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## The Silence of Organizations— The Transplant-Allocation Scandal

**Abstract** In the years around 2012, patients waitlisted for a liver transplantation were willfully advanced and received a donor liver earlier than expected. The urgency for a liver transplantation is based on the MELD (Model of Endstage Liver Disease)-Score, which includes three clinical/biochemical variables. These variables were manipulated from some, however, not all transplant centers in Germany. Therefore we are talking about a liver-allocation scandal and not about a transplant scandal (which would imply a completely corrupt transplant system). Research Results concerning the liver allocation scandal: The deviation of liver allocation policy was based on several reasons. None of these reasons are solely responsible for the deviation, since there is a multilayer interaction. One reason was the competition between various transplant centers. A second reason was the hierarchical structures in University Hospitals, mainly in surgical units. Further reasons were the need and the responsibility of a donor liver for the waitlisted patients in a certain transplant center. Financial benefits for the caregivers were not a major reason for the allocation deviation. Consequences for the allocation scandal: First of all, the “Bundesärztekammer” called for audits at all German transplantation centers. These audits comprised not only the liver transplant programs, but also kidney, kidney-pancreas, heart and lung transplant programs. Due to these audits several deviations in other programs, e.g. heart and lung, were discovered. What should we learn from the liver-allocation-scandal? Hierarchical structures in clinics should be questioned and a board of health workers (physicians, nurses, coordinators etc.) should be involved in the wait listing process. The allocation rules need revision and a public discussion, which includes also non-medical professions. The number of transplant centers may be reduced to decrease an unhealthy competition and to concentrate medical specialists in such centers. Finally the transplant medicine and its caregivers should not be stigmatized as “doing criminal or semi-criminal” deeds, just because they are serving patients with life-threatening diseases. This has a huge impact on further generation of nurses and doctors who are potentially seeking a career in the transplant medicine.

**Keywords** Transplant Allocation Scandal, organ shortage, scientific control, multi-center studies, investigator-initiated studies

## 1 Introduction

### *A brief History of deviation of the allocation of donor organs*

In the year 2012, it came to public attention that in 25 cases of liver transplantation, patients' charts had been manipulated in a hospital in Göttingen (see e.g., Gückel 2012). This fact was officially investigated by public prosecution in Braunschweig and in July 2012, when manipulations surfaced, the Euro-Transplant Leadership was asking for more rigid controls. As public prosecution went on, the focus was placed on 26 out of 91 cases from the years 2010 and 2011 in Göttingen (see e.g., Siegmund-Schultze 2012). Two doctors were accused of manipulating patients' charts in order to prematurely allocate a donor organ (in these cases liver transplants). By this time, the scandal had reached political institutions, and the Bundestag's Healthcare Committee (Bundestags-Gesundheitsausschuss) was called for an extraordinary meeting. Now, the attention was no longer only on Goettingen, where the scandal started: the transplantation program in Regensburg also came into focus. In August 2012, experts asked for more intensive and independent controls of local transplantation programs. In the following months, all transplant centers in Germany were investigated through a team of experts from the German Medical Association (Bundesärztekammer). The results went public and are available on the Medical Association's website<sup>1</sup>.

However, rumors of manipulated donor organ allocations had been circulating even before that. During the previous one or two years, rumors were being spread during the annual meeting of the German Transplant Association (Deutsche Transplantationsgesellschaft DTG) that manipulations may have occurred.

### *What was the transplant allocation scandal not?*

Before any details of the transplant allocation scandal are discussed, it is imperative to differentiate between the transplant systems in general and this specific allocation deviation.

The transplantation allocation scandal was not a failure of organ donation and the concept of brain death. Nor was it a failure of "Eurotransplant" or the German Organ Transplantation Foundation (Deutsche Stiftung Organtransplantation (DSO)) as an organization. Above all, however, it was not a failure of all transplantation centers, since by far not all transplantation centers were involved in the allocation scandal and a large number of employees in transplantation centers were committed to caring for their patients before and after transplantation. Unfortunately,

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1 <https://www.bundesaerztekammer.de/>

this transplantation allocation scandal has been described as a systemic crisis in transplantation medicine in general.

