How unethical subversion challenges organisational viability and accountability: the case of transplant medicine in Germany and the United States

Corresponding author:
Dr. Paola Mattei, Associate Professor of Comparative Social Policy, University of Oxford
(paola.mattei@sant.ox.ac.uk)

Co-authors:
Therese Feiler, St Antony’s College, and Jeremy Pillar, St Antony’s College, University of Oxford

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Introduction

In 2012 and 2013, German citizens witnessed an unprecedented public crisis surrounding the German organ transplant system. The unethical behaviours concerned the systematic manipulation of patients’ medical data in several transplant centres in order to deliberately alter the waiting time for an organ transplant. The newspapers and media triggered a sustained national debate on the gross misconduct and the lack of moral capacities of professionals involved in the manipulation of medical data. The crisis generated a wide range of policy responses, from changes in the legal regulations pertaining transplant medicine to ethics training for doctors, to the adoption of new legislative instruments aimed

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at strengthening the regulatory framework, to legal action in courts and criminalisation of professionals, and government mandated closures of transplant centres.

This paper aims, first, to document the effects of gaming the organ volume targets over patients’ wait times for liver transplant in Germany and the United States. In some cases, doctors have misreported deliberately information regarding patients’ medical data to fiddle the waiting lists. Gaming, defined as reactive subversion, was significant in the German organ crisis and led to a sizeable drop of organ donations. Second, the paper discusses governance changes associated with the economisation of transplant medicine and new policy reforms to improve the accountability and transparency of the organ regulatory system. The paper focuses on the governance conditions, such as the lack of transparent regulation and centralised supervisory external bodies, that may have facilitated the transformation of reactive gamers into “rational maniacs”, to use Hood and Bevan’s categorisation of actors who game the system (Bevan and Hood, 2005). Rational maniacs are those who do not share the goals of central controllers and aim to manipulate data to conceal their operations.

On one hand the paper explores the effects of the introduction of rewards to doctors in the form of performance bonuses, if volume targets were met. On the other, the paper reflects upon the highly problematic nature of gaming when it escalates at all levels of a governance system and when it involves unethical decisions, defined as subversion of ethical standards. Do rational maniacs lose their moral capacity, when they deliberately decide to break the rules defined by the organisation? How “deliberate” is their unethical behaviour, and how influential is the pressure of new governance arrangements on the individuals? This paper suggests that the ethics of hierarchist compliance, by constraining ethical choices may paradoxically lead to unethical subversion. This is deeply problematic as it undermines the capacity of doctors and professionals to behave as moral actors.
Public sector decision-makers are regularly subject to a number of simultaneous multiple diverse and conflicting expectations. These simultaneous expectations result in decision-makers facing various dilemmas, often relating to opposing values, which are resolved by choosing pragmatic alternatives that are considered appropriate based on certain ethical standards – making account-giving an innately ethical activity (Dubnick & Romzek, 1993). A purely procedural definition of accountability mechanisms does not capture fully the relationship between human motivation among service providers and professionals and the overarching governance system. Discussing merely in formal terms about ‘hybridization’, ‘delegation’ or ‘decentralization’ of accountability in public service organizations may provide the ‘magic’ space (Pollitt and Hupe, 2011) space to bring paradigmatic shifts about. Yet in order to understand and assess the effects of new governance arrangements, such as bonuses and performance rewards, in supporting or harnessing ethical behaviour, an empirical investigation is fruitful to document unethical practices in an area of medicine that is deeply sensitive, such as organ transplant. Hence, this article explores the relationship between recent governance healthcare reforms and individual moral demands. We are particularly interested in exploring the conditions under which governance arrangements collide with individual ethical codes.

Analysing the transplant system crisis in Germany through Christopher Hood’s (1996, 1998, 2000) theoretical framework, we investigate to what extent the German organ allocation misconducts stem from a tension between professional-ethical and economic values resulting from governance changes in the wake of hospital reforms (Mattei et al, 2013). The central question of the article is: what conditions produce significant gaming effects, and consequently make hospitals less protected against breaches of professional values, such as honesty and fairness?
Empirically investigating the cases of the German and U.S. transplant systems, we argue that the organ scandals bring to light a clash of professional values with formal administrative regulations, and that the tension is the sign of changing organisational viability, i.e. an increasing lack of congruence between accountability mechanisms in health organisations and professional values or moral purposes. The article will proceed as follows. After discussing the theoretical framework, we will then present the examples of the German transplant scandals. As a system comparable to Germany in terms of structural reforms and federal system, we make comparative remarks to the United States. Although transplant scandals of a similar scale did not happen in the U.S., the article points to similar potential problems. Each case will be discussed against the backdrop of organisational conditions and the difficulties of institutionalised values vis-à-vis professional moral decisions that the organs scandals in Germany in 2012/2013 have brought to light.

