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Mapping organ exchange: Transnational cooperation in transplantation and organ donation in Europe

FRANK MEYER

Abstract

Despite the tendency to harmonise many policy areas in Europe transnationally, the respective health systems of the member countries have remained predominantly nationally regulated and focused. The article illustrates the current state of transnational cooperation for the specific case of organ donation and transplantation medicine in Europe, a field in which cooperation was essential and has been established since the end of the 1960s in many forms. Yet, no homogeneous regime of European responsibilities emerged from this experience with cooperation. Instead, we find a patchwork of different ways to regulate organ donation and transplantation and to cooperate with other countries. Based on extensive empirical research in more than 30 European countries, the article elaborates an overview and a typology of the prevalent forms of cooperation and discusses the obstacles for a further harmonisation in this field.

Organ donation, transplantation, transnational, regulation, European Union, scale, organ exchange

Zusammenfassung

Organtausch: Transnationale Kooperation bei Transplantation und Organspende in Europa

Trotz zunehmender transnationaler Harmonisierung einer Vielzahl von Politikbereichen in Europa sind Gesundheitssysteme immer noch vorrangig national reguliert und fokussiert. Der Artikel illustriert den aktuellen Stand transnationaler Kooperation für den spezifischen Fall der Organspende und Transplantationsmedizin in Europa: einem Feld, in dem bereits seit dem Ende der 1960er Jahre verschiedene Formen der Zusammenarbeit etabliert sind und für dessen Erfolg essentiell waren. Dennoch, so das Hauptargument, entstand auf der Basis jener Kooperationserfahrungen kein einheitliches Regime europäisierter Verantwortlichkeiten, sondern vielmehr eine uneinheitliche Collage verschiedenster Arten und Weisen, Organspende und Transplantation zu regulieren. Dementsprechend erarbeitet der Artikel eine Übersicht und Typologie der aktuell etablierten Kooperationsweisen und erörtert auf der Basis extensiver empirischer Forschung in mehr als 30 europäischen Staaten die Hürden, die einer weiteren Harmonisierung in diesem Bereich entgegen stehen.

Organspende, Transplantation, transnational, Regulation, Europäische Union, scale, Organtausch

Systematising European cooperation in transplantation

Although organ donation has been established as a medical practice in many European countries since the middle of the 20th century, recent years have shown a significant increase in donation numbers. For instance, Spain has increased its number of actual donors (per million population) from around 35 in 2003 to 43.8 in 2016, and Croatia from 8.9 to almost 40 donors pmp (see TRANSPLANT-OBSERVATORY.ORG 2016). However, there have also been cases in which donation numbers dropped; for instance Germany's numbers plummeted from 15.9 donors pmp in 2007 (see *ibid.*) to a staggering 9,7 donors per million population in 2017 (see DSO.DE 2018).

The different performances of national systems are no surprise given their different organisational structure with regard to the consent systems in place, the different funding mechanisms, the different extent of political support etc. (see e.g. COORENOR 2013). In consequence, the national organ donation rates in Europe differ significantly from country to country with values between 0 and 43.8 donors pmp (see statistics from TRANSPLANT-OBSERVATORY.ORG 2016).

Whilst this fact alone may not raise eyebrows, the differences between the performance of these systems triggers pressure on the poor-performing systems as low donation figures mean less transplantations and thus a higher risk of terminally ill patients dying while waiting for a donor organ. Furthermore, less donors also mean a lower variety of blood types and tissue characteristics in the donor organ pool – a crucial issue given that a proper match between the donor and the recipient can reduce the risk of rejection of the transplanted organ after surgery and reduce the amount of immunosuppression medication needed.

Some organisational structures have been put in place in the second half of the 20th century to cope with these issues: Institutions such as Eurotransplant and Scandiatransplant are organisations based on agreements between member

states or transplant centres that engage in a legal form of organ exchange. Such transnational bodies are responsible for organ allocation – the medical procedure of finding the best matching recipient for a donor organ whilst ensuring the lowest possible time of the organ being without perfusion and furthermore minimising the rejection risk.

These forms of legal organ exchange differ significantly from internationally condemned forms of organ trade and organ trafficking (see WHO 2010a): Whilst the latter phenomena relate to recipients paying living donors or organ brokers for an organ and are considered criminal and unethical in most countries of the world, legal organ exchange is an officially mandated practice amongst many European states with established national transplantation systems and usually happens in specific cases or in case no proper recipient can be found within the donor country.