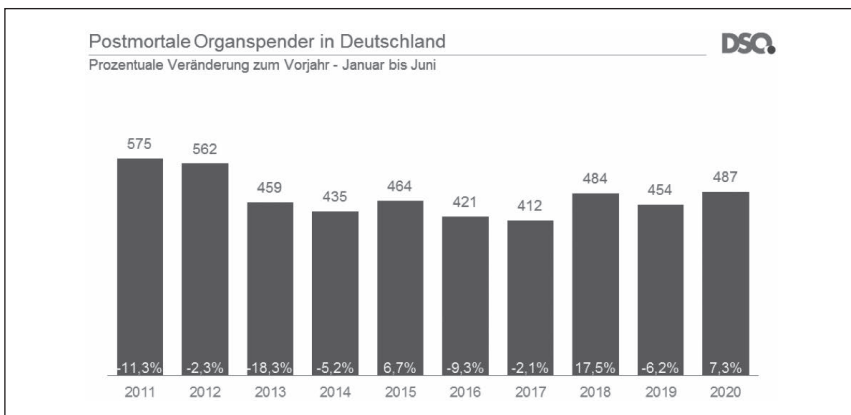
## 2 Drivers of deviation

A range of different drivers of deviation could be identified. Apart from environmental factors (especially the shortage of donor organs, the access of caregivers to databases and questionable guidelines), professional and organizational competition, hierarchical power structures within healthcare institutions, a lack of control mechanisms and the public view of transplant medicine could be identified as decisive. These drivers of deviation will be discussed in the following.

### 2.1 Environment

#### *Donor organ shortage*

One of the most important drivers of the transplant allocation scandal was the shortage of donor organs. In 2019, more than 9000 German patients were registered at Eurotransplant for an organ transplantation. In contrast, in the year 2019, 5300 German patients were newly listed, however, the number of organ recipients ( $n = 3538$ ) was much lower<sup>2</sup>. The number of organ donors is depicted in figure 1<sup>3</sup>. This fig-



**Figure 1** Organ donors in Germany between 2011 and June 2020.

- 2 [www.eurotransplant.org/patients/deutschland](http://www.eurotransplant.org/patients/deutschland)
- 3 <https://dso.de/organspende/statistiken-berichte/organspende>

ure is an image of the extraordinary disproportion of need and supply of donor organs. A sufficient number of donor organs would shorten the waiting time and thus reduce a considerable pressure on the allocation of donor organs. Patients who receive transplantations in time do have a much better chance of survival. In the case of a sufficient donor organ availability, the risk of any manipulations would vanish immediately. From my personal point of view, this was the most important trigger of allocation deviations. The daily care of patients on the verge of death puts an extensive pressure on the medical professionals who try to save their patients' lives.

### *Access of caregivers to medical databases*

Another cause was the possibility of false reports or manipulations through the caregivers. Transplant medical staff had access to the Eurotransplant database registration, which naturally made it possible to carry out manipulations unnoticed. Additionally, control mechanisms were not institutionalized, and, if they were available at all, they were at a low level. This was due in particular to highly specialized knowledge that was available to only few in the field of transplant medicine, so effective controls were rather difficult to implement. Transplant specialists who carried out these manipulations were well aware that the control mechanisms were not sufficient. These facts smoothed the way to the now well-known manipulations.

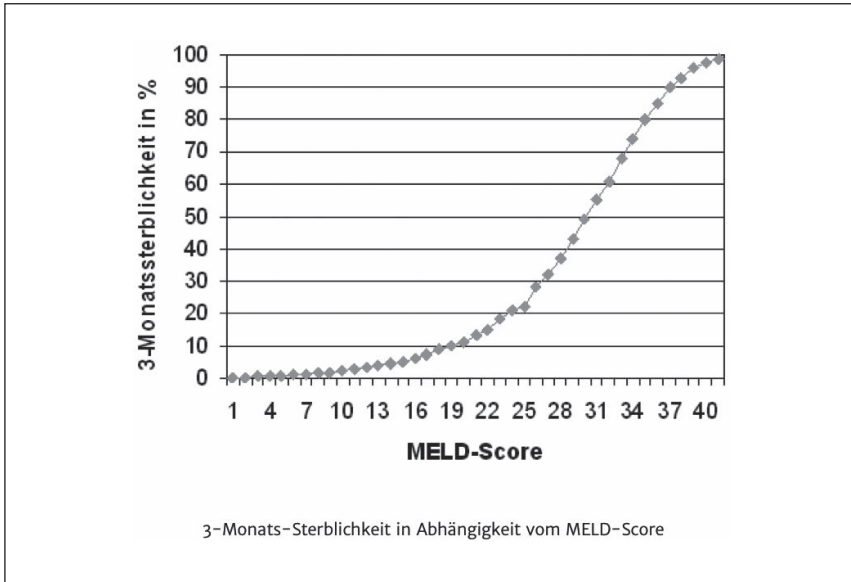
There are possible further reasons for dishonesty in the process of allocating patients. One might be a certain "team-spirit", as transplant medicine is a highly specialized field in medicine where only few specially trained people are working together.