Theory: from the legalistic ethics of compliance to the ethics of subversion

In the field of public administration multiple approaches exist on the relationship between ‘ethics’ and ‘accountability’, though the theoretical assumptions in this area of studies have remained at the margins, due to the predominant concerns with accountability mechanisms. In this paper, we focus on the definition of accountability as a principle supporting ethical behaviour of individuals in complex service delivery organisations. A more practically minded approach investigates practical tools in order to align individual ‘ethics’ with the values of the institution. We do not adopt here such practice-orientated approaches, though they are very useful contribution. Efficient organisations are those, so the arguments go, where individuals share the overarching goals. Lawton et al. (2013), for example, define ‘ethics’ as inherently personal, ‘a set of principles that provide a framework for right action;
an individual acts in accordance with that set of principles’. The ‘public service ethos’ motivates the individual to go to work, and simultaneously provides the content of their ‘ethical’ action. A more sophisticated theory of human motivation, such as LeGrand (2003) views as ‘knights’ those service providers that are able to think about the interests of others. Yet the possibility that ethical values come into conflict with the accountability normative principles of an institution is certainly not a primary concern of the more practical public management approaches, chiefly for two reasons. First, a ‘public service ethos’ is defined in very loose terms, and professional codes of teachers or doctors are not included. Second, these approaches assume that institutionalised ‘regulatory frameworks’ such as ‘codes of conduct, audit functions, anti-corruption agencies, standards committees and ethics officers’ (p. 9) are necessarily consistent with the overarching goals of institutions. Lawton et al are concerned with ‘how best to help public officials make better ethical decisions, both individually and collectively.’ (p. 9) Through ‘ethics training’, and moral education, there may be the possibility to get at the heart of people’s behaviour and to go ‘beyond the reach of the law’ (Galbraith, cit. p. 95). This practical ethics for public managers seeks the ‘ethicalization of the law’ (Vöneky et al., 2013).

In the legalistic ‘orthodox model’ (Maesschalk, 2004, p. 467) public organisations constrain both individual ethical choices and entrepreneurial freedom. The ethical thing to do is to follow (administrative) rules; it is an ‘ethics of compliance’. Compliance is embedded in government operations, it is fundamental to how public organizations function, and public managers are expected to be accountable to elected politicians through administrative controls (Mattei, 2009; Geuras and Garofalo 2010, p. 7) The assumption underlying the legalistic ethics of compliance is that the organisation is (still) dedicated to the public interest and public service. The individual public service ethos, the sense of public obligation can then be fully aligned with the organisation, which preserves liberal-democratic, constitutional
values and ensures the respect of basic human and constitutional rights against arbitrary executive power (Waldron, 1993; Larry D. Terry, 1995; Trappe, 2013).

The question of congruence between the values of the organisation and the internal ones of the individual is a crucial one, not only for its administrative implications but also for the conditions that support or harness ethical behaviour. Christopher Hood’s (1998) theoretical framework addresses the fundamental question of adequacy between values and organisations, namely the question of an organisation’s viability. According to Hood, variations in the ‘fundamental dimensions of human organisation’ (p. vii-viii) are linked to ‘irreducibly different attitudes and beliefs about social justice, blame and guilt ... and the nature of good government more generally’ (p. 7). For an organisation or way of life to be ‘viable’, the structure has to match the appropriate values and beliefs. (p. 10)

Hood uses the grid-group heuristic to describe four approaches to public management, according to a) their emphasis on ‘group’, i.e. the degree to which they promote groups or individuals, and b) their emphasis on ‘grid’, the degree to which ‘our lives are circumscribed by conventions or rules, reducing the area of life that is open to individual negotiation’ (Hood, 1998, p. 8). Four worlds views emerge from a combination of these two variables. Each one can be traced throughout history, and ‘incorporates a vision of how accountability should work and how it should be promoted.’ (Hood, 1998, p. 10) First (1) the hierarchist way holds members of an organisation to account through oversight and control within a hierarchy (high group/high grid). Second (2), the egalitarian way (high group/low grid) emphasises mutuality as a form of control and regulation. Here, weak formal leadership combines with communal, participative decision-making. Egalitarians stress three ideas: the group’s self-management, mutuality and ‘maximum face-to-face accountability’. (Hood, 2000, p. 122) Third (3) the individualist way of organisation is associated with the controlling function of markets, competition and deregulation (low group/low grid). Finally (4), the
‘fatalist way’ of organisation, where low group cohesion coincides with a narrow grid of rules and regulations (low group/high grid), is altogether ‘beyond markets, hierarchies, and solidarity’ (p. 160).

The same question of congruence between institutional principles and individual goals has been discussed recently by Melvin Dubnick with a moral theoretical underpinning. This looks at accountability as related to moral principles. It draws on Robert Nozick’s ethical theory “that sees action as the outcome of tensions between forces of a moral push and a moral pull” (Dubnick, 1996: 8). Further: “…actions result from choices public administrators must make among contending values - values that create moral pushes and pulls” (Dubnick, 1996: 9). Moral pushes are what Dubnick also characterises as the individualist ‘accountability of conduct (AC)’. The AC is concerned with describing and/or explaining a common human behaviour; how and why individuals account for their (typically erroneous) behaviour to others. Moral pushes are thus internal to an individual and motivate and determine a person’s own moral conduct – to enhance his/her own self-worth.

Moral pulls are what Dubnick calls the institutional ‘conduct of accountability (CA)’. The CA is more institutional and normative: “…the structures and procedures through which accountability is achieved” (ibid.: 6) – the context being crucial here. Moral pulls therefore determine a person’s moral conduct towards others based on their (i.e. the others’) values/demands. In other words, the moral pull of ‘A’ puts a moral constraint on ‘B’ and determines the behaviour of ‘B’ in accordance with the values/morals of ‘A’. Ethical action is said to have occurred when the moral push is equal to or greater than the moral pull.

There is a high level of complementarity between Hood’s framework and Dubnick’s efforts of establishing a Nozickian ethical theory of accountability as follows. Being accountable is a social relationship with a human dimension, beyond procedural rules. The condition of accountability is inherently ethical because it subjects one to the tensions of
The legal context narrows and manages expectations by establishing liabilities for the public administrator that are enforceable through judicial or quasi-judicial actions” (Dubnick, 1996: 11). In a peer or professional group institutional setting, accountability takes the form of responsibility – and professional/strong peer group standards. Together, four manifestations of accountability - liabilities, answerability, responsibility and responsiveness – form the institutional moral pulls of Dubnick’s framework. The internalization of the above four manifestations are what form the moral ‘pushes’ of Dubnick’s accountability framework. These include: obligations, obedience, fidelity and amenability. Liabilities internalize as obligations – “…based on either a positive commitment to the law or a desire to avoid exposure to legal sanctions” (ibid.: 13).Answerability manifests itself internally as deference to one’s superiors in the form of obedience. Fidelity - an internalized sense of honor and loyalty to the peer or professional reference group - is critical to the success of responsible accountability.