The developments in this field mirror more general developments in matters of the transnationalisation of social and welfare state politics in Europe. Yet, the social dimension of European integration has not led to complete harmonisation but created a heterogeneous picture of “bounded varieties of welfare” (FALKNER 2010, p. 305): A parallel existence of different degrees of entanglement and harmonisation in various sub-fields of social policies that has emerged in the course of the EU's “various direct and indirect effects of European integration” (*ibid.*). Rather important are the indirect effects of a more and more globalised Europe where mobility and the free flow of people, capital, technology and information creates opportunities for cooperation, yet also pressures to cooperate to keep up.

Transnational cooperation in transplantation and organ donation, as I will argue, mirrors these developments because it is a prime example for the extent to which national health systems have become entangled with each other in Europe, although they are still subject to national responsibility. At the same time, it also exemplifies how heterogeneous

transnational solutions in contemporary Europe are, given the acceptance of national differences even in matters seen to be in need of more harmonisation.

This article aims to illuminate the issue of legal transnational exchange of human organs in Europe. It will detail the procedures of organ donation and transplantation in the national context and highlight current practices of cooperating on a transnational scale. Based on empirical work on the extent and the different ways of regulating such exchange schemes, I will highlight their principles and outline the complex ways of dealing with national differences in that matter.

Methodology and aim

The article is the first of a series of articles focusing on the spatio-scalar regulation of health matters under the global condition. It is based on extensive empirical work under the auspices of the research project “Cross-border assemblages of medical practices” and was funded by the German research foundation. Between 2016 and 2018, I conducted 134 interviews with health officials, transplant professionals and patients in more than 30 European countries. These qualitative interviews aimed at uncovering the complexities in regulating and conducting organ donation and transplantation (for the transplant professionals and health officials) whilst also taking into account the subjective experiences of patients and their relatives. For this article's endeavour, an approach was chosen that focused on supplementing the available information on the organisation of organ donation and transplantation by the contextual information provided with transplant professionals and health officials. This approach aimed at composing a comprehensive image of similarities and differences between the different national systems with regard to their regulation and clinical practices.

Transplantation and organ allocation: a primer

Organ transplantation involves the transfer of a human organ from a deceased

(e.g. heart, lung, liver, kidney) or living (e.g. liver, kidney) donor to a severely ill recipient. Donation rates themselves are influenced by a multitude of factors oscillating around the individual's disposition towards donation, the medical procedures in the hospitals and the regulatory environment in each country (see MEYER forthcoming).

From a procedural point of view and using the example of Germany, an act of organ donation is the outcome of a series of medical procedures following the diagnosis of a patient's death according to nationally legitimate protocols and criteria (e.g. irreversible brain (stem) death, death after circulatory arrest; see DELMONICO 2010). If specific criteria have been met, the potential deceased donor is reported to an organ procurement organisation that organises the subsequent process according to specific legal and ethical standards (e.g. the DSO [Deutsche Stiftung Organspende] in Germany). In a next step, it is to be determined whether the prospective donor has documented his/her consent to organ donation. In some countries and, thus, legal frameworks, deceased patients may per se be considered to have consented if they have not officially registered their dissent. Yet, clinicians usually ask the family for further information on the medical history of the deceased person as well as their consent or authorisation to organ donation. After having obtained consent, medical examinations determine the suitability of the potential donor with regard to possible diseases that would contraindicate an organ transmission to another person. In a next step, the donor and his/her medical characteristics are reported to an organ allocation organisation which then matches the donor's organs with the ill patients' tissue and/or blood characteristics on organ-specific waiting lists. After the organ recovery, transport and transplantation into the respective recipients, the recipients have to maintain a lifelong medication of immunosuppression to prevent organ rejection.

The procedure of allocating a donor organ to a suitable recipient differs slightly

from country to country and from organ to organ, and is usually intersected by considerations of the organ-specific ischemic time (meaning the time outside the body without perfusion), its quality given the donor's medical history, the organ-specific immunological reactivity and the availability of substitute measures (such as dialysis for kidneys). Every measure taken in this regard aims at reducing the risk of post-transplant rejection (see e.g. KUMBALA, ZHANG 2013).

Considering the issue of ischemic time, medical studies report no significant irreversible downsides of kidneys with up to 24 h of cold ischemic time (meaning ischemia in the state of being cooled; see TERASKI 2011). In contrast, the maximum tolerated ischemic time for hearts is usually considered to be around 4 hours with higher time periods being debated (see e.g. MITROPOULOS ET AL. 2005). However, donor-specific diseases may compromise the organ's quality and ability to perform its function after this period of stress. Furthermore, the donor's age influences the organ's tolerance to longer ischemic times (see RUSSO et al. 2007).

