Centers and that the agreement was validated from the Court of Audit.[238] The signing of the contracts was announced by the ministry on 25 August 2008.[239] According to the announcement, the introduction of NAT was "the largest project in the history of the Ministry of Health."[240]

6.2.2. The use of NAT in the news (2008–2010)

In September 2008 "the nightmare of the risk of transfusions of infected blood came alive again" according to an article in the newspaper *Eleftherotypia*.[241] This dramatic description was accompanied with less dramatic titles in other articles in which one could read that "[Patient] infected with AIDS after transfusion" and "[they] transfused … AIDS to cancer patient."[242] The articles informed that a 70-year-old female cancer patient was detected seropositive to HIV. In the recent past she was transfused blood while being hospitalized. KEELPNO and SKAE, responsible for the haemovigilance services, were performing retrospective tests to examine the possibility that the patient had been infected with HIV through blood transfusion.[243] According to the articles, molecular screening technology was implemented for 75% of the donated blood, and would have been complete over the following two months.

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[238] Πράσινο φως για τον μοριακό έλεγχο του αίματος σε 9 κέντρα. (2008, August 9). *To Vima*, p. A13; Ολοκληρώθηκε σε υψηλές τιμές ο διαγωνισμός. (2008, August 9). *Rizospastis*, p. 12; Απείχε ο ΣΥΡΙΖΑ, υπέρ ψήφισε το ΚΚΕ. (2008, August 9). *I Avgi*, p. 13. (Vasilis Venizelos).

[239] Υπεγράφησαν οι συμβάσεις για τον μοριακό έλεγχο του αίματος. (2008, August 26). *I Avgi*, p. 17; Ακόμα δεν τον είδανε... (2008, August 27). *Rizospastis*, p. 4. The newspapers *I Avgi* reported that the representative of KKE signed the agreement at the final meeting of the committee (the representative of KKE was against the terms of the agreement, as mentioned before), see Απείχε ο ΣΥΡΙΖΑ, υπέρ ψήφισε το ΚΚΕ. (2008, August 9). *I Avgi*, p. 13. (Vasilis Venizelos); Τι αποκρύπτει ο "Ριζοσπάστης" για το αίμα. (2008, August 28). *I Avgi*, p. 24. *Rizospastis* replied that this was not true, see Ψεύδεται συνειδητά η «Αυγή» για το αίμα. (2008, August 29). *Rizospastis*, p. 4. The representative of KKE herself explained that she signed in order to confirm the legitimacy of the adjudicated contracts, see Τι ενέκρινε το ΚΚΕ για το αίμα. (2008, August 29). *I Avgi*, p. 24.

[240] Ακόμα δεν τον είδανε... (2008, August 27). *Rizospastis*, p. 4.

[241] 70χρονη μολύνθηκε με AIDS. (2008, September 19). *Eleftherotypia*, p. ?.

[242] Μολύνθηκε με AIDS ύστερα από μετάγγιση. (2008, September 19). *Ta Nea*, p. 16; Μετάγγισαν... AIDS σε καρκινοπαθή. (2008, September 19). *Ethnos*, p. ?. (Dimitris Karagiorgos).

[243] Μολύνθηκε με AIDS ύστερα από μετάγγιση. (2008, September 19). *Ta Nea*, p. 16; 70χρονη μολύνθηκε με AIDS. (2008, September 19). *Eleftherotypia*, p. ?; Μετάγγισαν... AIDS σε καρκινοπαθή. (2008, September 19). *Ethnos*, p. ?. (Dimitris Karagiorgos); Φόβοι για μετάγγιση μολυσμένου αίματος και σε άλλους ασθενείς. (2008, September 20). *To Vima*, p. A14; Καθυστερήσεις και «παράθυρα» στους ελέγχους. (2008, September 20). *Rizospastis*, p. 20; Εν αναμονή των αποτελεσμάτων για το μολυσμένο αίμα. (2008, September 20). *I Kathimerini*, p. 16. (Penny Mpouloutza); Ψάχνουν τα ίχνη του μολυσμένου αίματος. (2008, September 22). *Ethnos*, p. ?. (Dimitris Karagiorgos); Αναμένονται τα αποτελέσματα για το "ύποπτο" αίμα. (2008, September 23). *To Vima*, p. A14; Εν αναμονή των αποτελεσμάτων για τη μόλυνση της 70χρονης. (2008, September 23). *I Avgi*, p. 24.

Ethnos provided more detailed accounts regarding the actions taken by the haemovigilance center and juxtaposed, once again, molecular screening versus the "older methods" regarding the detention of a virus during the window period.[244] The possibility that this patient's infection was due to a transfusion was associated with past cases. For example, one could read that "it is not the first time that a citizen is infected by transfusion, something ascribed to the fact that until today just 75% of the blood intended for transfusions is being screened with molecular testing."[245] However, in another article this causal relation was somehow contested. If the infection was proved to be associated with a transfusion and the blood had been tested with NAT, then "the myth that molecular screening of blood is panacea is debunked," we read in *To Vima*.[246] The same article and one in *Rizospastis* argued for the improvement of voluntary blood donation to advance blood safety.[247] Over the following days, the newspapers reported that the officials organized a press conference in which they provided data from the haemovigilance control that showed that the HIV infection of the aforementioned female patient was not related to blood transfusion.[248]

The newspapers reported on the case of the HIV transfusion-transmitted infections publicized at the end of March 2006. In June 2007, an article in *Eleftherotypia* covered the judicial case of the blood donor who was charged with "repeated personal injury due to negligence."[249] A few months later, it was reported that the blood donor also took legal action and filed a lawsuit by stating that he was not the sole responsible for the infections and pointed at the liability of the Ministry of Health and the managers of the Ippokrateio General Hospital of Thessaloniki.[250] Furthermore, the family of the 17-year-old girl with thalassaemia, who was infected with HIV after the transfusion she had received, took legal action and claimed compensation from the Ippokrateio General Hospital.[251]