**The German Organ Transplant Crisis, 2012-2013**

**Context**

In summer 2012 the *Süddeutsche Zeitung* reported data manipulations in favour of particular patients waiting for liver transplants in Munich’s Klinikum Rechts der Isar. Similar reports on University Clinics of Göttingen, Leipzig and Regensburg gradually followed in all the public media. In the transplant centers of these hospitals, doctors had, at times, manipulated patients’ data in order to move them up on Eurotransplant’s waiting list for transplant livers. Eurotransplant is a supranational body that ‘pools’ and allocates organs to the transplant centres of its member states. Data to determine the MELD-score (Model for End-Stage Liver Disease) include factors such as patients’ levels of bilirubin and creatinine serums, whether
they have undergone dialysis or, if diagnosed with liver cancer, the stage to which it has progressed. A high MELD-score leads to being moved up on the priority list for receiving a donor’s liver.

In response to the media outcry, the German Medical Association (Bundesärztekammer, BÄK) in July 2012 formed a Task Force to investigate the matter. In addition to the existing Audit Commission, which regularly monitors hospitals’ organ allocation and responds to Eurotransplant’s complaints, the Task Force comprised members of their Standing Commission on Organ Transplant (STÄKO), their Audit Commission and the Monitoring Commission. On 9 August 2012 a declaration, entitled More Transparency and more Efficient Control in Transplant Medicine (Gemeinsame Erklärung, 2012) was signed and published by the key healthcare actors in the transplant process: the Audit Commission and Monitoring Commission, the German Medical Association (BÄK), the German Hospital Association (Deutsche Krankenhausgesellschaft, DKG), and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). This declaration was followed by Action Paper on 27. August, signed by the same organizations and the federal Health Minister Daniel Bahr: Strengthening Control, Creating Transparency, Earning Trust. (Spitzengespräch, 2012)

The recommendations became policy over the next months. In order to increase transparency of the waiting lists and the state’s control’, the Transplant Act was modified in late 2012. Now, within the hospitals, ‘transplant conferences’ have become mandatory procedures before patients are put on the waiting lists. A ‘several eyes’-principle was introduced and the doctors’ names need to be given to Eurotransplant. Moreover, if the donated organ is in danger of getting lost, Eurotransplant is now entitled to change over to the ‘fast-track allocation’. Up to then, a centre that got an offer from Eurotransplant could allocate the organ to its patients. In the future Eurotransplant also will acquire decision-
making power over the fast-track allocation. As promised, more controls and more transparency was introduced into the system: suspicion-independent monitoring of the transplant centres, publishing audit reports, and a closer collaboration with public prosecutors was agreed on. On 24 April 2013 the DKG and the Medical Association agreed that ‘there may not be made any agreements with clinicians anymore on particular services or operations.’ (Antrag, Drs. 17/13897, 2013) This was to address the problem of bonuses paid out to doctors by hospitals for particular operations. Notably, this is not strictly law. Rather, the hospitals now have a duty to transparently report in their annual ‘Quality Report’ on any bonus/target-agreements with doctors. Hence there is now a strengthened transparency on critical target agreements (Antrag, Drs. 17/13897, 2013).

Moreover, data manipulation became a criminal offence. On 14 June 2013, all fractions in the German Bundestag agreed on a legal amendment to the TPG (Transplant Act). It is now illegal at the punishment of up to two years imprisonment, to manipulate patients’ data for the sake of preferential treatment of patients on the waiting list, and to transmit wrongful patient data to Eurotransplant. Further changes in the legal framework for allocation are now conditional upon the agreement of the federal health ministry.

Throughout 2013 the BÄK Audit and Monitoring Commission systematically investigated the irregularities and screened the records of all German transplant centres for the years 2010 and 2011, focusing on liver transplants. They looked especially at infringements according to § 16 sect. 1, No. 2 and 5 TPG, which concern the waiting lists and documentation. On 04 Sept 2013 the Commission published its final report, stating a higher number and systematic rule violations in four hospitals. The relevant figures in the report are the following: Universitätsklinikum in Leipzig (241 cases investigated, 76 rule violations), Munich (Klinikum Rechts der Isar - 135 cases, 38 violations), Universitätsklinikum Münster (67 cases, 25 violations), and Universitätsklinikum Göttingen with 105 cases and 79
violations. (Überwachungs- und Prüfungskommission, 2013). Notably, these figures include all irregularities irrespective of their reason (mistakes, misinterpretations, etc. included). The Commissions documented irregularities also in the other transplant centres.

Meanwhile, legal prosecutors in the different federal states (Länder) initiated investigations. By January 2013, the public prosecutor in Braunschweig was investigating 26 medical staff of the Universitätsklinik Göttingen on the grounds of a ‘vague initial suspicion’, focusing on the manipulation of patients’ data (“Göttinger Chirurg”, 2013). The main target of investigations was the head of the Transplant Surgery. His trial started on 19 August 2013 and is set to finish in May 2014. He was charged with negligent homicide in 11 cases and bodily injury with fatal consequences in three cases. (“Angeklagter Transplantsmediziner”, 2013) In Leipzig, the Head of the Transplant Clinic was suspended, as well as two head doctors. Here the public prosecutor is investigating on the claims of ‘attempted or completed killing and grievous bodily harm’. In Bavaria, 3 cases were handed to the public prosecutor. In May 2013 the Bavarian state government announced the closure of liver transplant programmes in Munich’s Rechts der Isar and in Erlangen.

