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Preliminary remarks

“The future prospects of transplantation medicine in Germany” was the topic of a symposium held by the Standing Committee on Health and the Standing Committee on Science and Ethics of the German National Academy of Sciences Leopoldina on 20 February 2015. The task of the two committees is to initiate discussion on pressing societal issues. A group composed of members from both committees prepared the symposium and compiled this discussion paper.¹ The Leopoldina intends for this paper to prompt necessary further discussion among policymakers and the general public.

Transplantation medicine raises two basic legal and ethical questions. The first focuses on the conditions under which organ donation can take place, and how to tackle the major shortage of vital organ donations using legitimate means.² The second relates to the fair distribution of these scarce resources. For the most part, this paper seeks to answer the second question about the fair allocation of organs in the structural context of German transplantation medicine – not least because of public debate and distrust surrounding the issue. The key questions in the symposium were: Who makes the decisions relating to transplant indications and the recipients of donated organs? Whose responsibility is it to define allocation criteria and make these mandatory? Which institutions and practitioners are allowed to perform transplants? Who should take responsibility for the overall structure and organisation, and under whose supervision?

The editorial group in March 2015

1 The authors and participants of the symposium are listed at the end of this paper.

2 On the question of organ donation and the criteria for brain death in particular, see the public comment issued by the German Ethics Council on 24 February 2015 here: <http://www.ethikrat.org/dateien/pdf/stellungnahme-hirntod-und-entscheidung-zur-organspende.pdf>

Summary

This paper concerns the structural development of German transplantation medicine and the organ allocation system in the interest of all those involved, especially patients waiting for transplants.

The central issues are:

- The democratic legitimization of basic normative allocation criteria by parliament
- An effective legal protection framework for patients
- An independent organisational structure that avoids intertwining between specific institutions and practitioners and which facilitates clear accountability
- The further development of transplant centres, which are assessed for the quality of their processes, structures and results, and which conduct transplant research
- Comprehensive transparency at every level

The following considerations should serve as a springboard for the necessary discussions to further develop transplantation medicine. Whilst the standard of transplantation medicine in Germany is admittedly high, it urgently requires better and more effective structures.

Introduction

Transplantation medicine is a key treatment option for critically ill patients with organ failure, especially when quality of care is as high as in a country like Germany. Transplantation medicine is more than the surgical implantation of an organ: it refers to a medical and psycho-social process that can span years or decades and that includes the surgical procedure, the preparations and immediate aftercare, as well as appropriate and specific long-term follow-up care.

In addition to the purely medical aspects, transplantation medicine is about the distribution of a scarce resource. For a long time now, the number of patients waiting for an (often life-saving) organ has far exceeded the number of organs available. This raises questions about the fair distribution of this scarce and vital resource. While medical expertise is needed to “spell out” the allocation criteria, resolving the issue of allocation is a fundamental one and a task that society must address.

Although this paper does not address ways of legitimately and efficiently improving the critical shortage of available organs, two related aspects are relevant to the present discussion. Firstly, the allocation scandals that came to light in 2012 appear to have contributed to a distrust of transplantation medicine – and fewer donated organs. A second important reason for the low number of available organs appears to be a decrease in the registration of potential organ donors in hospitals. This problem should be resolved using a range of pragmatic measures relating to organisational structures, procedures and remuneration issues, as well as by raising awareness amongst medical professionals. There is scope for extensive research in the field of organ allocation. Defining the prognostic factors that help to elucidate „urgency“ and „chance of success“ of organ transplantation in a single patient as well as the assessment of its medical and psycho-social benefits is of utmost importance, since these criteria are essential to pinpoint the corresponding allocation criteria. There is also a need for clinical research on the provision of personalised care that best responds to the requirements of each patient.

In order to make transplantation medicine in Germany legally reliable, to guarantee a high medical standard, to protect public reputation, and to meet research demands, steps must be taken to optimise the existing legal and procedural regulations. Based on the discussions that took place in the symposium, the following pages outline some key considerations on the topic.

The legal and normative dimension

Uncertainty exists about organ allocation criteria and practice among the various actors involved in organ transplantation – including the German Medical Association (*Bundesärztekammer*). The legislator has delegated the definition of allocation criteria to the German Medical Association – and with this the legislator has delegated a legitimacy problem to the German Medical Association which it cannot be made responsible for: allocation criteria and allocation decisions always comprise normative judgments. These can neither be regulated by objective medical parameters nor delegated to individual occupational groups or professional associations.

Allocation criteria such as “urgency” and “chance of success”, which appear in the Transplantation Law, are only partially definable by the “state of medical science”. The question of how the stipulated “equal opportunity” criterion is to be met is not a medical issue either. There are many other unanswered questions that require clarification. The subject of alcohol abstinence may serve as an example with questions such as: How long must an alcoholic abstain from drinking before he or she receives a donated liver? Is the definition of a specific period of abstinence in the current guidelines of the German Medical Association permissible? There are no compelling medical arguments for this, and different approaches have been taken internationally. Is this compatible with basic patient rights?