Another important influence for the allocation process revolves around the immunological reactivity of an organ that, for instance, necessitates – in addition to blood group matching – an antigen-analysis in leucocytes that are known to be relevant for immunological responses (e.g. in the case of kidneys; see e.g. SHELDON, POULTON 2006). Livers, in contrast, tolerate certain antibody-incompatibilities, and are – in addition to correct blood-group-specific matching – matched with regard to donor-recipient similarities e.g. in size (see more specifically REDDY et al. 2013). This aspect further overlaps with the consideration of substitute therapies: Given that dialysis is a viable option for many kidney-transplant prospects and that the ischemic tolerance of the organ is relatively high, a precise matching is aimed for to reduce post-transplant complications. In contrast, a similarly established substitute therapy does not exist for liver diseases; in connection with the lower ischemic tolerance and

lower immunological reactivity, less time-consuming methods are pursued for matching.

The medical matching process aside, the allocation of an organ – depending on the respective country – furthermore incorporates e.g. considerations of distance, of fairness of distribution, of taking into account certain medical circumstances that need immediate or preferred treatment due to lower probabilities of donor organs (e.g. in high urgent cases, patients with high number of antibodies, paediatric patients, necessity for a multi-organ transplant). In some countries (and in case of some organs), some or all donor organs are utilised for patients in the transplant centre responsible for the donation whereas other countries do not have this kind of regional logic and employ a centralised (national) waiting list (e.g. the UK, Germany). This, of course, is influenced by the number of transplant centres in the respective countries, ranging between 1 (e.g. in Hungary, Finland, Norway) and more than 40 (in Germany).

In general, most allocation systems employ a database in which all donor and recipient characteristics are to be specified. After this, an organ and tissue-compatibility-specific priority list is generated that incorporates the potential recipients that have the highest tissue matching results (e.g. in Eurotransplant) and have acquired certain organ-specific scores due to the severity of their situation and/or their waiting time. This list ultimately determines the sequence of whom to offer the organ. In other countries, the respective surgeons may have more freedoms in deciding to whom the organ should be transplanted with regard to medical and patient-centred considerations (e.g. in Scandiatransplant). After having determined whether the potential recipient is actually fit for transplant and doing last-minute screenings of the donor, the donor organ and the potential recipient, the transplant will then go ahead. In that regard, many countries in Europe with a transplantation program utilise a complex system of algorithms, often computer-assisted, to perform these tasks and

determine the best recipient for a donor organ to minimise risk of post-transplant rejection. Thus, they are usually obliged to ensure that the allocation is performed according to medical rationales and legal requirements (e.g. according to the respective transplant act, acts on data protection, etc.) and have to document all decisions to provide quality control and liability.

Cooperation in organ allocation in Europe

Modern health systems are usually confined to their country of origin: They are set up to work within its geographic boundaries whereas additional services may be offered for travellers to different countries (e.g. in the case of the European Union). Whilst some responsibilities and efforts in social welfare have been under

direct or indirect influence of the European Union, health systems still remain a national priority (see e.g. SCHMUCKER 2009). Transnational entanglement in matters of health care in Europe resulted more from indirect consequences of court rulings on the basic freedoms in the European Union (see Schwarzenberg forthcoming). This is a phenomenon that Falkner highlights to be of specific importance for social policy, stating that such direct and indirect effects of European integration have created a heterogeneity of entanglements in social policies in the European Union (FALKNER 2009, p. 305). For matters of health policy, NEWDICK criticises that this complexity equals a fundamental governmental change because “by expanding the free movement principle to absorb public health care services, the power to regulate is shifted toward European institutions

and national authority is undermined” (NEWDICK 2009, p. 867).

However, in the field of transplantation, transnational cooperation has not been introduced top down but has emerged on the ground at the initiative of clinicians: Since the introduction of transnational organisations such as Eurotransplant in 1967 and Scandiatransplant in 1969, cooperation regarding the allocation of a deceased donor’s organ to a potential recipient based on tissue and blood characteristics has become frequent. As a matter of fact, 18 European countries with well-developed transplant programmes do engage in common allocation schemes (Eurotransplant, Scandiatransplant, NHS BT; see Fig. 1).

