Katerina Vlantoni

Title: Constructing notions of risk and safety in contemporary Greece: aspects of the introduction of biotechnology in the Greek network of blood banks

Abstract:
The recent introduction of molecular diagnostics in the Greek blood bank network represents the largest investment ever made in the Greek Public Health System. I concentrate on this case study in order to elaborate on the introduction of notions of risk and safety in contemporary Greece, and, also, in order to discuss issues of relevance to the introduction of biomedical technology in a country like Greece from a historical and sociological perspective. My focus is on understanding how risk and safety are interpreted and debated by different actors. For this purpose I perform research on the publications, reports and other work of doctors, medical professionals, and policy makers in Greece during the introduction of the new biomedical technology in blood screening. In addition, I discuss the public image of this biotechnology as it was portrayed in the Greek media (selected newspapers) during the same period.

During the 1990s in blood screening, the field of clinical microbiology and virology moved towards the incorporation of molecular technology. I focus on the introduction of a new technology of molecular biology the recent years which would complement (or replace) the techniques used previously in blood screening. The molecular diagnostics have been contested and debated internationally the previous decade and until they’ve begun being widely adopted. These debates deal with various arguments regarding the introduction of the new techniques in the different national settings. Therefore, I think it is important to examine the multiple facets of the introduction of this technology in Greece; as such an analysis would proliferate through a combination of primary sources. I concentrate on the construction of the various interpretations and negotiations of risk and safety as depicted in the aforementioned domains. The research is based on social studies of risk, enriched with approaches from the field of Science and Technology Studies, and History of Technology.

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A) Introduction

In this paper I shall introduce to some points from my PhD research, which is informed by approaches from the fields known as STS (Science, Technology, Society) and HSS/HTS (History, Science, Society and History, Technology, Society). My work is focused on the concept of risk in connection to medical and biomedical technologies. More specifically, I focus on the issue of blood safety in transfusion medicine, as this is related to issues surrounding biomedicine, biomedical technology and biotechnology. The introduction of molecular diagnostics in blood donation is presented as one of the largest investments ever made in the Greek Public Health System, and I use it in order to elaborate from an HTS-HSS/STS perspective on the introduction of biomedical technology and biotechnology in a country like Greece. The introduction of the biomedical technology under consideration in the Greek Blood Donation System lasted more than 5 years. Its importance was debated in the public sphere when an incident of HIV infections through blood transfusions occurred in 2006. My research comes to the Greek case after having paid attention to the international debates over the introduction of molecular diagnostics in blood transfusion systems during the last 15 years (since the middle of the ‘90s). In this presentation I shall focus on certain aspects of the Greek case.

I am interested in examining how the notions of risk and safety are constructed. The risk-related literature has been growing in a fast pace over the last decade. Stemming from the social sciences many approaches to risk have been developed. The work of Jane Summerton and Boel Berner has been very influential to my work. The authors suggest focusing on the question of how technological risks and uncertainties are constructed, negotiated and handled by different actors. From the field of STS, Wiebe Bijker explicitly notes in a recent book chapter that “(...) the often-used distinction between objective risk and risk perception does not hold. Risks cannot be conceptualised as an objective, quantifiable, context-independent phenomenon; and in makes no sense either to talk of the perception of such objective risks” 4. In addition, from the field of the history and social studies of medicine a lot of research has been developed regarding risk and uncertainty in medicine. Thomas Schlich suggests 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” 5 and at the end the decisions to be made regarding the acceptability of risks are political in nature.

Surrounding this discussion on the risk in blood transfusion is a parallel discussion on the public perception of risk, which apparently affects the implementation of Public Health policies in the western/developed world 6. There has been some research in other countries about the public perception of risk regarding blood transfusion (psychometric studies, and other). My focus is not on this type of

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2 A review of the social approaches to risk cannot be presented here due to the lack of space.
6 The issue of transfusion safety, and more specifically blood safety, is not uniformly worldwide and many contrasts exist among different parts of the world.
questions. This research is of great importance but these issues will not be addressed here. I concentrate on the investigation of the way the notions of risk and safety are constructed by certain actors, in the different contexts.

My primary material in this research is twofold. Through discourse and textual analysis I approach the publications of health practitioners in Greece. In addition, I examine the media coverage of the topic. I am dealing with the public image(s) of the technologies implemented in blood screening, and the public discussion about risk in Greece, as this is portrayed in the Greek media.

