

Organ donation in Germany: getting out of a tense situation

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The rate of post-mortem organ donations has dropped since serious infringements of the rules came to light. In the debate on ways out of the crisis, a number of essential issues are now in the spotlight again.

When the first German *Transplantationsgesetz* (Transplant Act) entered into force in 1997, post-mortem organ donation had reached an all-time low at 12.5 donors per million inhabitants. The Act was intended to create safety in core medical ethics issues and improve trust in transplant medicine – the beginning of a new era. The number of post-mortem organ donors increased only slowly, and compared to other European countries remained in the lower average band with a maximum of 16 donors per million inhabitants. More major legal amendments then came into force for the first time in 2012, namely the decision-based solution, whereby citizens receive regular information on organ transplantation and are asked to give their opinion on organ donation. The aim is to encourage willingness to donate organs (1). Another important change: the across-the-board introduction of transplant representatives in clinics with post-mortem donors.

In this new era, many see 16 July last year as the day when everything changed. That was when members of the *Deutsche Transplantationsgesellschaft* (DTG, German transplant society) at the 21st annual conference in Berlin learnt about systematic infringements of standard procedures for transplants.

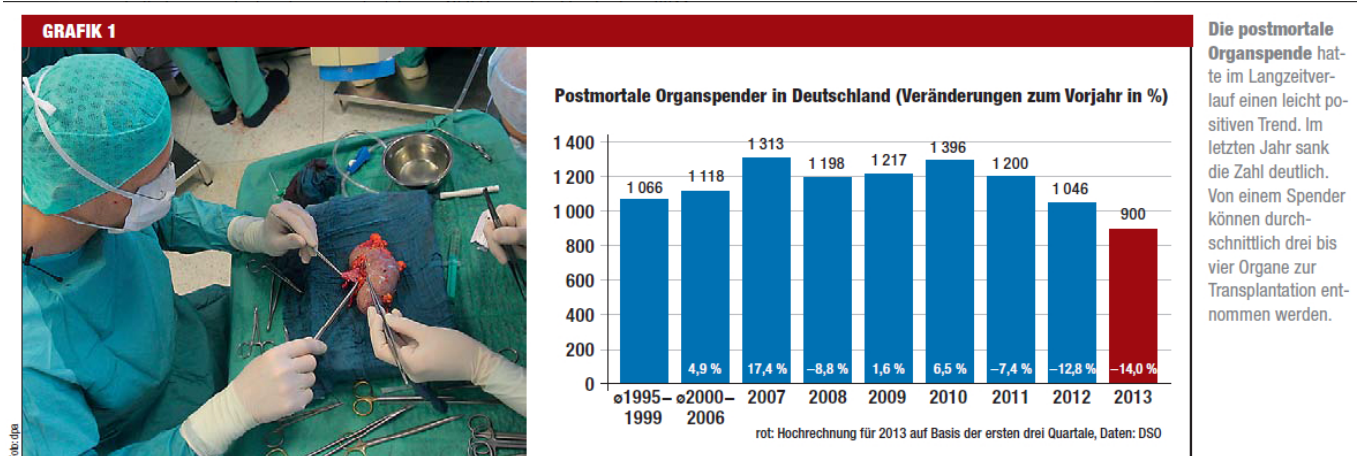
Serious irregularities

The *Prüfungs- und Überwachungskommission* (PÜK, Assessment and Monitoring Committee) of the *Bundesärztekammer* (BÄK, German Medical Association) had identified false indications on the state of health and on laboratory results for liver patients at the University Clinic of Göttingen, apparently with a view to its own patients being given preference for the allocation of post-mortem organs. The report was of irregularities relating to 26 out of 91 organ recipients, an unprecedented rate of systematic rule infringements in Germany.