Whatever the outcome of the legal trials, public distrust in the transplant system has grown significantly. In the first 9 months of 2013, the amount of organ donations went down to 754 from 892 in the previous year. Whilst in the first 9 months of 2011 the number of transplanted organs was at 3029, the number went down to 2912 in the same period the year after. In the first three quarters of 2013 the number dropped even further to 2501. (Bartens and Berndt, 2013)

Institutional settings and self- regulatory framework of organ transplant in Germany
The ‘traditional welfare state’ provides public healthcare on the grounds of constitutional rights in Germany. In terms of organisational viability the German system is a hybrid: mutual forms of professional medical accountability are integrated in a wider legal and political and hierarchical system of democratic legitimacy and *political* accountability (Mattei et al., 2013). The German hospital system, including its transplant centres, has been a corporatist system of welfare organisation. Originally envisioned as a mediate form of organisation between pure markets and state-provision, the medical self-administration functions already in remarkable professional independence (unlike, e.g. the NHS or the French centralist system).

This explains at least the centrality of some accountability mechanisms and actors, in relation to the organ crisis in 2012-2013 professional associations. Controls and audits were initiated from within and carried out by the medical self-administration relatively independent, upstream to public prosecutors. (“Staatsanwälte ermitteln”, 2013) The Standing Commission on Organ Transplant and the Audit and Monitoring Commissions investigated on the grounds of the allocation regulations of the TPG. Yet these monitoring bodies are not part of a higher structure of supervision. This raises the question of who is guarding the guardians. A legal expertise commissioned by the Federal Ministry of Health in 2013 pointed out: ‘It reflects the altogether problematic (lack of a) supervisory structure in the German transplant system that the Auditing and Monitoring Commissions are also not integrated into a clearly structured supervisory system.’ As a result of the legal field being largely self-regulatory, and because the two commissions are subject to private law, they are not subject to state supervision but ‘in the end are only controlled by the contract partners.’ (Augsberg, 2013, p. 36)

Unlike the British or French system, German organ allocation is not in the state’s hands. On the national level, the 1997 Organ Transplant Act (Transplantgesetz, TPG) required the institution of a central coordinator to prepare and manage donations. In July
2000 the German Foundation for Organ Donation (DSO, Deutsche Stiftung Organspende), a non-profit foundation subject to private law, took this role. It promotes organ donation and transplant to the public, coordinates with hospitals and registers the data of potential donors; it is also responsible for ‘organ procurement’. The DSO’s tasks are determined by its contract with the German Medical Association (BÄK), the SHI-Umbrella Organization and the Hospital Association. These are also the entities that supervise the DSO.

Whilst the DSO has a coordinating role, Germany, or rather the 43 transplant centres of its hospitals, are part of the Eurotransplant ‘international collaborative framework’ (Eurotransplant, 2013). The Stichting Eurotransplant International Foundation was founded in 1969. Subject to Dutch private law, it is also ‘a non-profit international service organization that facilitates patient-oriented allocation and cross-border exchange of deceased donor organs’ (Eurotransplant, 2013). Its member states are: Austria, Belgium, Croatia, Germany, Hungary, the Netherlands, Luxembourg and Slovenia. Eurotransplant manages the process of matching donors and patients, of allocating organs, and is also ‘engaged in developing best practice recommendations and policies’ (Eurotransplant, 2013). Even though all available organs within a country need to be offered to the foundation, the advantage for members is that they have access to a greater ‘organ pool’ (Eurotransplant, 2013; Molnár-Gábor, 2013, p. 326) from all its member states. Whereas the DSO is the ‘coordinator’ according to §11 TPG, Eurotransplant is the ‘mediator’ according to §12 TPG. (DSO, 2013) The regulative framework for organ allocation in Germany is set both by the TPG as well as the so-called Eurotransplant contract (ET–contract) between Eurotransplant, the BÄK, the SHI and other relevant actors of the self-administered healthcare structure. However, since the decision ultimately lies with Eurotransplant, their criteria significantly play into the actual allocation decision.
Governance changes and rational maniacs in the system

What about the organisational conditions that made the manipulations of data and unethical behaviour more significant? Through a variety of reforms and NPM measures an organisational shift had been brought about towards a marketised and economised healthcare sector (Mattei et al, 2013). In Hood’s (2000) terms, the already distanced corporatist system moved further away from the state towards individualist, low-grid market forms of organizations and framing or steering of professional care. This general development did not escape the transplant system. First, we identified a financial incentive within hospitals to perform liver transplants and to expand the volume of transplants. Health insurers release fixed sums to them for different kinds of transplants: liver transplants release up to 200,000 EUR in payments per treatment, kidney transplants, for example, yield 50-65,000 EUR and a bypass surgery yields 18,000 EUR. Second, there is competition between hospitals, specifically the 24 German liver transplant centres, for patients. Such competition can also be regional, as in the case of North Rhine-Westphalia. (Serie Organspende, 2012) At the same time, transplant centres are legally required to perform a minimum of 20 liver and 25 kidney transplants per yea. Third, doctors as individuals are financially incentivised. Bonuses are now included in about 50% of all physicians working contracts and in over 95% of head doctors’ contracts (Flintrop, 2013). In Göttingen, for example a 1,500 EUR bonus was released to the surgeon for each liver transplant.

