Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation
National Report Baseline Evaluation: Germany

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Zwischenbericht

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Contents

Zusammenfassung 1
Zielsetzung und Vorgehensweise ................................................................. 1
Ergebnisse .................................................................................................. 2
Schlussfolgerungen..................................................................................... 7

Summary 9
Goals and methodology ........................................................................... 9
Results ....................................................................................................... 10
Conclusions............................................................................................... 14

1. Introduction 15
1.1 Goals of the Report................................................................. 15
1.2 Methods and Data................................................................. 15
   1.2.1 Contents analysis of newspapers and magazines......................... 15
   1.2.2 Analysis of literature, reports and policy papers; expert interviews .... 17
   1.2.3 Secondary analysis of opinion polls ........................................ 17
1.3 Overview of relevant regulations..................................................... 18
   1.3.1 Supranational Law .................................................................... 18
   1.3.2 European Law/regulations ........................................................ 18
      1.3.2.1 European Union ................................................................. 18
      1.3.2.2 Council of Europe ............................................................. 19
   1.3.3 National Regulations ............................................................... 19
      1.3.3.1 Federal Law ........................................................................ 19
      1.3.3.2 Regulations and Guidelines put up by the German Medical Association 20

2. Form of the National XTP Debate 21
2.1 In which social context is XTP being debated?................................. 21
   2.1.1 Overview .................................................................................. 21
   2.1.2 Media ....................................................................................... 22
2.2 In which form (procedure) is XTP being debated?............................. 25
2.3 Which competencies and methodologies did national and local committees use to evaluate the ethical impact of XTP? ................................................................. 30
2.4 How do actors think that ethical issues of new technologies can/should be debated in public? ................................................................................................................................. 31

3. Contents of the Debate........................................................................................................ 32

3.1 In which context is XTP primarily debated (e.g. transplantation, animal rights)? How is XTP framed as a problem? ...................................................................................................................... 32
  3.1.1 German XTP arena......................................................................................................... 32
  3.1.2 Media analysis ............................................................................................................... 33

3.2 Which position do relevant actors take? What are their positions, interests and resources? 41
  3.2.1 Cluster of biomedical XTP research ............................................................................. 41
  3.2.1.1 Hanover region ........................................................................................................ 42
  3.2.1.2 Munich region ......................................................................................................... 43
  3.2.1.3 Charité, Berlin .......................................................................................................... 43
  3.2.1.4 Medical School of Würzburg .................................................................................... 44
  3.2.1.5 Robert Koch Institute and Paul Ehrlich Institute .................................................... 44
  3.2.1.6 Scientific Societies .................................................................................................. 45
  3.2.1.7 German Medical Association .................................................................................. 46
  3.2.1.8 Positions within the biomedical cluster .................................................................... 47

  3.2.2 Humanities cluster ...................................................................................................... 47
  3.2.2.1 Chair for Ethics in the Life Sciences at the Eberhard Karls University of Tübingen ....... 48
  3.2.2.2 Research group "Technology Assessment of Modern Biotechnology in Medicine/ Neurobiology" at the University of Hamburg ......................................................... 48
  3.2.2.3 European Academy for the Study of Consequences of Scientific and Technological Advance Bad Neuenahr-Ahrweiler GmbH .......................................................... 49
  3.2.2.4 Institute Technology – Theology – Natural Sciences ................................................ 50
  3.2.2.5 Philosophical Seminar of the University of Münster, argos Institute Münster ............................................................................................................................ 51
  3.2.2.6 Institute of Ethnology at the University of Göttingen .............................................. 51
3.2.2.7 Chair for Criminal Law and Criminal Trial Law at the Georg August University of Göttingen

3.2.2.8 Institute of Jurisprudence at the University of Lüneburg

3.2.3 NGOs in the field of animal welfare and genetic engineering

3.2.4 Industry

3.2.5 Parties, policy and administration (ministries and agencies)

3.2.5.1 Initiatives on the level of the Federal Parliament (Bundestag)

3.2.5.2 Initiatives on the level of federal states

3.2.6 Churches

3.2.7 Public

3.2.7.1 Attitude towards organ transplantation

3.2.7.2 General attitude towards organ transplantation

3.2.7.3 Attitude towards organ donation

3.2.7.4 Willingness to serve as organ donor

3.2.7.5 Attitude towards different treatment options within transplantation medicine, among them xenotransplantation

3.2.7.6 Attitudes towards applications of genetic engineering, among them xenotransplantation

3.2.7.7 Attitudes towards xenotransplantation in a citizens’ forum

3.2.8 Patients

3.3 Which ethical questions are raised on the various levels in the XTP debate?

3.4 Which solutions are being debated or have been taken?

4. Actors of Debate

4.1 Which actors are involved in the debate? In which form are they involved?

4.1.1 Media analysis

4.2 Which potential actors are excluded/do not participate? Why?

4.3 Which particular coalitions between actors do exist?

4.4 How do international actor-networks influence the discussion on ethical aspects of XTP?
5. What are the expectations of the participants of the Neosocratic Dialogue?

6. Which actors could participate in the Neosocratic Dialogue?

7. Cited Literature
Zusammenfassung

Zielsetzung und Vorgehensweise

Das Projekt "Stärkerer Einbezug der Öffentlichkeit in Diskurse über ethische Fragen der Xenotransplantation (XENO)" hat das Ziel auszuloten, inwieweit das Instrument des Neo-Sokratischen Gesprächs geeignet erscheint, ethische Fragen in der gesellschaftlichen Debatte über die Xenotransplantation zu erörtern. Diese Untersuchung wird parallel in Österreich, Spanien und Deutschland durchgeführt. Das Projekt gliedert sich in die folgenden Schritte:

1. Charakterisierung der gesellschaftlichen Debatte über die Xenotransplantation in den drei untersuchten Ländern,
2. Länderspezifische Konzeption und Organisation der Neo-Sokratischen Gespräche,
3. Durchführung und begleitende Evaluierung von je zwei Neo-Sokratischen Gesprächen pro Land,
4. Länderspezifische und länderübergreifende Auswertung der Erfahrungen und Ergebnisse aus den Neo-Sokratischen Gesprächen,
5. Information der relevanten Akteure über die Projektergebnisse,

Mit diesem Bericht werden die Ergebnisse des ersten Arbeitsschrittes für Deutschland vorgelegt. Ähnliche Berichte liegen auch für Österreich und Spanien vor. Ziel dieses Arbeitsschrittes ist es,

- die gesellschaftliche Debatte über die Xenotransplantation in Deutschland zu charakterisieren,
- Faktoren zu identifizieren, die Form, Inhalt und Verlauf der Debatte beeinflussen,
- mögliche Teilnehmer für die geplanten Neo-Sokratischen Gespräche zu identifizieren und ihre Haltung zur Xenotransplantation darzustellen,
- mögliche Themen für die geplanten Neo-Sokratischen Gespräche zu identifizieren, sowie Hinweise für die Ausgestaltung dieser Gespräche zu erhalten.

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1 Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation (XENO), Contract No. HPRP-CT-2001-00013
In diesem Arbeitsschritt wurden folgende Methoden eingesetzt:

- Inhaltsanalyse von Presseartikeln zur Xenotransplantation in ausgewählten, auflagenstarken bundesdeutschen Tageszeitungen und Nachrichtenmagazines,
- Analyse von Positionspapieren, Stellungnahmen, Projektberichten, parlamentarischen Initiativen etc. zur Xenotransplantation,
- Sekundäranalyse von Meinungsumfragen mit Relevanz für die Xenotransplantation,
- Auswertung von Erkenntnissen aus Vorläuferprojekten unseres Instituts zur Xenotransplantation.

Ergebnisse


Über die mediale Berichterstattung hinaus wurde das Thema Xenotransplantation in Deutschland in vielfältigen Formen und Kontexten von unterschiedlichen Akteuren thematisiert; hierzu wurden formelle und informelle, dauerhafte und temporäre Arbeitsgruppen gebildet, die mehrere Dokumente (Stellungnahmen, Positionspapiere, Berichte, etc.) zu diesem Thema erarbeitet haben. Eine gesellschaftliche Debatte hat sich in dieser Intensität und Differenziertheit weder in Spanien noch in Österreich entwickelt, wohl aber in anderen Ländern (z. B. Großbritannien, USA, Schweiz) sowie auf supranationaler Ebene (z. B. Weltgesundheitsorganisation – WHO, Organisation für wirtschaftliche Zusammenarbeit und Entwicklung – OECD, Europarat – Council of Europe), so dass Deutschland nur innerhalb der in diesem Projekt untersuchten Länder eine besondere Stellung einnimmt, nicht aber im internationalen Vergleich.

Die gesellschaftliche Debatte über die Xenotransplantation findet in Deutschland in einer Arena statt, die durch die Sichtweisen zweier komplementärer Cluster geprägt wird, dem Transplantationsmedizin/Naturwissenschaften-Cluster sowie dem Geisteswissenschaften-Cluster. Jeder dieser Cluster setzt sich aus einer spezifischen "Community" zusammen, die

Abbildung z1: Akteurscluster und ihre Interaktionen in der deutschen Xenotransplantationsarena

Form, Inhalt und Verlauf der Debatte über Xenotransplantation wird – sowohl in Deutschland als auch international – ganz wesentlich durch den Transplantationsmedizin/Naturwissenschaften-Cluster geprägt. Er umfasst diejenigen Akteure, die die Entwicklung und Anwendung der Xenotransplantation zum Ziel haben:

• **Naturwissenschaftler.** Für die Realisierung der Xenotransplantation sind Immunologen essenziell, die die Kontrolle der Abstoßungsprozesse bei der Organtransplantation untersuchen sowie Molekularbiologen und Veterinärmediziner, die gentechnisch veränderte Tiere als Organquelle für die Xenotransplantation bereitstellen. Soll Xenotransplantation klinische Realität werden, sind die Transplantationsmediziner auf die Zuarbeit dieser naturwissenschaftlichen Disziplinen zwingend angewiesen; umgekehrt stellt die Aussicht auf eine klinische Anwendung der Xenotransplantation eine Zielorientierung für die Forschungsarbeiten dieser naturwissenschaftlichen Disziplinen dar und ermöglicht die Erschließung zusätzlicher Forschungsressourcen. Dementsprechend besteht eine enge Kooperation dieser Naturwissenschaftler mit den Transplantationsmedizinern. In Deutschland sind diese Wissenschaftler vor allem an öffentlichen Forschungseinrichtungen tätig, die an Universitäten und Universitätskliniken, aber auch in der Ressortforschung des Landwirtschaftsministeriums angesiedelt sind. Eine weitere Gruppe der Naturwissenschaftler stellen die Virologen dar. International hatten Virologen Mitte der 1990er Jahre eindringlich davor gewarnt, dass durch Xenotransplantationen möglicherweise Pandemien ausgelöst werden könnten. In der Folge wurden erste klinische Anwendungen der Xenotransplantation, die unmittelbar bevorzustehen schienen, nicht genehmigt. Deshalb entwickelte sich sowohl international als auch in Deutschland zunächst ein Konflikt zwischen den Transplantationsmedizinern und den Virologen. Hierzu trug auch bei, dass die Virologen (zunächst) außerhalb des etablierten Systems der Transplantationsmedizin standen, in dessen Rahmen sich die Entwicklung der Xenotransplantation bis dahin vollzogen hatte, in Wechselwirkung mit
der Politik aber erheblichen Einfluss auf die Gestaltung der Rahmenbedingungen für die Xenotransplantation, die Verteilung der Ressourcen und die zeitliche Entwicklung der Xenotransplantation gewannen. In Deutschland wurde der potenzielle Einfluss der Virologen auf die Entwicklung der Xenotransplantation durch die institutionelle Anbindung der führenden Arbeitsgruppen unterstrichen, die sich mit virologischen Aspekten der Xenotransplantation befassen: sie sind in behördlichen Forschungs--instituten angesiedelt, deren Aufgabe es ist, das Gesundheitsministerium in allen Fragen der Epidemiologie und des Infektionsschutzes zu beraten. Weitere Arbeitsgruppen befinden sich in öffentlichen Forschungseinrichtungen an Universitäten. Durch intensive Kommunikation zwischen diesen ursprünglich rivalisierenden Gruppen gelang es jedoch, sehr viel realitätsnähere, weniger durch Euphorie bzw. Schreckensszenarien geprägte Sichtweisen auf die Erfolgsaussichten, Risiken und Optionen im Umgang mit der Xenotransplantation zu entwickeln, die von beiden Gruppen gemeinsam getragen und vertreten werden, so dass der ursprüngliche Konflikt heute weitgehend beigelegt ist.


Innerhalb des Transplantationsmedizin/Naturwissenschaften-Clusters hat sich in den letzten Jahren folgende gemeinsam getragene Position zur Xenotransplantation entwickelt: Xenotransplantation wird als eine zumindest akzeptable, teilweise auch als anzustrebende Option zur Behebung des Mangels an menschlichen Spenderorganen in der Transplantationsmedizin angesehen. Allerdings sei eine klinische Anwendung noch verfrüht. Es sei eine weitere Erforschung erforderlich, um eine langfristige Funktion der Xenotransplantate im Empfänger und die mikrobiologische Sicherheit für die Bevölkerung sicherzustellen. Regulierungen und Richtlinien sollten international entwickelt und aufeinander abgestimmt werden. Vor dem Schritt zu einer klinischen Anwendung müssten Nutzen und Risiken sowohl

Diese gemeinsam getragene Position ist das Resultat eines schwierigen und mehrere Jahre dauernden Prozesses, in dem sich zwei verschiedene wissenschaftliche Kulturen einander annähern mussten, die sich in ihrem beruflichen und kulturellen Hintergrund, ihren Erfahrungen, Motiven, Zielen und ihrem beruflichen Selbstverständnis unterscheiden. In diesem Prozess wurden auch Positionen und Sichtweisen integriert, die ursprünglich von Vertretern des Geisteswissenschaften-Clusters (s. u.) in die Debatte eingebracht worden waren, deren Aufgreifen aber zur Erzielung von gesellschaftlicher und politischer Toleranz der Xenotransplantation essenziell erschien. Durch diese letztlich gelungene interdisziplinäre Integration stellt sich der Transplantationsmedizin/Naturwissenschaften-Cluster heute als derjenige dar, dessen Sichtweise in der gesellschaftlichen Debatte am stärksten vertreten ist und der sie damit am stärksten prägt.

Der Geisteswissenschaften-Cluster umfasst universitäre Lehrstühle und öffentliche Forschungseinrichtungen, die in den Disziplinen Ethik, Philosophie, Rechtswissenschaften und Technikfolgen-Abschätzung mit Schwerpunkt auf bioethischen und biomedizinischen Fragestellungen tätig sind. In diesen Einrichtungen wurde die Xenotransplantation auf eine Art und Weise betrachtet, die weitgehend komplementär zu der des Transplantationsmedizin/Naturwissenschaften-Clusters ist: Der Geisteswissenschaften-Cluster thematisierte zusätzlich die Akzeptabilität der Xenotransplantation – grundsätzlich bzw. im Vergleich zu Alternativen zur Behebung des Organmangels; tierethische und tierschützerische Aspekte; psychologische Aspekte und Auswirkungen auf die Identität bei Xenotransplantatempfängern; Nutzen und Risiken für die allgemeine Bevölkerung; Allokationsfragen auf individueller, nationaler und internationaler Ebene; normative Fragen in der Regulierung der Xenotransplantation; das Verhältnis des Menschen zu seinem Körper, zu Gesundheit und Krankheit, zu Leben und Tod, zu Mensch und Tier; die sozialen Netzwerke, in denen sich Xenotransplantation entwickelt; sowie den historischen und kulturellen Hintergrund der Organtransplantation.

Das Verhältnis zwischen dem Geisteswissenschaften-Cluster und dem Transplantationsmedizin/Naturwissenschaften-Cluster ist schwierig, obwohl sich Vertreter der jeweiligen Cluster kennen, häufig (auf Veranstaltungen) treffen, ihre Standpunkte ausgetauscht haben und auch der Transplantationsmedizin/Naturwissenschaften-Cluster Sichtweisen und Argumentationen des Geisteswissenschaften-Clusters in dem Maße integriert hat, das erforderlich war, um gesellschaftliche und politische Toleranz für die Xenotransplantations-Forschung zu erzielen. Da die Xenotransplantation-Debatte national und international
insbesondere in dem institutionellen Rahmen der Transplantationsmedizin verläuft, ist es für Vertreter des Geisteswissenschaften-Clusters schwierig, Zugang zu und Einfluss in diesem System zu gewinnen, insbesondere, wenn sie der Xenotransplantation kritisch gegenüberstehen.

Politik und Ministerien weisen der Xenotransplantation mittlere bis geringe Priorität zu. In Abhängigkeit vom Kontext greifen sie sowohl auf Repräsentanten des Transplantationsmedizin/Naturwissenschaften-Clusters als auch des Geisteswissenschaften-Clusters zurück. In internationale Komitees, die sich mit der Entwicklung supranationaler Richtlinien für die Xenotransplantation befassen, wurden Angehörige des Transplantationsmedizin/Naturwissenschaften-Clusters entsandt, um Deutschland zu repräsentieren. Darüber hinaus wird eine Regulierung der Xenotransplantation in Deutschland angestrebt.

Schlussfolgerungen

Summary

Goals and methodology

The project "Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation (XENO)\(^2\)" has the goal to find out to which extent the instrument of Neo-Socratic Dialogue appears suitable for discussing ethical aspects of xenotransplantation in public debate. This analysis is carried out in parallel in Austria, Spain and Germany. The project comprises the following steps:

1. Characterization of public debate of xenotransplantation in the three countries investigated,
2. Country-specific design and organisation of Neo-Socratic Dialogues,
3. Realization and parallel evaluation of two Neo-Socratic Dialogues per country,
4. Country-specific and cross-country assessment of the experiences with and results from the Neo-Socratic Dialogues,
5. Information of relevant stakeholders about the project results,
6. Monitoring of the international development of xenotransplantation.

This report presents the results of the first working step for Germany. Similar reports have been prepared for Austria and Spain. Goals of this working step are

- to characterize the public debate of xenotransplantation in Germany,
- to identify factors which influence form, contents and course of the debate,
- to identify possible participants for the planned Neo-Socratic Dialogues and to outline their positions towards xenotransplantation,
- to identify possible issues for the Neo-Socratic Dialogue and to obtain information how to design these dialogues appropriately.

The following methodology was applied in the first working step:

- Contents analysis of press articles on xenotransplantation published in selected German daily newspapers and weekly magazines with high circulation,

\(^2\) Contract No. HPRP-CT-2001-00013
• Analysis of position papers, statements, project reports, parliamentary initiatives etc. on xenotransplantation,
• Secondary analysis of opinion polls with relevance for xenotransplantation,
• Analysis of information obtained during previous xenotransplantation projects of our institute.