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[244] Ψάχνουν τα ίχνη του μολυσμένου αίματος. (2008, September 22). *Ethnos*, p. ?. (Dimitris Karagiorgos).
[245] Μολύνθηκε με AIDS ύστερα από μετάγγιση. (2008, September 19). *Ta Nea*, p. 16.
[246] Αναμένονται τα αποτελέσματα για το "ύποπτο" αίμα. (2008, September 23). *To Vima*, p. A14.
[247] Αναμένονται τα αποτελέσματα για το "ύποπτο" αίμα. (2008, September 23). *To Vima*, p. A14; Καθυστερήσεις και «παράθυρα» στους ελέγχους. (2008, September 20). *Rizospastis*, p. 20.
[248] Δεν ήταν τελικά από μετάγγιση το κρούσμα έιτζ. (2008, September 25). *I Kathimerini*, p. ?. (Penny Mpouloutza); Δεν ευθύνεται η μετάγγιση αίματος για το κρούσμα AIDS στην 70χρονη. (2008, September 25). *Ethnos*, p. ?. (Dimitris Karagiorgos); Δεν είναι από μετάγγιση η μόλυνση της 70χρονης ασθενούς από HIV/AIDS. (2008, September 25). *I Avgi*, p. 19. (Vasilis Venizelos).
[249] Παραπέμπεται 39χρονος για μετάδοση AIDS. (2007, June 14). *Eleftherotypia*, p. ?.
[250] Μήνυση από τον 40χρονο που έδωσε μολυσμένο αίμα. (2008, January 31). *Ethnos*, p. ?. (Vasilis Ignatiades).
[251] Αγωγή σε νοσοκομείο για μόλυνση από AIDS έπειτα από μετάγγιση. (2008, January 14). *Ta Nea*, p. 55. (Kostas Kantouris).

Over 2009–2010, the issue of the use of the molecular diagnostics did not appear frequently in the news. In an article in *Ta Nea*, it was reported that, due to the judicial case regarding the charges against the blood donor of the March 2006 case of HIV transfusion-transmitted infections, the Public Prosecutor had reconsidered the criminal liability of blood donors and of doctors.[252] According to the article, the prosecutor "accepted that in such cases [transfusion-transmitted infections due to window period] criminal liability cannot be ascribed to the doctor or to other officials of the hospital management, on the ground that the equipment for the machine for the detection of AIDS is a matter of the state and of the financial capability of the hospitals to acquire such specialized machines."[253]

An article in *I Avgi* focused on the increase of new HIV infections in Greece and on the lack of integrated policies regarding the prevention and the therapy of HIV/AIDS. Regarding the health policy about HIV, it was mentioned that "Avramopoulos boasts that he is the Minister of Health who installed molecular screening of blood (NAT) in all the hospitals of the country. He is also the Minister during whose duty the number of new infections of HIV/AIDS increased considerably."[254]

Other articles during these years referred, once again, to the serious problems that the blood transfusion centers faced, highlighting the lack of personnel.[255] The problems were exemplified in a story about units of blood forgotten at a bus station in a city in central Greece.[256] According to the articles, the units of blood were under transportation to a Center of Molecular Screening of Blood located in a neighboring city hospital (in which one of was based) to be screened by NAT before distribution. The transport of the blood had been outsourced by a private company but the contract ended and the transport by regional buses was considered an acceptable practice.[257] A few months later, *I Avgi* published an article noting that the Council of State had found illegitimate the practice of transporting the blood to the nine Centers of Molecular Screening of Blood by the two companies that were awarded the contract for the

[252] Ευθύνες στους αιμοδότες για την ερωτική τους ζωή. (2009, January 5). *Ta Nea*, p. 16. (Mina Moustaka).
[253] Ευθύνες στους αιμοδότες για την ερωτική τους ζωή. (2009, January 5). *Ta Nea*, p. 16. (Mina Moustaka).
[254] Πολιτική και κοινωνική αφασία για το HIV/AIDS. (2009, April 28). *I Avgi*, p. 38. (Vasilis Venizelos).
[255] Επικίνδυνες πρακτικές σε βάρος της αιμοδοσίας. (2009, January 17). *Rizospastis*, p. 18; Αιμορραγεί το σύστημα αιμοδοσίας. (2010, April 17). *I Kathimerini*, p. ?. (Penny Mpouloutza).
[256] Ξέχασαν ασκούς αίματος στο... ΚΤΕΛ. (2010, July 16). *I Kathimerini*, p. ?. (Penny Mpouloutza); Ξέχασαν φιάλες αίματος στα ΚΤΕΛ. (2010, July 16) *Ethnos*, p. ?. (Vasilis Ignatiades).
[257] Ξέχασαν ασκούς αίματος στο... ΚΤΕΛ. (2010, July 16). *I Kathimerini*, p. ?. (Penny Mpouloutza); Ξέχασαν φιάλες αίματος στα ΚΤΕΛ. (2010, July 16) *Ethnos*, p. ?. (Vasilis Ignatiades).

implementation of NAT.[258] The article specified that the transport of the units of blood was not agreed on the contracts.[259]

The implementation of NAT was also mentioned in an article dedicated to the financial problems and the large debts of the public hospitals in Greece.[260] According to this article, the hospitals had huge expenditure rise in the previous few years, meaning before 2010. The increase in the expenditure for reagents was especially high, even by considering as additive to the use of NAT during that period.[261]

In August 2010, the newspapers covered the occurrence of a public health emergency associated with cases of infections with the West Nile Virus (WNV) in northern Greece.[262] WNV is commonly transmitted by infected mosquitos; however, it can also be transmitted to through blood transfusion.[263] During the news coverage related to this issue, the newspapers reported on the emergency measures for blood safety regarding the possible transmission of WNV through transfusion. According to the news, EKEA decided to temporarily defer blood donation in the areas where WNV infections occurred and to exclude the blood collected in these areas (put in quarantine) from future transfusions. All this donated blood would be tested with NAT for WNV.[264] The articles did not elaborate on the molecular screening technology but emphasized

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[258] Παράνομη η μεταφορά αίματος στα Κέντρα Μοριακού Ελέγχου!. (2010, October 20). *I Avgi*, p. 17. (Vasilis Venizelos).

[259] Παράνομη η μεταφορά αίματος στα Κέντρα Μοριακού Ελέγχου!. (2010, October 20). *I Avgi*, p. 17. (Vasilis Venizelos).

[260] Έτσι χρεοκόπησαν τα δημόσια νοσοκομεία. (2010, March 7). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou). This article was published in 2010 that the country of Greece faced a government-debt crisis. After April 2010 Greece has been on a bailout loan from the International Monetary Fund and the Eurozone countries. On 4/11/2009 national elections were held in Greece and the political party PASOK formed the government. Nea Demokratia was the major opposition party.