For the moment we are assuming that the medical professional code is congruent with the formal regulations on paper, which determines the MELD-score and organ allocation. This has been the claim of the BÄK and underlies the scandals themselves. In this sense of compliance with documentation of allocation regulations, the medical self-administration has long reported a clash between professional duties towards patients and target/financial
accountability regimes within hospitals. The head of the ‘Chefarzt-Verband’ admitted the problematic nature of contracts with bonuses. (Flintrop, 2012) Even the doctor on trial in Göttingen considered bonuses ‘unethical’. (Windmann, 2013) Frank Ulrich-Montgomery, head of the BÄK said at the 04 Sept 2013 press conference: ‘It was not the preferential treatment of private patients, Eurotransplant “non- residents” or the enrichment of individuals [that lead to the manipulations]. There are rather structural incentives out of the hospital financing, out of the competitive pursuits of individual hospitals and the supposed pursuit of fame and honour.’ (Montgomery, 2013)

Altogether this suggests that we have two ‘competing logics’ (Bode, 2011) at a moral level within transplant centres, i.e. standards by which doctors both act and are held accountable. These conditions allow doctors to be ‘knights’ according to hospital’s economised controlling regime. Yet it allows them to become ‘rational maniacs’ (Bevan and Hood, 2004) breaking another standard, be that professional-ethical prioritizing of the patient or the MELD-system. According to Article 1 of the Professional Code, physicians ‘serve the health of the individual and of the population. The medical profession is not a trade. It is by nature a liberal profession.’ (Code for Art. 1 - Tasks of Physicians; italics added) Similarly the Medical Vow reads that ‘The maintenance and restoration of the health of my patients shall be the primary principle of my actions.’ (Medical Vow, 2011)

Since the number of patients who could benefit from an organ transplant exceeds that of donors, organ allocation based on exclusively medical considerations is difficult. As the Swiss Federal Council pointed out: ‘The hypothesis that allocation is made according to medical criteria is wrong: allocation is made according to ethical principles. … The mode of allocation itself is based on value decisions.’ (Molnár-Gábor 2013, p. 327; Lang 2005) The regulations for organ placements implemented by the German Medical Association equally do not follow strictly medical criteria. The 1987 West German ‘transplant codex’, the
‘transplant community’s’ precursor to the TPG, already contained ethical, legal and administrative principles. (Galden, 2007, p. 20). Moreover, up to 2007 livers were allocated according to the criterion ‘chances of success’ rather than ‘urgency’, as they are now.

Eurotransplant themselves point out that allocation is based on ‘valid medical and ethical criteria’. There are first ‘two principles’ or criteria: ‘Expected outcome’ and ‘Urgency’ (as determined by experts in an objective and transparent way), although it is not clarified here in which order. Further taken into account is the ‘national organ balance’ in pursuit of a reasonable balance in the exchange of organs between countries’ and ‘waiting time’.

(Eurotransplant 2013a)

The fact that organ transplants and organ allocation is understood in economic terms, a quasi-market of ‘supply’ and ‘demand’ presupposes a frequently questioned economic framework for the transplant system and surrounding debates (Schicktanz and Schweda, 2009). Sitter-Liver (2003, p. 48) points out that the latter ‘suggests the economization of a process which is primarily to be regulated according to criteria of justice’. Yet criteria of justice (e.g. the justice of preferring a young patient to an old one) are inherently moral and social, and so need to be related to political and judicial accountability mechanisms.

Therefore, as Sitter-Liver argues, the justice of organ allocation cannot be divorced from the political community.

As foundations the DSO and Eurotransplant system are organizations based on “mutuality” – an organizational framework of high professional group cohesion, interdependence and professional values distinct from hierarchical-political accountability mechanisms, whether on a national or international level. At the same time, we find clear economizing tendencies, a quasi-market framework of ‘supply’ and ‘demand’ and a resulting allocation criterion of a ‘balance of resources’. In this sense, the organizational structure of organ allocation can be seen as a hybrid between ‘market’ and ‘mutuality’ outside political-
hierarchical legitimacy and accountability. As expressed by Lang (2005), Germany’s transplant law lies in ‘the field of tension between economic pressure, regulated self-regulation and the state’s functional responsibility’. Bruno Meiser, head of Eurotransplant, in an interview in August 2013 defended the allocation mechanisms/organisation and demanded high penalties for ‘criminal doctors’ (referring to the allocation irregularities). He explicitly denied the need for the state to directly supervise organ allocation: ‘There is no reason why private law organisations should not organise organ donation and organ allocation. Should the Bundestag decide who gets an organ? Again: not the system has failed, but some doctors have exploited the system.’ (“Um Leben und Tod”, 2013) Meiser’s binary choice between private-law foundation and party-political dissonance, however, does not quite grasp the (ethical) questions of social justice and democratic legitimacy raised by the BÄK’s regulations, Eurotransplant’s allocation and, in consequence, the 2012 organ scandals.

Although Eurotransplant operates within the broad framework set by the TPG and the BÄK’s regulations, there is a significant lack of clarity on how e.g. principles of ‘urgency’ and ‘expected outcome’ are to be weighed (Molnár-Gábor 2013: 336-337). Eurotransplant’s own rules of allocation, i.e. on how to weigh the principles in a concrete case, are part of a guide, which lays down the decision-making process for every organ and the process. This manual is de facto secret (even to the BÄK Audit Commission, which in 2012 requested clarification from Eurotransplant), which has raised serious concerns of ‘rechtsstaatlich transparency’ and hence Eurotransplant’s accountability (Bader, 2010, pp. 198-200). The criterion of ‘national organ balance’ is not covered by the ET-contract; nor is it included in the TPG and the BÄK regulations. In fact, it is not part of any national legal framework. Yet the criterion appears to be a regular point of contention between Eurotransplant and the BÄK’s Audit Commission. For example, the latter tends to decide against an ‘allocation
infringement’ claimed by Eurotransplant on the grounds that the legal basis is missing. (e.g. Audit Report, 2012 p. 14)