Results

Since 1995, when significant scientific breakthroughs were achieved in xenotransplantation research, a public debate of this topic has evolved in Germany. This public debate is reflected in the media response of xenotransplantation: a total of 112 press articles were identified in six selected German print media in the period from January 1995 to July 2002. So, similar attention is devoted to the xenotransplantation topic by the German, Austrian and Spanish print media. However, the media coverage of xenotransplantation is dwarfed by the attention which German media pay to the topic of "Human embryonic stem cells". This topic has received extraordinary publicity in Germany over the last years – more than 1,800 articles on stem cells were published from 2000 to 2002.

In addition to the media reports the topic of xenotransplantation was addressed by different stake-holders in a broad variety of forms and contexts in Germany; formal and informal, long- and short term working groups were formed which worked out several documents (e. g. statements, position papers, reports etc.) on xenotransplantation. A public debate of similar intensity and sophistication has developed neither in Spain nor in Austria, but has emerged in other countries (e. g. United Kingdom, USA, Switzerland) and on a supranational level (e. g. World Health Organisation – WHO, Organisation for Economic Cooperation and Development – OECD, Council of Europe). Therefore, Germany holds a special position among the countries under investigation in this project but not in a broader international perspective.

The public debate of xenotransplantation in Germany takes place in an arena which is shaped by the views of two complementary clusters, the transplantation medicine/natural sciences cluster and the humanities cluster. Each of these clusters is made up by a specific community which has evolved its own lines of argumentation and positions towards xenotransplantation. Sceptical to disapproving attitudes towards xenotransplantation are most likely to be encountered in the humanities cluster. In addition, it has closer relationships to non-governmental organisations which take a critical to disapproving stance towards genetic engineering or stand in for animal welfare, respectively, than the transplantation medicine/natural sciences cluster. Policy and administration take an intermediate position and – depending on the context – make use of expertise from both the transplantation medicine/natural sciences cluster and the humanities cluster. To sum up, the public German xenotransplantation debate can be characterised as an expert debate. Its course and results
are made available to the interested public via media and print publications. Patients, the general population and non-governmental organisations play a more recipient and marginal role. Figure s1 gives a schematic overview.

**Figure s1: Stakeholders’ cluster and their interactions in the German xenotransplantation arena**

Source: ISI Research 2002

Form, contents and course of the xenotransplantation debate is shaped significantly by the transplantation medicine/natural sciences cluster – internationally as well as in Germany. This cluster comprises players whose goal is the development and application of xenotransplantation:

- **Transplantation surgery.** Members of this group are located at transplantation centres at university hospitals and are part of the established system of organ transplantation and its regulation. This group is of opinion that xenotransplantation is a scientifically-technically very challenging, yet very promising option for solving the very serious problem of donor organ shortage. In comparison with other options for alleviating donor organ shortage xenotransplantation has the advantage that it could be neatly integrated into the established structures and processes of transplantation surgery and could be applied “universally” for all organ failures despite their different causes. In addition, xenotransplantation offers the potential to extend surgery to indications which are traditionally not treated surgically (e.g. diabetes, Parkinson’s disease). Members of this
stakeholders’ group feel especially devoted to the ethical goal of helping and curing and give special emphasis to the well-being and benefit of the individual patient. Relating to ethical aspects of xenotransplantation, this group is anxious to develop practical solutions to ethical problems which arise in case of clinical application of xenotransplantation.

- **Natural sciences.** If xenotransplantation is to be realised one day, the involvement of immunologists is essential who investigate the control of rejection processes in organ transplantation, and also of molecular biologists and veterinarians who provide genetically engineered source animals. for the clinical implementation of xenotransplantation, transplantation surgeons absolutely depend on these disciplines from the natural sciences. Conversely, the prospect of clinical xenotransplantation provides a research goal for the natural sciences in this field, and also opens up the opportunity to tap additional resources for research. Accordingly, there are close cooperations between these natural scientists and transplantation surgeons. In Germany, these natural scientists work predominantly in public research institutions which are located at universities or university hospitals, but also at a research institute of the Ministry of Agriculture.

- Another group of natural scientists are virologists. It were the virologists who had urgently warned against xenotransplantation internationally in the mid1990s as xenotransplantations which seemed to be imminent at that time could not obtain approval. Both internationally and also in Germany, a conflict between transplantation surgeons and virologists arose. Among others, this conflict was fuelled – among other reasons – by the fact that virologists (initially) were not part of the established system of organ transplantation which had provided the frame for xenotransplantation development so far, but in interaction with politics gained significant influence on shaping the frame conditions for xenotransplantation, the allocation of resources and the speed of xenotransplantation development. In Germany, the potential influence of the virologists on xenotransplantation development was underlined by the institutional location of the leading virological research groups: they are located in administrative research institutes which have the task to give advice to the German Ministry of Health in all questions concerning epidemiology and prevention of infectious diseases. Additional research groups are located at public research institutes at universities. Due to intensive communication, these initially rivaling groups succeeded in developing common positions regarding chances of success, risks and options in dealing with xenotransplantation which were much closer to reality, less euphorical or scaremongering than in the beginning. Today, the initial conflict has been settled to a great extent.
• **Industry.** The globally active company Novartis, based in Switzerland, holds a key position in xenotransplantation development. Through its daughter companies (initially Imutran, UK; now Immerge BioTherapeutics, USA) and cooperation partners in all relevant scientific disciplines has been one of the main drivers of xenotransplantation development and its most important sponsor. Due to its prominent position and by the allocation of research resources (money, transgenic source animals, samples from xenograft recipients), it significantly influences which research groups can carry out publishable xenotransplantation research. Moreover, the company has considerable influence on the shaping and harmonisation of the legal framework for xenotransplantation: by its striving for clinical xenotransplantation, it challenges the administration in charge to act. In addition, it uses its leading position at the forefront of xenotransplantation research in order to establish its way to handle xenotransplantation as a regulatory standard and as a benchmark for its competitors. As a consequence, representatives of Novartis are present in all relevant negotiations and international committees. The company has businesses in Germany, cooperates with German research groups and influences the German public xenotransplantation debate indirectly via these groups.

Within the transplantation medicine/natural sciences cluster, the following common position was developed over time: xenotransplantation is seen as an at least acceptable, or desirable option, respectively for alleviating the shortage of human donor organs in transplantation surgery. However, a clinical application would be premature. Further research is required in order to guarantee long-term functionality of xenografts in the recipient and microbiological safety for the general population. Regulations and guidelines should be developed and harmonised internationally. Before clinical application, benefits and risks both for the individual patient and the general population should be considered carefully and thoroughly. One is fully aware that it is a must that this decision must be supported by the general public. However, there is no common opinion within this cluster which importance and commitment should be assigned to such a public debate and how it should be shaped regarding participants, institutionalisation, issues and legitimation.

This common position is the result of a difficult process which lasted several years. This process required the joining of two different scientific disciplines with their specific professional and cultural background, their experience, motivations, goals, and the image one has of oneself or one’s profession, respectively. During this process, positions and lines of argumentation were also integrated which had initially been brought into the debate by representatives of the humanities cluster, and which seemed to be essential in order to gain political and social tolerance of xenotransplantation. Due to this finally successful interdisciplinary integration, it is the transplantation medicine/natural sciences cluster which is most prominently represented in the public debate and which thus shapes it most strongly.
The **humanities cluster** comprises academic chairs and public research institutions which are active in the disciplines of ethics, philosophy, jurisprudence, technology assessment, with a focus on bioethical and biomedical issues. These institutions adopted a thematic and methodological approach which was largely complementary to the transplant surgeons' natural scientists' one: the humanities cluster also extended the debate to the acceptability of xenotransplantation as such and in comparison to alternatives; animal welfare issues; psychological/identity issues; benefits and risks for the general public; allocation problems on individual, national and international level; normative questions in law; questions of life and death; the relation of man to his own body and to animals; alternatives to xenotransplantation, social networks in which xenotransplantation evolves; as well as the historical and cultural backgrounds of organ transplantations.

Although representatives of the humanities cluster and the transplantation medicine/natural sciences cluster have rather frequent contacts (e.g. during workshops and symposia), know each other, have exchanged their individual positions, and although the transplantation medicine/natural sciences cluster has integrated lines of argumentation of the humanities cluster to an extent which was essential for social and political tolerance of xenotransplantation, the relation between these two clusters is difficult. Due to the fact that the xenotransplantation debate takes place within the institutional setting of transplantation medicine, it is difficult for representatives of the humanities cluster to gain access and influence in this system, especially if they take a critical stance towards xenotransplantation.

**Policy and ministries** have assigned medium to low priority to xenotransplantation. Depending on the context, they make use both of representatives from the transplantation medicine/natural sciences cluster as well as the humanities cluster. Members of the transplantation medicine/natural sciences cluster have been chosen as German delegates to international committees which have the task of developing supranational guidelines for xenotransplantation. In Germany, it is planned to regulate xenotransplantation also on national level.

**Conclusions**

In summary it may be said that for years, a much more differentiated debate has evolved in Germany in comparison with Austria and Spain, and stable actor constellations and coalitions have formed. Therefore, the planned Neo-Socratic Dialogues will take place against a different background than in Austria and Spain. Interesting results regarding possibilities and limits of this instrument in cross-country comparison can be expected.
1. Introduction

1.1 Goals of the Report

The baseline evaluation has the following objectives within the XENO project:

1. To analyse the current xenotransplantation (XTP) discourse in Austria, Germany and Spain.
2. To identify factors which might influence the debate of the current XTP discourse in Austria, Germany and Spain.
3. To identify actors for the Neo Socratic Dialogue (NSD) and to analyse their position towards XTP.
4. To produce a base-line-report on current XTP debates for the Neo Socratic Dialogue, the evaluation of the Neo Socratic Dialogue and the follow-up-evaluation.
5. To identify issues for the NSD.

This report summarises the results of the German baseline evaluation and therefore covers the German part of the above mentioned topics.

1.2 Methods and Data

The methods used in the baseline evaluation are

1. contents analysis of newspapers and magazines,
2. analysis of literature, reports and policy papers,
3. previous studies on XTP in Germany carried out by our institute which included interviews with relevant actors, participation in symposia, conferences and workshops on XTP,
4. secondary analysis of opinion polls.

1.2.1 Contents analysis of newspapers and magazines

Five print media were chosen for analysis (table 1.1): three daily newspapers which are available all over Germany, one tabloid and two magazines. The time period for analysis was 1/1995 to 7/2002. Search terms were "Xenotransplantation", "Organtransplantation AND Schwein" (organ transplantation AND pig) and "Transplantation AND Tierorgan" (transplantation AND animal organ).
Table 1.1: German print media selected for XTP contents analysis

<table>
<thead>
<tr>
<th>Name of print media</th>
<th>Type of print media</th>
<th>Circulation (^3)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frankfurter Allgemeine Zeitung (FAZ)</td>
<td>daily newspaper</td>
<td>400,600</td>
<td>liberal, formerly conservative</td>
</tr>
<tr>
<td>Süddeutsche Zeitung (SZ)</td>
<td>daily newspaper</td>
<td>418,900</td>
<td>liberal</td>
</tr>
<tr>
<td>Tageszeitung (taz)</td>
<td>daily newspaper</td>
<td>63,700</td>
<td>left</td>
</tr>
<tr>
<td>Bild-Zeitung</td>
<td>daily tabloid</td>
<td>4,264,800</td>
<td>populistic</td>
</tr>
<tr>
<td>Spiegel</td>
<td>weekly magazine</td>
<td>1,010,300</td>
<td></td>
</tr>
<tr>
<td>Focus</td>
<td>weekly magazine</td>
<td>733,800</td>
<td></td>
</tr>
</tbody>
</table>

The retrieved articles were analysed with respect to the following categories:

- Contents of the article, with the following sub-categories:
  - definition of XTP
  - advantages/benefits/goals of XTP
  - scientific-technical hurdles
  - use and modification of source animals
  - alternatives to XTP
  - social issues relevant for XTP
- Context of the article
- Ethical issues mentioned in the article
- Actors mentioned in the article
- Positions of the relevant actors

The category "Options for overcoming scientific-technical hurdles" could not be discriminated against contents of the article and were therefore included in the contents subcategories.

---

\(^3\) Sold copies Monday-Friday in 2000
1.2.2 Analysis of literature, reports and policy papers; expert interviews

Relevant literature, reports and policy papers were identified by database searches, manual searches of relevant scientific journals, searches in parliamentary archives, by internet searches, by interviews and informal contacts with stakeholders in German and international XTP and by participation in symposia, conferences and workshops on XTP from 1997 to 2001. These sources of information were analysed with respect to the questions relevant for the XENO project.

Knowledge of XTP in Germany and internationally was acquired during the following previous projects on XTP of our institute:

- Technology Assessment Xenotransplantation (commissioned by the Swiss Science Council, Programme Technology Assessment, Bern, Switzerland; 1997-1998) (Hüsing et al. 1998),
- State of the Art of R&D Activities and Trends in the Field of Xenotransplantation of Organs (commissioned by the Office of Technology Assessment at the German Parliament, Bonn/Berlin, Germany; 1998-1999) (Hüsing et al. 2000),
- Technology Assessment Cellular Xenotransplantation (commissioned by the Centre for Technology Assessment TA-SWISS at the Swiss Science and Technology Council, Bern, Switzerland, 1999-2001) (Hüsing et al. 2001).

1.2.3 Secondary analysis of opinion polls

Opinion polls and studies which address issues of relevance for organ transplantation and xenotransplantation were identified by database searches in MEDLINE, by manual literature searches and by internet searches.

Several opinion polls in the German population were identified which – among others – also address issues with relevance to organ transplantation.

Few opinion polls which address attitudes towards xenotransplantation have also been carried out

- in representative samples of the general German population,
- in samples of patients who are awaiting organ transplantation or who already have undergone an organ transplantation.

These polls and studies were analysed for the XENO project.
1.3 Overview of relevant regulations

At present, there is no specific regulation on xenotransplantation in Germany. Moreover, there are diverging opinions whether existing regulations already cover all relevant aspects of XTP appropriately, or whether an amendment of existing regulation or even the implementation of new, XTP-specific regulation is required in Germany. The following supranational and national laws and regulations have to be taken into account when dealing with legal aspects of XTP in Germany (Sauter et al. 1999b, p. 63ff.; Beckmann et al. 2000; Vesting et al. 2001).

1.3.1 Supranational Law

- World Medical Association Declaration of Helsinki/Tokio: Ethical Principles for Medical Research Involving Human Subjects

1.3.2 European Law/regulations

1.3.2.1 European Union

At present, there is no directive or regulation on EU level which is specific for XTP.


An opinion has been published by the Scientific Committee on Medicinal Products and Medical Devices: Opinion on the State of the Art Concerning Xenotransplantation (European Commission Health & Consumer Protection Directorate-General 2001).
1.3.2.2 Council of Europe

- Committee of Ministers: Recommendation No R (97) 15 of September 30, 1997 (Council of Europe et al. 1997)
- Parliamentary Assembly of the Council of Europe: Recommendation 1399 of January 29, 1999 (Council of Europe et al. 1999)
- Committee of Ministers: Response to Recommendation 1399 (Doc. 8363 of March 25, 1999)
- Draft Guideline on Xenotransplantation (worked out by the Working Group on Xenotransplantation CDBI/CDSP-XENO under the Steering Committee on Bioethics (CDBI) and the European Health Committee (CDSP))

1.3.3 National Regulations

1.3.3.1 Federal Law

- Federal Constitution (Grundgesetz): It has to be checked whether xenotransplantation is compatible with several basic rights, guaranteed in the German Federal Constitution, especially with Human Dignity (Menschenwürde, Art. 1), Right of life and physical integrity (Recht auf Leben und körperliche Unversehrtheit, Art. 2, Abs. 2, Satz 1), Animal protection (Tierschutz, in the constitution since 2002).
- Pharmaceuticals Act (Arzneimittelgesetz AMG). An animal organ provided for transplantation into the human body is a drug in the sense of this law, independent of being genetically modified or not.
- Genetic Engineering Act (Gentechnikgesetz GenTG). This act applies to the genetic modification of source animals and the production of a xenograft, as long as this xenograft can be considered as a genetically modified organisms (GMO).
- Animal Protection Act (Tierschutzgesetz, TierschG), This act applies to the keeping of source animals (e.g. housing), their use in animal experiments as a donor or recipient of xenografts, to their genetic modification, to the killing of source animals for retrieval of organs, tissues and cells.
Infectious Disease Act (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen, Infektionsschutzgesetz, IfSG). This act came into force on January 1, 2001. It replaces several acts (e.g. the Bundesseuchengesetz (BSeuchG)), and several decrees, and thus offers a comprehensive, consistent and more systematic legal frame for the prevention and management of infectious diseases. § 4 of this act assigns important competencies to the Robert-Koch-Institut, Berlin, especially the development of concepts for the prevention of transmissible diseases and the early identification and prevention of spreading infections. It is this act which applies to the risk of infection associated with xenotransplantation, its prevention and management.

Transplantation Act (Gesetz über die Spende, Entnahme und Übertragung von Organen, Transplantationsgesetz, TPG). Germany was one of the last countries in the EU to regulate organ transplantation in a law. The Transplantation Act is in force since December 1, 1998. It does not apply to non-human grafts and therefore is not directly relevant for XTP.

1.3.3.2 Regulations and Guidelines put up by the German Medical Association

1.3.3.2.1 Transplantation in general

- Guidelines for determining brain death (Richtlinien zur Feststellung des Hirntodes) (Wissenschaftlicher Beirat der Bundesärztekammer 1998)
- Recommendations for cooperation of hospitals and transplantation centres in postmortem organ retrieval (Empfehlungen für die Zusammenarbeit zwischen Krankenhäusern und Transplantationszentren bei der postmortalen Organentnahme) (Wissenschaftlicher Beirat der Bundesärztekammer 1999a)
- Guidelines for organ transplantation according to § 16 transplantation act (Richtlinien zur Organtransplantation gemäß §16 Transplantationsgesetz) (Bundesärztekammer 2000)
- Guidelines for the waiting list and the allocation of organs (Richtlinien für die Warteliste und für die Organvermittlung) (Schreiber et al. 2000)

1.3.3.2.2 Xenotransplantation in particular

- Position of the Scientific Advisory Board of the German Medical Association regarding Xenotransplantation (Stellungnahme des Wissenschaftlichen Beirats der Bundesärztekammer zur Xenotransplantation) (Wissenschaftlicher Beirat der Bundesärztekammer 1999).
A draft guideline for the regulation of xenotransplantation has also been finalised by the German Medical Association in 2002, but has not yet been released for publication.