[261] Έτσι χρεοκόπησαν τα δημόσια νοσοκομεία. (2010, March 7). *Eleftherotypia*, p. ?. (Dimitra Efthymiadou)

[262] Πέντε κουνουπο-κρούσματα κάθε μέρα. (2010, August 17). *Eleftherotypia*, p. ?. (Dani Vergou); 64 τα κρούσματα του ιού του Δυτικού Νείλου - 8 στην Εντατική. (2010, August 19). Ta Nea, p. 11. (Foteini Stefanopoulou); Ακόμη τρεις νεκροί από εγκεφαλίτιδα. (2010, August 20). *To Vima*, p. A14; Στα 77 τα επιβεβαιωμένα κρούσματα. (2010, August 20). *Rizospastis*, p. 15; Από Δευτέρα ο έλεγχος του αίματος που έχει μπει σε καραντίνα. (2010, August 20). *I Avgi*, p. 7; Επτά τα θύματα του ιού του Δ. Νείλου. (2010, August 20) *Ethnos*, p. ?. (Maria Ritzaleou).

[263] West Nile virus most commonly transmitted to humans by mosquito bites. WNV may also be spread through blood transfusions and organ transplants. It is possible for an infected mother to spread the virus to her child through breast milk. There are no medications to treat or vaccines to prevent WNV infection. Fortunately, most people infected with WNV will have no symptoms. About 1 in 5 people who are infected will develop a fever with other symptoms. Less than 1% of infected people develop a serious, sometimes fatal, neurologic illness.

[264] Καραντίνα στις μεταγγίσεις. (2010, August 18). *Ta Nea*, p. 13. (Foteini Stefanopoulou); Ακόμη τρεις νεκροί από εγκεφαλίτιδα. (2010, August 20). *To Vima*, p. A14; Λιγοστεύουν τα αποθέματα αίματος. (2010, August 19). *Rizospastis*, p. 17; Από Δευτέρα ο έλεγχος του αίματος που έχει μπει σε καραντίνα. (2010, August 20). *I Avgi*, p. 7;

the time-consuming procedures to supply the Centers of Molecular Screening of Blood of northern Greece (one in Larisa and one in Thessaloniki) with reagents for WNV testing, which could cause blood shortage. In addition, the news coverage focused on the preventive actions taken by the officials that included spraying for the mosquitoes in the affected areas. According to the articles, the following days the hospitals began to test the units of blood with molecular screening for WNV and the units were found negative to the virus.[265]

6.2.3. Summing-up the findings for 2007–2010

During these years, the prevailing theme in the newspapers coverage was about the procurement process for NAT. The actions of the participating actors were presented in detail. The stories focused on the policy events, the political discussions, the parliamentary actions, the officials' response and the actions of the two companies involved. During specific periods, as analyzed above, the issue was framed as a "scandal" in which financial and other vested interests were in conflict. The newsworthiness of these accounts was apparent when some stories were published on front-pages. Therefore, the issue was considered both affecting public health safety, as the articles mentioned the "dangers" emerging by the lack of NAT screening of all the donated blood, and a political/economic scandal.

On the one hand, the discourse on public policy about the commission of NAT was presented as a series of consecutive events which contributed to a lengthy process and delays. The references to the initial timetable were rather limited. Accountable for the delays were portrayed all the actors. After November 2007, the competing interests of the companies, vendors of molecular screening technology, featured more prominently and the two companies actively participated on the disputes regarding the process. On the other hand, the use of NAT was characterized as an urgent matter of public health. The claims of associations of people with thalassaemia were frequently reported in connection to the non-universal use of NAT. For them, the state was accountable for the delays.

Ο ιός του Νείλου χορεύει και το υπουργείο κωφεύει. (2010, August 18). *Eleftherotypia*, p. ?. (Sakis Apostolakis); Επτά τα θύματα του ιού του Δ. Νείλου. (2010, August 20) *Ethnos*, p. ?. (Maria Ritzaleou).

[265] Με καθυστέρηση τα χρήματα για ψεκασμούς. (2010, August 24). *Eleftherotypia*, p. ?. (Sakis Apostolakis); Φόβοι για αύξηση των κρουσμάτων. (2010, August 24) *Ethnos*, p. ?. (Maria Ritzaleou); Στα 9 έφθασαν τα θύματα από τον ιό του Δυτικού Νείλου. (2010, August 25). *Ta Nea*, p. 11. The following article reported that one unit of donated blood tested positive to the WNV, «Πυρετός» για τον ιό του Δυτικού Νείλου. (2010, August 26) *Ethnos*, p. ?. (Maria Ritzaleou).

The coverage was event-oriented. In November 2007 the journalistic coverage of an event (a case of HBV transfusion-transmitted infection) triggered more detailed accounts about the procurement process. Additionally to the policy developments, the news stories covered news about the problems in the operation of EKEA, its limited funding and understaffing. However, these accounts were not associated with policies, and the decision on the allocation of the recourses to the blood transfusion service. The same applies when the newspapers referred to the need to enhance voluntary blood donation in Greece.

Two other news stories are considered important as they connect to the focus of this study. In the first, the prosecutor considered that the use of NAT is a matter of the state, meaning that the state had to decide whether to invest in such a technology (ruling out, in his view, liability of the physicians or the hospital's management). Since the cost of blood screening is being financed by the hospitals, then the decision to use NAT was directly connected to the hospitals budget. In March 2010, an article reported on the accumulated debts of the hospitals, according to a health economics research for 2005–2008, and noted cases of overpricing of consumables and corruption. The article noted that the expenses in several categories of consumables raised, including an increase in the reagents which seemed big even when the use of molecular screening was considered. I refer to these two articles because in news accounts about the "largest investment" of the Ministry of Health, the prevailing discourse excluded considerations about the financing of NAT and its cost.

One last comment about this period is devoted to the news stories regarding the alleged case of a transfusion-associated infection in September 2008, just after the completion of the procurement (the retrospective control showed that the transmission was not related to a transfusion). In an article in *To Vima* was remarked that molecular screening is not a "panacea" and the development of volunteer donorship would advance blood safety. Moreover, it was noted that NAT could reduce the window period further by some days, but not to eliminate it. In this case, the description of NAT as safe was dissipated; since NAT was not compared to other screening methods, the polarizing effect no longer applied.

6.3. Concluding remarks

Chapters 5 and 6 have focused on the public image of the blood screening technologies by analyzing articles in Greek newspapers published between 1995 and 2010. This last section summarizes the main research findings. I associate them with recurring patterns in media

coverage of risk issues as depicted in the secondary literature. I focus on particular aspects of the media discourse about the molecular diagnostics technology, and biomedical technology in general.