Concluding the introduction, I am presenting some results from my research on the international discussion on the case I am investigating in order to set the context. I have examined the debates and controversies regarding the introduction of molecular diagnostics (NAT – Nucleic Acid Techniques) since the middle of the 1990s. I have gathered and analysed international literature (from practitioners, professionals and scientists) on the topic that examines the introduction of the NAT techniques in different countries. I have attempted to follow their debate regarding the introduction of this new technology, and re-construct their argumentation on risk and blood safety.

From this research I have noticed that there have been considerable debates regarding the introduction of the molecular diagnostics in the blood screening in transfusion medicine. The main screening tests since the 1980’s have been the serological tests. Since the detection of a virus with these tests supposes the


10 Further research I plan to perform includes a series of interviews with practitioners in the Greek blood banks system. Furthermore, I consider that the analysis can proliferate through the examination of other relative groups which include patient groups (especially thalassemia patient groups) and blood donors associations.


12 The enzyme immunoassay (or enzyme-linked immunosorbent assay ELISA) is a biochemical technique designed to detect the presence of an antibody or an antigen in a sample. These assays have been used as
séroconversion of it, the time period from the infection until the development of detectable antibodies or antigens, is called “window period”. During this period a virus cannot be detected, and the blood is characterized as false negative\textsuperscript{13}. In blood screening, the field of clinical microbiology and virology moved towards the focus of molecular technology. The nucleic acid testing techniques (NAT) are gene-based and have been developed to screen blood for evidence of very recent and earlier viral infections (before the presence of antibodies or antigens)\textsuperscript{14}.

The debates regarding the introduction of NAT in blood screening can be summarized in the following points:
\begin{itemize}
  \item Poor cost-effectiveness: since the two techniques are complementary, the additional cost of introducing NAT is considered very high, and not comparable with other medical interventions.
  \item The resources could be committed to other interventions in transfusion medicine that are considered more cost-effective.
  \item The future developments in blood screening (pathogen and viral inactivation) could render the new test unnecessary and investment is questioned.
\end{itemize}

While I analysed the literature I noticed that notions of risk and safety are associated with different factors. At one hand we can discern a notion of objective risk that is connected to quantifiable measurements through mathematical and statistical modelling. Following this approach, we can consider the new available technology as superior regardless of other social and economic parameters. At the other hand, some clusters of researchers question the technology-driven decisions, as they consider the issue of risk in the wider context of transfusion medicine. I have attempted to show that the risk is not inherent in the techniques and irrespective to the variables considered.

\section*{B) In Greece}

\textit{The introduction of NAT in Greece}

The introduction of NAT in the Greek Blood Donation services did not happen uniformly in all the blood donation centres. Greece has not been a country that produces such technologies, nor being one of the first to implement it. Additionally, during the various stages of the implementation of the new screening technology, it received extensive media coverage.

The discussion about the introduction of NAT in the Greek blood transfusion services began, like in other European countries, at the beginning of 2000. However, the introduction of the NAT screening tests was not official instituted. At 2003, when it was still optional, NAT was implemented in a small number of hospitals which hosted blood bank centres. In 2005 the Presidential Decree 138/2005 involved the harmonisation of the Greek legislation with the provisions of the Directives 2002/98

\textsuperscript{13} These false negative samples constitute the residual risk of transfusion transmitted infections in blood transfusion (the probability that a potentially infectious donation will be released into the blood supply).

\textsuperscript{14} NAT detects a virus’s genetic material and for that reason offers the potential of reducing the window period.

The techniques that have been commercially developed in USA and Europe are the amplifying techniques of PCR (polymerase chain reaction) and TMA (transcription mediated amplification). NAT techniques can be applied in single samples, and in minipools (SD and MP NAT).
The same year a new law was voted in the Greek Parliament (3402/2005) for the reorganisation of the blood donation system, changing the regulatory framework through the creation of the National Centre of Blood Donation, which would be responsible for all the nationwide Blood Centres and Hospital based Blood Donation Services.