2. Form of the National XTP Debate

2.1 In which social context is XTP being debated?

2.1.1 Overview

In order to get an overview of the German XTP debate, the following social contexts must be taken into consideration, as they are involved to a varying extent in the debate:

- Policy, government and administration,
- Natural/medical scientific disciplines relevant for XTP, especially transplantation medicine, immunology, microbiology/virology/infectious diseases, veterinary sciences,
- Humanities (ethics, philosophy, law, cultural and social sciences),
- NGOs in the field of animal welfare/animal rights and genetic engineering,
- The Evangelical and Roman Catholic Churches,
- Other interest groups,
- Media.

Representatives of transplantation medicine and the natural scientific disciplines required for XTP form the core group of the German debate. They have been involved over the full time period investigated here (1995 to 2002) and can be considered as the most influential and agenda-setting group. This group is agenda-setting, as it has gained most influence on shaping the frame conditions under which XTP might one day be applied in Germany. However, due to several reasons which will be outlined in coming sections of this report, they had to incorporate several "non-scientific" issues of XTP into their argumentation, positions and action which originate from other social contexts, especially the humanities and NGOs. Policy and government, the churches and other interest groups only play a minor or temporary role.

Therefore, the importance and role of these social contexts in the debate varied over time and were also (loosely) interconnected. Actors and contents of the relevant debates and their interaction with one another in time course will be outlined in detail in chapters 3 and 4.
Although XTP in Germany is a biomedical topic which has, to a restricted extent, made its way into the public awareness, the "real", high intensity debate on a high quality level which may also have political implications has been restricted to a limited circle of specialists. The focus of this report will be on the characterisation of this specialist debate. It is, however, necessary, to characterise also the "public" debate. For this purpose, a print media analysis was carried out and the results are also presented in this report.

2.1.2 Media

The extent of media coverage can be taken as an indicator for the public debate on a given topic. Therefore we analysed the question how often selected German print media reported about XTP, its potentials, and its scientific and ethical problems. The methodology applied is outlined in chapter 1.2.1.

We identified a total of 112 articles in six different print media with a national coverage in the time period from January 1995 to July 2002. More than 50 % of the articles were published in the years 1998, 1999 and 2000 (figure 2.1). This distribution pattern of media coverage of XTP is similar to the pattern found in Austria, but differs from the pattern in Spain which shows declining article numbers in 2000.

Figure 2.1: Articles on XTP in six selected German print media

![Figure 2.1: Articles on XTP in six selected German print media](image)

Source: ISI research 2002

To put the media coverage of XTP into perspective, we compared it to the media coverage of stem cells – a biomedical topic which has received extraordinary publicity in Germany over
the last years. The publications on stem cells were retrieved with the search term „Stammzellen“ (stem cells) from the three daily newspapers FAZ, SZ and taz as well as from the two weekly magazines Spiegel and Focus (thus the tabloid Bild was omitted for this search) and the number in 2002 refers to the first eight months. Figure 2.2 shows that XTP media coverage is dwarfed by the attention media pay to the stem cell topic.

**Figure 2.2: Articles on XTP in five selected German print media in comparison to articles on stem cells**

![Graph showing comparison of articles on stem cells and XTP](image)

Source: ISI research 2002

Table 2.1 shows that most articles on XTP were published in German daily quality papers, with the FAZ in the leading position (41 articles, 27 %), followed by the SZ (28 articles, 25 %). So, about two thirds of all identified XTP articles were published in these two daily newspapers.

The placing of an article in a special section of the print medium can be used as an indicator of the importance journalists ascribe to the topic and of the context in which they frame it. Therefore, we analysed the sections in which XTP articles were published (figure 2.3). The 11 articles published in the Bildzeitung could not be assigned to different sections of the newspaper as no such information was available (category "Missing" in figure 2.3). 53 articles (47 %) were published in the science/medicine sections of the respective print media, followed by publication in the policy section (16 articles; 14 %) and the feature pages (12 articles, 11 %). The category "Others" comprises publications in the sections "Miscellaneous", "Economy", "Letters" and Supplement (figure 2.3).
Table 2.1: Numbers of articles on XTP in six German print media 1995-2002 per type of media

<table>
<thead>
<tr>
<th>Print media</th>
<th>Articles on XTP</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage</td>
<td></td>
</tr>
<tr>
<td>Daily quality newspaper</td>
<td>86</td>
<td>77</td>
<td></td>
</tr>
<tr>
<td>FAZ</td>
<td>41</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>SZ</td>
<td>28</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>taz</td>
<td>17</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Daily tabloid</td>
<td>11</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Bild</td>
<td>11</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Weekly magazine</td>
<td>15</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Spiegel</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Focus</td>
<td>10</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>112</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Source: ISI research 2002

Figure 2.3: Sections of the German print media in which XTP articles were published

Source: ISI research 2002
2.2 In which form (procedure) is XTP being debated?

Different social contexts have evolved different forms or procedures of debate. Table 2.2 gives an overview of such procedures, measures and forms of debate. A variety of forms has been used in Germany for xenotransplantation debate. A more detailed explanation and background information is given in chapter 3.
Table 2.2: Overview of procedures, measures and forms of debate and their factual usage in Germany

<table>
<thead>
<tr>
<th>Actors, social context</th>
<th>Forms of debate</th>
<th>Implemented</th>
<th>Remarks, description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Political parties</td>
<td>Assigning XTP experts</td>
<td>x</td>
<td>Only SPD, Bündnis90/Die Grünen</td>
</tr>
<tr>
<td></td>
<td>Forming XTP working groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initiating hearings</td>
<td>x</td>
<td>Only Bündnis90/Die Grünen in Bavaria</td>
</tr>
<tr>
<td></td>
<td>Initiating workshops, symposia in endowments</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Launching parliamentary initiatives</td>
<td>x</td>
<td>Few interpellations, mainly by Bündnis90/Die Grünen, in the Federal and Bavarian parliament</td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Publishing position papers</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Parliament</td>
<td>Parliamentary discussion</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Parliamentary initiatives</td>
<td>x</td>
<td>Few interpellations, mainly by Bündnis90/Die Grünen, in the Federal and Bavarian parliament</td>
</tr>
<tr>
<td></td>
<td>Topic in parliamentary committees</td>
<td>x</td>
<td>Committee on Education, Research and Technology Assessment commissioned its Office of Technology Assessment (TAB) to carry out a technology assessment study on XTP, and discussed the resulting report; committees of the Bavarian parliament also dealt with XTP</td>
</tr>
<tr>
<td></td>
<td>Call for XTP legislation</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Call for XTP moratorium</td>
<td>(x)</td>
<td>German delegates to the Council of Europe Parliamentary Assembly supported the call for an XTP moratorium of the CoE Parliamentary Assembly; no initiative on the national level</td>
</tr>
<tr>
<td></td>
<td>Parliamentary XTP commission</td>
<td>x</td>
<td>Enquete-Commission “Law and Ethics of Modern Medicine” formed in autumn 2000 was asked to address XTP issue but never did</td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>
## Table 2.2 continued

<table>
<thead>
<tr>
<th>Actors, social context</th>
<th>Forms of debate</th>
<th>Implemented</th>
<th>Remarks, description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy, government and administration</td>
<td>Forming position on political priority of XTP</td>
<td>x</td>
<td>XTP seen as topic of medium priority in Ministry of Education and Research</td>
</tr>
<tr>
<td>Ministries and their agencies</td>
<td>Launching appropriate support schemes</td>
<td>x</td>
<td>Few research projects were funded</td>
</tr>
<tr>
<td></td>
<td>Working out XTP legislation</td>
<td>x</td>
<td>Diverging opinions whether XTP requires XTP specific legislation or existing legislation is sufficient, legislation planned for 2002-2005</td>
</tr>
<tr>
<td></td>
<td>Topic in advisory boards</td>
<td>x</td>
<td>Planned for the agenda of the Ethics Advisory Board of the Ministry of Health in 1997/1998 but was not realised.</td>
</tr>
<tr>
<td></td>
<td>Improving the XTP knowledge base by initiating research in agencies</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Agencies</td>
<td>Participation in international committees</td>
<td>x</td>
<td>No representative from ministries; Germany is represented by delegates from agencies or academia</td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Counselling of ministries in XTP questions</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participation in international committees</td>
<td>x</td>
<td>1-2 representatives in OECD/WHO committees</td>
</tr>
<tr>
<td></td>
<td>Improving the XTP knowledge base by carrying out research</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forming XTP networks</td>
<td>x</td>
<td>Deutsche Arbeitsgemeinschaft Xenotransplantation founded in 1998</td>
</tr>
<tr>
<td></td>
<td>XTP workshops and symposia</td>
<td>x</td>
<td>Annual XTP symposium since 1998</td>
</tr>
</tbody>
</table>
Table 2.2 continued

<table>
<thead>
<tr>
<th>Actors, social context</th>
<th>Forms of debate</th>
<th>Implemented</th>
<th>Remarks, description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Religion/churches</td>
<td>Assigning XTP experts</td>
<td>?</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Forming XTP working groups</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initiating hearings</td>
<td>?</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Initiating workshops, symposia in their academies</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Publishing position papers</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Transplantation medicine/natural scientific experts</td>
<td>Doing active XTP research</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Performing clinical XTP</td>
<td>(x)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initiating XTP workshops and symposia</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Forming XTP working groups</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Publishing position papers</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Putting up guidelines and recommendations</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Participation in (inter)national committees</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
Table 2.2 continued

<table>
<thead>
<tr>
<th>Actors, social context</th>
<th>Forms of debate</th>
<th>Implemented</th>
<th>Remarks, description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Humanities</td>
<td>Doing active XTP research</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initiating XTP workshops and symposia</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forming XTP working groups</td>
<td>x</td>
<td>Informal groups</td>
</tr>
<tr>
<td></td>
<td>Publishing position papers</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Putting up guidelines and recommendations</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participation in (inter)national committees</td>
<td>(x)</td>
<td>Only national committees</td>
</tr>
<tr>
<td>NGOs (animal welfare, genetic engineering, patient organisations)</td>
<td>Assigning XTP experts</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forming XTP working groups</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initiating workshops and symposia</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td></td>
<td>Supporting public debate</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Publishing position papers</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Launching campaigns</td>
<td>(x)</td>
<td>Minor activities of local scope with strong reference to anti-animal experimentation</td>
</tr>
</tbody>
</table>

Source: ISI research 2002
2.3 Which competencies and methodologies did national and local committees use to evaluate the ethical impact of XTP?

At the present state of debate, the politically most important debate takes place in international committees on supranational level, e.g. at the Council of Europe (Working Group Xenotransplantation), the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO), aiming at putting up international guidelines for XTP. At present, there seems to be a tendency that results achieved in these committees will most likely also be adopted on national level, perhaps with slight modifications. Therefore, competencies and methodologies applied in these supranational committees seem to be more important than those used in national committees.

It is difficult to decide which national and local "committees" should be included for answering the question of competencies and methodologies, as XTP has been discussed in several formal and informal groups (see table 2.2). The following selection of three committees may therefore be considered as somewhat arbitrary:

- A Xenotransplantation Working Group of the Scientific Advisory Board of the German Medical Association (Bundesärztekammer, BÄK), which has worked out a position on xenotransplantation (Wissenschaftlicher Beirat der Bundesärztekammer 1999), also see chapter 3.2.1.7, and has drafted a regulation on XTP which has not yet been released. This working group of the advisory board, which worked out the position paper, has an interdisciplinary composition (5 physicians, some of them with focus on transplantation medicine; 1 veterinarian (focus on genetic modification of animals); 1 immunologist, 1 virologist/infectiologist; 2 theologians (1 protestant, 1 roman catholic); 3 law experts). It can be assumed that the theologians were primarily responsible for the ethical aspects. However, in the position paper ethical questions were only raised but not further elaborated. Moreover, the bibliography of the position paper does not take into account the actual state of the art in ethical reflection of XTP which had already been achieved at that time in Germany.

- A xenotransplantation task force jointly commissioned by the two large German churches, the protestant Council of the Evangelical Church in Germany (Rat der Evangelischen Kirche in Deutschland) and the roman catholic German Bishops' Conference (Deutsche Bischofskonferenz), also see chapter 3.2.6. This task force also had an interdisciplinary composition which differs significantly from the XTP working group of the German Medical Association: History of Medicine and Science (1 expert), theology (2), psychotherapeutic medicine (1), surgery (1), law (1 guest expert).

- A local ethics committee at the university hospital Charité in Berlin which is responsible for approving research projects involving humans. At this hospital, this local ethics committee had given approval to an experimental xenotransplantation procedure which involved the extracorporal connection of a patient with fulminant hepatic failure to two pig
livers which were perfused with the patient’s blood over 60 hours. The patient was a 38-year-old lorry driver from Lithuania who suffered from sudden hepatic failure and was not eligible for organ transplantation due to his origin from Lithuania. He survived the highly experimental procedure for eight days but then died due to multiple organ failure (Sago 1999; Koch 1999). The research group, led by Professor Neuhaus, afterwards received harsh criticism for carrying out this procedure because it was carried out at a time (February 1999) when the information basis on the risks of infection by XTP was very incomplete and there was an informal agreement among German surgeons that XTP procedures should not yet be carried out due to the uncertainty with respect to the balancing of benefits and risks. Moreover, questions were raised whether informed consent had really been obtained from the patient.

Therefore, we have evidence that the ethical impact of XTP was taken into account by XTP committees by inclusion of experts from biomedical ethics or theology, respectively.

2.4 How do actors think that ethical issues of new technologies can/should be debated in public?

Before the question can be answered how ethical issues of XTP should be debated in public the questions must be asked

- whether ethical issues of XTP should be debated in public at all, and
- which ethical issues are considered relevant for public debate.

The agenda of the XTP debate in Germany has been set predominantly by experts from the medical/natural sciences field. This group, however, only considers a limited scope of ethical questions as relevant (see chapter 3.3 for detailed discussion), and therefore only these ethical issues which are directly linked to the clinical application of XTP are taken into consideration for public debate. On the other hand, there is evidence that the public differs significantly from biomedical/scientific experts with respect to the ethical issues the public considers as important (e.g. impacts of XTP on identity).

In "the early days" of XTP (in the period of 1995-1997) the involvement of other groups and views than those of transplant surgeons or clinical practitioners was not considered as necessary or desirable by the transplant surgeons. The intensive warnings of virologists that XTP bore the risk of possibly pandemic infections was seen as unjustified delay of XTP development and irresponsible scaremongering. Over time it became clear that these objections were well-founded and had to be taken seriously. A more intensive communication between these formerly separate scientific groups followed in which the initial positions were
modified by both sides and came closer to one another. Moreover, a very important incidence was the call for a moratorium of clinical XTP in order to gain time to initiate and conduct a public debate on how individual benefit of XTP should be balances against its collective risk. This call for a moratorium came from a group of leading XTP researchers, led by Fritz Bach, in the USA in February 1998 (Bach et al. 1998) and also had a major impact on the experts' debate in Germany.

As a consequence, practically all German XTP actors from the biomedical field are aware of the importance that XTP is accepted or at least tolerated by patients, in politics and administration and the general public – if this acceptance or tolerance cannot be achieved further XTP research is seen as no longer possible. Against this background, most experts see a public debate as desirable and worth supporting. However, there is a broad scope of diverging opinions between individuals who should be included in this debate, which importance and which function should be assigned to this debate and which consequences this should have on XTP research and clinical application of XTP. Moreover, no well-founded ideas have been developed by this XTP expert group how this public debate and the inclusion of ethical issues should be implemented. There is, however, consensus among the XTP experts that a premature rush to the clinic would most likely lead to failure of the XTP, would evoke negative reactions from the public and as a consequence would do significant harm to XTP research in general. Therefore, an implicit consensus was formed that no clinical XTP should be performed in order to publicly demonstrate the XTP experts' sense of responsibility.

3. Contents of the Debate

3.1 In which context is XTP primarily debated (e.g. transplantation, animal rights)? How is XTP framed as a problem?

3.1.1 German XTP arena

In general, the public debate on XTP in Germany has remained restricted to experts coming from different social contexts, with a focus on experts from

- academic and clinical transplantation medicine and natural sciences required for XTP (immunology, virology, veterinary medicine/source animal breeding and housing, infectiology), and
- academic humanities.
Other actors such as the churches, NGOs (especially animal welfare and genetic engineering groups), and government, politics and administration have contributed to a lesser extent to the debate.

Actors from the transplantation medicine/natural sciences cluster frame the problem of XTP in a rather different way than actors from the academic humanities cluster. This different framing is outlined in the following paragraphs:

The transplantation medicine/natural sciences cluster frames the problem of XTP as a technology-driven solution to severe problems of current transplantation surgery:

- lack of sufficient human donor organs,
- long waiting lists of patients in need of an organ,
- problems in just allocation of scarce human organs to the waiting patients,
- psychological stress for clinical staff, patients and relatives due to emergency surgery.

The comparative advantage of XTP over alternative solutions to relieving the problem of organ shortage is twofold: it is a solution to the whole field of transplantation surgery and bears the potential of even expanding this field to the curing of diseases which traditionally do not fall into the field of surgery (e.g. diabetes, Parkinson's disease). Moreover, it is a logical extension of current transplantation surgery and can be neatly integrated into the existing system without the need to alter it significantly. Moreover, this cluster focuses on developing pragmatic solutions to XTP problems which arise in case of clinical application of XTP, especially the prevention and management of the risk of infection, and stress the benefit for the individual patient.

On the other hand, the academic humanities cluster also extended the debate to the acceptability of XTP as such and also in comparison to alternatives, animal welfare issues, psychological/identity issues, benefits and risks for the general public, allocation problems on individual, national and international level, normative questions in law, questions of life and death, relation of man to his own body and to animals, alternatives to XTP. So the humanities adopted a thematic and methodological approach which was largely complementary to the transplant surgeons/natural scientists one. Some of the humanities actors also adopted a problem-driven instead of technology-driven approach.

3.1.2 Media analysis

The predominant publication of XTP articles in the science/medicine section (cf. figure 2.3) is in line with the framing of XTP as a problem which is mainly seen as challenging, yet most
likely feasible medical-scientific development. The scientific-technical feasibility was the dominant background for 49 articles. This holds especially true for the first two years of our analysis period where nearly all articles reflected this background. After the first euphoria had diminished and more problems had become evident (e.g. rejection and severe side effects of heavy immunosuppression, risk of infection, physiological incompatibilities), the balancing of risks against benefits became relevant (22 articles). 15 articles put XTP into the context of organ shortage or reflected upon regulatory problems (12 articles). The results are summarised in figure 3.1. As individual articles were counted several times if they fell into several categories, 100 % exceeds 112 publications and is equivalent to 144 articles.