From the analysis, it becomes clear that the media coverage tends to focus on "events" rather than more general issues. A "crisis" attracts greater media interest. With respect to the news discourse on risk, risks commonly appear in the news in reports of events, i.e. disasters, sudden catastrophes and tragedies (Hughes et al., 2006, p. 255; Spencer & Triche, 1994, p. 200; Wilkinson, 1999, p. 22). On this particular topic, concerning the blood transfusion service and the blood supply in Greece, the newspapers coverage was "event" orientated; it focused on specific events, such as the cases of transfusion-transmitted infections reported during the years I analyzed. The first reference to molecular diagnostics was during January 1999, after the reporting of such a case.

To be more specific, the newspapers referred to the implementation of NAT screening in Greece when a case regarding transfusion-transmitted infections was exposed (March 2006). Until then, the use of NAT (mostly in pilot programs) in Greek blood transfusion centers was not reported. More importantly, due to this event, the issue of blood safety received extensive coverage, as did the technologies used in blood screening. In addition, stories about the persons involved (mostly about the "victims") and stories about the judicial cases appeared in the news. Moreover, general themes regarding transfusion safety and blood sufficiency were reported in association to the specific events, throughout all periods.

Regarding the presentation of the blood screening technologies, again the largest coverage was noticed during the coverage of the March 2006 case. The comparative accounts for the serologic and molecular screening had a polarizing effect. The NAT screening techniques were presented as advanced, modern, effective and safe. The serology screening techniques were characterized as traditional, conventional and risky. The superiority of NAT technology was presented as part of the advances of the biotechnology era. The prevailing discourse on the use of a new molecular technology (NAT) was connected to the discourse of the progress of molecular biology. The coverage of biotechnology has been associated positively with the frame of "progress" (Nisbet & Lewenstein, 2002).

A more complex picture of the media coverage emerges when a theme is analyzed over time. From the analysis above, it seems that in general articles during the period before 2006, the method of serologic screening was not presented in detail and the risks of transfusion-transmitted

infections were not stressed. This changed in 2006, when a specific event attracted media attention and it was directly connected to policy developments. In addition, the screening technologies were compared and were not always presented as complementary.

The issue of blood safety and the blood screening technologies used after March 2006 was directly connected to policy development, regulations, institutional processes and the actions of officials. The response of the officials and the bureaucratic procedures attracted the media's attention. The possibility of attributing accountability to an official body, institution or government can be an important criterion for the coverage of a news story about risks. This has been apparent in the analysis performed. As we have argued elsewhere, the issues associated with blood screening have received extensive media coverage, as they have been framed as "scandals" (Vlantoni & Morfakis, 2015). In 2006, the scandal was connected to the case of transfusion-transmitted infections. From the middle of 2006 and until the summer of 2008, the scandal was economic and political; it was about the public procurement of the NAT technology.

In the March 2006 case, the framing of a scandal dominated the news discourse. By implying the inaction of public officials as the cause of a tragic event, this event could be framed as a major political issue. Although this association was apparent, it did not become dominant. The emphasis on the lack of the modern screening methods became the main cause of this event, as monocausal frames in the social construction of the news are commonly preferred by the media (Spencer & Triche, 1994, p. 211). In this process, the influence of news sources is very important. According to research findings, media privilege official sources; press releases and announcements of policy initiatives are a key source of news stories about risk (Hughes, et al., p. 253). Thus, the announcement of the universal use of NAT during a press conference – a policy presented with carefully arranged deadlines – consolidated the power of official voices. It became a powerful news source that defined the problem and offered a solution. The issues of risk and safety were then ascribed to the use of molecular screening of blood.

The realization of this policy was lengthy. The newspapers continued more extensive coverage, as noted, in connection with other specific events. These events included both cases of transfusion-transmitted infections and policy developments. The news stories covering these events were overtly critical of the "delays" in the procurement process. Occasionally, they featured articles on the competing interests of the two companies, associating the prospect of profit-making with the delays affecting public health safety. The framing in the news discourse was of a political/economic scandal.

As I have said before, individual articles and more limited analysis can provide a more simplified picture (Boholm, 2009). When analyzing a theme about risk over time, the picture becomes more complex. The analysis of the articles showed that, for cases of transfusion-transmitted infection, the coverage was connected with other issues of transfusion safety (and not merely to blood screening). An important link was made with voluntary blood donation. This issue was covered consistently by some newspapers (the more regular coverage was by *Rizospastis*) and was addressed particularly as a factor that could contribute to the minimizing of the risk of transfusion-transmitted infections. However, alternative public health policies to enhance voluntary blood donation, with reference to their cost and expected outcome, were not debated in relation to the implementation of NAT.

The same applies regarding the overall operation of the blood transfusion service in connection to policies regarding its reorganization and modernization. The news accounts referred to problems in the function of the blood transfusion service which comprised many services nationwide and lacked central control as well as to its understaffing. The processes on the reorganization of the service were, however, presented as public policy options. As mentioned in Chapter 4, the event of 2006 was crucial in causing a policy shift. Media and the political pressure influenced this shift from investing on the modernization of the blood transfusion service to the investment on the use of molecular screening of blood. The news discourse did not include discussions on policy alternatives and the allocation of the resources.

The lack of a broader discussion in the newspapers regarding the implementation of NAT (and, at the same time, the accounts concerning the screening technologies during the coverage of the cases of transfusion-transmitted infections) can be considered as a discourse legitimizing the political decisions. Although the central event was a crisis during which the government was considered accountable and blamed, the overall discourse about the molecular screening technology acted toward its legitimization and acceptance. The concentration on these issues obscured a possible discussion regarding the adoption of a costly new medical technology in terms of public health benefit. Since the implementation of NAT, described by Ministry of Health as the largest project ever made by the ministry, was not debated in the public sphere. The newspapers did not constitute a space for dialogue regarding a public health safety issue, nor did they provide a forum for alternative policy options.

Chapter 7: *Conclusion*

In this dissertation, I have presented my research on the introduction and use of a new technology in medicine: genetic screening technologies in the field of transfusion medicine and blood-banking. The central debate covered deals with the contrast between those who promoted the introduction of the new technology (NAT) and those who thought the available technology (ELISA) was adequate. The debate was rather complex, involving different versions of NAT and variations in its uses. There were even differences in the perception of the ELISA–NAT relationship, with some of the protagonists stressing the differences between the two, while others perceived them as complementary. The introduction of NAT quickly established a fact that all those involved could not transcend, leading to the focus of the contrast shifting from a comparison between ELISA and NAT to a comparison between different versions of NAT (and/or versions involving complementary uses of NAT and ELISA).