17 countries are member of transnational organ exchange schemes without common allocation, and most of the other

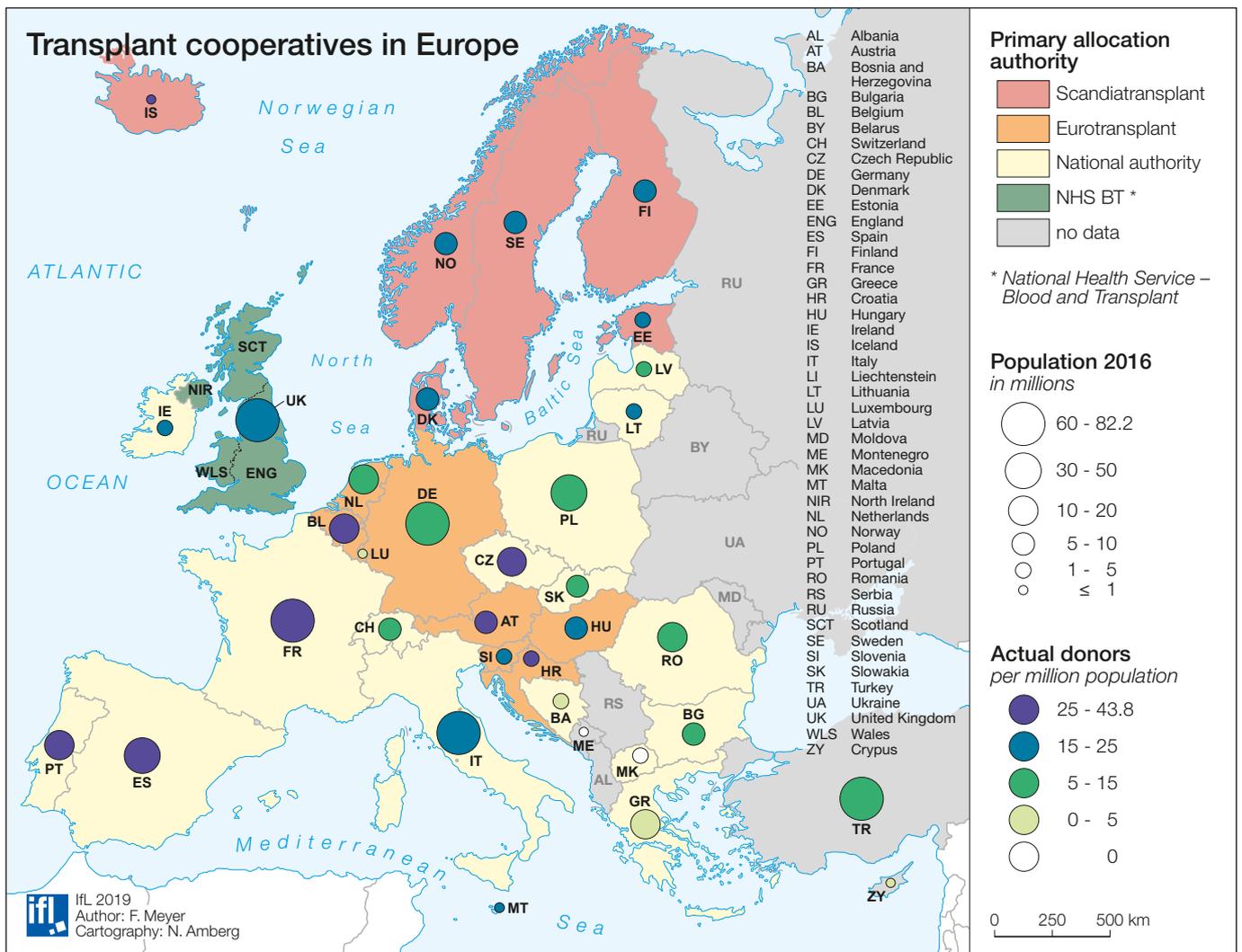


Fig. 1: Transnational transplant cooperatives devoted to organ allocation in Europe

European countries with a noteworthy transplant programme have at least bilateral agreements on organ exchange and support activities to boost their own transplant programme (see Fig. 2). Transnational institutional regulation, in this field, has remained rather scarce.