The initial plan of the nationwide implementation of the molecular diagnostic technology for the blood screening in Greece was planned through the creation of 14 blood centres. In the beginning of 2006, 8 centres had implemented the NAT screening techniques, whereas for the remaining 6 the Ministry of Health was planning the implementation during the same period. In March 2006 the media covered a story about an HIV transfusion transmitted infection in Greece. The infected blood was released from a centre that did not perform NAT screening. The event was a headline for many days and a public debate was evoked with repercussions on the public health policy procedures. Despite the promises for the acceleration of the NAT implementation in all the centres, this did not happen until 2008. Additionally, a new plan for the National Blood Donation scheme was presented, with the creation of 9 Blood Centres in which the blood from all the local blood banks would be tested. In August 2008 the Ministry of Health made an official announcement on signing a convention on the procurement of the NAT equipment for all the centres. Notably, the procurement procedures were also debated a lot in the Greek media and from the health practitioners because of the delays that were caused in the NAT implementation since the end of 2005. In Greece both commercial systems were implemented (PCR by Roche, and TMA by Gen-Probe).

The view of health practitioners in Greece:

The sources that I have examined in order to approach the arguments of the health practitioners in Greece are the following:

- Journal HAEMA (AIMA), *The Journal of the Hellenic Society of Haematology*
- Newsletter of the Hellenic Society of Clinical Chemistry and Clinical Biochemistry
- Bimonthly journal of the Greek Society of Microbiology
- The medical journal *Epitheorisi Ygeias*, a bimonthly interdisciplinary medical periodical

In these sources the results of my research were poor. Several articles were identified regarding various issues surrounding transfusion medicine. Only a few articles were dealing with the molecular diagnostics and the specific factors of the implementation of the new technique in Greece.

As I examined the journal *HAEMA* I noticed the lack of articles or reviews regarding the transition in haematology to molecular diagnostics in blood screening. The most relevant article identified is a review article titled “Transfusion-transmitted infections: epidemiology, risks and prevention”, in 2001. The introduction of NAT testing for the reduction of residual risks in blood transfusion was discussed with no particular reference to the context of its adoption in Greece. I spotted one more review article which discusses the transfusion risks and the authors suggest that more

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15 One is the National Centre of Blood Donation, and the other 8 are based on Hospital Blood Centres.
16 It is published by MediForce Services S.A. and it is available through subscription. It is addressed to health managers, doctors, pharmacists, engineers, qualified nurses, health technicians and laboratory staff, students of health science and health professions, and others.
attention needs to be paid toward addressing the issue of transfusion safety, than solely dealing with blood safety\textsuperscript{18}. I have identified this argument also in the international discussion.

In 2002 the Hellenic Society of Haematology held a daily educational conference on the topic ‘Molecular biology in blood donation’\textsuperscript{19}. On the contents we distinguish seven papers regarding the molecular diagnostic techniques on blood screening. Five of these articles present the ‘state of the art’ in molecular diagnostics with respect to HIV, HBV, HCV, other viruses, and other infectious agents\textsuperscript{20}. It is interesting to notice that there is no discussion about possible implementation of the techniques in Greece, especially in connection to local characteristics. The other two articles come from two haematologists (both are Directors of Blood donation Centres in Athenian Hospitals). L. Dadiotis is asking in the title ‘Serological screening with the supplement of NAT. Is that the message of Haemovigilance?’\textsuperscript{21} and he is discussing the estimation of the risks in a specific national, social and economic context, the protection measures that can be implemented, and the cost-effectiveness aspects, with respect to the pursuit of safe blood. Therefore, he is raising the importance of alternative approaches to transfusion safety in contrast to the technology driven shift towards the molecular diagnostics. He is also concluding with the significant role of the media in the presentation of blood donation cases. This argumentation has been encountered in the international debate. On other article M. Mosxou-Parara\textsuperscript{22} is discussing the various strategies toward the reduction of transfusion errors. In connection to the scientific and technological developments in transfusion medicine, she is reminding that there is still room for improvement in transfusion medicine by focusing to the everyday practices, meaning alternatives to the marginal advances in blood screening.

In the published proceedings of an educational seminar of the Hellenic Society of Clinical Chemistry and Clinical Biochemistry I have examined an article by N.Diakoumi-Spyropoulou\textsuperscript{23}. The author examines the molecular diagnostics (review of the technique) and discusses the possible introduction in Greece. She is addressing the issue of risk in connection to the multiple variables surrounding blood screening (for example cost-effectiveness, alternative solutions, and the issue of worldwide inequalities in blood safety).

In the journal of the Greek Society of Microbiology a research article was published in 2008 dealing with the results from the implementation of NAT. I have spotted also other research articles on the results and the yield of NAT screening in Greece (from various blood centres) published in medical journals, and medical conference proceedings.

\textit{Media coverage:}


\textsuperscript{19} Hellenic Society of Haematology (2002). Proceedings of educational conference “Molecular biology in blood donation” 13/12/2002. [In Greek].