**Constitutional rights and arguments on political morality: the German approach**

As Molnár-Gábor (2013) shows, the legal basis of Eurotransplant’s allocation criteria, as well as the reach of effective allocation decisions violate the German constitution. With its current powers of ‘normatively relevant decisions’ it touches upon citizens’ constitutional rights. Hence, the state cannot delegate these responsibilities. In legal circles this understanding is widely shared. The fact that neither political nor judicial accountability is warranted, since there is no legal procedure for affected patients vis-à-vis a Dutch private-law organization, aggravates this problem of constitutionality. The only way to align the current system with the German constitution would be to either re-found Eurotransplant under international law or to organize organ allocation through public legal and judicial systems. In terms of Hood’s (2000) typology, this current gap underlines the distance of the DSO/Eurotransplant system from the ‘traditional welfare state’.

Both the media scandals and the initial charges of manslaughter in Göttingen (although not in the other Länder) were based on a tacit acceptance of Eurotransplant’s and the BÄK’s regulations. (cp. Augsberg, 2013, p. 58) From this angle, the more or less systematic manipulations, if not the marker of ‘rational maniacs’, at least seemed to fit Hood and Bevan’s description of ‘reactive gamers’, professionals ‘who broadly share the goals of central controllers, but aim to game the target system if they have reasons and opportunities to do so.’ (2005, p. 100) In other words, it appeared that the scandals brought to light a point of ‘hitting the target, missing the point’. However, current legal analyses of the criminal charges, previously unchartered territory, may suggest that the doctors breaking allocation
rules were hardly viewed as ‘rational maniacs’ by courts. In this vein the Göttingen surgeon’s criminal charges were significantly revised.

For example, Kudlich (2013) investigates the charge of intentional killing, which could be seen as the marker of the ‘rational maniac’. Yet he points out that the charge of completed act of killing does not apply to patients who received an organ despite the manipulation, even if they received it later. It is certainly possible that persons who moved down the list of organ receivers due to manipulations could have survived with the transplant. However, this assumption includes many uncertainties (e.g. lots of patients die despite transplants, from bad health, etc.) Hence, Kudlich emphasises, those patients are not protected by the regulations that the doctors infringed. Similarly Fateh-Moghadam says: ‘From the point of view of the patient on the waiting list the manipulation presents at best an increase of an already existing risk not to receive an organ in time’. This reason is that, those patients have no [legal] claim to a particular organ, but rather a legally guaranteed chance to receive an organ.’ (“Kein normaler Fall”, 2013) He sees the reason for the public prosecutor’s charges in these problems. In Göttingen it could not be proven that a particular patient had died because of the manipulations. (“Kein normaler Fall”, 2013) The senior public prosecutor of Munich, Thomas Steinkraus-Koch, also expected that the defendants would not be judged on criminal charges, but rather rule infringements. Even if the doctors were charged with ‘falsifying medical certificates’, this would not be criminally relevant, since they falsified data not vis-à-vis a public authority or insurance, but Eurotransplant, a private-law foundation. Criminal liability is excluded in such a case. (Haarhoff, 2013)

Moreover, the BÄK’s allocation rules remain under constant flux, as does the MELD-score. Fateh-Moghadam (2013) points at a concrete example. He argues that the rule according to which alcoholics may only receive a transplant liver on the condition they have been ‘dry’ for at least 6 months represents a ‘discrimination against alcoholics covered up as
a medical counter-indication’. (see Lang, 2005) With this criterion the BÄK reaches beyond its legal mandate, which is to determine whether a patient can be successfully transplanted or not. At the same time, the (alcoholic) patient has a right to be put on the waiting list. So with reference to his or her legal right to lie (Fateh-Moghadam, 2013), the doctor may even be morally obliged to manipulate data in the face of this unlawful criterion. In other words, a doctor’s ethical decision can mean trumping a tacit quasi-economic bias and discrimination feeding into the waiting list according to the BÄK regulations: that giving a liver to an alcoholic is an uneconomical waste of a rare resource.

The U.S. case

It is beyond the scope of this paper to offer a full comparison of the German case with the U.S. organ allocation system. However, as a comparative benchmark we identify similar problems in the U.S. as those discussed in the previous section. Both healthcare systems are framed by a federal political system (again, as opposed to the U.K. or France) within which professionals, and especially the ‘transplant community’ (Galden, 2007, p. 25) enjoys a high level of self-administrative freedom. Although significantly less heated by the media than in Germany, reports of data manipulations have also occurred in the U.S. In one instance during the late 1990s, Temple University Medical Center decreased patients’ waits for heart transplants by falsely reporting that some were more seriously ill than they actually were. UNOS, the United Network for Organ Sharing, first discovered this policy violation in 1999, but failed to act. Only when confronted with twelve additional such cases at the hospital in 2001, and sixty-four in 2002, did UNOS put the centre on probation for three years, a relatively mild form of punishment. Similarly, in 2002, the University of Illinois’ liver transplant program deceptively claimed that several relatively healthy patients had been sent to the hospital’s Intensive Care Unit
(ICU) in order to strategically advance their position on waiting lists in the competitive Chicago liver transplant market. While the Centers for Medicare and Medicaid eventually stepped in to impose a $2 million fine on the hospital, its liver transplant program was not shut down. (Snyder, 2010, p. 553)

It thus appears that hospitals in the United States have at least occasionally tampered with medical records in order to better their patients’ chances of receiving an organ transplant, including in cases that resemble the recent scandal that engulfed the German healthcare system. However, as the general lack of substantive, publicly-available evidence and the 2006 investigative report undertaken by The Los Angeles Times reveal, it is unclear how many such instances have occurred unnoticed in the past three decades, particularly in light of a near-absence of federal oversight and the high degree of unchecked secrecy provided to UNOS and its member centres. (Ornstein & Weber, 2006) This gap in primary and secondary research would need to be filled in the future.