Politicians and doctors reacted quickly at the time. In August 2012, the *Bundesministerium für Gesundheit* (Federal Ministry of Health) adopted a list of measures to be taken immediately, together with all institutions and organisations, including the assessment of all 24 liver-transplant programmes. In early September of this year, the PÜK published its report (2, 3). The committees detected serious infringements of procedures in 218 of the 1 180 assessed liver transplants, from a total of 2 303 liver transplants (mainly in 2010/11). Only four centres were affected: the university clinics of Leipzig, München rechts der Isar, Münster and Göttingen. There, the number of infringements had increased from 26 to 79 out of 105 assessed cases.

After the events had been reported and investigations had been conducted by public prosecutors, a number of public opinion surveys showed that support for organ donation had fallen. The number of post-mortem organ donors fell dramatically in August and September 2012, and decreased over the entire year by 12.8% compared to 2011. This year, it could fall again by 14% compared to 2012 according to projections, as now reported by Dr Rainer Hess, member of the Interim Board of the *Deutsche Stiftung Organtransplantation* (DSO, German Foundation for Organ Transplants) at the 22nd DTG Congress in Frankfurt am Main ([graph 1](#)). The DSO links the substantial decrease mainly to knowledge of the misconduct, which may have influenced both the general public and clinic staff: "There was less approval among family members but also fewer reports from the clinics", says Birgit Blome, DSO spokesperson.

Graph 1: Deceased organ donors in Germany, change compared to previous year in %



In 2012, the rate of post-mortem organ donors roughly matched the figures for 1997 with 12.8 donors per million inhabitants. By the end of this year, this figure may have decreased. Hess reports that the average number of organs removed and transplanted per donor increased to 3.5.

"The transplant scandal was a painful demonstration of how dramatically willingness to donate organs can be affected by maladministration and misconduct in individual centres", says Dr Frank Ulrich of the University Clinic of Frankfurt am Main, one of the two conference chairmen. It would be necessary to regain and consolidate the trust of the public and patients through quality and transparency.

The conflict between the potential trust-building effects of publishing test results on regulatory conformity and quality of supply in individual centres, and the risk of a reputation-damaging effect for doctors or individual hospitals has long been a subject of debate in transplant medicine.

"There should have been an active, more open discussion, and a reaction to misconduct earlier, even within specialist circles", says the Chairman of the DTG Ethics Committee, Prof. Richard Viebahn of the *Knappschaftskrankenhaus* hospital in Bochum. At the same time, there is a risk that this specialist field may lose its appeal to young doctors, due to increasing regulatory pressure on the highly complex everyday work involved.

Causal research necessary

Now, one year after the allegedly serious misconduct became public, some DTG members would like to have engaged in a more intensive discussion of the type, causes and consequences of procedural infringements in the official context of the annual conference. The DTG Board of Directors referred to specialist opinions, e.g. at the start of the year: consideration should be given to "why an infringement of the rules and ethical principles of transplants was possible to the extent now evident, without this being noticed earlier" (4). Ten DTG members currently have their membership suspended.

Review of the infringements

"I am amazed that the review of the transplant scandal was not given much time at the annual meeting, for even some of us doctors have been unsettled", says a transplant doctor who had investigated a possible case of misconduct as a member of a university medical committee. The very fact that many of them worked as consultants or were involved in investigation bodies was seen by others as an obstacle to the debate, in view of the required neutrality in ongoing procedures and the possibility of unconsidered statements during spontaneous discussion.

The Chairman of the *Ständige Kommission Organtransplantation* (StäKO, Permanent Committee for Organ Transplants) of the BÄK, Prof. Hans Lilie from the University of Halle, announced the next steps of the StäKO relating to the review of procedural infringements: at a two-day conference, the StäKO will soon review the scientific issues behind certain procedural infringements together with the relevant centres and external experts, and use the findings to further develop standard procedures. Developing standard procedures is one of the duties and competences of the body, but not their interpretation in individual cases, on which the StäKO has recently received a growing number of inquiries, explained Lilie. "The StäKO cannot and does not wish to take on this area of medical responsibility", says Lilie. Such matters should be dealt with by interdisciplinary transplant conferences. However, in principle, transplant medicine had to recognise that, unlike other specialist fields, the doctor is not free to decide when to perform the treatment envisaged for the patient. Viebahn suggests that for future cases where an indication which deviates from one of the standard procedures might make sense, external audits or transplant conferences should be in place. Exceptional decisions could therefore be reached in a transparent manner, he told the *Deutsche Ärzteblatt* (German Medical Journal).