There are at least two core reasons based on which countries come together to conceive transnational bodies with such existential responsibilities (see also WEISS et al. 2015). *First*, this move mirrors the rationale behind economies of scale, because the more variance in donors and recipients can be pooled in general, the higher is the possibility to find a suitable organ for a patient in need of it in time to save his/her life (see SCHNEIDER et al. 2011, p. 1372). Tissue characteristics (e.g. antigens, blood type), donor/recipient similarities (e.g. age, size), the

recipient's waiting time, special medical requirements (e.g. urgency, immunological sensitisation in the recipient due to past pregnancies or transplants) as well as distance between the place of donation and of transplantation are taken into account. Thus, the higher the donor population and the recipient population, the more combinations between them are possible, and the higher is the likelihood of finding an optimal match. This is specifically important for children and for patients with rare blood groups and "particular anatomical characteristics" (see SCHNEIDER et al. 2011, p. 1372). *Second*, cooperation in terms of allocation serves the notion of equal treatment and reduces the importance of geography in transplantation: In contrast to GHAOUÍ et al. (2015) and their diagnosis of geographic disparities for the US-based UNOS-system, large allocation

schemes with centralised lists are seen to minimise the downsides for recipients living in low donation countries or regions (see also Fig. 1). Thus, such schemes create a notion of fairness and equal distribution of medical opportunities.

However, whether an organ crosses the border or not is different for every allocation organisation and is usually laid out in its fundamental allocation manual (e.g. EUROTRANSPLANT 2016). Yet in general, high urgent cases, rare tissue characteristics, paediatric patients, highly-sensitised patients (with a high number of antibodies), etc. are currently widely considered legitimate cases of leaving the national realm. In contrast, most organs do not leave their country of procurement given that a national priority has remained a prevalent principle – disregarding a possible membership in transnational