The regulation of organ transplants in the United States has always been highly decentralized. It relies on a combination of very limited federal and state-level oversight alongside private, non-profit sectorial governance. At the same time, we have a highly economised system on the level of hospitals. Even if few, the incidents detailed raise questions regarding the forces pushing doctors to forge records. While the accountability mechanisms of regulation and oversight may be one condition (see below), it alone does not necessarily spur such actions. Yet the little scholarly literature available with regards to the U.S. does point to the potential role of competitive market pressures.

No less than 78 per cent of all medical procedures in the United States are performed on a fee-for-service basis, generally bolstering doctors’ and hospitals’ incentives to complete as many operations as they can. (U.S. Bureau for Labour Statistics, 2010) Such incentives are further strengthened by the continually rising prices surgeons can levy for organ transplants
in the face of low supply and ever-growing demand: the average liver transplant alone now costs more than $577,000. (UNOS, 2014) Halldorson et al. highlight that competition between transplant centres creates an urgent need to recuperate ‘fixed costs, to make incremental profits with each additional transplant, and to preserve [] market share.’ (Halldorsen et al, 2012, p. 97) Competitive market pressures thus fuse with the high prices transplant surgeons command to generate financial incentives encouraging unethical – in the sense of non-patient centred – revenue-raising behaviour.

The current system of organ transplant regulation first came into being thirty years ago. In the wake of medical breakthroughs and a rapid demand for kidney transplants in the late 1970s and early 1980s, surgeons around the country fashioned largely informal alliances with other colleagues and hospitals in order to obtain organs and conduct procedures. Like the German ‘transplant community’, the mutual-professional organisation, partly due to its spearheading place and expertise, formed the backbone of the American transplant system. Aware of the inequities this system might, and quickly did produce, the United States government introduced the Organ Procurement and Transplant Act (OPTA) in 1984 to regulate organ donations and allocations, thirteen years prior to Germany’s nationally binding Transplant Act (TPG). OPTA established a similarly thin supervisory framework. A single private, non-profit contractor, the United Network for Organ Sharing (UNOS), was charged with the creation of a national Organ Procurement and Transplant Network (OPTN) to facilitate organ recovery and placement, as well as the development of equitable organ distribution policies. (UNOS, 2013a, pp. 4-5)

Like the BÄK, UNOS’ responsibility for ‘equitable policies’ indicates its far-reaching ethical standard-setting role and its distance from the political-legal system as a source of accountability and legitimacy. Since beginning its contract in 1986, UNOS has established regulatory oversight structures and undertaken policy enforcement largely on its own. For
administrative purposes, UNOS created 11 geographic regions across the country, which were further segmented into 58 territories, or Organ Procurement Organizations (OPOs). (UNOS, 2013b) Today, these territories encompass a total of approximately 270 authorized transplant centres, the majority of which are private institutions that compete for patients. (Kidneylink, 2014) Each OPO features a separate waiting list for patients in need of a transfer; an available organ is first offered to those of a compatible blood type in the territory in which it was recovered, and rarely makes its way to another OPO due to the length of waiting lists in each. (UNOS, 2013b, pp. 2-5; Snyder, 2010).

A forty-two-member board of directors, convened two-to-four times each year, makes all UNOS policy decisions regulating the quality and practice of organ transplant. While the group’s decisions are subject to review and final approval by the United States Department of Health and Human Services (HHS) – as we saw a practice introduced in Germany only in 2013 – UNOS’ board consists mainly of private-sector professionals in the field of organ transplant. As UNOS is not only a regulator, but a membership organization to which each active transplant centre in the country pays fees, physicians and the hospitals with which they are associated are largely in charge of policing themselves. (UNOS 2013b, pp. 8-9; Ornstein and Weber, 2006)

Nevertheless, government regulation is not completely absent from this governance structure and, quite unlike the German system outside legal accountability mechanisms, functions as the overall umbrella. The U.S. Centers for Medicare and Medicaid Services have the authority to oversee federally funded transplant centres, and can sanction both policy violators and underperformers. Moreover, certain policies governing the recovery of organs are mediated by state-level institutions; while the federal Uniform Anatomical Gift Act (UAGA) of 1968 establishes baseline regulations regarding the manner and scope of permissible anatomical donations, different states have imposed an array of minor
modifications to this provision in the past few decades, most often clarifying how and by
whom consent to donate an organ can be given. (Cotton and Sandler, 1986)

Government regulators do not necessarily always fulfil their role as enforcers of last
resort. Using statistics available in UNOS reports, *The Los Angeles Times* found that
approximately one-fifth of transplant centres operating in 2006 failed to meet the
government’s minimum standards for patient survival or performed too few operations to
guarantee competency. Most were nevertheless allowed to continue functioning without
review or sanction by the Centers for Medicare and Medicaid Services. Hence, while federal
regulators nominally have the authority to override UNOS and withdraw a transplant centre’s
certification and accompanying funding, it appears they might do so only rarely. Structural
deficiencies further muddle the two agencies’ ability to provide effective oversight: not only
do their regulatory duties overlap, but they neither share information in a meaningful way,
nor act according to common evaluation standards. (Ornstein & Weber, 2006)

**Discussion and Conclusion**

Public management is a complex task that entails multiple, diverse and conflicting
expectations. Institutional structures and rules are created as a means of dealing with these
complex expectations. These rules, structures and mechanisms rely on the use of
accountability mechanisms. Accountability types differ based on types of administrative and
institutional control: legal, organisational, professional and political. They also differ on the
manifestation of moral pushes and moral pulls in these institutional settings (Dubnick, 2013).
In this paper we have focused on mutuality (Hood et al, 2004) and the tension between
organisations (transplant centers) where economic and production values become
predominant and the moral demands to which individual doctors are exposed to. Some of
these moral pulls come from the institutional principles of the regulatory framework of transplant medicine. But, other moral demands also come from internal pushes, increasingly influenced by the new governance systems of financial rewards and bonuses.