Adoption of a code of ethics

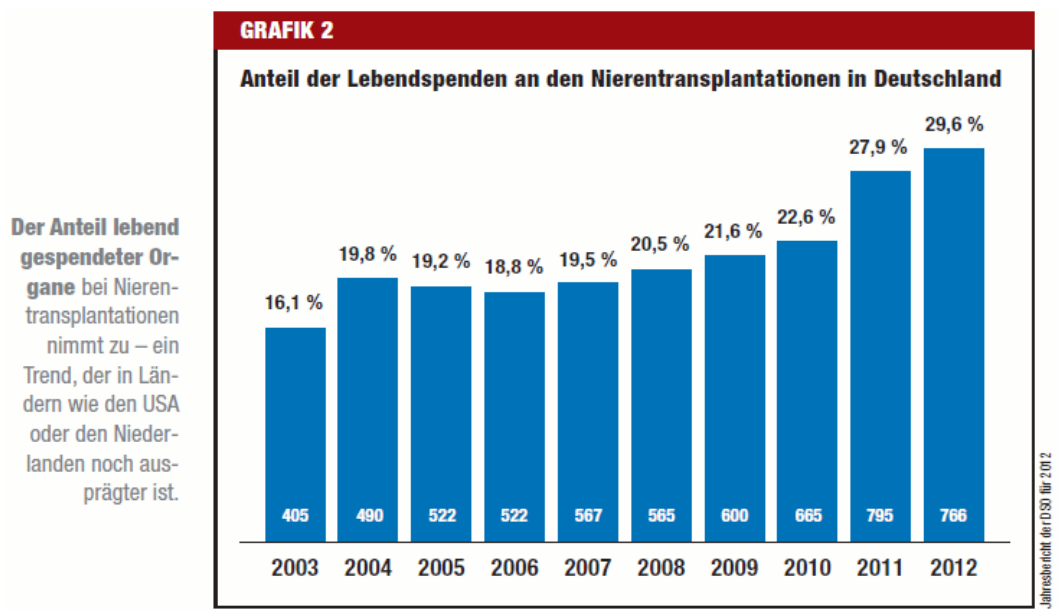
The need to adhere strictly to the rules and also to ensure transparency and appropriate information for the public are focal points in a transplant code developed by the DTG Committee on Ethics, which has now been adopted by the members. The Code also notes that no special measures with the exclusive aim of removing or allocating an organ should be taken before diagnosis of brain death.

The code also refers to aspects which should be given greater attention in the context of the serious lack of organs: according to the law, living donations are secondary to post-

mortem donations. However, the organs shortage – for post-mortem kidneys, the average waiting time is five and a half years – and demographic development could lead to reassessment. This should above all be an option for kidneys ([graph 2](#)). With a view to an improved assessment of risks to the donor after nephrectomy, a new research association is investigating the clinical and psychosocial outcome for donors, taking account of data collected before nephrectomy ([5](#)).

Graph 2: Part of living donors in the kidney transplants in Germany

Growing – a tendency which is even more important in the USA or in the Netherlands



However, greater thought must also be given to living donations of parts of unpaired organs such as the liver, states Prof. Peter Neuhaus of *Charité Berlin*. The balance between urgency and prospect of success for liver allocation should also be reassessed as a matter of urgency, as recently stressed by experts at a hearing of the *Deutsche Ethikrat* (German Council of Ethics).

When faced with the organ shortage, the ongoing move towards an ever larger proportion of previously damaged post-mortem organs and greater emphasis on urgency vis-à-vis success prospects in treatment, doctors obviously find themselves increasingly torn when they have to decide on whether to place patients on the waiting list or whether a specific organ is suitable for a specific patient.