What interests me during the research and the writing that led to the present dissertation is not a narrative that concludes with a definite winner but one that seeks to understand the strategies of those who participated in the debate. As I understand it, my case confirms that it is both more accurate and meaningful to talk about a pattern of competing sociotechnical orientations rather than about a debate with definite winners and losers. In this sense, my dissertation adds to the understanding of this pattern by adding a case from biotechnology/biomedical/medical technology to studies of this pattern that covered competition between the old horse-drawn and the new engine-driven truck (as well as competition between older and newer versions of an engine-driving technology), the old high-wheeled and the new bicycle with even-size wheels, the new metallic and the old wooden airplane, the old analog and the new digital computer, the old picture-less phone and the new picturephone (Bijker, 1995; Lipartito, 2003; Mom & Kirsch, 2001; Schatzberg, 1994; Tympas, 2012).

In the case considered here, the main manifestations of the two competing orientations can be summarized in the following table:

Table 7.1 Summary of dissertation conclusions: competing blood screening technology orientations

	Existing technology: ELISA	New technology: NAT
Type	(Bio)chemical assays – serologic screening	Genetic assays – (bio)molecular screening
Risk object	Blood transfusion (blood as appropriated through the overall sociotechnical practice of blood screening and transfusion)	Blood as appropriated through the technology of blood screening
Technology	Less emphasis on technology	More emphasis on technology
	Sensitivity over range	Precision of risk estimation
	Explicit reference to sociotechnical trade-offs	Self-referential in regards to technology (zero risk approach for the technology of blood screening to be used)
Risk	Measuring/estimating residual risk with models	Modeling estimated risk to prove risk reduction
Goal	Patient safety/transfusion safety	Blood safety/zero risk
Proponents	Experts from the rankings of blood transfusion professionals	FDA, Companies (Roche, Gen-Probe/Chiron), the media (and experts connected to them)
Approach	Improving donor screening/improving the practice of transfusion	Shortening the window period of the blood screening technology
Cost-effectiveness	Cost-effective	Poor cost-effectiveness
Cost versus estimated benefits	Cost-benefit analysis comparing risk from blood transfusion due to the technology used in blood screening and the rest of blood transfusion practice	No such cost benefit analysis/comparison
	Cost-benefit analysis comparing the overall blood transfusion risks (risks due to the technology used in blood screening and the rest of the risks in blood transfusion practice) to other medical risks	No such cost benefit analysis/comparison
Allocation of resources	Alternative interventions in the field of transfusion medicine or other medical field, with higher anticipated benefit	Use of new technology (incremental anticipated benefit)

Plasma industry	Less compatible with market for (commercialization of) blood products (e.g. plasma products)	More compatible with market for (commercialization of) blood products (e.g. plasma products)
Control	Less centralized control of blood transfusion system	More centralized control of blood transfusion system

I have focused on contesting views regarding the possible use of technologies based on molecular biology diagnostics. I presented the debates regarding the use of these technologies, especially NAT, in the US and in Greece. By focusing on the debates that took place, I placed risk at the center of my analysis to discern the competing views with regard to the use of the technology. I suggest that "risk object" is a key STS concept for understanding the processes of the formulation of these opposing views. For my research, understanding the social construction of the object of risk played a major role in addressing the research questions set out in the first chapter.

In Table 7.1, I relate the technologies to the various issues that were part of the debates. The discussion about the use of genetic technologies in blood screening began in the aftermath of HIV crises, at a time of increased concerns regarding blood safety. At the time, the ELISA technology for donor and blood screening was well established. In the early 1990s, the risk of transfusion-transmitted HIV infection was reduced to such levels that it was not possible to measure it directly. For those involved in the field of blood transfusion, this led to great research efforts to estimate the risk by using risk modeling.

For the first group of actors (transfusion medicine physicians and blood bank professionals), the risk was considered low. The introduction of new technologies was not considered to be beneficial for blood transfusion safety. To them, I argue, the risk object, linked to the harm to the recipient of blood, was not the blood as appropriated through the technology of blood screening. Their approaches placed the overall process of blood transfusion as the risk object in the sociotechnical network of transfusion. To them, the precision of risk estimation of the blood screening technologies was useful, but not the parameter of the utmost importance. Having sensitivity over a range was more important.

For the regulatory agency (FDA) and the giant companies in the medical diagnostics sector, the production of risk estimates became part of the pursuit of the development of new screening technologies. Molecular screening technologies were to be developed to reduce the "window" period of serologic screening. This was entrenched within the technocratic goal of zero

risk in the use of technology for screening the blood supply. This approach emplaced blood as the risk object, and set blood safety as the goal. While the contestations took place, both groups of actors based their arguments on modeled "objective" estimates of risk. For the transfusion medicine physicians and blood bank professionals, the estimates of risk were further used to produce cost-effectiveness analyses that showed the poor ratio connected to the new technology. As a further step, they used a comparative approach to show the limited benefit of the new technology (NAT). More specifically, they compared the expected benefit of using the new technology to that expected by reducing the risks placed on other parts of the sociotechnical network of transfusion. In doing so, they showed that the use of NAT was not the best solution to reduce the overall risks of transfusion or other medical risks. Thus, they were against the use of NAT.

FDA and its allies managed to prevail in the definition of the risk object based on risk estimates produced by abstracted modeling. The "objective" risk produced as a "fact" by this modeling determined decision-making. In addition, the FDA and its allies rendered the cost-benefit analyses of their opponents irrelevant. As a result, they managed to enclose the risk object on their own network of control.

This network comprised of the following: the FDA, as the regulatory agency that influenced other actors on the alleged superiority of the new technology; the NHLBI, which co-formulated the national strategy to reduce the "window" period by funding the creation of commercial NAT; and two interested companies, which were given assurance that there would be demand in order to commercialize a new technology for blood screening. For the FDA, NAT technology had the preferred characteristics, compatible with the role of the agency and its need to extend control of the blood industry in the US. The network finally enclosed the blood bank professionals, once the use of the NAT technology became an imperative for the commercial selling of the "surplus" plasma from blood donations. This followed a decision by the European regulatory agency, which matched the goals of the FDA.

In the case of the sociotechnical network of blood transfusion with ELISA screening, the network focused on the social processes associated with donor screening and retention of regular volunteer blood donors; the human interactions among physicians, nurses, etc., and the patients; and the prevention of infectious diseases at the societal level. With the use of NAT, the sociotechnical network was bound to the costly technology, with fewer resources for other areas and great central control of the overall process.

The crucial event in Greece was a case of transfusion-transmitted infection that attracted attention to the risks involved. The media and the state authorities ascribed the goal of safety to NAT. This role played by the media was crucial in presenting NAT as a novel biotechnology and in connecting its use to the modernization of the blood transfusion service. The government and all political parties uniformly advocated the use of genetic technologies in blood screening. The relevant discussion did not permit consideration over the cost and benefit, nor did it allow for investing in the overall sociotechnical practice of blood transfusion.