### *Questionable guidelines*

A third reason was that the guidelines were in part at least questionable. Patients with the worst prognosis are given preference for transplantation. Thus, patients who can expect a more favorable outcome of the transplantation will remain on the waiting list for longer. This was and still is engraved, as already mentioned, by the lack of organ donations. Patients with a more favorable prognosis, as time goes by, often become patients with a worse prognosis. The reason for this is a progressive loss of organ function in a relatively short time period. The correlation of mortality and the MELD score is shown in figure 2.<sup>4</sup>, where the relationship between survival and MELD-score points is impressively shown.

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4 MELD is short for Model for Endstage Liver Disease. Retro- and prospective studies have shown the MELD-score to be an excellent tool for estimating the gravity of terminal chronic illness.



**Figure 2** The relation between mortality/survival in correlation to the MELD-score

In summary, the allocation system in Germany, especially with regard to liver and heart transplantation, is a system with a high demand for critically ill patients and a low supply of donor organs. This was, beside other causes, one of the main reasons for organ allocation manipulations.

## 2.2 Professional and organizational competition

Transplantation medicine is a highly competitive field due to the high level of specialization and the complex nature of the treatment. Specialists are required for these treatments and only they can treat the patients in question with acceptable chances of success. On the one hand, this leads to competition between the major transplant centers, especially because top specialists are recruited by large transplant centers. On the other hand, performing well in this highly competitive environment naturally has advantages for the progression of an individual career. Finally, the reputation of a transplant center or a university hospital with a successful and big transplant program is also enhanced. Thus, individual medical professionals and transplant centers alike have a strong interest in establishing a highly competitive, high-performance work environment. This may in turn lead to deviant behavior by transplantation specialists due to the immense pressure put on them in this competitive context.

### 2.3 Hierarchical power in institutions

A further point is the hierarchical power that is exercised in these highly specialized areas. Data published by Markus Pohlmann and his team (Pohlmann 2018, Pohlmann/Höly 2017) showed that the employees tended to adhere more to the instructions of the chief of the department than to official guidelines and regulations. This became all the more apparent when the specialists realized that regulations were often not congruent with reality (e.g. donor organ shortage versus critically ill patients on the waiting list). In this context, we would like to refer once again to the challenges of success and urgency. If the sickest patients are given preferential treatment on the one hand, and on the other hand, the waiting time for patients who could still be successfully transplanted becomes longer, the consequences of the gap of donor organ shortage are amplified: This is where the practitioners in a transplant center are in a considerable dilemma.

What also turned out to be true is that financial benefits for transplant surgeons or transplant physicians or even the clinic (almost exclusively University Hospitals) were usually not demonstrable. Here, it is particularly worth mentioning that the revenues only just cover the costs of a transplant, often even leading to a shortfall in coverage.

Due to the high prestige of transplant medicine, there was a desire to expand transplant programs. However, this expansion is not only for the sake of increasing prestige, it has a lot to do with the economic management of such a cost-intensive therapy. The more transplantation procedures carried out, the higher is the cost-effectiveness because smaller transplantation programs tend to be uneconomical due to so-called “jump-fixed costs”. To illustrate this with an example: for each action (waiting list management, inclusion on the waiting list, organ harvesting and transplantation, early postoperative inpatient, and later outpatient follow-up care), a core of trained staff must be maintained. Whether they care for a few patients per year or several dozen, the staff must be available in any case. In addition, an infrastructure must be available with regard to laboratory, imaging diagnostics, etc.

Furthermore, the desire to be more visible nationally and internationally and to enlarge transplant programs has additional reasons: for example, large transplantation programs have easier access to public and industrial research funding. This is particularly important because without scientific support, transplant medicine would stagnate. As has already been mentioned, a large number of well-educated people are required for such programs and every institution naturally wants to have the best and most talented people for training and subsequent work in transplant medicine.

## 2.4 Lack of control mechanisms

As has already been mentioned, uncontrolled access to the Eurotransplant database was a major problem, with uncontrolled manipulation of data being entered. When data were entered through the program leader or leaders, the remaining staff were not courageous enough to communicate allocation deviations. It has already been mentioned above that this uncontrolled input was also due to the fact that there were few people who could even see through these manipulations. In the meantime, this has been made impossible by the fact that the doctors involved in the treatment no longer have access to the Eurotransplant database. In most centers, the transplant coordinators are exclusively responsible for data entry.