Criticism of allocation criteria

For liver transplants, current developments are leading to a clear deterioration in short-term results, and also in long-term survival in Germany ([6](#), [7](#)). Whereas patients who received transplants from *Charité Berlin* 20 years ago, and who were over the age of 55 at the time of the operation, had the same 20-year survival prospect as an equivalent control group in the normal population, the results are likely in future to be significantly worse, according to the summary of a current assessment by *Charité* of a total of 313 patients ([8](#)). The dominant criterion of urgency in the case of liver allocation and the politically desired disempowerment of surgeons in the selection and matching of donors

and recipients are said to be responsible for the deteriorating results. DTG Secretary-General Prof. Bernhard Banas from Regensburg evidently wanted to prevent misunderstandings in these discussions: the issue could in any case not lead to the *Transplantationsgesetz* being bypassed.

As made clear at the DTG conference, transplant specialists set great hopes on the implementation of a national transplant register, and on uniform, extensive data collection across the board. By the end of the year, an assessment is to be submitted to the Federal Ministry of Health. Statutory provisions are to be adopted (9). Only an extensive scientific database with criteria to measure and evaluate success can determine the issue of fairness, said Prof. Christian P. Strassburg of the University of Bonn: Should success be gauged on the immediate preservation of life, the expected survival time, quality of life, individual or systemic value? These are questions which must be answered by society.

For the first time in Germany, a public opinion survey has been conducted on the importance of success prospects vis-à-vis urgency, albeit a pilot study covering 200 visitors to an outpatients' ward at the *Klinikum rechts der Isar*, Technical University of Munich (10). The results show that, as in other countries, equal opportunity takes top priority, and that immediate preservation of life is top concern with regard to the fair distribution of organs. 69% supported the statement: "Prevention of immediate mortal danger (urgency) is a more important argument than the long-term chances of success." 57% rejected the statement that scarce donor organs should not be given to patients whose prognosis is unsure. 78% agreed that patients with no other chance of survival should, even if half of them will still die, receive transplants as a matter of priority, since everyone must be given a chance of survival.

The district court of Göttingen is examining questions of whether possible infringements of the BÄK standard procedures might be criminal, due to infringement of the principle of equal opportunities on the waiting list. The first criminal proceedings in relation to infringements of standard procedures started there in the summer. The defendant, a 46-year-old former senior consultant, is accused of attempted manslaughter. In eleven cases, false information on patients was allegedly given to the organ allocation body and laboratory results manipulated with the aim of pushing his own patients to the top of the waiting list for a liver, so that they would receive an organ faster. In doing so, the accused was aware that other seriously ill patients were not being considered for the allocation of livers and may have died. According to the prosecution, this justifies the charge of attempted manslaughter.

One of the core legal issues is whether the statutory offence of attempted manslaughter can be established even if no specific injured party can be identified from the waiting list. It is possible only to narrow the possible injured parties down to a small group (11). The waiting list does not have a fixed order of priority, but is rather established as a so-called match-list whenever an organ becomes available, in agreement with the ET rules and the national standard procedures of the member countries.

In three cases, the doctor is accused of bodily harm with fatal consequences, and has been held in investigative custody since January of this year. He is accused of

transplanting livers in the absence of indications or even in some cases despite contraindications. Stable out-patient organ recipients had not been well enough informed about the unfavourable risk/benefit ratio and had died from the consequences of the transplant. The three ancillary actions are based on the same grounds. The accused doctor, on the other hand, talks of "determining fatal developments". A number of experts have raised considerable doubts as to the indications concerning organ transplant or the correct time of treatment, and criticise the sometimes extremely patchy documentation on diagnoses and decision-making procedures, but have problems providing direct answers to questions concerning intent.

The question of whether, at ^{Gesetz zur Regelung der Entscheidungslösung im Transplantationsgesetz, vom Juli 2012. Bundesgesetzblatt 2012; 33: 1504–5}

the end of the

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