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APPENDIX

A. Newspaper circulation

In the following three tables I present data regarding the average daily circulation numbers for three selected years (1999, 2006 and 2008) as retrieved from Athens Daily Newspaper Publishers Association (Ένωση Ιδιοκτήτων Ημερήσιων Εφημερίδων Αθηνών). The statistics on the newspapers circulation were retrieved from < http://www.eihea.com.gr/>.

*With light grey shading are indicated the newspapers included in the research presented in Chapters 5 and 6.

1999		
Newspapers (by type)	**Average daily circulation**	**Percentages**
Morning newspapers (include Sunday edition)		
I KATHIMERINI (Η ΚΑΘΗΜΕΡΙΝΗ)	48.043	49,19%
TO VIMA (ΤΟ ΒΗΜΑ)	33.469	34,27%
RIZOSPASTIS (ΡΙΖΟΣΠΑΣΤΗΣ)	11.666	11,94%
I AVGI (Η ΑΥΓΗ)	2.298	2,35%
ACROPOLIS (ΑΚΡΟΠΟΛΙΣ)	1.106	1,13%
I NIKI (Η ΝΙΚΗ)	672	0,69%
O LOGOS (Ο ΛΟΓΟΣ)	413	0,42%
TOTAL	**97.666**	**100,00%**
Afternoon newspapers (do not include Sunday edition)		
TA NEA (ΤΑ ΝΕΑ)	90.230	23,55%
ELEFTHEROTYPIA (ΕΛΕΥΘΕΡΟΤΥΠΙΑ)	72.023	18,80%
ETHNOS (ΕΘΝΟΣ)	52.659	13,74%
ELEFTHEROS TYPOS (ΕΛΕΥΘΕΡΟΣ ΤΥΠΟΣ)	47.374	12,36%
APOGEVMATINI (ΑΠΟΓΕΥΜΑΤΙΝΗ)	30.473	7,95%
EKSOUSIA (ΕΞΟΥΣΙΑ)	18.810	4,91%
ADESMEFTOS TYPOS (ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ)	15.576	4,07%
STO KARFI (ΣΤΟ ΚΑΡΦΙ)	13.566	3,54%
I VRADINI (Η ΒΡΑΔΥΝΗ)	9.370	2,45%
ELEFTHEROS (ΕΛΕΥΘΕΡΟΣ)	7.237	1,89%
ATHINAIKI (ΑΘΗΝΑΙΚΗ)	6.803	1,78%
ADESMEFTOS TYPOS (MHTSHS) [ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ (ΜΗΤΣΗΣ)]	5.870	1,53%
AVRIANI (ΑΥΡΙΑΝΗ)	5.734	1,50%
*ELEFTHERI ORA (ΕΛΕΥΘΕΡΗ ΩΡΑ) **	3.580	0,93%
ESTIA (ΕΣΤΙΑ)	3.483	0,91%

TO ONOMA (TO ONOMA)	358	0,09%
TOTAL	**383.146**	**100,00%**
Sunday newspapers		
TO VIMA TIS KYRIAKIS (ΤΟ ΒΗΜΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	194.748	21,70%
KYRIAKATIKI ELEFTHEROTYPIA (ΚΥΡΙΑΚΑΤΙΚΗ ΕΛΕΥΘΕΡΟΤΥΠΙΑ)	193.254	21,54%
ETHNOS TIS KYRIAKIS (ΕΘΝΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	159.130	17,73%
I KATHIMERINI TIS KYRIAKIS (Η ΚΑΘΗΜΕΡΙΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	128.329	14,30%
TYPOS TIS KYRIAKIS (ΤΥΠΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	92.272	10,28%
APOGEVMATINI TIS KYRIAKIS (ΑΠΟΓΕΥΜΑΤΙΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	31.033	3,46%
RIZOSPASTIS KYRIAKATIKOS (ΡΙΖΟΣΠΑΣΤΗΣ ΚΥΡΙΑΚΑΤΙΚΟΣ)	23.394	2,61%
ADESMEFTOS TYPOS KYRIAKATIKI EKDOSI (ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ ΚΥΡΙΑΚΑΤΙΚΗ ΕΚΔΟΣΗ)	21.769	2,43%
I VRADINI TIS KYRIAKIS (Η ΒΡΑΔΥΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	11.551	1,29%
ADESMEFTOS TIS KYRIAKIS (ΑΔΕΣΜΕΥΤΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	7.725	0,86%
ELEFTHEROS TIS KYRIAKIS (ΕΛΕΥΘΕΡΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	6.906	0,77%
AVRIANI KYRIAKATIKI (ΑΥΡΙΑΝΗ ΚΥΡΙΑΚΑΤΙΚΗ)	5.827	0,65%
ELEFTHERI ORA TIS KYRIAKIS (ΕΛΕΥΘΕΡΗ ΩΡΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	5.796	0,65%
I KYRIAKATIKI AVGI (Η ΚΥΡΙΑΚΑΤΙΚΗ ΑΥΓΗ)	4.726	0,53%
TO PARON (ΤΟ ΠΑΡΟΝ)	4.049	0,45%
I EPOXI (Η ΕΠΟΧΗ)	2.333	0,26%
PRIN (ΠΡΙΝ)	1.867	0,21%
ACROPOLIS KYRIAKIS (ΑΚΡΟΠΟΛΙΣ ΚΥΡΙΑΚΗΣ)	1.423	0,16%
I NIKI TIS KYRIAKIS (Η ΝΙΚΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	750	0,08%
O LOGOS TIS KYRIAKIS (Ο ΛΟΓΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	406	0,05%
TOTAL	**897.287**	**100,00%**

2006		
Newspapers (by type)	**Average daily circulation**	**Percentages**
Morning newspapers (*include Sunday edition)		
I KATHIMERINI (Η ΚΑΘΗΜΕΡΙΝΗ)	60.125	46,99%
TO VIMA (ΤΟ ΒΗΜΑ)	50.882	39,77%
RIZOSPASTIS (ΡΙΖΟΣΠΑΣΤΗΣ)	9.796	7,66%
TRAFFIC	2.844	2,22%
I AVGI (Η ΑΥΓΗ)	2.028	1,59%
ANO KATO (ΑΝΩ ΚΑΤΩ)	1.143	0,89%
ACROPOLIS (ΑΚΡΟΠΟΛΙΣ)	434	0,34%
I NIKI (Η ΝΙΚΗ)	357	0,28%
O LOGOS (Ο ΛΟΓΟΣ)	332	0,26%
TOTAL	**127.941**	**100,00%**
Afternoon newspapers (* do not include Sunday edition)		
TA NEA (ΤΑ ΝΕΑ)	67.660	24,45%