In addition, the matter creates fundamental problems relating to constitutional law. The German Medical Association is a medical doctors’ self-governing body and as such has limited legitimacy when it comes to making these types of ultimately normative distinctions. From the perspective of constitutional law, this is the responsibility of the legislator, i.e. parliament. Since organ allocation is about *Lebenschancen* (life chances) but also about establishing hierarchies of normative allocation criteria, only an institution with democratic legitimacy should be allowed to decide on regulation with this kind of constitutional relevance.

Yet the complexity of defining and adequately weighting allocation criteria can only be reduced, not completely resolved. Moreover, due to the complexity of organ donation and the uniqueness of individual patients, allocation criteria must leave room for individual medical judgement. All the more reasons why open social debate and transparent decision-making by parliament are needed for such criteria to be accepted.

Transparency is vitally important for transplantation medicine. Transparency and traceability are the main pillars of trust including the allocation criteria and their weighting, decision-making and organisational structures, process quality control, and any necessary sanctions. Transplantation medicine also needs to transparently present its long-term record from national and international studies.

Another unresolved problem involves properly respecting the rights of patients who have not been put on a waiting list or who have been removed from one. They need the option of having an independent authority reviewing such decisions. To guarantee this, clear jurisdictions need to be defined and communicated, and the judiciary needs to be given the ability to take decisions quickly in light of the reduced life expectancy of the persons affected. One option would be to set up a judicially and statutorily defined authority for rapid decisions on transplantation issues – with suitable structures to ensure that it is equipped with the necessary specialist expertise.

The transplant centres

There is a broad consensus that the current number of German clinics offering transplantation surgery (47) is too high. Competition between different institutions and conflicts of interest may arise – a situation which is undoubtedly aggravated by misplaced incentives in the pricing system for German hospitals (DRG). To ensure that this complex medical procedure is of the best possible quality, institutions must have constant access to qualified medical professionals – far more than just the transplant surgeon – and be able to offer the necessary care during preparation for a transplant procedure and post-operative care.

Minimum quantities should not be the guiding principle when reducing the number of transplant centres, but the quality of a centre's structures, processes and results. In addition, a factor in determining the quality of a centre should be the scope of its research activities in all areas of transplantation medicine – from basic research to targeted clinical research and health services research to ethics. A strong focus on international – particularly European – collaboration and coordination when establishing structures and criteria is also desirable. Finally, the entire transplant process – including preparatory activities and post-operative care – should be limited to certified transplant centres in Germany. Enforcing these requirements for certification will significantly reduce the number of centres qualified for performing transplants. Furthermore, surgical procedures for transplant patients must be prepared and performed in a cost-effective manner, even more so the comprehensive aftercare.

The organisation of waiting lists presents a further problem. In the current system, for example, centres with longer waiting lists have better chances of receiving an organ. This offers the wrong kind of incentive. A transparent process for compiling waiting lists is needed, together with the operationalization of criteria and the pooling of different waiting lists for all transplant centres. This makes it easier to

compare criteria and to control the decisions taken on indications and listings. When making concrete listing decisions, in addition to the four-eyes principle it would be practical to elicit the opinions of professionals from outside transplantation medicine, such as experts on medical ethics.

Organisational structures

The organisation of transplantation medicine in general and organ allocation in particular has been the result of an evolutionary process. The distribution of donated organs has always been a highly complex task that also includes monitoring procedures and their quality. To a large extent, this complicated task is currently performed by the German Medical Association, which calls on experts working on a voluntary basis. Due to its complexity this system has reached its limits. In order to meet the demands of organ allocation on a long-term basis – whilst also maintaining the trust of the general public and medical professionals – it is highly preferable to establish a neutral and independent institution for the organisation and quality control of transplantation medicine. A primary objective in establishing such an institution – it could, for example, be a (semi-)public body at the Federal level – would be to dissolve existing personal and institutional intertwinings and to avoid potential conflicts of interest.

With a core of experts employed on a full-time basis, the organisational structure of such an institution should enable more timely reactions to medical developments than has been possible so far. Moreover, the institution would be able to implement findings from research, also from health services research, for the benefit of patients within a short amount of time. The German Medical Association would still be responsible for evaluating the “current state of medical science” based on the available evidence, and for issuing scientifically founded medical guidelines for decision-making. The proposed institution could also oversee a national transplant register, which would be of central significance for research, for ensuring the quality of results, and for monitoring indication and listing decisions. The institution should also be responsible for regularly certifying accredited transplant centres.

Establishing this kind of independent institution outside of the self-governing system would have the advantage of ensuring transparent and long-term accountability structures, as well as promoting and se-

curing the development of practical knowledge. As with comparable institutions in other industrial sectors, the implementation of compliance structures is advisable.

Finally, this kind of independent institution should act as a contact point offering nuanced advice on organ donation and stimulating lively debate on organ donation and allocation in public and political discourse.

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