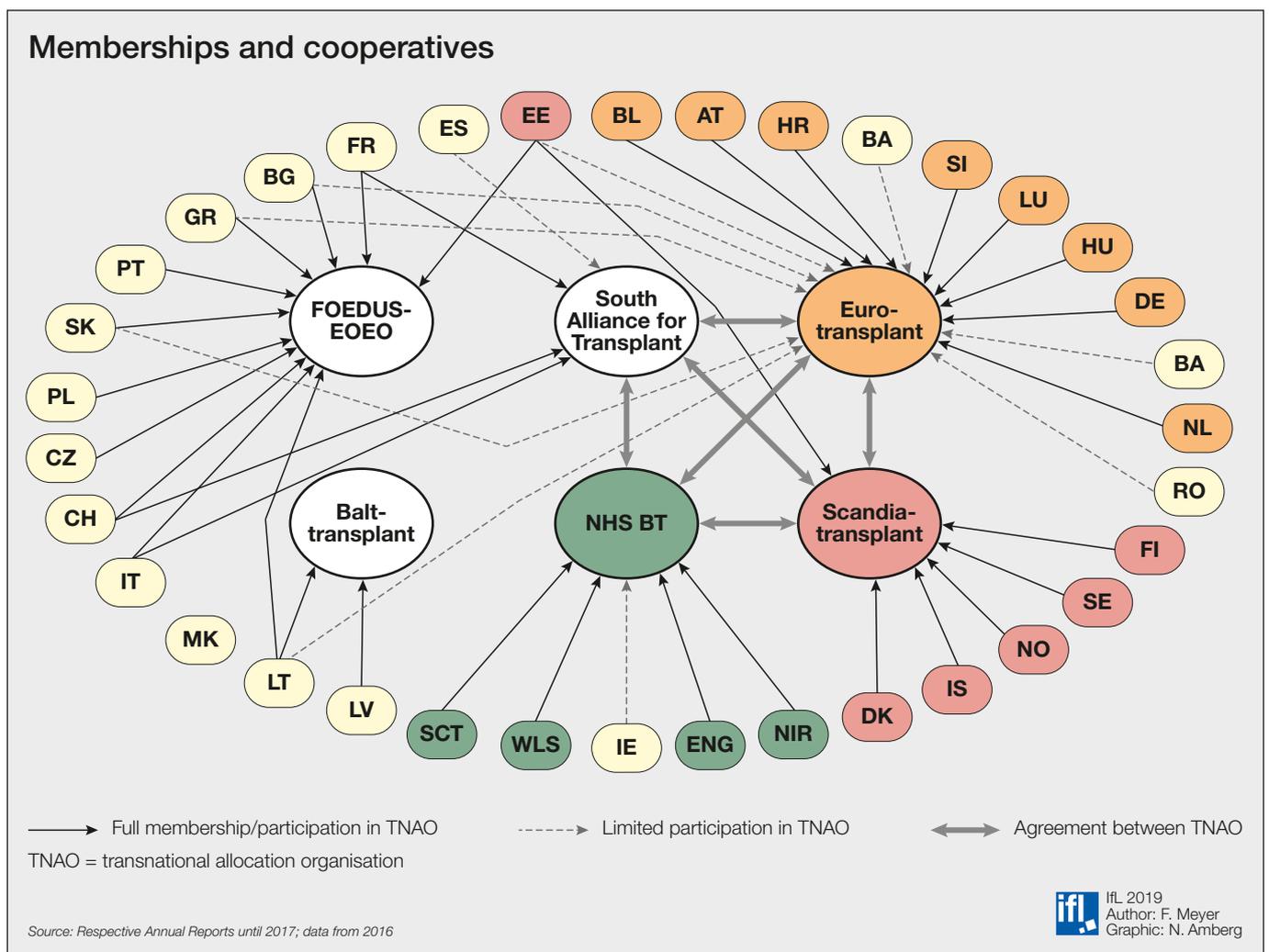


Fig. 2: Membership in transplant cooperatives in Europe

organisations. And even when transnational organ exchange happens, payback or balance systems have usually been put into place: This means that for every organ that has been given to a country or foreign transplant centre, an organ of similar quality (e.g. donor age, etc.) has to be given back to the country (in Eurotransplant) or donating centre (in ScandiTransplant) within a certain time frame (see e.g. EUROTRANSPLANT 2017, p. 14).

This kind of transnational exchange mechanism is a further extension of sub-national organ exchange, e.g. between regions (often tied to hospitals) or transplantation centres. As such, the presence of several levels of exchange indicates the systems' need to enlarge their pools of donors and recipients as the fundament for an efficient allocation system. How exactly these forms of exchange relate to each other proves to be quite heterogeneous in comparison, as the way in which different actors such as governments, medical councils, local, regional and national actors on the clinical and political side work together differs considerably between countries (see e.g. COORENOR 2013, p. 2). This is related to e.g. a possible primacy of certain urban centres that happen to hold key hospitals and may serve as the only transplant centre, has – however – been tackled elsewhere (ibid.).

Data on and types of allocation cooperation schemes

Of course, statistics are compiled to calculate allocation relations, which is especially relevant in those cooperation schemes maintaining payback systems as it proves to be crucial in order to uphold the balance between importing and exporting entities and identify imbalances (see also KIRSTE 2006, p. 54) and thus local, regional or national deficits in mobilising donors. However, precise figures on international organ exchange – even if it is happening within completely legal frameworks and on the grounds of sensible medical reason – are usually not published at all, or only in highly aggregated manner. For instance, in the course of preparing this scientific manuscript, several organ allocation

organisations have politely declined access to data. But if these organisations – simultaneously – stress their high transparency in order to counter disbeliefs, reservations and suspicions about organ donation (and what is more frequently problematized in public: organ trade), why do they restrict access to this kind of data?

Often, access to the data is limited to staff from the respective hospitals that is supposed to possess the necessary knowledge to interpret it properly, given the different regulations applying to different organs, the chronological delay with which payback-imbances are levelled and with respect to the medical statuses of donors and recipients which resist perfectly levelled balances between organ procurement organisations. While I received many rejections to access this data, one reply particularly highlighted the risk of providing, as it was termed, an incomplete picture and the risk of leading to wrong conclusions.

I immediately recalled incidents from my fieldwork in which organ donation professionals in hospitals detailed the reluctance they sometimes face by potential donors and their families with regard to their wish to specify or exclude a specific group of recipients from the organ allocation (see e.g. for a review on this matter for the UK: CRONIN 2010): I heard these stories from Switzerland, where professionals from one transplant centre at one point in time, had strong reservations about sending “their” organs to one specific other centre that was seen to underperform in donor detection (a state of affairs that has since been enhanced). In Northern Ireland, I heard stories of Catholic Northern Irish citizens asking for the exclusion of English recipients (as usually all UK-devolved administrations have one common waiting list). Also, online commentary sections on news about organ donation usually provide an interesting variety of specimen of rants about “immigrants” invading in order to get “our” organs (a matter that in principle violates Eurotransplant-guidelines) (see e.g. 20MIN.CH 2017).