There is little doubt that any transplant system with its variety of actors, multiple expertise, responsibilities and interests is highly complex. In this paper we have comparatively analysed the difficult questions raised by the 2012/13 organ transplant scandals in Germany. In comparison to Germany – where investigations and the sanctioning of manipulations largely depended on the medical self-administration and a combination of public and political moral outrage, the U.S. public appears to be significantly less sensitive to the tension between professional ethical code and governance, i.e. accountability mechanisms, of the transplant system. Both at the hospital level and the federal and state levels the viability of the transplant system as an economised rather than professional-medical organisation sets off fewer alarm bells than it did in Germany.

Whereas the economisation of transplant medicine at the hospital level may be linked more directly to the NPM reforms in the past few decades, the regulatory structure and powers of the medical self-administration in Germany, specifically in the transplant system, has its own, though not necessarily distinct, historical legacies in the highly corporatist medical self-administration. The moral debate and moral ideas that characterised the German crisis in 2012/2013 caught the political system by surprise and unprepared to respond effectively to the significant gaming and violations by well-respected and high status doctors.

The case of the German crisis illustrates a significant tension and the unintended effects of a potentially serious mismatch between the institutionalised economic and production values of Eurotransplant/DSO/BÄK system on the one hand, and the basic constitutional rights and demands of the German social-political system on the other. The political system turned to the Basic Law and the constitutional rights of patients to respond to
the crisis. How to deal with the ethics of subversion and the rational maniacs? The political system turned to the courts with efforts to criminalise the professions. The self-administration of medical associations lost the moral capacity to provide a sufficient response to the accountability demands advanced by the German public. Courts, then, appropriated the policy problem and used the constitutional rights approach to deal with rational maniacs, because the existing professional self-administration could not provide an acceptable and widely shared public response to what cam to be viewed as a moral collapse.

Against the backdrop of a shift towards market forms of organisation and competitive institutional types of control in the German health care system (Mattei et al, 2013), this paper suggests that the gaming and data manipulations are related to the emergence of new governance conditions. This may bring about a clash between production values and moral values, and a serious challenge for organisational viability. Institutional changes were introduced to strengthen political accountability in the governance structures. Since 2012, the DSO has been calling itself ‘public-law oriented’ (italics added) and has members of the medical self-administration on its governing board. ‘In addition, the Länder and the Federation have been given significant influence on the work of the DSO as four out of twelve members with voting rights are from the Federal Ministry of Health and the Health Ministers‘ Conference of the Länder.’ A greater far-reaching proposal was declined by the federal Health Committee in June 2013. (Ausschuss für Gesundheit, 2013) The Left party had demanded (BT-Drs. 17/12225) to change the DSO’s legal form ‘for the sake of stronger public and democratic control’; a similar proposal by the Green party was also declined. This was due to the partisan opposition by the CDU/CSU and FDP majority in the Committee.

However, the demands for greater accountability and ‘transparency’ led to strengthening Eurotransplant’s decision-making role in the regulatory system of organ transplant. If a donated organ is in danger of getting lost, for instance, Eurotransplant is now
entitled to change over to the ‘fast-track allocation’. As the Bundestag notes, ‘from a strictly patient-oriented allocation according to the regulations, there is now a change to transplant-centre-oriented allocation.’ (Antrag, 2013, Drs. 17/13897)

The changes to the Transplant Act, according to which deliberate data manipulations would be punished with up to 2 years imprisonment, was quickly approved in the German parliament. Despite this tendency towards criminalization of professionals – possibly in line with a long-term trend towards the ‘litigation society’ (Howard, 1981) – the legal approach to the current cases of data manipulation remains highly contested. Kudlich (2013) argues that doctors’ manipulations do constitute a criminal offence. Yet he is concerned that the existing legal regulations are too permissive. He therefore advocates the legislative introduction of a strict liability tort that covers the data manipulations viewed as an endangerment of patient’s life.

Other legal scholars, such as Fateh-Moghadam, contend that any legal accountability mechanisms and sanctions cannot be divorced from the constitutional rights system. As our empirical findings show, the organ transplant crisis was viewed as a constitutional issue, and the arguments concentrated from the start on issues of political and professional morality and doctors’ capacity to uphold the constitutional rights of patients.

To conclude, the German transplant scandals of 2012-2013 represent a complex world of unethical practices and subversive gaming in the hands of rational maniacs at the interface of market pressures, professional moral demands and a peculiar history of self-administration and self-regulation. Through an empirical investigation of the organ transplant scandals and the moral public debate, and especially the ethical questions intertwined with organisational viability, the paper has identified the risk of a very serious tension between institutional moral pulls and individual moral pushes. The lack of congruence between the two levels has profoundly problematic consequences for organisational survival and viability in the long-
term, and for patients. The economisation of organ allocation, combined with a predominantly self-regulatory framework of institutional controls, collides with the foundational moral principles of professional care and patients’ rights, enshrined in the German constitution. This is not to suggest that the problem of rational maniacs be left in the hands of courts alone, but it shows how the ethics of subversion is far from being the accidental logic of isolated cases, but it is supported by new governance systems and their lack of transparency and democratic accountability.

References


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