Furthermore, there was no internal control system that monitored the transplant programs and reported deviations from the guidelines. There was no internal ombudsman or whistleblower system that made it possible to report obvious deviations to the responsible head of the transplant program or their superior. In this context, it has to be mentioned that there were no internal guidelines making clear to employees the ethical and regulatory barriers within which they were to operate.

Furthermore, until 2012 there was no external control system in the sense of a control commission of the German Medical Association (Bundesärztekammer).

## 2.5 Public view on transplant medicine

The question arises as to why the public has taken such a negative view of this so-called transplantation allocation scandal, and why public dislike of transplant medicine is repeatedly upcoming. First of all, transplantation medicine is connoted by the public (with the exception of those directly affected) as not very positive. Although the results of transplantation medicine have improved massively in recent decades, its public perception remains rather unfavorable. Possibly, this is also due to the long-standing discussion about brain death diagnostics.

In contrast, for instance heart disease and, above all, cancer, its treatment, and its success or failure are perceived rather positively—despite the fact that in oncology in particular, outcomes are by far not as good as in transplant medicine, at least for several types of cancer (e.g. lung, pancreas etc.).

Not only in public opinion but also in the media and in the entertainment industry, transplantation medicine is portrayed rather negatively. This is especially true for films, novels, and short stories, independently of whether a rule violation in association with transplantation medicine has occurred at all.

These points certainly augmented the so-called scandal and made it even worse. As a result of these observations, a public discussion is necessary to clarify the role of transplant medicine in our society.

### 3 Summary and outlook

*What is left after the perception of the transplant scandal has calmed down?*

First of all, we need to ask ourselves: Has the transplant scandal changed anything at all?

For one thing, yes. A public and independent control system by the German Medical Association (Bundesärztekammer) has been established. This allows the detection of systemic deviations and their correction and also improves the transparency of transplant medicine in Germany.

However, does it actually meet the needs of patients? In no way, because the key challenge, the shortage of organs, is still unsolved. And this has been even more the case since the German Parliament (Bundestag) declined the “contradiction solution” that would have made every German citizen an organ donor by default and would thus probably have been an effective measure against the shortage of donor organs. This legislation means that in the upcoming years, no significant increase in donor organs can be expected.

*What can we learn from the allocation scandal in transplant medicine?*

The allocation scandal has led to a reconditioning and to a new culture of ethics in transplantation medicine. Internal measures (within the hospital) have led to a division of tasks and responsibilities and thus to the introduction of a more-eye-principle. In particular, certification procedures, overseen by external consultants and repeated regularly, have led to a significant improvement. Furthermore, transparency is provided by the control mechanisms of the German Medical Association (Bundesärztekammer). Finally, the head of a transplant center and the leadership of such hospitals must set an example of honesty and authenticity through so-called “ethical leadership.” They need to demonstrate that adherence to rules and fairness in a transplant program is more important than sheer competition with other transplant centers. External measures have already been mentioned, such as independent control committees and, once again, the presence of a higher number of donor organs.



*Outlook: the potential to improve outcome quality and adhere to the regulations in transplant medicine*

Are there any other tools to improve quality, control, and transparency of transplantation programs? As we have learned from the immediate past, no increase in donor organs can be expected. In contrast, the number of wait-listed patients will increase per year. The only benefit we can achieve for the patients is the improvement of outcome quality with the help of multi-center studies.

We should request a comprehensive “scientific control” of transplant medicine. This means that almost all patients listed for solid organ transplantation should be included in so-called investigator-initiated studies (IIT). There are several advantages at hand: unhealthy competition will stop, relevant and scientifically justified questions can be asked, and a high level of transparency and efficiency can be demonstrated by measuring results. Finally, innovative strategies for further treatment options can of course be drawn from these results. There are other examples from clinical medicine that have demonstrated this with great success over decades (e.g. in pediatric oncology) (see Pui et al. 2015).

Further advantages of the studies in transplantation medicine are so-called observational study monitoring boards. These are independent experts who regularly assess the course and results of the studies to ensure that a high level of data quality is available, that no violations of study protocols occur, and that the evaluation and publication of the data is carried out transparently and appropriately.

Finally, scientific monitoring would have a further advantage that public, private, and industrial research funds could be raised.

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