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MÜNCHEN

Institute of Ethics,
History and Theory
of Medicine

CITIZENS' STATEMENT

Xenotransplantation

Co-authored by the Participants of
the 2019 Munich Citizens' Conference
on Xenotransplantation

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Organizers' Foreword

In Germany, xenotransplantation (the transplantation of animal cells, tissues or organs into humans) is on the brink of being executed in the form of clinical trials, more specifically, the transplantation of pig islet cells into humans. Since xenotransplantation raises many issues and questions that are relevant to society, we found it important that German citizens also received an opportunity to not only form an informed opinion on xenotransplantation, but also to become involved in shaping the essential public discourse. Hence, the Institute of Ethics, History and Theory of Medicine at the LMU Munich organized a citizens' conference on xenotransplantation.

The participant group of the citizens' conference comprised a total of 18 citizens from Munich and its surrounding areas, who were of both male and female gender and were selected randomly. The Municipal Administrative Office provided 5000 addresses chosen at random and extended a personal invitation to the addressees, inviting them to take part in the "Citizens' Conference on Xenotransplantation". At the end of last year, the participants were selected based on socio-demographic criteria (gender, age, place of residence).

The participants convened on three weekends. On the first weekend, they gained an overview of xenotransplantation and in turn contemplated their questions on the topic. On the second weekend, we invited expert speakers (see annex), who the participants listened to and later involved in discussions. On the third weekend, these participants wrote the citizens' statement and submitted it to the speakers of the xenotransplantation research association, Prof. Dr. Eckard Wolf and Prof. Dr. Bruno Reichart, which is financed by the German Research Foundation. On 22 May 2019, the citizens' statement was introduced to the public at the International Press Club in Munich as part of a health forum organized by the national newspaper *Süddeutsche Zeitung*.

The Institute of Ethics, History and Theory of Medicine at the LMU Munich organized and held the citizens' conference. The German Research Foundation (SFB-TRR 127) financed this conference.

The process of discussing and writing was moderated by an external team of moderators in an open-minded manner. The participants of the citizens' conference were supported in forming their opinion without any intervention with regards to its content. The citizens' statement's views and recommendations presented here are those of the participants and not those of the organizers.

We would like to thank all of the participants and contributors to the citizens' conference on xenotransplantation.

Johannes Kögel & Prof. Dr. Georg Marckman, MPH

Preamble

We are a group of citizens from in and around Munich with a range of educational backgrounds, occupations as well as experiences, and ranging in age from 19 to 69.

Our motivation for participating in the citizens' conference on xenotransplantation stems from an interest in the topic and the opportunity to be actively involved in a planning procedure and making citizens' voices heard. We convened at the citizens' conference with considerable interest, yet with little understanding or previous knowledge of xenotransplantation. In the beginning, there were a range of fears and uncertainties in the room, for instance that the conference may be a pseudo debate on signing off on research interests. In the course of the citizens' conference, however, and with the accompanying increase in knowledge, our take on the matter changed from skeptical to a more sophisticated, predominantly positive opinion on xenotransplantation.

Xenotransplantation has turned out to be a complex topic, which, apart from medical considerations, also encompasses a range of questions pertaining to human and animal ethics, as well as politics, economics, law, society, psychology, religion and philosophy.

In our composition of this statement, we felt obliged to our conscience and always had the common good in mind. A range of opinions emerged in the process, which we discussed in an open and constructive manner.

Our predominantly positive tendencies should not disguise our diversified and controversial opinions about some of the aspects of xenotransplantation. With this citizens' statement, we hope to contribute to further public discussions in the political, societal and scientific realm.

Overview of Research and Development

The information provided in the experts' statements and from the internal group discussions created a comprehensive view of the current state of research and development in this field.

The majority of the group sees great opportunities and potential that is if the research achieves its intended goals.

But:

Our impression is that there is only limited experience when it comes to the application of xenotransplantation in humans. Due to the insufficient amount of available data / insufficient data situation, we see a potential risk that should not be underestimated. It is not clear to us how long it will take until the method can be established as a standard procedure. In the long run, will xenotransplantation develop as a full-fledged alternative solution to allotransplantation or does it merely serve as a form of bridging technology?

The animal testing conducted to date makes human implementation appear realistic. Successful xenotransplantation would enable higher organ availability as well as improve the planning capabilities of such transplantations. In theory, there is also the potential that xenotransplants could become more compatible with the recipient.

Two different approaches, which can be found at different research stages, have become solidified: on the one hand, the transplantation of solid organs and on the other hand, the transplantation of cells.

Solid Organs:

From our perspective, the production of a xenotransplant could facilitate greater control over organ quality. An especially significant problem in allotransplantation is time pressure: from the procedure, to the extraction, to the implantation. Here, we see a great advantage in xenotransplantation due to the predictability of the procedures.