Figure 3.1: Context of XTP in the identified articles

Source: ISI research 2002

The contents analysis of the articles showed that the **most important topics** covered were scientific-technical hurdles (68 of 112 articles), advantages/benefits and goals of XTP (66 of 112 articles) and the use and modification of source animals (61 of 112 articles) (figure 3.2). 49 articles mentioned social impacts of XTP, 33 articles gave a definition of XTP and
8 articles featured alternatives to XTP. The three most important categories (hurdles, benefits, animal modification) remained more or less constant over time. Alternative options to XTP only became relevant from 2000 onwards when new hopes came from research with human embryonic stem cells (first successful cultivation in the USA published in late 1998); moreover, increasing the numbers of human organ donations was also discussed.

**Figure 3.2: Predominant issues covered in German print media reports on XTP**

In the following paragraphs, the three predominant XTP issues covered in the German media reports will be analysed in more detail.

**Benefits, advantages and goals of XTP** were mentioned in 66 of 112 articles. The most important benefit/goal was seen in its contribution to solving the shortage of human organs (56 articles), followed by improving patients’ quality of life (13 articles), the saving of lives of those patients on the waiting list by bridging with an animal organ until a human organ
becomes available (5 articles). Other advantages were only mentioned scarcely: fighting illegal organ trade, no need for "organ tourism", saving of costs, and qualitatively superior organs (figure 3.3).

**Figure 3.3: Benefits, advantages and goals of XTP in German media coverage of XTP**

Source: ISI research 2002

With respect to the **scientific-technical hurdles** media pay most attention to the risks of infection (54 articles), followed by rejection (27 articles), the state of the art of XTP in general, side effects of immunosuppression (e.g. risk of cancer) and physiological incompatibilities between animal organ and human recipient (6 articles) (figure 3.4). Physiological incompatibilities only entered the media in 1998 after the publication of the first technology assessment study on XTP in German language, authored by Fraunhofer ISI (Hüsing et al. 1998).

The coverage of the risk of infection can be differentiated further: risk of infection in general (44 articles), risk of infection with porcine endogenous retrovirus (PERV) (23 articles),
possibility of causing a pandemic (14 articles), unknown infectious agents (13 articles) and only 3 articles cover how the risk of infection could be managed.

The issue "rejection" can be differentiated in the following way: hyperacute rejection (25 articles), rejection in general (15 articles), acute rejection (8 articles) and chronic rejection (6 articles).

**Figure 3.4: Scientific-technical hurdles in German media coverage of XTP**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>38%</td>
</tr>
<tr>
<td>Immunosuppression</td>
<td>14%</td>
</tr>
<tr>
<td>Physiological incompatibilities</td>
<td>4%</td>
</tr>
<tr>
<td>Present state of the art of XTP</td>
<td>19%</td>
</tr>
<tr>
<td>Xenograft rejection</td>
<td>25%</td>
</tr>
</tbody>
</table>

Source: ISI research 2002

If the use of source animals is covered in the XTP articles, they most often refer to the genetic modification of the source animals (53 articles of 61 "animal articles"). Although the sheep Dolly was cloned in 1996, and cloning has been an option for XTP right from its beginning, it is not before 2000 that cloning is also mentioned in the context of XTP in the German press. In 2000, the first successful cloning of pigs was reported (Polejaeva et al. 2000; Onishi et al. 2000; Betthauser et al. 2000), and in late 2001/beginning of 2002 the first knock-out piglets obtained by cloning procedures and especially bred for XTP purposes were born (Lai et al. 2002; Dai et al. 2002). In total, 18 articles feature the cloning of source animals. 7 articles cover the issue of animal welfare, and 6 articles discuss the breeding of "germfree" animals under specific pathogen-free conditions (figure 3.5). During the first
years, source animals are almost exclusively referred to as objects of genetic modification whereas the issue of source animal welfare enters the German print media from 1998 onwards.

**Figure 3.5: Use and genetic modification of source animals in German media coverage of XTP**

![Diagram showing uses and genetic modification of source animals]

Housing of source animals (SPF conditions) 7%

Adverse effects on animal welfare 8%

Cloning of source animals 21%

Genetic engineering of source animals 64%

Source: ISI research 2002

If XTP is put into perspective with social issues, it is most often public acceptance of this new technology and the need for a public debate to achieve acceptance (25 articles). However, in most cases this is only postulated without reflecting upon how this “public debate” is to be achieved. Moreover, it is implicitly assumed that the outcome of this debate will be a positive one for xenotransplantation, that is, that this "public consultation exercise" has to be performed as a necessary intermediate step in the (implicitly undisputed) striving towards clinical application of XTP. Nearly as important as the issue of public acceptance is regulation: 16 articles have initiatives for regulation as a subject, 10 articles report on the present state of XTP regulation. Moreover, economic aspects are covered in 18 articles,
which especially focus on potential markets for animal organs and the achievable profits (figure 3.6).

**Figure 3.6: Social issues in German media coverage of XTP**

Source: ISI research 2002

Ethical questions are rarely raised in the German media in the context of XTP. 33 articles reflect upon balancing risks of XTP against its benefits, the impacts of XTP on animal welfare is pointed out in 16 articles. Other ethical questions are patients’ rights (8 articles), cultural values (6 articles) and just organ allocation/equal access to organs (6 articles) (figure 3.7).
Finally, it was analysed which position media reports on XTP take, whether they tend to support and promote XTP, whether they come to ambivalent opinions or whether they take a negative stance. In total, 21 articles showed a tendency pro XTP, 64 articles were balanced and 27 articles showed a tendency contra XTP. However, if one follows the tendency of attitudes over time, there is a trend from balanced-positive to balanced-negative (figure 3.8). This becomes more obvious if one compares the tendency from 1995-1998 with the tendency from 1999-2002 (table 3.1).
Figure 3.8: Tendency of attitudes in press articles on XTP over time

Table 3.1: Tendency of articles on XTP in the German press

<table>
<thead>
<tr>
<th>Period</th>
<th>pro</th>
<th>balanced/ambivalent</th>
<th>contra</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995-1998</td>
<td>27</td>
<td>51</td>
<td>22</td>
</tr>
<tr>
<td>1999-2002</td>
<td>13</td>
<td>62</td>
<td>25</td>
</tr>
</tbody>
</table>

3.2 Which position do relevant actors take? What are their positions, interests and resources?

3.2.1 Cluster of biomedical XTP research

Scientists involved in biomedical XTP research are the most important, because most influential and agenda-setting group in Germany. Research on XTP of organs is primarily carried out in Hanover and Munich, followed by Berlin. Research on cellular xenotransplantation (pancreatic islet cells) is carried out in Würzburg and Gießen.
3.2.1.1 Hanover region

For many years, transplantation surgery has been a special strength at the Medical School of Hanover (Medizinische Hochschule Hannover). XTP activities in rodent, dog and non-human primate models have been carried out for several years. Immunological as well as virological aspects have been investigated. Leading scientists are Prof. Manns (transplant surgeon), Prof. Haverich (Director of the Clinic for Thoracic and Cardiovascular Surgery), Prof. Steinhoff (formerly Hanover, now heart surgery Rostock), Prof. Winkler and Dr. Martin (biologist, Leibniz Research Laboratory for Biotechnology and Artificial Organs; Leibniz-Forschungslabor für Biotechnologie und künstliche Organe (LEBAO)).

Close cooperation exist with the Institute for Animal Breeding and Animal Behaviour (Institut für Tierzucht und Tierverhalten der Bundesforschungsanstalt für Landwirtschaft) in Mariensee near Hanover (Prof. Niemann). This is a research institute which belongs to the Federal Ministry of Consumer Protection, Food and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft). This institute is specialised in genetic engineering of livestock. Here, several transgenic pig lines for XTP have been bred and delivered to the Medical School of Hanover for experimentation. Other (minor) partners in this project on genetic modification of source animals were the Gesellschaft für Biotechnologische Forschung in Braunschweig, a national research centre for biotechnology which provided genes and vectors, and the Fraunhofer Institute of Toxicology and Aerosol research, Hanover (Prof. Paul). Joint projects have been carried out with the non-human primate centre in Göttingen and the Pettenkofer Institute in Munich (Prof. von der Helm, retired in 2001) on the XTP risk of infection.

XTP research in this regional cluster near Hanover is funded by internal funds of the institutions, research grants from the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) and the Deutsche Forschungsgemeinschaft. Moreover, companies (especially Novartis) finance several projects. Up to 1998, it was speculated whether transplant surgeons from Hanover would be among the first to carry out clinical xenotransplantations with human patients, because they appeared eager and ambitious enough to do so. However, in the following years the focus of research was shifted from XTP to regenerative medicine (e. g. stem cells), so that priority of XTP research within this group clearly declined. This group has influence at least on national level, since Prof. Haverich is a member of the Standing Committee Organ Transplantation of the German Medical Association (Ständige Kommission Organtransplantation der Bundesärztekammer) and a member of the Working group Xenotransplantation of the Scientific Advisory Board of the German Medical Association (Arbeitsgruppe Xenotransplantation des Wissenschaftlichen Beirats der Bundesärztekammer).
3.2.1.2 Munich region

Another centre of XTP research is in Munich which offers a comparable mixture of different, interdisciplinary XTP competencies as Hanover. The core group is located at the Institute for Surgical Research, Medical School of Großhadern in Munich. Its head, Prof. Hammer, a veterinarian and biomedical researcher, has been active in the field of physiology of XTP for about 30 years. In 1995, when the scientific breakthrough in XTP was achieved in the UK by using genetically modified source animals, he was the researcher with the longest experience in XTP in Germany. XTP animal experiments on rejection and physiology have been carried out for years. First experiments with organs from transgenic pigs were carried out in cooperation with Imutran Ltd. (UK), but the terms of cooperation were seen as not acceptable. Therefore, a cooperation was initiated with the Chair for Molecular Livestock Breeding and Livestock Genetics of the Ludwig Maximilians Universität München (Prof. Wolf) with the aim, that this institute should provide transgenic source animals. Further cooperations are carried out with the University of Ulm, Department of thoracic and vascular surgery (D. Abendroth). Risks of infection are investigated in cooperation with the Pettenkofer-Institut, Munich. In 2000, Prof. Hammer's research group was the target of a parliamentary initiative launched by members of the Bavarian parliament (Social Democrats) regarding xenotransplantation experiments in his laboratory which involved 19 non-human primates (see chapter 3.2.5.2).

Funding of this group comes from university funds, several grants, industry grants and grants from Bavaria. Prof. Hammer and his superior, Prof. Reichart, are members of the Working group Xenotransplantation of the Scientific Advisory Board of the German Medical Association (Arbeitsgruppe Xenotransplantation des Wissenschaftlichen Beirats der Bundesärztekammer). Prof. Hammer has a leading position within the working group of xenotransplantation of the German Association of Transplant Surgery. A member of his research group, PD Schmoeckel, has participated in working out guidelines for XTP in the International Society of Heart and Lung Transplantation (ISHLT) (Cooper et al. 2000).

3.2.1.3 Charité, Berlin

Xenotransplantation research is carried out at the Clinic of General, Visceral and Transplantation Surgery at the Medical School Charité in Berlin (Prof. Neuhaus, Prof. Gerlach). It is the largest centre for organ transplantation in Germany and is specialised in liver transplantation. Their research activities focus on extracorporeal liver support systems which have been in development for several years. In February 1999, Prof. Neuhaus performed an afterwards much criticised XTP procedure on a Lithuanian patient with fulminant hepatic failure who was connected for 60 hours to two extracorporeal pig livers (Sago 1999; Koch 1999) (details see chapter 2.3). Prof. Gerlach developed liver assist devices with pig liver cells (Gerlach 1996; Busse et al. 1999). In 1999, it became evident that
it would be very difficult to obtain approval for clinical procedures with animal cells. Although research with porcine liver cells still continues, the research focus was shifted to human liver cells from various sources. Funding comes from the European Commission (e.g. within the framework of the European Union Demonstration Project (PL43532), from various grants from the Deutsche Forschungsgemeinschaft (DFG), the Bundesministerium für Bildung und Forschung (BMBF - Projektträger BEO) and from internal funds.

3.2.1.4 Medical School of Würzburg

Xenotransplantation of pig islet cells for the therapy of diabetes is the focus of research at the Experimental Transplantation Immunology, University Hospital of Surgery, Medical School of Würzburg. Leading scientist is immunologist Prof. Karin Ulrichs. Islet cell XTP has been carried out for years in pig-rodent-models. The Würzburg team is determined to bring islet cell XTP to clinical application, the time frame, however, is uncertain. Prof. Ulrichs plays a leading role in the national debate (member of the Working group Xenotransplantation of the Scientific Advisory Board of the German Medical Association (Arbeitsgruppe Xenotransplantation des Wissenschaftlichen Beirats der Bundesärztekammer), has a leading position within the working group of xenotransplantation of the German Association of Transplant Surgery, and is the "official national delegate" in the Working group Xenotransplantation at the Council of Europe. Moreover, she is active on WHO and OECD level.

3.2.1.5 Robert Koch Institute and Paul Ehrlich Institute

Risks of infection are the focus of research at the Robert Koch Institute (RKI) in Berlin (Dr. Denner, Prof. Kurth), at the Paul Ehrlich Institute (PEI) in Langen (Dr. Tönjes, Dr. Ehlers), at the LEBAO in Hanover (Dr. Martin) and at the Pettenkofer Institute in Munich (Prof. von der Helm, retired).

The RKI and PEI are research institutes or agencies of the Federal Ministry of Health. They have the task to counsel the government and administration in all questions related to infectious diseases and risks of infection, to work out strategies for prevention and management of infection and to supervise the safety of drugs and vaccines. Due to the fact that RKI and PEI are institutes with "official" tasks for the Federal Ministry of Health, these scientists were the first to be consulted on a political level when warnings of the risk of infection were substantiated internationally. At the PEI, research focuses on porcine endogenous retroviruses (PERVs). At the RKI, also porcine circoviridae and herpesviridae are investigated. Close research cooperations exist with all important XTP infection research groups (e.g. in the USA and the UK). Dr. Tönjes is member of the Working group Xenotransplantation of the Scientific Advisory Board of the German Medical Association
3.2.1.6 Scientific Societies

The German Transplantation Society (Deutsche Transplantationsgesellschaft (DTG)) is a scientific association which has the aim to support the transplantation medicine in Germany with regards to organisational, clinical and scientific aspects. The DTG took up the issue of XTP in 1998, when it founded the "Section Xenotransplantation", led by Prof. Claus Hammer, Munich. The DTG also comprises the Kommission Xenotransplantation, a part of the Scientific Advisory Board of the DTG. The Section Xenotransplantation and the Kommission Xenotransplantation are only open to members of the DTG. Members of the DTG are recruited from the disciplines surgery, inner medicine, urology, anaesthesia, immunology and also includes transplantation coordinators and other persons which support transplantation medicine.

Moreover, in 1998, two initially rivalling annual scientific symposia on XTP were founded. The leading scientists from RKI and PEI, Dr. Denner and Dr. Tönjes, founded the German Working Group Xenotransplantation (Deutsche Arbeitsgemeinschaft Xenotransplantation (DAX)) in February 1998. This working group intends to be an interdisciplinary forum for XTP researchers (primarily from Germany, but also open to members from Austria and Switzerland) from all relevant disciplines (transplantation surgery, immunology, physiology, veterinary medicine, microbiology, virology, other basic research scientists). It is also open to ethicists, representatives of public life, industry and the administration which is responsible for approval. It has the following tasks:

- Exchange of information and data from clinical, experimental and ethical studies on the subject of xenotransplantation,
- Supporting the scientific cooperation of all groups involved and exchange materials (e. g. tissue samples, microbiological strains) required for research,
- Based on these interdisciplinary cooperations a permanent evaluation of the risks of xenotransplantation shall be carried out, and competent advice shall be given to national (e. g. German Medical Association) and international (e. g. OECD, WHO) committees.

The main activity of the DAX is an annual one-day symposium on XTP. The agenda is drawn up by Dr. Denner and Dr. Tönjes who also invite the speakers. From its foundation in 1998 to 2003, the DAX has organised six of these symposia.

The other annual scientific symposium on XTP was initiated by transplantation surgeons from the University of Gießen (Dr. Grimm) in autumn 1998. In contrast to the DAX
symposium, there is a call for papers for the symposium, and a scientific committee which selects the contributions for presentation. Although the DAX symposium stresses more the virological aspects and the Gießen symposium focuses more on transplantation medicine, both symposia are rather similar in their scope. In 2001, the scope of the Gießen symposium was broadened because interest in XTP had gone down. Before 2001, it focussed on XTP, but then stem cell research and bioartifical organs were also included and the symposium was renamed as “Symposium on Innovative Organ Replacement”.

In 2002, the Society for Virology (Gesellschaft für Virologie e. V.) published a position paper on chances and risks of xenotransplantation which was authored by Dr. Denner. This position paper summarises the present state of xenotransplantation research and concludes that at the present time, xenotransplantation cannot be considered as an ethically uncritical alternative to the therapeutic applications of human embryonic stem cells. Intensive research is required to reach functionality of xenografts and microbiological safety of this technology (Gesellschaft für Virologie 2002).

3.2.1.7 German Medical Association

The German Medical Association (Bundesärztekammer (BÄK)) is the central organisation in the system of medical self-administration in Germany. It is the joint association of the 17 Länder Medical Associations (Landesärztekammern) and thus an organisational combination of public-law corporations. It represents the interests of the 369,319 doctors (as at 31.12.2000) in matters relating to professional policy. The individual doctor is only indirectly a member of the BÄK via compulsory membership of his or her local medical association. The German Medical Association plays an active role in the opinion-forming process in relation to health policy in society, and in legislative procedures. It also works out guidelines and standards in order to provide guidance to doctors, especially in new or controversial biomedical fields (e. g. brain death, research with fetal tissue, different aspects of transplantation surgery, genetic testing etc.).

The question whether existing law and regulation is sufficient for XTP (and if required, specific XTP guidelines drawn up by the medical professions as a selfregulation would be sufficient) or whether the issue requires specific regulation on the level of national or even supranational law is still open in Germany. Against this background, the German Medical Association formed a Working Group on XTP with the task to work out a position paper or XTP regulation, respectively. On the composition of this working group see chapter 2.3. This position paper was published in 1999 (Wissenschaftlicher Beirat der Bundesärztekammer 1999b). In this paper, the working group supports XTP in general. Clinical XTP procedures should, however, not yet be performed until more information becomes available on risks and benefits. A draft, still confidential regulation has been worked out by 2002.
3.2.1.8 Positions within the biomedical cluster

Although individuals within the biomedical cluster differ from one another in various aspects of their opinions, the following "common" position has emerged over the years (on the process of this evolution see chapter 4.3): At present, the common opinion in the German biomedical xenotransplantation community is: Xenotransplantation is acceptable in general, but should not yet be performed; in future only under certain conditions. Pigs, but not non-human primates should be used as source animals; non-human primates may be used in preclinical research as model for man (xenograft recipient, infection studies). Intensive research is required to reach functionality of xenografts and microbiological safety of this technology. Risks and benefits both for individual patients and the general population must be balanced against each other. Regulations and guidelines should be developed and harmonised internationally.