These issues have been subject of extensive scientific coverage within the debate on attitudes towards or reservations

about organ donation (e.g. for Germany see CAILLE-BRILLET et al. 2017). MILLMAN (2013) for instance highlights the relevance of myths and superstition during the decision-making process for the case of Northern Ireland. Using a meta-analysis of the available literature, IRVING et al. (2012) have more generally abstracted eight key factors that influence the decision on organ donation: relational ties to the recipient, religious beliefs, cultural beliefs, family influence, body integrity, past experiences with the health care system, general level of knowledge and personal reservations despite positive attitudes. As a consequence, the notion that donation willingness is an issue to be developed rather than a pre-given stable characteristic among a population has been established (see AVSEC et al. 2016). However, the literature that specifically focuses on attitudes towards transnational cooperation remains scarce so far. Quite often, this issue is tainted with matters of organ trade based on the high complexity of the legal system and the prevalence of negative coverage about domestic transplantation systems (see e.g. HAARHOFF 2014 for Germany; see also NASHAN et al. 2017).

While organ exchange today is often discursively entangled with illicit organ trade, the medical exchange of organs was one of the key ideas behind organisations such as the 1967-founded Eurotransplant foundation that sought to optimise the allocation process to maximise the outcome for the organ recipients. This has been possible due to medical progress in the 1960s that led to increased ischemic times, increased ability to analyse tissue characteristics, to lower rejection risks and the necessary information-technological inventions.

Yet, a larger variety of opportunities has also triggered aspirations to achieve the best match with regard to the maximum distance for travel; thus, the largest totality of possible recipients could be tested against the limited pool of donors. While following this logic, it would seem reasonable to bundle the donor pools of several countries from a medical perspective, this would clash with the national containers that have so far aspired to hold the

exclusive right to care for the respective country's population. Yet, so far only one transnational exchange organisation has fully abandoned national borders in this regard and introduced common waiting lists: the NHS Blood and Transplant that, however, has built this system on the very special case of statehood of the United Kingdom and its devolved administrations.

Transplant professionals do indeed see a risk in fully disclosing the exchange relations and anticipate public backlash although organ exchange is non-commercial and fully backed by the legislation on organ transplantation. As the replies to data inquiries reveal, professionals in this field seem to fear that disclosing the extent to which organ exchange happens and the balance that is achieved may lead to lessening support or plummeting donation numbers. In the following, I will use the data gathered either through public sources or by bilateral contacts with the respective organisations (e.g. Eurotransplant, Scandiatransplant, NHS BT) to abstract four types of cooperation in terms of transnational allocation between nation states.

Allocation cooperation Type A: Bilateral exchange

Many European countries still have a predominantly nationally organised organ procurement and organ allocation system in place and manage separate national

waiting lists. Such systems are characterised by the primacy of national responsibility to allocate organs within national borders and conduct only limited exchange cooperation with other countries (see fig. 3). Yet, most of these countries do employ at least some kind of cooperation that occurs either with some foreign hospitals that have development programmes in place to assist the establishment of transplant programmes for educational reasons (see also Fig. 2). Or – more commonly – there is an occasional exchange of surplus organs with those countries with which specific bilateral exchange agreements have been established beforehand, often based on trust and a common framework for guaranteeing medical quality standards. This type of allocation cooperation is based on an understanding of reciprocity to avoid exchange imbalances; in such cases, specific time spans are defined within which the exchanged organs have to be “paid back” by providing a suitable donated organ from the country that has formerly received one. Examples of type A of allocation cooperation, for instance, are Balttransplant (Latvia, Lithuania, formerly also Estonia) and the South Alliance for Transplant (France, Italy, Spain, Switzerland, Portugal). Also, bilateral agreements exist between certain countries and the hospital in Vienna for cases of lung transplantation, in the course of

which transplant programmes are to be developed.

Allocation cooperation Type B: Multilateral exchange

Some countries – in practice – engage in multiple complementary exchange schemes at once. For instance, allocation cooperation schemes of type A sometimes overlap with type B – the institutionalised multilateral exchange. Whereas, in these cases, there are still separate national procurement and allocation systems and waiting lists, some countries have opted to take part in transnational exchange frameworks (see Fig. 3). Payback-mechanisms may or may not be employed in this kind of framework. For instance, FOEDUS EOEO has been introduced in the course of the EU's FOEDUS Joint Action programme to support the establishment of an intra-EU common exchange scheme. While a centralised system for the whole European Union was opposed e.g. on grounds of inability to tackle the corresponding long ischemic times (see also SCHNEIDER et al. 2011, p. 1372), the EOEO-mechanism continues to be used by some European countries. Yet the data for FOEDUS EOEO shows that organ exchange still happens rather occasionally: Between June 2015 and March 2017, a total of ten countries (Bulgaria, Czech Republic, France, Greece, Italy, Lithuania, Slovakia, Spain, Poland,