According to our opinion, when it comes to the xenotransplantation of solid organs, there are currently still a number of incalculable risks involved. We fear a possible influence on the xenotransplant recipients' metabolic processes. The donor animal has to be genetically modified, inherent with all of the resulting risks. Science regards the risk of zoonotic disease (infections that are transferable from animal to human) as minor. Nevertheless, it cannot be completely ruled out.

Cells:

Research on the transplantation of islet cells as compared to solid organs is more advanced. The transplantation of islet cells can be beneficial for a large group of people, who, for example, suffer from diabetes. Due to the deployed methodology (encapsulation of the xenotransplants), immunosuppression is not necessary, and the danger of zoonosis also appears to be significantly reduced.

Demands from the Perspective of Research and Development

The aforementioned circumstances lead us to make the following claims:

1. We demand that further comprehensive laboratory examinations of the possible risks and dangers, particularly when it comes to the transmission and onset of diseases, are conducted before the first human trial.
2. We demand particularly careful and thorough education of the patient in the case of human application, particularly in cases of first-time application.

Ethical Considerations

We believe that life support and healing bear an existential importance to humanity.

Discussions with the experts made it clear that, according to the current state of research, only a limited target audience with certain medical conditions (physical and psychological) is eligible for xenotransplantation. Furthermore, there is also the risk of discrimination when procuring allotransplants and xenotransplants. For these reasons, the distribution of organs should be incumbent upon a neutral, state-controlled institution, as is the case with allotransplantation. Here, allocation is based on medical urgency criteria.

According to the experts' statements, the three largest monotheistic religions do not specify any restrictions pertaining to xenotransplantation that is if it serves the protection of human life and takes animal welfare into account. In this sense, apart from the Christian religions, there are no concerns among Jewish and Islamic faiths when it comes to the transplantation of pig organs into humans. As a result, religious aspects should not play a role when it comes to transplanting pig organs into humans. Thus, these religions do not restrict the individual in his/her decision-making processes.

Animal Welfare Considerations

When it comes to animal welfare, our impression is that xenotransplantation is more respectful of animal well-being than either the agricultural or food industry. This refers to tightened laws, regulations and controls of animal protection laws (e.g.: pig welfare

regulations, pig hygiene regulations, animal protection law and genetic engineering law).

We question whether the minimum legal conditions for animal farming provide the donor animal with a sufficiently dignified life, in particular with regard to isolation, the possibility to reproduce, heavy pharmaceutical intake and a lack of contact to conspecifics.

Demands for Animal Welfare

1. We demand active research to improve livestock husbandry for the purposes of xenotransplantation.
2. We demand enforced regulations for livestock husbandry for the purpose of xenotransplantation through independent government organizations.

Social and Psychological Matters

We are of the opinion that presenting this sensitive topic to the public has an influence on its acceptance. Thus, the way we talk about xenotransplantation as a society has a direct influence on its acceptance.

For example, we have dealt with its symbolic character (e.g.: “pig heart” or “lion heart”) and its resulting influence on the recipient.

Society’s attitude from a psychosocial standpoint could also depend on whether xenotransplantation is a ‘medical’ solution and thereby whether the saving of lives stands in the foreground. A focus on the ‘animal organ’ will, however, probably provoke very controversial reactions.

To the best of our knowledge, there are no studies or experiences concerning the psychological and social effects of xenogeneic transplants on recipients. In the past, the focus was on the application of porcine heart valves and their medicinal indications, the usage and the advantages for the human alongside the related medicinal risks and effects. The process of xenotransplantation eliminates the potentially psychologically burdensome question of organ donation.

Bearing in mind the recipient’s personal attitude, medical need and social environment, appropriate psychosocial care should be guaranteed. Such clarification and consultation are necessary for self-understanding and self-acceptance.

Demands from a Social-Psychological Perspective

We ask the media to treat the topic of xenotransplantation in a responsible and sensible manner, and to provide balanced information. To avoid major insecurities, fears and prejudices through a state of misinformation, it is imperative to inform the public in a preventative and comprehensive manner through relevant institutions (for instance the Federal Center for Health Education).

In addition, we also wish for a social climate in which the medical and personal decision in favor of xenotransplantation is respected with human dignity. Stigmatization should not occur.

Inquiry into Social Responsibility

The participants of the citizens' conference do not have a single view on the matter, but differ in opinion. The points of view range from general approval to distrust of decision-making processes and institutions involved, to severe doubts whether xenotransplantation is the best way for alleviating organ shortage.