The German XTP actors from the biomedical field are well aware of the importance that XTP must be accepted or at least tolerated by patients, in politics and administration and the general public – if this acceptance or tolerance cannot be achieved further XTP research is seen as no longer possible. Therefore, the formerly separate groups of virologists and transplant surgeons have (more or less) joined, and they have also incorporated several issues into their argumentation which seemed to be essential to achieve political and public tolerance/acceptance but which were formerly only addressed by the Humanities/NGO cluster (see below).

3.2.2 Humanities cluster

In Germany, all important chairs of ethics or philosophy with emphasis on biomedicine became active in the field of xenotransplantation. Moreover, several law schools with emphasis on biomedicine and institutions with expertise in technology assessment became active. These institutions adopted a thematic and methodological approach which was largely complementary to the transplant surgeons/natural scientists one: while the transplant surgeons/natural scientists focussed on developing pragmatic solutions to XTP problems which arise in case of clinical application of XTP and stress the benefit for the individual patient, the humanities also extended the debate to the acceptability of XTP as such and also in comparison to alternatives, animal welfare issues, psychological/identity issues, benefits and risks for the general public, allocation problems on individual, national and international level, normative questions in law, questions of life and death, relation of man to his own body and to animals, alternatives to XTP, social networks in which xenotransplantation evolves, historical and cultural backgrounds of organ transplantations. Some of the humanities actors also adopted a problem-driven instead of technology-driven approach. This cluster also has links to NGOs in the animal welfare and genetic engineering field.
In the following paragraphs, some of the activities within the humanities cluster is described in more detail.

3.2.2.1 Chair for Ethics in the Life Sciences at the Eberhard Karls University of Tübingen

The Chair for Ethics in the Life Sciences at the Eberhard Karls University of Tübingen (Lehrstuhl für Ethik in den Biowissenschaften der Eberhard-Karls-Universität Tübingen), led by Prof. Eve-Marie Engels, was one of the first academic institutions which took up research on ethical questions of xenotransplantation. Comprehensive ethical reflections were carried out both for xenotransplantation of organs as well as cells (Hüsing et al. 1998; Hüsing et al. 2001) in cooperation with the Fraunhofer Institute for Systems and Innovation Research, Karlsruhe and were used as an information base for political decisions in the framework of legislative procedures for a transplantation act in Switzerland. A critical stance towards xenotransplantation is taken; alternative options are seen as superior to xenotransplantation. A problem-oriented approach was chosen within the project “New perspectives of transplantation medicine: biological, medical and ethical aspects of xenotransplantation and organ production from embryonic stem cells” (“Neue Perspektiven der Transplantationsmedizin: Biologische, medizinische und ethische Aspekte der Xenotransplantation und der Organherstellung aus embryonalen Stammzellen”), funded by the Deutsche Forschungsgemeinschaft within its bioethics initiative. From this project, a dissertation resulted (Schicktanz 2001; Schicktanz 2002b; Schicktanz 2002a) which was awarded a prize of the Erna-Graff-Stiftung. This prize can – among others - be awarded to scientific dissertations which provide new ethical arguments for setting limits to the use of animals.

3.2.2.2 Research group “Technology Assessment of Modern Biotechnology in Medicine/Neurobiology” at the University of Hamburg

At the University of Hamburg, the research group “Technology Assessment of Modern Biotechnology in Medicine/Neurobiology” within the research centre “Biotechnology, Society and Environment” (Forschungsschwerpunkt Biotechnik, Gesellschaft und Umwelt (FSP BIOGUM), Forschungsgruppe Technologiefolgen-abschätzung der modernen Biotechnologie in der Medizin/Neurobiologie) analyses social and ethical controversies in biomedicine. Within its research focus on new biotechnical methods for the production of tissue and organ replacement and their interrelation with reproductive medicine, a dissertation, supervised by Prof. Dr. Regine Kollek, was published on “Xenotransplantation as biotechnical addition of allotransplantation” (De Wit 2001). This dissertation puts an emphasis on an intensive discussion of the scientific-medical aspects of xenotransplantation, investigates the aspects of health economy of indefinite availability of organs and carries out an investigation of the processes which underlie the genesis of this technology from a sociological perspective. The dissertation also defines prerequisites for the application of xenotransplantation to humans. It concludes that with regard to the scientific-medical problems (rejection, physiological
compatibility and risk of infection) there is a considerable need for further research and for providing evidence for safety and efficacy of xenotransplantation in long-term experiments in non-human primates (one-year survival at least). Moreover, a need for thorough discussion of the ethical, social, economic and legal framework is pointed out. From the ethical point of view, it is seen as not acceptable to introduce xenotransplantation as a bridge to allotransplantation but only as a supplement. It is stressed that compliance with monitoring schemes as an element of risk management can only be on a voluntary basis so that a social consensus which risk to take is required as well as international cooperation and harmonisation.

3.2.2.3 European Academy for the Study of Consequences of Scientific and Technological Advance Bad Neuenahr-Ahrweiler GmbH

The European Academy for the Study of Consequences of Scientific and Technological Advance Bad Neuenahr-Ahrweiler GmbH (Europäische Akademie zur Erforschung von Folgen wissenschaftlich-technischer Entwicklungen Bad Neuenahr-Ahrweiler GmbH) is an independent scientific institution which is concerned with the scientific study of consequences of scientific and technological advance for the individual and social life and for the natural environment. The main focus is to examine foreseeable mid- and long-term processes that are especially influenced by natural- and engineering sciences and the medical disciplines. In 1998, an interdisciplinary project group on xenotransplantation was formed (Beckmann 1997) which consisted of the following representatives from fields relevant for xenotransplantation:

- Prof. Dr. Jan P. Beckmann (Chair), Institute of Philosophy, FernUniversität Hagen
- Prof. Dr. Dr. Gottfried Brem, Veterinarian University of Vienna, Institut of Livestock Breeding and Genetics
- Prof. Dr. Friedrich Wilhelm Eigler, Director, Department of General Surgery (retired), Medical School Essen
- Prof. Dr. Walter H. Günzburg, Veterinarian University of Vienna, Institute of Virology
- Prof. Dr. Dr. Claus Hammer, Institute of Surgical Research, Medical School Großhadern
- Prof Dr. Dr. h.c. Wolfgang Müller-Ruchholtz, Medical School Kiel, Institute of Immunology
- Prof. Dr. Dr. h.c. Hans Ludwig Schreiber, President of the Georg-August-University of Göttingen and Chair for Criminal Law and Criminal Trial Law

The goal of this working group was to probe the medical possibilities of xenotransplantation, analyse its scientific difficulties, its ethical implications and its social relevance and thus contribute to a professionally well-founded and ethically justified "status quo" report for public
discussion. This report was published in 2000 (Beckmann et al. 2000). It recommends a cautious stepwise approach towards clinical xenotransplantation under strictly controlled conditions. In the first place, SPF populations of source pigs have to be established from which xenografts should be derived. Then the risk of xenograft rejection should only be taken if xenograft survival in the recipient of several months can be expected; this will most likely be the case firstly for cellular xenografts. However, the risk of infection still needs to be clarified. Sufficient confidence in the virological safety of xenografts may first be reached with cellular xenografts derived from cell lines. It is seen as justifiable to take the virological risk of organ xenotransplantation in the attempt to treat an individual case in which there is clearly no alternative, and with the patients informed consent, as well as that of his medical and social environment. In this way, the risk of infection can be clarified through experience. Moreover, a strict oversight of xenotransplantation procedures is recommended: a central commission is proposed which drafts regulations and quality criteria for different forms of xenotransplantation (cells, tissues, organs) and the aftercare protocols. Moreover, this commission should be in charge of central registration of xenotransplantation procedures, and only licensed institutions should be allowed to carry out xenotransplantations. Moreover, a discussion with and in the public is recommended, without saying how this discussion should be carried out (Beckmann et al. 2000, p. 315ff.).

3.2.2.4 Institute Technology – Theology – Natural Sciences

The Institute Technology – Theology – Natural Sciences (TTN) is a co-operating institution at the Ludwig Maximilian University of Munich. It is a scientific, public, independent institution that is funded by grants, membership fees, donations from the private as well as from the business sectors, and by the patronage of the Lutheran Church in Bavaria. TTN was founded with the aim to support the interdisciplinary dialogue on ethical problems in technology and natural sciences. It focuses on ethical questions in the fields of biotechnology and genetic engineering, medicine, information and communication technology, energy technology and their economic applications.

In September 1999, the institute published a position paper on xenotransplantation (Haniel et al. 1999). Authors of this position paper are the chairman of the board of the institute, Prof. Dr. Dr. Trutz Rendtorff; Prof. Dr. Ernst-Ludwig Winnacker as a member of the board of the institute and at the same time president of the Deutsche Forschungsgemeinschaft, and Dr. Anja Haniel, a member of the scientific staff of the institute. In this position paper, xenotransplantation is seen as one among several options to solve the organ shortage problem. No fundamental ethical objections against xenotransplantation are identified so that research into xenotransplantation should be supported. However, its clinical application at the present state of research is rejected for ethical reasons, because there are significant uncertainties with regard to functionality, compatibility and risk of zoonotic infections and because alternative options (including stem cells) are not yet fully exploited. As clinical
xenotransplantations are seen as not unlikely in the nearer future, procedures for relevant regulations should be initiated before clinical xenotransplantations are carried out. This could be done by establishing an expert committee with xenotransplantation scientists, medical doctors, representatives from policy, law and ethics (Haniel et al. 1999).

In November 2000, TTN carried out a three-day citizens' forum on xenotransplantation in which 60 pupils and students took part as lay panel. This citizens' forum was partially financed by the Programme "Public Understanding of Science (PUSH)" of the Donors' Association for the Promotion of Sciences and Humanities (Stifterverband für die Deutsche Wissenschaft). It aimed at broadening the participants' knowledge of xenotransplantation and at supporting dialogues and mutual understanding between experts and lay people (Haniel 2002; Anonymous 2000) (also see chapter 3.2.7.7).

3.2.2.5 Philosophical Seminar of the University of Münster, argos Institute Münster

Research into ethical aspects of xenotransplantation was also carried out at the Philosophical Seminar of the University of Münster by Dr. Michael Quante, who prepared an expertise on ethical aspects of xenotransplantation for the Office of Technology Assessment at the German Parliament (Quante 1998; Quante et al. 2001), and at the Institut für gesellschaftswissenschaftliche Studien, praktische Philosophie und Bildung – argos e. V. where a comparative international analysis of published expertises on xenotransplantation was carried out (Bayertz et al. 1998) (also see chapter 3.2.5.1).

3.2.2.6 Institute of Ethnology at the University of Göttingen

The cultural dimension of organ transplantation and reproductive medicine was investigated by a research group of the Institute of Ethnology at the University of Göttingen, led by Prof. Dr. Brigitta Hauser-Schäublin. The project was initiated in 1996 and funded by the Deutsche Forschungsgemeinschaft. Organ transplantations depend on massive medical interventions into the physical nature of the respective patients and thus also into their personal identity. It was the aim of the project to understand the cultural conditions which made the development of such medical technologies possible and also to understand the cultural conditions which play a role in the process which enables the individual patient to cope with this massive intervention and to integrate it into his life. The result of the project was that technologies such as organ transplantation or reproductive medicine originate from western societies and are built on three prerequisites which are typical for western societies and the prevailing image of man:

4 It is a joint action of industry involving around 3,000 companies, industrial associations and individuals. The Stifterverband finances its funding programme exclusively from charitable donations of its members and sponsors.
- the development of anatomy as a method to enlarge one's knowledge of life and disease from the investigation of dead bodies,
- the division of man into a spiritual-mental and a physical part, and
- the "de-personalization" of body parts and organs.

It was found out that patients and their relatives could cope best with organ transplantation if they managed to perceive body and body parts as objects which are not connected to a person's individuality, with other words, if they had adopted the typically western cultural traditions on body and physical nature. Although the project did not focus on xenotransplantation many of the findings for organ transplantation seem transferable to xenotransplantation.

### 3.2.2.7 Chair for Criminal Law and Criminal Trial Law at the Georg August University of Göttingen

Prof. Dr. Hans Ludwig Schreiber holds the chair for Criminal Law and Criminal Trial Law at the Georg August University of Göttingen (*Lehrstuhl für Strafrecht und Strafprozessrecht*). His research focuses – among others – on bioethics and biolaw, especially law with regard to genetic engineering, and on organ transplantation and law. Among others, Prof. Schreiber is chairman of the Standing Committee Organ Transplantation of the German Medical Association, and also member of the Working group Xenotransplantation. Under his supervision, a dissertation has been prepared, but not yet published, on legal aspects of xenotransplantation (Jungeblodt 2002). This PhD student also co-authored an expertise on legal aspects of xenotransplantation, commissioned by the Office of Technology Assessment at the German Parliament (TAB) (Quante et al. 1998; Quante et al. 2001).

### 3.2.2.8 Institute of Jurisprudence at the University of Lüneburg

In 1999, a dissertation on the subject of consent to precautionary measures aiming at diminishing the transmission risks of unknown pathogens by xenotransplantations according to the German, Spanish and English Law was started at the Institute of Jurisprudence (*Institut für Rechtswissenschaften*) at the University of Lüneburg, being supervised by Prof. Dr. Jürgen Simon. This dissertation is completed, but not yet published. Prof. Simon also was the principal investigator in the EU project "Xenotransplantation: ethical, social, economical and legal aspects". This international project with 22 European partners had the aim to outline the present scientific-technical state of the art in xenotransplantation, to give a prognosis of the further development, to analyse the existing legal framework and to make suggestions for its xenotransplantation-specific amendment under the aspect of a legal frame and the examination of the need of new laws, and to analyse economic effectiveness and costs of xenotransplantation.
3.2.3 NGOs in the field of animal welfare and genetic engineering

There are several NGOs in Germany which are active in the animal welfare or genetic engineering field. Representatives of these NGOs have closely monitored XTP development and debate, e.g. by following the scientific literature or attending conferences and meetings (e.g. annual DAX and DTG symposia on XTP). They also sometimes were participants in panel discussions and published articles in their members’ journals (e.g. (Peters 1995; Peters 1996; Löhr 1997; Riewenherm et al. 1997; Riewenherm 1997). This holds especially true for the Bundesverband der Tierversuchsgegner - Menschen für Tierrechte e.V. and the Gen-ethisches Netzwerk.

However, due to the limited financial and personal resources, XTP was not chosen as a priority topic within the respective NGOs. The limited resources already were required for other topics and campaigns. Therefore, no XTP campaigns were launched, although initiatives taken by other actors were supported (e.g. parliamentary initiative against XTP animal experiments in Munich, see chapter 3.2.5.2).

The NGOs have more intensive links with the humanities cluster than with the biomedical cluster, and the former cluster intensively incorporated the NGOs’ issues into their debate. Nevertheless, in the XTP topic, the NGOs have remained marginal actors in the debate up to now.

3.2.4 Industry

The globally active company Novartis, based in Basel, Switzerland, holds a key role in the development of xenotransplantation. In the early 1980s, it introduced the immunosuppressive drug cyclosporine into transplantation medicine, which dramatically increased the success rate of solid organ transplantation. For several years, Novartis (or its predecessor Sandoz) held a nearly monopolistic position in the immunosuppressant market and still has a leading research position in improving the effectiveness of immunosuppression medication for transplant recipients. Moreover, it also engages in research activities on alternative options for solving the organ shortage problem, among them xenotransplantation.

Since the beginning of the 1990s, Novartis through its daughter companies and cooperation partners has been one of the main drivers of xenotransplantation development and its most important sponsor. It holds the largest herd of genetically engineered pigs as source animals and has research cooperations with the leading xenotransplantation researchers worldwide. Due to its initially monopolistic role regarding transgenic source animals, through its allocation policy of distributing transgenic pigs only exclusively to selected research groups, Novartis had considerable influence which research groups were able to carry out relevant,
publishable xenotransplantation research. Moreover, the company has considerable influence on the shaping and harmonisation of the legal framework for XTP: by announcing its will to carry out clinical xenotransplantation in the near future in the middle of the 1990s, it challenged the administration in charge to act; it presented experimental and epidemiological evidence on the risk of infection associated with XTP (Onions et al. 1998; Paradis et al. 1999) and is present in all relevant negotiations (De Wit 2001, p. 239ff.), where Novartis as a player at the forefront of XTP research establishes its way to handle xenotransplantation (e.g. regarding animal housing, screening for pathogens in pigs and humans, monitoring of patients after transplantation) as a standard and as a benchmark for its competitors.

These activities of Novartis described above hold true worldwide and also in Germany. In Germany, Novartis is an important sponsor of symposia, meetings and congresses in transplantation medicine and also gives significant financial support of projects in transplantation and xenotransplantation research. It has established close contacts to academic groups and makes use of their expertise both in allo- and xenotransplantation. Moreover, it was essential both for Novartis and PEI/RKI to cooperate because Novartis could give the RKI-PEI researchers the required ready access to research materials, and at the same time the company gained access to the administration which is in charge of oversight and control of XTP.

3.2.5 Parties, policy and administration (ministries and agencies)

3.2.5.1 Initiatives on the level of the Federal Parliament (Bundestag)

Until 1998, an intensive scientific debate of XTP had developed internationally and also in Germany. In addition, a political debate also had emerged, but the issue only seemed to be debated abroad, not in Germany: On the political level, the only perceivable activity until 1997 was a minor interpellation\(^5\) (Kleine Anfrage) of the Green party fraction in the Federal Parliament (Bundestag) (Kiper et al. 1997). This minor interpellation, submitted on November 3, 1997 comprised questions regarding

- the scope and budget of public support for XTP research in Germany,
- ethical assessment of microchimerism in xenotransplanted recipients,
- ethical assessment of XTP as such,
- the risk of infection by retroviruses, aspects of risk prevention and management,

\(^5\) Any member of the Federal Parliament (Bundestag) has the right to submit a minor interpellation. In these minor interpellations, the Federal Government may be asked to furnish information on specifically designated issues. The Federal Government is requested to reply to a minor interpellation in writing within two weeks. Minor interpellations and the Government's reply are not discussed in parliament.
• state of science and technology of xenotransplantation in general, and in particular of xenografting animal brain cells into human patients suffering from Parkinson’s disease or Chorea Huntington,
• time scale of realisation of clinical xenotransplantation,
• alternatives to XTP,
• animal protection and animal rights, cloning,
• legal aspects.