ELEFTHEROTYPIA (ΕΛΕΥΘΕΡΟΤΥΠΙΑ)	59.117	21,36%
ETHNOS (ΕΘΝΟΣ)	43.154	15,59%
ELEFTHEROS TYPOS (ΕΛΕΥΘΕΡΟΣ ΤΥΠΟΣ)	36.320	13,12%
ESPRESSO	18.609	6,72%
APOGEVMATINI (ΑΠΟΓΕΥΜΑΤΙΝΗ)	14.751	5,33%
ADESMEFTOS TYPOS (ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ)	10.242	3,70%
PRESS TIME	7.377	2,67%
ELEFTHEROS (ΕΛΕΥΘΕΡΟΣ)	6.124	2,21%
ESTIA (ΕΣΤΙΑ)	2.930	1,06%
I XORA (Η ΧΩΡΑ)	2.740	0,99%
AVRIANI (ΑΥΡΙΑΝΗ)	2.651	0,96%
I VRADINI (Η ΒΡΑΔΥΝΗ)	2.578	0,93%
*ELEFTHERI ORA (ΕΛΕΥΘΕΡΗ ΩΡΑ) **	2.346	0,85%
MESIMVRINI (ΜΕΣΗΜΒΡΙΝΗ)	175	0,06%
TOTAL	**276.774**	**100,00%**
Sunday newspapers		
PROTO THEMA (ΠΡΩΤΟ ΘΕΜΑ)	220.247	19,20%
TO VIMA TIS KYRIAKIS (ΤΟ ΒΗΜΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	207.575	18,10%
KYRIAKATIKI ELEFTHEROTYPIA (ΚΥΡΙΑΚΑΤΙΚΗ ΕΛΕΥΘΕΡΟΤΥΠΙΑ)	205.645	17,93%
I KATHIMERINI TIS KYRIAKIS (Η ΚΑΘΗΜΕΡΙΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	165.720	14,45%
ETHNOS TIS KYRIAKIS (ΕΘΝΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	147.312	12,84%
TYPOS TIS KYRIAKIS (ΤΥΠΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	43.560	3,80%
ESPRESSO TIS KYRIAKIS (ESPRESSO ΤΗΣ ΚΥΡΙΑΚΗΣ)	39.753	3,47%
RIZOSPASTIS KYRIAKATIKOS (ΡΙΖΟΣΠΑΣΤΗΣ ΚΥΡΙΑΚΑΤΙΚΟΣ)	25.071	2,19%
PRESS TIME TIS KYRIAKIS (PRESS TIME ΤΗΣ ΚΥΡΙΑΚΗΣ)	20.340	1,77%
I VRADINI TIS KYRIAKIS (Η ΒΡΑΔΥΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	12.469	1,09%
TO PARON (ΤΟ ΠΑΡΟΝ)	12.025	1,05%
APOGEVMATINI TIS KYRIAKIS (ΑΠΟΓΕΥΜΑΤΙΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	11.799	1,03%
ADESMEFTOS TYPOS KYRIAKATIKI EKDOSI (ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ ΚΥΡΙΑΚΑΤΙΚΗ ΕΚΔΟΣΗ)	9.312	0,81%
I XORA TIS KYRIAKIS (Η ΧΩΡΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	5.612	0,49%
TRAFFIC TIS KYRIAKIS (TRAFFIC ΤΗΣ ΚΥΡΙΑΚΗΣ)	4.622	0,40%
I KYRIAKATIKI AVGI (Η ΚΥΡΙΑΚΑΤΙΚΗ ΑΥΓΗ)	4.319	0,38%
ELEFTHERI ORA TIS KYRIAKIS (ΕΛΕΥΘΕΡΗ ΩΡΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	3.528	0,31%
AVRIANI KYRIAKATIKI (ΑΥΡΙΑΝΗ ΚΥΡΙΑΚΑΤΙΚΗ)	2.846	0,25%
I EPOXI (Η ΕΠΟΧΗ)	2.218	0,19%
PRIN (ΠΡΙΝ)	1.639	0,14%
TO PARASKINIO (ΤΟ ΠΑΡΑΣΚΗΝΙΟ)	686	0,06%
I NIKI TIS KYRIAKIS (Η ΝΙΚΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	367	0,03%
O LOGOS TIS KYRIAKIS (Ο ΛΟΓΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	340	0,03%
TOTAL	**1.147.005**	**100,00%**