Disregarding the individual views of the participants, the citizens' conference recommends following measures:

Granting sustainability

Parts of the group fear that with the use of xenotransplantation there may potentially be far-reaching risks for the greater population, such as zoonosis, genetical changes, etc.

The participants assessed the benefits and risks associated with xenotransplantation with varying degrees of emphasis.

Undisputed among the participants is the need for:

- Comprehensive and strict control / monitoring of the development and application of xenotransplantation.
- Parallel, mutually controlling institutions: interdisciplinarily staffed and coordinated with each other.

In specific cases and where appropriate, special measures such as observation, isolation and even quarantine should be taken, but also independent supporting measures.

Distribution of Available (but Limited) Resources

Since the previously explained core objective of medical research is to preserve life and improve the quality of life, further measures should also be put forward in addition to xenotransplantation, especially in face of the reality of limited resources:

- **Prevention**
Limit or reduce existing mortality hazards in the hospital and health sector: multidrug-resistant germs, incorrect medication, inadequately qualified staff as well as staff shortages, etc.
- Apart from the increase (now under discussion) in willingness to donate organs, we also support further measures to improve allotransplantation, such as the qualification of medical staff, structural improvements and similar matters.

In addition, xenotransplantation should not be the only avenue of research; alternatives (e.g.: tissue engineering, in vitro) should also be provided with appropriate funds.

Conclusion

The topic of xenotransplantation is demanding for society as a whole.

In general, we see great potential in xenotransplantation, but also dangers and unknown risks. As a group, we are aware that the current state of knowledge is not sufficient in assessing all of these risks.

Most of us, but not all of us, have expressed the notion that the potential chances are worth taking these risks under the above-mentioned conditions.

Xenotransplantation could lead to alleviating pain and as a supplement to allotransplantation it could save lives. As such, the current state of research with regards to islet cell transplantation already gives us reason for hope.

Every recipient has to actively confront him/herself with the following questions:

- Is a human's life worth more than an animal's life?
- Does it make sense to prolong the human life at any cost?

That is why patient education is especially important to us.

In its current state, we see xenotransplantation as only one of many alternatives to allotransplantation. Apart from xenotransplantation, other alternatives should also be researched in parallel: namely preventative measures, better infrastructure, artificial hearts and tissue engineering. Furthermore, donor readiness should also be increased.

The majority of us are in favor of continuing research on xenotransplantation.



Annex

List of Participants

Name	Occupation
Dr. Alexander André	Software Entrepreneur
Regina Feurle	Body Therapist
Karin Gräbe	Social Work Student
Dr. Julia Graf	Corporate Consultant
Herbert Gruber	Taxi Entrepreneur, Translator
Elena Haberzettl	Student, FOS
Lilli Hermoni	Professional Software Tester
Jana Herrnecker	Language Instructor (retired)
Knut Hüneke	Project Manager, Organizational Developer
Christoph Leimböck	Paramedic (retired early)
Nicole Liebe	Social Worker
Olga Mannheimer	Publicist
Erwin Marschall	IT Consultant (retired)
Monika Menge	Social Worker, Geriatric Nurse
Gitta Schwind	Alternative Practitioner (TCM)
Mohsin Syed	Electrical Engineer
Thomas Tischner	Architectural Engineer
Marius Zeeb	Biotechnology Student

List of Associated Experts

- Dr. med. Dr. med. vet. Thomas Brill
Biomedical Center of LMU Munich
- Dr. med. Angelika Eder
German Organ Transplantation Foundation (DSO)
- Dr. med. Sonja Güthoff
Walter Brendel Center of Experimental Medicine at LMU Munich
- Prof. Dr. med. Barbara Ludwig
University Hospital Dresden
- Prof. Dr. rer. pol. Günter Neubauer
Institute of Health Economics, Munich
- Prof. Dr. med. vet. Heiner Niemann
Hannover Medical School, Former Leader of Institute of Farm Animal Genetics
(Friedrich-Loeffler-Institut) in Mariensee
- Prof. Dr. theol. Dr. rer. soc. Jochen Sautermeister
University of Bonn
- Prof. Dr. iur. Ulrich Schroth
Professor Emeritus for Criminal Law, Criminal Procedural Law, Philosophy of
Law and Legal Sociology at LMU Munich
- Prof. Dr. rer. nat. Ralf Tönjes
Paul Ehrlich Institute, Langen
- Dr. rer. nat. Tamara Zietek
Doctor against Animal Testing

Information on Citizens' Conference

Composed 7 April 2019

Timeline of Citizens' Conference: 23/24 February, 16/17 March, 6/7 April 2019

Organized by: Institut für Ethik, Geschichte und Theorie der Medizin, LMU München

Financed by: German Research Foundation (SFB-TRR 127)

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