\textsuperscript{20} The authors are two biologists, one biochemist, one clinical pathologist and one haematologist, all working in blood donation centres in Greece.

\textsuperscript{21} Ibid. p.81.

\textsuperscript{22} Ibid. p.105

\textsuperscript{23} Diakoumi-Spyropoulou N. (2005). Molecular Biology Techniques Τεχνικές in the screening of blood transfusion. Educational conference EEKX-KB (17/12/2005), κείμενα διαλέξεων, 142-156. [In Greek].
In order to examine the media coverage I have searched five newspapers. The selected newspapers are **Ta Nea** [Το Νέο] and **To Bima** [Το Βίμα] (both belong to the Lambrakis Press S.A.), **Kathimerini** [Καθημερινή], and **Rizospastis** [Ριζοσπάστης]24. The newspapers were chosen by the following criteria: a) their daily circulation, and b) covering the political spectrum.

Some important aspects from the research are the following. The first articles that I encounter regarding the use of molecular diagnostics in the blood bank setting are at the beginning of the year 1999. The possibility of the early adoption of these techniques in Greece is discussed. This discussion happens in connection to the reporting of a case of transfusion transmitted infection of HIV which occurred in 1998 and came into public in January 199925. This incident was discussed also during 2000. In these articles the techniques used in the blood donation systems are discussed in connection to blood safety and the residual risks.

The following years I have spotted some relevant articles dealing with various issues regarding transfusion medicine. In 2006 the issue of blood safety received media coverage when the newspaper **To Bima** (in 28/03/2006)26 published a front-page headline regarding an incident of transfusion transmitted infection of HIV to two patients (a 16 year old thalassaemic, multi-transfused girl, and another older patient)27. The incident occurred from the blood donation of the same donor (in window period donation) in the Ippokrateio hospital of Salonika28. The immediate period after the public disclosure of this incident I encounter many relevant articles, as the incident evoked a political and social discussion. Briefly here, I would like to refer to way the two techniques were presented. The first days I have noticed that the new technology (NAT) was presented as inherently superior to the previously used techniques, regardless the multifaceted dimensions of its implementation. In addition, the new technique was considered more advanced in the context of the ideology of the superiority of the biotechnologies and biomedical technologies in general. Risk and safety are used as opposites and the articles also discuss the possibility of ‘zero-risk’ in transfusion medicine and the opinion of experts. Some days later I come across articles that discuss the issue of blood safety in the context of transfusion safety. In these articles health professionals were interviewed and more positions were presented.

The following period the newspapers have frequent reports regarding the implementation of NAT all over the country. Another incident of HIV transfusion transmitted infection occurred in May 2005 in an 85-year old patient29. In this case

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24 I have searched these newspapers for the period 1996-2010, by using combinations of keywords. The results were examined and the relevant articles are: **Ta Nea** 45; **To Bima** 30; **Kathimerini** 40; **Rizospastis**, 81.


26 (2006, 28, March). Μετάγγιση θανάτου σε δεκαεξάχρονο κορίτσι! (Death transfusion to 16-yar old girl!), To Βήμα, 01.


28 SKAE (Hellenic Coordinating Haemovigilance Centre). **Summary Report.** Athens, 2008. SKAE report has data on the infections per donations tested.

the blood sample was tested with NAT (in minipools), but was released in the blood supply. In the media coverage of this incident we can see discussions about the techniques in detail.

Concluding remarks

By examining the publications of health practitioners in Greece and the media coverage with regards to the introduction of the molecular diagnostics in blood screening I am attempting to view how the notions of risk and safety are constructed and debated. I am focusing on the concept of risk as it is connected to the specific medical technologies. As far as the positions of the health practitioners are concerned more research needs to be done since the results have been poor until now. Regarding the media, I have identified a vast number of articles as the media coverage of the transition in blood screening has been extensive. The crucial event seems to be the 2006 case of the HIV transfusion transmitted infection.

In this attempt we can see opposing views. One somehow more technocratic, following the model of adopting technology based solutions that are connected to objective risk measurements. At the other hand, we came across approaches that concentrate also to the context and the variables surrounding the implementation of the new technology.

από παλιά μετάγγιση. Ο ιός ξέφυγε και απ’ το μοριακό έλεγχο ((HIV infection from old transfusion, the virus was not detected by NAT). Ριζοσπάστης, 21.