2008		
Newspapers (by type)	**Average daily circulation**	
Morning newspapers (*include Sunday edition)		**Percentages**
I KATHIMERINI (Η ΚΑΘΗΜΕΡΙΝΗ)	52.764	46,47%
TO VIMA (ΤΟ ΒΗΜΑ)	45.581	40,14%
RIZOSPASTIS (ΡΙΖΟΣΠΑΣΤΗΣ)	9.484	8,35%
I AVGI (Η ΑΥΓΗ)	2.462	2,17%
TRAFFIC	1.717	1,51%
I NIKI (Η ΝΙΚΗ)	654	0,58%
ANO KATO (ΑΝΩ ΚΑΤΩ)	368	0,32%
O LOGOS (Ο ΛΟΓΟΣ)	299	0,26%
ACROPOLIS (ΑΚΡΟΠΟΛΙΣ)	215	0,19%
TOTAL	**113.542**	**100,00%**
Afternoon newspapers (* do not include Sunday edition)		
TA NEA (ΤΑ ΝΕΑ)	58.541	24,58%
ELEFTHEROTYPIA (ΕΛΕΥΘΕΡΟΤΥΠΙΑ)	46.416	19,49%
ETHNOS (ΕΘΝΟΣ)	41.670	17,50%
ELEFTHEROS TYPOS (ΕΛΕΥΘΕΡΟΣ ΤΥΠΟΣ)	31.512	13,23%
ESPRESSO	20.844	8,75%
APOGEVMATINI (ΑΠΟΓΕΥΜΑΤΙΝΗ)	11.813	4,96%
ADESMEFTOS TYPOS (ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ)	11.391	4,78%
ELEFTHEROS (ΕΛΕΥΘΕΡΟΣ)	5.602	2,35%
AVRIANI (ΑΥΡΙΑΝΗ)	3.589	1,51%
ESTIA (ΕΣΤΙΑ)	2.757	1,16%
I VRADINI (Η ΒΡΑΔΥΝΗ)	1.744	0,73%
*ELEFTHERI ORA (ΕΛΕΥΘΕΡΗ ΩΡΑ) **	1.235	0,52%
I XORA (Η ΧΩΡΑ)	1.014	0,43%
TOTAL	**238.128**	**100,00%**
Sunday newspapers		
PROTO THEMA (ΠΡΩΤΟ ΘΕΜΑ)	190.949	17,07%
TO VIMA TIS KYRIAKIS (ΤΟ ΒΗΜΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	190.278	17,01%
KYRIAKATIKI ELEFTHEROTYPIA (ΚΥΡΙΑΚΑΤΙΚΗ ΕΛΕΥΘΕΡΟΤΥΠΙΑ)	158.075	14,13%
I KATHIMERINI TIS KYRIAKIS (Η ΚΑΘΗΜΕΡΙΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	156.648	14,01%
ETHNOS TIS KYRIAKATIKI (ΕΘΝΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	125.077	11,18%
TYPOS TIS KYRIAKIS (ΤΥΠΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	90.669	8,11%
REAL NEWS	84.264	7,53%
ESPRESSO TIS KYRIAKIS (ESPRESSO ΤΗΣ ΚΥΡΙΑΚΗΣ)	35.085	3,14%
RIZOSPASTIS KYRIAKATIKOS (ΡΙΖΟΣΠΑΣΤΗΣ ΚΥΡΙΑΚΑΤΙΚΟΣ)	23.667	2,12%
TO PARON (ΤΟ ΠΑΡΟΝ)	13.758	1,23%
ADESMEFTOS TYPOS KYRIAKATIKI EKDOSI (ΑΔΕΣΜΕΥΤΟΣ ΤΥΠΟΣ ΚΥΡΙΑΚΑΤΙΚΗ ΕΚΔΟΣΗ)	10.483	0,94%

APOGEVMATINI TIS KYRIAKIS (ΑΠΟΓΕΥΜΑΤΙΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	8.725	0,78%
I KYRIAKATIKI AVGI (Η ΚΥΡΙΑΚΑΤΙΚΗ ΑΥΓΗ)	5.439	0,49%
TO ARTHRO (ΤΟ ΑΡΘΡΟ)	4.217	0,38%
AVRIANI KYRIAKIS (ΑΥΡΙΑΝΗ ΚΥΡΙΑΚΑΤΙΚΗ)	3.871	0,35%
I VRADINI TIS KYRIAKIS (Η ΒΡΑΔΥΝΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	2.811	0,25%
TO PARASKINIO (ΤΟ ΠΑΡΑΣΚΗΝΙΟ)	2.673	0,24%
ELEFTHERI ORA TIS KYRIAKIS (ΕΛΕΥΘΕΡΗ ΩΡΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	2.528	0,23%
TRAFFIC TIS KYRIAKIS (TRAFFIC ΤΗΣ ΚΥΡΙΑΚΗΣ)	2.509	0,22%
I EPOXI (Η ΕΠΟΧΗ)	2.339	0,21%
I XORA TIS KYRIAKIS (Η ΧΩΡΑ ΤΗΣ ΚΥΡΙΑΚΗΣ)	1.955	0,17%
PRIN (ΠΡΙΝ)	1.600	0,14%
I NIKI TIS KYRIAKIS (Η ΝΙΚΗ ΤΗΣ ΚΥΡΙΑΚΗΣ)	596	0,05%
O LOGOS TIS KYRIAKIS (Ο ΛΟΓΟΣ ΤΗΣ ΚΥΡΙΑΚΗΣ)	293	0,03%
TOTAL	**1.118.507**	**100,00%**

B. Full list of the newspaper articles

The following list includes all the articles that were gathered for the research performed and presented in chapters 5 and 6 of the dissertation. The articles are presented by newspaper and in chronological order. In the end of the list are presented the additional articles gathered for the specific dates 29 and 30 March 2006.

Τα Νεα (Τα Νέα)

Προσβλήθηκαν δύο ασθενείς από αφροδίσιο. (1973, June 9). *Τα Νεα,* p.1.

Προσβλήθηκαν δύο ασθενείς από αφροδίσιο. (1973, June 9). *Τα Νεα,* p.7.

Πόσο ασφαλείς είναι οι μεταγγίσεις αίματος. (1993, November 8). *Τα Νεα,* p.20-21. (Mairi Katsanapoulou, Stefanos Dianellos)

Επάρκεια ίσον ασφάλεια. (1993, Novemver 9). *Τα Νεα*, p.18. (Mairi Katsanapoulou)

Αποθήκευση-ανακύκλωση. (1993, Novemver 10). *Τα Νεα*, p.33. (Mairi Katsanapoulou)

Σιωπούσαν για το μολυσμένο αίμα. (1993, October 9). *Τα Νεα*, p.65.

Στο αρχείο οι μηνύσεις για το μολυσμένο αίμα. (1995, May 12). *Τα Νεα,* p.11.

Θα εντοπίζεται γρηγορότερα ο ιός του AIDS. (1995, August 12). *Τα Νεα,* p.20.

Εντοπισμός μολυσμένων με γρήγορο τεστ. (1995, November 28). *Τα Νεα*, p.43.

Μεταγγίσεις. (1995, December 29). *Τα Νεα*, p.39.

Για 10 χρόνια ακόμα θα σκοτώνει ανθρώπους το AIDS. (1996, July 30). *Τα Νεα*, p.28-29 *(Health 2-3)*. (Mairi Katsanapoulou)

Όλα όσα πρέπει να γνωρίζουμε για το AIDS. (1996, July 30). *Τα Νεα*, p.29 *(Health 3)*.

Αν χρειαστείτε αίμα, ας έχετε παρακαταθέσει το δικό σας. (1996, August 13). *Τα Νεα*, p.26 (*Health 2)*.

Βρεφος φορέας από μετάγγιση. (1999, January 15). *Τα Νεα*, p.21. (Roula Tsoulea)

Θα εντοπίζουν άμεσα τον ιό. (1999, January 18). *Τα Νεα*, p.38.

Πιο αυστηρός ο έλεγχος αίματος για ασφαλείς μεταγγίσεις. (1999, January 19). *Τα Νεα*, p.21.

2ο θύμα από μετάγγιση ζητεί μισό δισ. (1999, October 4). *Τα Νεα*, p.1.

Και 2ο θύμα από μετάγγιση. (1999, October 4). *Τα Νεα*, p.22. (Dionysis Nasopoulos)

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