On November 27, the Federal Ministry of Health on behalf of the Federal Government submitted its written reply (Bundesregierung 1997). According to this reply, the Federal Government has the following position towards XTP:

It states that clinical xenotransplantation involving humans cannot be justified at present, but sees XTP as a possible alternative, especially in the case of hearts and kidneys, to allotransplantation, provided that questions regarding biological safety and functionality can be answered sufficiently. The Federal Government is of opinion that recipients of animal organs are not impaired in their identity as a human being and that it is justifiable to genetically engineer source animals for their use in XTP. Other possible alternatives, such as artificial hearts or tissue-engineered organs are seen as in an early stage of development so that any comparative assessment of these alternatives would be speculative and premature. The Federal Government is of opinion that the existing legal frame for XTP is sufficient. In addition, it is planned that the Ethics Advisory Board of the Federal Ministry of Health should discuss the issue in depth in 1998 (but it never did6). Regarding research policy, medium priority is assigned to XTP research involving transgenic source animals. This type of research has been publicly funded from federal funds with a budget of approximately 300,000 /year, and, according to the Federal Government, should be continued on this level. Comparable sums are invested in research programmes of artificial organs.

Shortly afterwards, in January 1998, the Parliamentary Committee for Education, Science, Research, Technology and Technology Assessment commissioned the Office of Technology Assessment at the German Parliament (TAB) to make a comparative review of XTP reports and studies which had been published between 1996 and 1998 by governments, national agencies and international organisations worldwide. This task was carried out by scientists

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6 Although it was planned that the Ethics Advisory Board of the Federal Ministry of Health, established in 1995, should discuss the issue in depth in 1998, this plan was not realised in 1998. In October 1998, general elections led to a political change in the government, and as a consequence, the Ministry of Health was no longer led by a Christian Democratic minister, but by a minister from the Green Party, and the fate of this advisory board remained unclear. In 1999, it was reinstituted, but in early 2001, the minister of health changed again and in May 2001, the Federal Chancellor established the German National Ethics Council which had overlapping competencies and responsibilities with the Ethics Advisory Board. If the Ethics Advisory Board of the Ministry of Health had dealt with XTP, at least the results did not reach the public.
from the argos Institute (argos Institut für gesellschaftswissenschaftliche Studien, praktische Philosophie und Bildung e. V.) in Münster. Eight reports were reviewed. They showed a growing scepticism whether XTP could fulfil the expectations in foreseeable time to be developed to a safe therapeutic approach. Moreover, the reviewed reports unanimously called for specific guidelines which aim at risk prevention and for criteria for starting clinical trials.

When this review was ready for publication in summer 1998, the Swiss Parliamentary Office of Technology Assessment published its technology assessment study on XTP (Hüsing et al. 1998) which had been carried out by a project team led by the German Fraunhofer Institute for Systems and Innovation Research, Karlsruhe in cooperation with Prof. Engels from the Chair of Ethics in the Life Science at the University of Tübingen. This was the first comprehensive technology assessment study on XTP written in German. Although it (also) focussed on the specific situation in Switzerland, it offered a comprehensive information base for all German-speaking countries. As a reaction, the Parliamentary Committee for Education, Science, Research, Technology and Technology Assessment commissioned the TAB to broaden the thematic scope of its monitoring project on XTP and to commission three additional studies:

- a state-of-the-art report on organ XTP, with special reference to safety problems, possible time horizons for clinical XTPs and a benchmark of German XTP research activities in international comparison. This study was carried out by Bärbel Hüsing from the Fraunhofer Institute of Systems and Innovation Research and Silke Schicktanz from the Chair of Ethics in the Life Sciences at the University of Tübingen (Hüsing et al. 2000),
- a literature review on the ethical debate of XTP, carried out by Michael Quante, Münster (Quante 1998; Quante et al. 2001),
- a literature analysis on the legal situation in Germany, carried out by Michael Quante and Stefan Jungeblodt (Göttingen) (Quante et al. 1998; Quante et al. 2001).

All four studies on XTP formed the basis of a XTP report published by the TAB (Sauter et al. 1999b). It was submitted to and approved by the Parliamentary Committee for Education, Research and Technology Assessment in December 1999. The report was very well received by parliamentarians and the public. This was due to several factors:

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7 Due to general elections in October 1998, the composition and also the name of the committee in charge changed in October 1998. The responsibility for technology assessment for the German Parliament and the work of the TAB was transferred to the Committee for Education, Research and Technology Assessment.
the high quality of the report, which was the first monitoring report of the TAB which was published as a printed matter\(^8\) of the Federal Parliament (Sauter et al. 1999a),

the fortunate timing because parliament was in the process of discussing the establishment of an enquete commission\(^9\) on biomedical issues\(^10\) at that time,

the media showed exceptional interest which was also due to the fact that in March 2000, the first successful cloning of pigs was reported in the scientific literature.

In October 2000, the Parliamentary Committee for Education, Research and Technology Assessment discussed the report in depth. As a result, it called on the Enquete Commission "Law and Ethics in Modern Medicine" to deal with xenotransplantation intensively. Moreover, it called on the Federal Government to explain its attitude towards financial support of XTP research (Sauter 2001). The Committee of Health also dealt with the report but did not formulate special conclusions or recommendations. During its period of work from March 2000 to summer 2002, the Enquete Commission "Law and Ethics in Modern Medicine" dealt with three thematic groups:

(1) Reproduction medicine and embryo protection (especially preimplantation diagnosis and different technologies for assisted reproduction),

(2) Applied medical research/New diagnostic and therapeutic methods (especially stem cell research with the aim of regenerative medicine and organ replacement, transplantation medicine) (Deutscher Bundestag Referat Öffentlichkeitsarbeit 2002),

(3) Genetic data.

Although the commission planned to deal with xenotransplantation within the thematic group 2, it did not have enough time to do so (Enquete-Kommission "Recht und Ethik der modernen Medizin" 2002).

In January 1999, a Parliamentary assembly of the Council of Europe took place. During this assembly, the assembly agreed on a recommendation regarding XTP, calling for a XTP moratorium (Council of Europe et al. 1999). A member of the German delegation to this

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\(^8\) This form of publication had previously been reserved to final reports of very large TAB projects.

\(^9\) Enquete Commissions can be established by the Bundestag, if political decisions on comprehensive and important issues are to be prepared. Enquete commissions are one of the most important interfaces between policy and science because in contrast to parliamentary committees which only have parliamentarians as members, enquete commissions comprise both members of parliament and experts which work together on an equal basis. Enquete commissions have the task to give advice to parliament, they collect and analyse information on the impacts of technical, economic and social developments, point out options for regulation and development and work out recommendations for political decisions. At the end of their work, they publish a report which serves as a basis for future decisions of the Bundestag.

\(^10\) This enquete commission "Recht und Ethik der modernen Medizin" was established in April 2000 and completed its work in summer 2002.
assembly, the member of parliament Wolfgang Wodarg, Social Democratic Party, held a speech on XTP in which he supported the call for a moratorium. A report of this assembly was given to the German Bundestag in November 1999 (Deutscher Bundestag 1999).

In September 2000, parliamentarians from the Liberal Party F. D. P. submitted a major interpellation to the Federal Government which – among a total of 53 questions in the context of "Requirement of a broad public debate on therapeutic cloning" – also contained two questions on XTP (Heinrich et al. 2000). The answer of the Federal Ministry of Health on behalf of the Federal Government was quite similar to the previous one, given in 1997: Considering the shortage of transplantable human organs, XTP research should be continued as XTP is considered as a possible alternative to allotransplantation. However, XTP is not ready for application because of the risks for patients. Moreover, the risks of infection for third parties cannot yet be sufficiently assessed so that it is not yet possible to say with confidence which medical measures will be required for limiting and dealing with these risks of infection (Bundesregierung 2001).

XTP falls into the competencies and responsibilities of several ministries: the Ministry for Education and Research (BMBF) for XTP research, the Ministry for Health is responsible for the clinical application of XTP and the prevention and management of possible risks of infection, and the Ministry of Justice for legal aspects of XTP. Within these ministries, XTP has been treated as an issue of low priority. The ministries follow the XTP development, but have delegated their possible political influence on the shaping of XTP policy mainly to national and international committees and individual scientists from the biomedical/natural science cluster who function as national representatives in international committees.

There are diverging opinions whether XTP should be regulated on the level of acts, or whether guidelines and recommendations drawn up by scientific and medical associations are sufficient. Moreover, the juridical dispute is still not settled whether XTP requires specific regulation, or whether existing regulation is sufficient. The Ministry of Health has the leading role in drafting a national XTP regulation. It is planned to start the parliamentary procedure on such a national legislation in the period 2002-2005.

3.2.5.2 Initiatives on the level of federal states

XTP has also been an issue of political activities on the level of at least one federal state, Bavaria. In February 1997, the Green Party fraction within the Bavarian Parliament launched a written request to the Bavarian Government regarding XTP in Bavaria, with a focus on the use of animals and clinical XTP involving humans. In July 1997, the Ministry of Education, Cultural Affairs, Science and Arts gave its reply. It described the XTP research projects which are carried out at the Medical School Großhadern in Munich and the Surgical Clinic of the University of Würzburg. Moreover, it states that it is not possible to foresee whether and
when xenotransplantations of organs from transgenic source animals will be carried out in Bavaria. A need for deliberation regarding ethical aspects and health risks to humans is seen. It is announced that ethical aspects will be addressed by a project within the Institute Technology – Theology – Natural Sciences and by networking between scientists from medicine and natural sciences and ethicists. The risk issue is addressed by ongoing research (Staatsministerium für Unterricht, Kultus, Wissenschaft und Kunst 1997).

In March 1998, the same parliamentarians proposed a motion that XTP research projects, presently carried out at Bavarian universities, should be stopped for the time being. Moreover, an independent institution should be commissioned with the assessment of the ethical aspects of XTP (Münzel et al. 1998). This motion was discussed in three committees of the Bavarian Landtag (Ausschuss für Hochschule Forschung und Kultur 1998) and in the Bavarian Parliament (Bayerischer Landtag), but was rejected by the votes of the Christian Social Party and the Social Democratic Party (Bayerischer Landtag 1998).

Two and a half years later, parliamentarians from the Social Democratic Party became alerted to a planned XTP animal experiment at the Medical School Großhadern under the supervision of Prof. Claus Hammer. There were suspicions that the approval procedure for this animal experiment had not been correct, because more non-human primates were allowed to be used and killed in these experiments than were absolutely needed. By an urgent motion, a moratorium for these experiments was achieved (Maget et al. 2000) until the matter had been discussed during a hearing of the Committee for Universities, Research and Culture. Moreover, the Tierschutzbund Bayern, a Bavarian NGO dedicated to animal welfare, also supported this political initiative by a postcard campaign and local demonstrations. Another animal rights NGO, the Bundesverband der Tierversuchsgegner - Menschen für Tierrechte e.V., took legal measures (Dienstaufsichtsbeschwerde) against the Bavarian government in order to withdraw Prof. Hammer the permission to carry out any animal experiments. The focus, however, was not XTP but animal experiments.

Again one year later, the Green Party took up again the issue of XTP and organised a hearing on XTP in September 2001. Its main intention was to summarise the present state of XTP in order to prepare further political initiatives on the level of the state Bavaria. As a result of this hearing, the fraction of the Green Party proposed a motion to carry out another hearing on XTP (Dürr et al. 2001). This new hearing should be initiated by the Committee of University, Research and Culture and the Committee of Social, Health and Family Policy. The XTP reports prepared by the TAB (Sauter et al. 1999b) and the Fraunhofer Institute for Systems and Innovation Research (Hüsing et al. 2001) should serve as a basis for this hearing. This motion was accepted, and the hearing took place in November 2002.
3.2.6 Churches

In order to gain an overview and orientation regarding XTP before its clinical application, the protestant-catholic contact and dialog group that provides a framework for consultation and agreement between the Council of the Evangelical Church in Germany (Rat der Evangelischen Kirche in Deutschland) and the German Bishops’ Conference (Deutsche Bischofskonferenz) suggested establishing a task force with the mandate of elaborating the most important aspects for an ethical assessment of xenotransplantation. The Church Office of the Evangelical Church in Germany and the Secretariat of the German Bishops’ Conference asked representatives from various fields of expertise to participate in the task force:

- Prof. Dr. Dietrich von Engelhardt (medical and science history), Lübeck,
- Prof. Dr. Johannes Fischer (systematic theology), Basel,
- Dr. Wiltrud Kernstock-Jörns (medical psychotherapy), Berlin,
- Prof. Dr. Johannes Reiter (moral theology), Mainz,
- External Lecturer Dr. Hans J. Schlitt (surgery), Hanover,
- Prof. Dr. Kurt Seelmann (criminal law, medical law and philosophy of law): observer's contribution (legal aspects), Basel.

Under the aegis of Dr. Ursula Beykirch, Bonn, and church official Dr. Renate Knüppel, Hanover, the task force developed and formulated a joint position which was published in 1998. In the course of the discussions it became clear that Dr. Kernstock-Jörns would not be able to support some of the essential statements, particularly in relation to psychological aspects of transplantation medicine and the ethical evaluation of xenotransplantation. It was not possible to integrate in the text her rejection of continued research on xenotransplantation, which is based on a different view of the relationship between humans and animals and on a different concept of human medical therapy. Her personal position is reflected in a separate chapter at the end of the publication. The task force's text does not provide a comprehensive and conclusive discussion of all issues related to xenotransplantation. Rather, it should be regarded as a contribution to the general debate and an aid to ethical discernment, reflecting the present level of knowledge on xenotransplantation (Kirchenamt der Evangelischen Kirche in Deutschland et al. 1998, p. 5-6).

The group provided information and arguments on the issues

- Scientific-medical state of XTP research,
- Cultural-historical aspects,
Reactions and attitudes in the general population,
Psychological aspects,
Legal aspects,
Ethical aspects, especially opportunities and risks; ethical conflicts, ethos of researchers.

This choice of topics and the weight which is given to them clearly differs from the "main stream" framing of the XTP problem. The group identified the following decisive ethical conflicts:

- the conflict between the right to live of man and the right to live of animals, the conflict between solidarity between human beings and solidarity between man and animal,
- the conflict which originates from the different perception of affected and non-affected persons,
- the conflict which originates from the conception of an animal organ in a human body,
- the conflict between accepting one’s own finite nature which is inherent to one’s physical nature, and pushing these limits at any cost.

The group (with the exception of Dr. Kernstock-Jörns) came to the conclusion that different positions with regard to XTP can be taken which are all well founded by arguments. However, XTP is seen as only one option to respond to the shortage of human donor organs. Dealing with the organ shortage problem in a responsible way must comprise the search for and inclusion of alternative, other options than XTP. This research of XTP and alternative options has to orient itself by the saving of human lives, by the dignity of man and by the respect of animals (Kirchenamt der Evangelischen Kirche in Deutschland et al. 1998).

In addition, XTP was taken up by several protestant and catholic academies. Their target group are interested lay people from different backgrounds. These academies offer seminars, symposia, workshops and discussions on different topics. Several discussion- and dialogue-oriented events on XTP were organised and carried out by theses academies.

3.2.7 Public

3.2.7.1 Attitude towards organ transplantation

In Germany there are no figures available on clinical xenotransplantation treatments, because organ xenotransplantation is a medical procedure which is not carried out in clinical practice. However, transplantations of organs derived from human donors have been carried out since 1963, and more than 60,000 organs have been transplanted in Germany during the
past four decades (figure 3.9). In the last ten years, the number of transplanted organs has risen to a total of 3,710 in 2001 (figure 3.10), but the increase is mainly due to a rising proportion of kidneys and partial livers from living donors.

**Figure 3.9: Organ transplantations in Germany since 1963**

![Graph showing organ transplantations in Germany](image)

Each year, 3,500-3,700 organs are donated and transplanted in Germany (figure 3.10) which are derived from approximately one thousand donors (table 3.2). With 13.1 donors per million inhabitants, Germany has a middle position in international comparison, but a much lower donation rate than Spain and Austria which are the leading countries internationally (table 3.2). It can be concluded that there is a reluctance in the general population of Germany to donate organs for transplantation.
Table 3.2: Organ donations in selected countries in 2001

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of organ donors</th>
<th>Organ donors per million inhabitants</th>
<th>Multiorgan donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>1335</td>
<td>32.5</td>
<td>84.4%</td>
</tr>
<tr>
<td>Austria</td>
<td>191</td>
<td>23.7</td>
<td>77.8%</td>
</tr>
<tr>
<td>USA</td>
<td>6081</td>
<td>22.6</td>
<td>n. a.</td>
</tr>
<tr>
<td>Belgium</td>
<td>222</td>
<td>21.6</td>
<td>47.7%</td>
</tr>
<tr>
<td>Portugal</td>
<td>202</td>
<td>20.2</td>
<td>78.7%</td>
</tr>
<tr>
<td>R. Ireland</td>
<td>68</td>
<td>18.2</td>
<td>81%</td>
</tr>
<tr>
<td>France</td>
<td>1066</td>
<td>17.8</td>
<td>n. a.</td>
</tr>
<tr>
<td>Latvia</td>
<td>41</td>
<td>17.8</td>
<td>n. a.</td>
</tr>
<tr>
<td>Italy</td>
<td>988</td>
<td>17.1</td>
<td>n. a.</td>
</tr>
<tr>
<td>Finland</td>
<td>88</td>
<td>17</td>
<td>48.9%</td>
</tr>
<tr>
<td>Czech.Rep</td>
<td>172</td>
<td>16.7</td>
<td>48.3%</td>
</tr>
<tr>
<td>Malta</td>
<td>6</td>
<td>15</td>
<td>100%</td>
</tr>
<tr>
<td>Norway</td>
<td>65</td>
<td>14.4</td>
<td>83%</td>
</tr>
<tr>
<td>Hungary</td>
<td>137</td>
<td>13.7</td>
<td>19%</td>
</tr>
<tr>
<td>Canada</td>
<td>420</td>
<td>13.5</td>
<td>n. a.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>95</td>
<td>13.2</td>
<td>76.8%</td>
</tr>
<tr>
<td>Germany</td>
<td>1073</td>
<td>13.1</td>
<td>77%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>777</td>
<td>13.1</td>
<td>83%</td>
</tr>
<tr>
<td>Denmark</td>
<td>70</td>
<td>12.9</td>
<td>74.3%</td>
</tr>
<tr>
<td>Luxemburg</td>
<td>5</td>
<td>12.5</td>
<td>100%</td>
</tr>
<tr>
<td>Sweden</td>
<td>108</td>
<td>12.1</td>
<td>75.9%</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>187</td>
<td>11.7</td>
<td>61.4%</td>
</tr>
<tr>
<td>Poland</td>
<td>450</td>
<td>11.6</td>
<td>38.4%</td>
</tr>
<tr>
<td>Slovenia Rep.</td>
<td>23</td>
<td>11.5</td>
<td>85%</td>
</tr>
<tr>
<td>Estonia</td>
<td>14</td>
<td>10</td>
<td>7.14%</td>
</tr>
<tr>
<td>Australia</td>
<td>180</td>
<td>9.3</td>
<td>81%</td>
</tr>
<tr>
<td>Israel</td>
<td>59</td>
<td>9</td>
<td>37.2%</td>
</tr>
<tr>
<td>Croatia</td>
<td>32</td>
<td>7.3</td>
<td>62.5%</td>
</tr>
<tr>
<td>Greece</td>
<td>32</td>
<td>3.2</td>
<td>n. a.</td>
</tr>
<tr>
<td>Turkey</td>
<td>89</td>
<td>1.3</td>
<td>n. a.</td>
</tr>
<tr>
<td>Romania</td>
<td>21</td>
<td>0.95</td>
<td>76.19%</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>2</td>
<td>0.26</td>
<td>n. a.</td>
</tr>
</tbody>
</table>

n. a. data not available


Several opinion polls have been carried out in the general population which also refer to certain aspects of attitudes towards organ transplantation. However, no comprehensive representative survey or opinion poll could be identified which covers all aspects in depth. Therefore, the following results were compiled from different surveys which were carried out by different polling institutes, in different years and in different samples of the general population. Therefore, the obtained data cannot be directly compared, but at least give an indication of the general trends.
The surveys which were analysed are listed in table 3.3. They cover both the period before and after the German Transplantation Act came into force (December 1998). Taken together, they cover the following aspects of organ transplantation:

- general attitude towards organ transplantation,
- attitude towards organ donation,
- willingness to serve as an organ donor,
- attitude towards different treatment options within transplantation medicine.
Table 3.3: Overview of analysed opinion polls on various aspects of organ transplantation in Germany

<table>
<thead>
<tr>
<th>Polling institute</th>
<th>Period of investigation</th>
<th>Methodology</th>
<th>Sample</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>forsa, Gesellschaft für Sozialforschung und statistische Analysen mbH, Berlin</td>
<td>August 8-31, 2001</td>
<td>computer-assisted telephone interviews</td>
<td>3,254 persons over 14 in Germany</td>
<td>Opinion poll commissioned by Bundeszentrale für gesundheitliche Aufklärung</td>
</tr>
<tr>
<td>Institut für Demoskopie Allensbach</td>
<td>September 27 – October 6, 2000</td>
<td>personal interviews</td>
<td>1,137 persons over 16 in Germany</td>
<td>Opinion poll commissioned by Körber-Stiftung</td>
</tr>
<tr>
<td>Akademie für Technikfolgen-Abschätzung in Baden-Württemberg, Stuttgart in cooperation with ZUMA and INRA Deutschland; quoted as Zwick und Renn 1998</td>
<td>Spring 1998</td>
<td>telephone interviews</td>
<td>persons in the German &quot;Land&quot; Baden-Württemberg</td>
<td>Study commissioned by the Landesforschungsbeirat</td>
</tr>
<tr>
<td>EMNID-Institut, Bielefeld</td>
<td>1997, 1998</td>
<td>n. a.</td>
<td>n. a.</td>
<td>General population in Germany</td>
</tr>
<tr>
<td>Institut für Demoskopie Allensbach</td>
<td>1991, 1994</td>
<td>n. a.</td>
<td>1,105 persons over 16 in Germany</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: DSO 2002; www.dso.de; accessed October 15th, 2002
3.2.7.2 General attitude towards organ transplantation

One survey covers general attitudes towards organ transplantation (table 3.4). It shows that organ transplantation is seen as a good and right treatment by the large majority of Germans.

Table 3.4: Attitude of the German population towards organ transplantation 1997 and 1998

<table>
<thead>
<tr>
<th>Question: Do you think that organ transplantation is a good idea and the right thing, or are you against organ transplantation</th>
<th>1997</th>
<th>1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>good idea, right thing</td>
<td>83,5 %</td>
<td>73,8 %</td>
</tr>
<tr>
<td>am against it</td>
<td>10,1 %</td>
<td>13,2 %</td>
</tr>
<tr>
<td>don't know</td>
<td>4,4 %</td>
<td>13,0 %</td>
</tr>
<tr>
<td>no answer</td>
<td>0,2 %</td>
<td>0,1 %</td>
</tr>
</tbody>
</table>

Source: Emnid Institute 1997, 1998

Another survey which was carried out in the population of Baden-Württemberg (a region in the south-west of Germany) addressed attitudes towards "new" technologies. One question put organ transplantation into perspective with other technologies (table 3.5). It shows that organ transplantation is seen as positive by approximately two thirds of the respondents. The authors of the study explain this by the fact that organ transplantation fulfils societal needs in the field of health which is always given very high priority. On the other hand, the large majority of the respondents does not favour genetic engineering, a technology which is crucial for the success of xenotransplantation.
Table 3.5: Attitude of the population in Baden-Württemberg towards different technologies 1998, among them organ transplantation

<table>
<thead>
<tr>
<th>Question: What do you think of the following technologies?</th>
<th>Percentage of respondents with &quot;good&quot; or &quot;very good&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solar energy</td>
<td>89 %</td>
</tr>
<tr>
<td>3-litre-car</td>
<td>83 %</td>
</tr>
<tr>
<td>Organ transplantation</td>
<td>67 %</td>
</tr>
<tr>
<td>Space research</td>
<td>42 %</td>
</tr>
<tr>
<td>Multimedia</td>
<td>39 %</td>
</tr>
<tr>
<td>Robots in industry</td>
<td>36 %</td>
</tr>
<tr>
<td>Cellular phones</td>
<td>30 %</td>
</tr>
<tr>
<td>Genetic engineering</td>
<td>21 %</td>
</tr>
<tr>
<td>Nuclear energy</td>
<td>21 %</td>
</tr>
</tbody>
</table>

Source: Zwick and Renn, 1998

3.2.7.3 Attitude towards organ donation

One survey covers the population's attitude towards organ donation (table 3.6). It shows that organ donation is seen as positive as organ transplantation, but that this is an issue which is intensively only dealt with by relatively few people.

Table 3.6: Attitude of the German population towards organ donation in 2001

<table>
<thead>
<tr>
<th>Question: Which view do you take of organ donation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>positive</td>
</tr>
<tr>
<td>neutral</td>
</tr>
<tr>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question: Have you already gone into the issue of organ donation intensively, or have you dealt with it only a little or not at all?</th>
</tr>
</thead>
<tbody>
<tr>
<td>intensively</td>
</tr>
<tr>
<td>a little</td>
</tr>
<tr>
<td>not at all</td>
</tr>
</tbody>
</table>

Source: forsa 2001
3.2.7.4 Willingness to serve as organ donor

The willingness of the respondents to serve as an organ donor themselves is covered in two surveys (table 3.7). Approximately two thirds of the respondents are in principle willing to serve as an organ donor. This share of the population is significantly lower than the share which supports organ transplantation (see table 3.4). And only a minority takes the initiative and gets an organ donor card in order to explicitly state one’s will towards organ donation. This issue is addressed in two other surveys (table 3.7).

Table 3.7: Attitude of the German population to serve as an organ donor themselves

<table>
<thead>
<tr>
<th>Question</th>
<th>Would you agree that your organs are used for transplantations after your death?</th>
<th>Would you on principle agree or not that after your death your organs are explanted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes, agree</td>
<td>74,6 %</td>
<td>64,6 %</td>
</tr>
<tr>
<td>no, don't agree</td>
<td>19,3 %</td>
<td>33,4 %</td>
</tr>
<tr>
<td>no answer</td>
<td>6,0 %</td>
<td>1,9 %</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Question</th>
<th>Have you considered seriously to get an organ donor card, or is that out of the question for you?</th>
<th>Do you yourself have an organ donor card?</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes, have one</td>
<td></td>
<td>6 %</td>
</tr>
<tr>
<td>have considered seriously</td>
<td>30 %</td>
<td>21 %</td>
</tr>
<tr>
<td>undecided, perhaps, could be</td>
<td>28 %</td>
<td>36 %</td>
</tr>
<tr>
<td>is out of the question for me</td>
<td>36 %</td>
<td>38 %</td>
</tr>
<tr>
<td>no</td>
<td></td>
<td>87 %</td>
</tr>
</tbody>
</table>

Table 3.8: Attitudes of the German population towards different treatment options within present and future transplantation medicine

<table>
<thead>
<tr>
<th>Question: It has been possible for a long time that hearts and other organs can be transplanted. Due to scientific progress even more will soon be possible. For which issues on this list you would say: it is a good thing if one can do that in case of organ damage or diseases.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung transplantation 80 %</td>
</tr>
<tr>
<td>Blood vessel transplantation 68 %</td>
</tr>
<tr>
<td>Nerve transplantation 59 %</td>
</tr>
<tr>
<td>Womb transplantation 37 %</td>
</tr>
<tr>
<td>Transplantation of single brain cells 26 %</td>
</tr>
<tr>
<td>Implantation of a brain chip which improves brain performance 21 %</td>
</tr>
<tr>
<td>Brain transplantation 10 %</td>
</tr>
<tr>
<td>Transplantation of one's own head to another body 4 %</td>
</tr>
<tr>
<td>none of these/no answer 14 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question: Assumed you were suffering from severe heart disease and are in need of a new heart. If you could choose, what from this list would you like most, what would you take?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart of a human organ donor 53 %</td>
</tr>
<tr>
<td>Heart which was grown from your own body cells 47 %</td>
</tr>
<tr>
<td>Artificially produced heart 37 %</td>
</tr>
<tr>
<td>Heart from an animal, e. g. pig or baboon 8 %</td>
</tr>
<tr>
<td>Heart derived from the cells of an embryo 6 %</td>
</tr>
<tr>
<td>none of these/no answer 7 %</td>
</tr>
</tbody>
</table>

Source: Institut für Demoskopie Allensbach 2000

The discrepancy between the very positive attitude towards organ transplantation and organ donation and the striking reluctance to get an organ donor card might be explained by results from the 1994 Institut für Demoskopie Allensbach survey: Only 17 % of the respondents are confident that there will be no misuse of donated organs (e. g. sale) while 63 % fear such a misuse and 20 % are undecided. 37 % of the respondents do not fear that holders of an organ donor card will be more easily declared as clinically dead, while two thirds suspect such a possibility to a certain extent (35 % fear this, 28 % undecided or don't know). There
are no data available from opinion polls which indicate whether these suspicions have declined after the transplantation act has come into force in 1998.

3.2.7.5 Attitude towards different treatment options within transplantation medicine, among them xenotransplantation

Although the German population has a very positive attitude towards organ transplantation (see table 3.4), they show a differentiated opinion towards different treatment options, as can be seen from the results of a survey carried out in 2000 by the Institut für Demoskopie Allensbach (table 3.8). If people are given the choice between different options, xenotransplantation is preferred by a very small share of the (healthy!) population (8 %). These results are in strong contrast to a survey carried out among severely ill patients who have already received a (human) organ or are on the waiting list (Schlitt et al. 1999) (see chapter 3.2.8). In this group 58 % would accept xenografts even if they were inferior to allografts, and even 77 % would accept them if they were equal to allografts.

3.2.7.6 Attitudes towards applications of genetic engineering, among them xenotransplantation

Moreover, a survey on genetic engineering has been carried out in the general population of the EU which also covers attitudes towards xenotransplantation and in addition allows for a cross-country comparison of attitudes. Table 3.9 summarises the results for Germany, figures 3.11-3.14 put them into perspective with other European countries. Although these data were obtained in the context of genetic engineering while the data from most of the other surveys quoted here were obtained in the context of transplantation medicine, they show a critical stance of the German population towards the option of xenotransplantation: 42 % of the German respondents consider xenotransplantation as not useful for society, as morally not acceptable (60 %), as risky (55 %) and as an approach that should not be encouraged in society (55 %), respectively. This result is in line with results from other surveys on genetic engineering, which show that the overall judgement of a technology is not only influenced by the perception of the associated risk (Slaby et al. 2001), but that its moral acceptability also plays a major role (Hampel 1999).
### Table 3.9: Attitudes of the German population towards xenotransplantation

<table>
<thead>
<tr>
<th>Question</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you definitely agree, tend to agree, tend to disagree or definitely disagree that it is useful for society to introduce human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants?</td>
<td>47 %</td>
<td>42 %</td>
<td>11 %</td>
</tr>
<tr>
<td>Do you definitely agree, tend to agree, tend to disagree or definitely disagree that it is risky to introduce human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants?</td>
<td>55 %</td>
<td>33 %</td>
<td>12 %</td>
</tr>
<tr>
<td>Do you definitely agree, tend to agree, tend to disagree or definitely disagree that it is morally acceptable to introduce human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants?</td>
<td>28 %</td>
<td>60 %</td>
<td>12 %</td>
</tr>
<tr>
<td>Do you definitely agree, tend to agree, tend to disagree or definitely disagree that society should be encouraged to introduce human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants?</td>
<td>32 %</td>
<td>55 %</td>
<td>13 %</td>
</tr>
</tbody>
</table>

Source: Durant et al. 1998
Figure 3.11: Attitude of the German population towards the usefulness of XTP for society in international comparison

Source: Durant et al. 1998: 249

Figure 3.12: Attitude of the German population towards the riskiness of XTP in international comparison

Source: Durant et al. 1998: 252

Figure 3.13: Attitude of the German population towards the moral acceptability of XTP in international comparison

Source: Durant et al. 1998: 255
3.2.7.7 Attitudes towards xenotransplantation in a citizens’ forum

In November 2000, the Institute Technologie – Theology – Natural Sciences (TTN) at the Ludwig Maximilians University of Munich (see chapter 3.2.2.4) carried out a citizens’ forum on xenotransplantation in cooperation with the Evangelische Akademie Tutzing. Citizens’ fora are a certain type of consensus conference, in which lay persons form an informed opinion on a given topic after intensive consultation of experts from the field. In this citizens’ forum on xenotransplantation the group of lay persons was formed by 60 pupils and students. At the beginning of the forum, 75 % of the lay participants said they would agree to receive an animal organ in case of failure of their own organ. An even larger share supported research on xenotransplantation. After the three-day forum, the share of those willing to receive an animal organ had dropped to 26 %, and hardly 40 % still supported research on xenotransplantation. This increase in negative attitudes towards xenotransplantation was explained by the fact that in the beginning of the event, participants felt ill informed on the details of xenotransplantation, but learned during the forum of the unsolved questions in xenotransplantation (e. g. rejection, physiological compatibility between donor and recipient, risks of infection). These unsolved questions were given as reasons for the more negative or sceptical attitudes after the forum (Anonymous 2000; Haniel 2002). This result is in line with findings from other projects on attitudes towards biotechnological innovations which showed that more information does not “automatically” lead to larger acceptance of the innovation, but to a more decided and differentiated opinion (e. g. Zimmer 2002; Hampel 1999, p. 33ff.).

3.2.8 Patients

There are numerous patient organisations and self help groups in the field of organ transplantation in Germany. Some of these organisations operate on a national level (e. g. Bundesverband der Organtransplantierten e.V., Verband Organtransplantierter Deutschlands
e.V.), others on a regional level (e.g. Herztransplantation Südwest e.V., Interessengemeinschaft organtransplantierter Patienten e.V., Berlin), and others are linked to transplantation centres and offer support primarily to those patients who were transplanted in this transplantation centre (e.g. Aachener Förderkreis für Organtransplantationen e.V., Selbsthilfegruppe Organtransplantierter im Förderkreis Herzzentrum Münster e.V.). There are also organ-specific patient organisations (e.g. Dialysepatienten Deutschlands e.V., Selbsthilfe Lebertransplantierter Deutschland e.V.) and groups targeted at certain patient groups (e.g. children (Bundesverband Herzkranke Kinder e.V.) or for transplant recipients who do a lot of sport (Deutsche Sportvereinigung für Organtransplantierte e.V.)).

These different organisations have in common that they inform patients and their relatives as well as the public about organ transplantation and organ donation, that they give advice and support to individual patients, that they look after their members and that they maintain a network of contacts to all relevant actors in transplantation medicine. The larger organisations are also active on a political level by safeguarding the interests of their members. Their field of political activity are mainly questions related to the German Transplantation Act and its implementation, in the field of health and social policy as well as policy for the handicapped.

Xenotransplantation is not a field of high priority to patient organisations because it is still rather far from the clinic, and patients and their relatives organised in patient groups have different topics with higher relevance on their agenda. Nevertheless, representatives from patient organisations attend scientific meetings and conferences in transplantation medicine, review the scientific literature for new technological developments and treatment options, and exchange information with members from the transplantation surgery community. Through these channels, information on xenotransplantation was also transferred to organ transplantation patients, and they were referred to further reading on this subject: For example, the internet forum organ donation and transplantation (http://organspende.solution.de/orgatrans/org-start.html) offers in the category "Information" a text on xenotransplantation and links to further reading and position papers of other actors. However, patient organisations take a predominantly recipient role. No position paper on xenotransplantation from patient organisations could be identified.

It can be assumed that the assessment of XTP varies widely between individual patients, but should in total be more favourable of XTP than the general population. Internationally, several surveys of patients’ attitudes towards XTP have been carried out (e.g. (A National Kidney Foundation Study 1997; Arundell et al. 1997; Ward 1997; Mohacsi et al. 1997; Coffman et al. 1998; Julvez et al. 1999; Sanner 2001b; Sanner 2001a; Omnell Persson et al. 2001)). One survey was carried out in Germany in 1998 (Schlitt et al. 1999).

It was the aim of this study in Germany to analyse the attitudes of patients toward transplantation of xenogeneic organs and evaluate factors influencing these attitudes.
Attitudes toward xenogeneic compared with allogeneic organ grafts were evaluated by means of detailed questionnaires in 1,049 patients in Germany, who either had received transplants (n=722) or were on the waiting list for various organ grafts (n=327). Answers were correlated to demographic data as well as to the physical and mental conditions of the patients.

The survey indicates that 77 % of patients would accept xenografts while 7 % would refuse them if results of xenotransplantation were comparable with those of allotransplantation, 16 % were undecided. If xenotransplantation were associated with increased risks due to more intensive medication 58 % would still basically accept xenografts. Acceptance of xenografts was significantly higher in patients who had received transplants and among males. Age, religion, waiting time, and type of organ were not found to influence acceptance rates. Xenografts were thought to be associated with considerable or severe emotional stress by 23 % of patients, versus 3 % for allografts. The pig was the preferred donor animal, and gene therapeutic manipulation for improvement of results would be accepted by 84 %. Major concerns for the patients were inadequate graft function/increased risk of rejection (60 %), risk of disease transmission (52 %), emotional concerns (24 %) and animal-rights concerns (15 %). The authors conclude from the results of this survey that the potential acceptance rate of xenografts would be quite high, with a more positive attitude in transplanted patients than in waiting-list patients. Interestingly, patients waiting for a life-saving organ (heart, lung) were especially sceptical in comparison to already transplanted patients. Major concerns about xenotransplantation currently are functional inferiority and transmission of diseases (Schlitt et al. 1999).

### 3.3 Which ethical questions are raised on the various levels in the XTP debate?

The ethical questions which are raised in the media have been outlined in chapter 3.1.2.

Table 3.10 gives an overview of ethical questions which have been raised within the German XTP arena. However, many of the questions have only be addressed in depth by ethicists, philosophers and academic law schools. This group of actors only holds a minor position within the German XTP arena as it is not very influential with respect to shaping the general discourse.

The influential actors' group consists mainly of representatives of the science/medicine disciplines. As far as they are concerned with ethical questions they focus on those questions which will be of relevance if one assumes that XTP will really be applied to human patients. Reflections on the questions whether XTP is an ethically acceptable option in general (and therefore should be done at all) or whether it is inferior to alternative options on an ethical basis are not performed. Moreover, this group pragmatically focuses on measures...
how these ethical requirements can be fulfilled in practice without doing deeper reflection on the ethical issues as such. As they are mostly from the medical profession, they refer to the ethic of helping and curing which guides their decisions. Moreover, they focus on the beneficience for the individual patient whereas positive and negative impacts on the level of society is not taken into consideration with similar intensity. In table 3.10, the ethical issues which are primarily addressed by this influential group is printed in bold italics.
### Table 3.10: Ethically relevant aspects of XTP which have been raised in the German XTP arena

<table>
<thead>
<tr>
<th>Aspects of xenotransplantation</th>
<th>Ethical question</th>
</tr>
</thead>
</table>
| Xenotransplantation aims at satisfying the demand for organs for transplantation, as a result saving lives and improving quality of life in transplant recipients | *Is saving of lives and improving quality of life by organ transplantation a legitimate aim?*  
What are the impacts of transplantation on our concept of medicine, of health, disease and death ("spare part replacement") |
| At present, the common opinion in the xenotransplantation community is:  
Xenotransplantation is acceptable in general, but should not yet be performed, in future only under certain conditions. | *Is xenotransplantation an ethically acceptable means to achieve the aim of saving lives and improve quality of life?*  
*a) in general/in principle?*  
*b) now/when? relevant prerequisites and frame conditions?*  
Do we have to differentiate with respect to organs, to cultural background, to religious background, to source animals? |
| The aim of xenotransplantation can only be achieved if the following prerequisites are fulfilled: |  
- availability of those organs which are in short supply  
- equal access to xenotransplants for all patients in need of an organ  
- xenotransplant function must be at least equivalent to allotransplant function  
At present, it is  
- an open question whether xenotransplantation will supply all required organs,  
- Is resource allocation to xenotransplantation justified if xenotransplantation only provides a partial solution to the organ shortage problem? Is resource allocation to xenotransplantation instead of alternatives within the research system justified? |
### Table 3.10 continued

<table>
<thead>
<tr>
<th>Aspects of xenotransplantation</th>
<th>Ethical question</th>
</tr>
</thead>
<tbody>
<tr>
<td>• clear that xenotransplantations will be at least as expensive as allotransplantations (= expensive high-tech option); it is an open question who will have to cover the costs in future,</td>
<td>How can equal access for all patients be guaranteed?/Is resource allocation within the national health care system to xenotransplantation justified? Is resource allocation to xenotransplantation justified on a supranational level?</td>
</tr>
<tr>
<td>• most unlikely that xenotransplants will function as good as allotransplants within the foreseeable future. This is due to four unsolved scientific-technical problems (rejection, physiology, psychology, infection).</td>
<td>(Would xenotransplantation as the only option violate the patient's right for autonomy and justice if he refuses xenotransplantation for personal reasons (religion, cultural values, psychological reasons)?) How can equal access of patients in need of an organ to allotransplantation and xenotransplantation be guaranteed?</td>
</tr>
<tr>
<td>All in all, at the present state of the art, it is unlikely that a patient would benefit from xenotransplantation; a prolongation of life for several days without improvement of quality of life seems achievable.</td>
<td>How can free and informed consent of patients be guaranteed? How should the patients' well-being be weighed against advancement of science and commercial interests? Which milestones must be achieved in preclinical research before first xenotransplantations may be performed on humans? Who should be involved in these decisions? To which extent should both private and public sector be involved in xenotransplantation R&amp;D? What are the criteria of organ allocation to individual patients if allotransplants are superior to xenotransplants? How can discrimination of xenograft recipients compared to allograft recipients be avoided?</td>
</tr>
<tr>
<td>In the medium term, bridging the waiting time until an allotransplant becomes available seems possible. As a result, xenotransplantation as inferior option will aggravate the problems of human organ shortage and human organ allocation.</td>
<td></td>
</tr>
</tbody>
</table>
Table 3.10 continued

<table>
<thead>
<tr>
<th>Aspect of xenotransplantation</th>
<th>Ethical question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overcoming xenograft rejection requires genetically engineered, cloned, &quot;humanised&quot; source animals, intensive immunosuppressive medication, tolerance induction in the recipient.</td>
<td>Does humanising of source animals and incorporation of animal organs into humans violate &quot;natural barriers&quot;?</td>
</tr>
<tr>
<td>It is an open question whether animal organs will function properly in the human host; it may not be possible to overcome all incompatibilities by genetic engineering of the source animal and medication.</td>
<td></td>
</tr>
<tr>
<td>In analogy to allotransplantation, it can be assumed that xenotransplantation may have impacts on mental state, identity and personality.</td>
<td></td>
</tr>
<tr>
<td>Transplant recipients may be infected by known animal pathogens; previously unknown pathogens may emerge which might be a health hazard to patients, contact persons and the general population.</td>
<td>How should individual benefit be weighed against collective risk? How can the patient's right to opt out at any time be weighed against the request for life-long monitoring and precautionary measures?</td>
</tr>
</tbody>
</table>
| To rule out infection by known animal pathogens, "germ-free" source animals will be bred, genetically engineered and raised under specific pathogen free conditions. To recognise emergence of unknown pathogens, life-long monitoring of patients (and others?) is required; for management of infection, precautionary measures and quarantine will be imposed. | *Which risk assessment and risk management strategies and measures are appropriate? Who should be involved in these decisions?*  
*How can free and informed consent be guaranteed? Which are the persons concerned from whom informed consent must be obtained?*  
*How can economic benefits and burdens be fairly divided between private and public sector?* |
### Table 3.10 continued

<table>
<thead>
<tr>
<th>Aspect of xenotransplantation</th>
<th>Ethical question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animals function in different roles in xenotransplantation:</td>
<td><em>Is it ethically justified to use animals for the purpose of xenotransplantation?</em></td>
</tr>
<tr>
<td>• as lifesaver and improver of quality of life (death of animal)</td>
<td>a) in general?</td>
</tr>
<tr>
<td>• as foreign body (rejection; requirement for humanisation of source animal (genetic engineering, cloning));</td>
<td><em>b) now? when? relevant prerequisites and frame conditions?</em></td>
</tr>
<tr>
<td>• as pathogen source (genetic engineering, cloning, breeding and raising under SPF conditions),</td>
<td><em>Do we have to differentiate with respect to the different usages of animals in xenotransplantation?</em></td>
</tr>
<tr>
<td>• as model for man (preclinical research).</td>
<td><em>Do we have to differentiate with respect to different animal species?</em></td>
</tr>
<tr>
<td>At present, the common opinion in the xenotransplantation community is: pigs, but not non-human primates should be used as source animals; non-human primates may be used in preclinical research as model for man (xenograft recipient, infection studies).</td>
<td>What are the impacts of mankind's relation to animals?</td>
</tr>
</tbody>
</table>

The ethical issues which are primarily addressed by the influential science/medicine actor group in the German XTP arena are printed in bold italics.

Source: ISI research, ISI XTP projects 1997-2001
3.4 Which solutions are being debated or have been taken?

At present, the common opinion in the German biomedical xenotransplantation community is: Xenotransplantation is acceptable in general, but should not yet be performed; in future only under certain conditions. Pigs, but not non-human primates should be used as source animals; non-human primates may be used in preclinical research as model for man (xenograft recipient, infection studies).

Policy and relevant ministries have adopted a wait-and-see attitude. There are diverging opinions whether XTP should be regulated on the level of acts, or whether guidelines and recommendations drawn up by scientific and medical associations are sufficient. Moreover, the juridical dispute is still not settled whether XTP requires specific regulation, or whether existing regulation is sufficient. It is planned to bring a draft legislation into parliament after 2002.

As there is no other societal group which takes the initiative in XTP debate in Germany, one awaits international regulation. As only few information from these working groups is publicly available, it is assumed that some of the following questions are addressed:

- What are the relevant requirements and conditions for the housing, breeding and usage of source animals?
- Which milestones must be achieved in preclinical research before first xenotransplantations may be performed on humans? Who should be involved in these decisions?
- How should the patients’ well-being be weighed against advancement of science and commercial interests?
- What are the relevant requirements and conditions for clinical XTP?
- How can free and informed consent be guaranteed? Which are the persons concerned from whom informed consent must be obtained?
- Which risk assessment and risk management strategies and measures are appropriate? Who should be involved in these decisions?
- How can equal access of patients in need of an organ to allotransplantation and xenotransplantation be guaranteed?
- What are the criteria of organ allocation to individual patients if allotransplants are superior to xenotransplants?
- To which extent should both private and public sector be involved in xenotransplantation R&D?
• How can economic benefits and burdens be fairly divided between private and public sector?

At present, it is not known which answers or solutions to these questions are taken into consideration.

4. Actors of Debate

4.1 Which actors are involved in the debate? In which form are they involved?

4.1.1 Media analysis

The analysis of six German print media shows that media coverage of XTP is clearly dominated by scientists and physicians (73 articles), followed by companies (17 articles), the media itself (12 articles), representatives of (federal) agencies (10 articles). All other actors, e.g. patients, churches, the general public, financial services or animal activists are only represented in two or three articles (figure 4.1).

The following actors are mentioned (listed in declining order with respect to frequency of media coverage):

• Paul-Ehrlich-Institut, Langen,
• Robert-Koch-Institut, Berlin,
• Herzchirurgische Klinik, Großhadern,
• Leibnitz-Laboratorium für künstliche Organe, Hannover,
• Transplantationsmedizinische Kliniken der Medizinischen Hochschule, Hannover
• Bundesanstalt für Landwirtschaft, Mariensee bei Hannover,
• Charité, Berlin
• Fraunhofer-Institut für Systemtechnik und Innovationsforschung, Karlsruhe,
• Fraunhofer-Institut für Toxikologie und Aerosolforschung, Hannover,
• Gesellschaft für Biotechnologische Forschung, Braunschweig,
• Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, Bonn/Berlin,
  Institut für Molekulare Tierzucht und Haustiergenetik, Universität München.
4.2 Which potential actors are excluded/do not participate? Why?

Potential actors who could have an interest in XTP and therefore participate in the XTP debate are patients in need of an organ transplant and staff in hospitals where XTP surgery might take place (e.g. nurses, veterinarians). However, these potential actors do not participate in the debate. This may be due to the fact that XTP only becomes relevant for these groups if it reaches the stage of clinical application. However, at present it cannot be foreseen whether and when this will be the case. At this stage of XTP development, there are other, more important issues on the agenda of these actors than XTP.

4.3 Which particular coalitions between actors do exist?

XTP develops in an arena where actors from different social contexts and from different scientific disciplines with their specific professional and cultural background, their experience, motivations, goals, and the image one has of oneself or one's profession,
respectively, must interact. This integration process has been difficult in Germany as well as internationally, but also very interesting from a sociological point of view. At present, the national debate can be characterised by two complementary clusters, the transplantation medicine/natural sciences cluster and the humanities cluster. Each of these clusters has evolved a specific “community” and a specific line of argumentation. The transplantation medicine/natural sciences cluster has more impact on the public debate because its framing of the XTP problem sets the agenda also for the public debate. Policy and administration take an intermediate position: depending on the context, they make use of both clusters. These coalitions and interactions are depicted in figure 4.2 and are described in more detail in the following paragraphs.

**Figure 4.2: Coalitions in the German XTP arena**

At present, the transplantation medicine/natural sciences cluster has acquired the agenda-setting role in the public debate in Germany as well as internationally. However, this cluster only formed over time and showed interesting internal dynamics, starting from hostility, then developed along the lines of timid communication, tolerating each other to forming certain coalitions and common positions: It is important to note that a clear distinction must be drawn within this group between clinical practitioners, e.g. transplant surgeons with direct contact to patients, and biomedical researchers primarily working at the lab bench without immediate clinical practice, e.g. virologists, immunologists and infectiologists. In the time 1995-1997 the former group was fascinated by the scientific achievements of XTP
(overcoming hyperacute rejection for the first time with the help of genetically modified, partially "humanised" source animals) that they were eager to apply this new technology in practice – this was, however, prevented by the fact that they did not readily have access to these genetically modified source animals. Nevertheless, the clinical application of XTP seemed to be imminent.

Simultaneously, virologists warned intensively that clinical XTP would be premature and bore the risk of "opening Pandora's box", the risk of initiating a pandemic. This led to conflicts between the different groups of biomedical scientists in which the transplant surgeons were considered as careless and irresponsible by virologists while surgeons thought the same of virologists. This conflict could be observed internationally and also in Germany. In Germany, the conflict was aggravated by the fact that the virologists, due to their affiliation with a federal agency, were the first to be consulted on a political level when warnings of the risk of infection were substantiated internationally. This was received very critically by the transplant medicine group who saw themselves as the ones who should have (more) political influence and take the initiative. Moreover, it was suspected that the virologists wanted to prevent clinical XTP, and that they would suggest strict XTP legislation, perhaps even a moratorium. The foundation of two rather similar, albeit competing XTP working groups and XTP symposia (within the RKI and the DTG) can be seen as indicators for this conflict.

The initial rivalry between transplant surgeons on the one side and natural scientists on the other side has gone down over time in Germany as well as internationally, although it is still there on a low level. Over time it became clear that the virologists' objections were well-founded and had to be taken seriously. Moreover, it became clear that further XTP research would no longer be possible if acceptance or at least tolerance of XTP by patients, in politics and administration and the general public could not be achieved. An important incidence was the call for a moratorium of clinical XTP in order to gain time to initiate and conduct a public debate on how individual benefit of XTP should be balanced against its collective risk. This call for a moratorium came from a group of leading XTP researchers, led by Fritz Bach, in the USA in February 1998 (Bach et al. 1998) and also influenced the experts' debate in Germany.

As a result, a more intensive communication between these formerly separate scientific groups followed in which the initial positions were modified by both sides, came closer to one another and became more realistic, i.e. less enthusiastic or less scaremongering, respectively. This integration of two different scientific cultures which differ from one another regarding their professional and cultural background, their experience, motivations, goals, and the image one has of oneself or one's profession, respectively was a difficult process. Nevertheless, this interdisciplinary opening of the biomedical experts' debate was perceived as a great challenge and achievement by the persons involved. As a result, the formerly separate groups of virologists and transplant surgeons have (more or less) joined and now form a single cluster, which frames the problem of XTP as a technology-driven solution to
severe problems of current transplantation surgery and which has also incorporated several issues into its argumentation which were formerly only addressed by the Humanities/NGO cluster but seemed to be essential to achieve political and public tolerance/acceptance.

The counterpart of the biomedical cluster is the humanities cluster. The humanities cluster has much closer relations to NGOs than the biomedical cluster. Although representatives of the two clusters have rather frequent and regular contacts (e.g. during workshops and symposia) and know each other and their individual positions, the relation between these two clusters has remained problematic until today. As XTP debate nationally and internationally takes place in the system/setting provided by the traditional transplantation surgery system, it is very difficult for representatives of the humanities cluster to gain access and influence in this system. Only individual actors from the humanities cluster have been accepted as equal by the biomedicine cluster, while the majority of the humanities actors has not been truly integrated and has only been tolerated to a certain extent, especially if they take a critical stance to XTP. As a consequence, the thematic and methodological contribution of the humanities cluster has only been adopted by the biomedicine cluster to that extent that was required for achieving acceptance for XTP on the political and public level, and for reaching certain goals (e.g. preventing an XTP moratorium, achieving financial support for XTP research, gaining influence on the process of developing XTP regulations etc.). From the point of view of the biomedicine cluster this (little) opening towards the humanities was a major achievement, and is viewed by some individuals as equivalent to "public debate".

The ministries have delegated their possible political influence on XTP development mainly to committees and individual scientists from the biomedical/natural science cluster who function as national representatives in international committees. Depending on its position towards XTP, political parties have more or less intensive links with the biomedical and/or humanities cluster.

4.4 How do international actor-networks influence the discussion on ethical aspects of XTP?

Researchers both from the biomedical cluster as well as from the humanities cluster are in close contact with the international research community, take part in international conferences and closely follow the international debate. Moreover, some international cooperations in research projects have been established. NGOs in the genetic engineering and animal rights area also have contacts with their counterparts abroad (especially in Switzerland, UK) and exchange information and publications on XTP. Few German experts (Ulrichs, Denner) are members in supranational working groups or committees on XTP, e.g. at the Council of Europe (Working Group Xenotransplantation), the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO), aiming at putting up international guidelines for XTP.
Presently, the XTP debate in Germany is pending because most committees have come to a certain interim result and are now awaiting decisions from international working groups on supranational level. At present, there seems to be a tendency that results achieved in these committees will most likely also be adopted on national level, perhaps with slight modifications. Therefore, international actor-networks strongly influence the discussion of XTP.

5. What are the expectations of the participants of the Neosocratic Dialogue?

Several different motives can be distinguished why XTP actors participate in the neo-socratic dialogue:

- They support XTP and/or the public debate on XTP in general, and therefore also take part in a neo-socratic dialogue,
- They are dissatisfied with the way in which public debates on XTP are usually conducted, and are eager to get to know a new instrument,
- They have no special expectations regarding the neo-socratic dialogue, because they cannot imagine what this instrument really is about. However, they are curious and open to this new experience.

6. Which actors could participate in the Neosocratic Dialogue?

Actors from all groups involved in the German XTP debate could participate in the Neosocratic Dialogue.
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