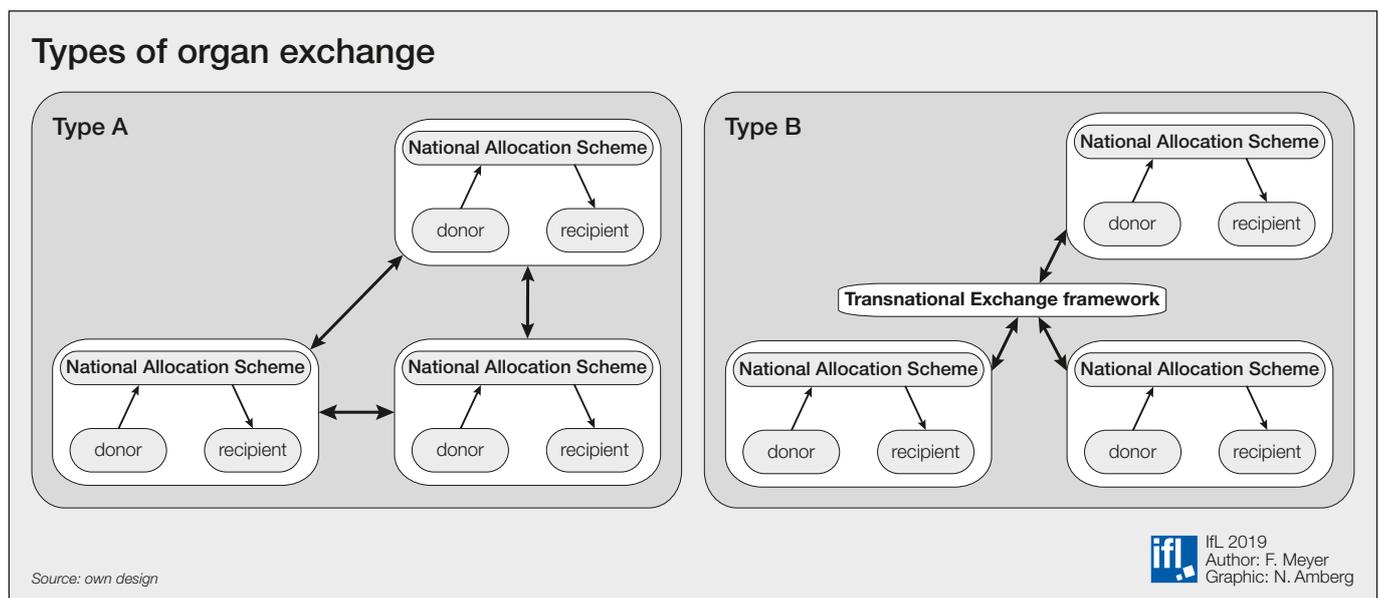


Fig. 3: Allocation cooperation – Type A and B

and Switzerland) have exchanged a total of 53 organs (CARELLA et al. 2017). Either, member countries offer surplus organs that otherwise could not be allocated to a suitable recipient in their country of origin. In other cases, countries in urgent need of organs with certain specific tissue criteria issue calls for organs through such a framework.

Allocation cooperation Type C: Partially integrated multilateral allocation

Allocation cooperatives of type B are characterised by a relatively high national independency to engage in transnational exchange frameworks. In contrast, transnational multilateral allocation organisations such as Eurotransplant (Germany, Belgium, Bulgaria, Luxemburg, Netherlands, Austria, Slovenia, and Croatia) or Scandiatransplant (Norway, Sweden, Finland, Denmark, Estonia, and Iceland) form a third type of organisation (see Fig. 4). Here, participating countries (in case of Eurotransplant) or hospitals (in case of Scandiatransplant) commit to a common allocation scheme with a centralised waiting list. While the responsibility to allocate an organ is transferred to the common organisation, there may or may not be mechanisms for national prioritisation in place: In the case of Eurotransplant, for instance, organs are only exchanged in case of high urgent or highly

sensitised patients, paediatric patients or in specific medical programme schemes. However, the majority of organs is usually transplanted within the respective country of procurement with payback systems in place to guarantee a certain balance between the respective member countries.

Allocation cooperation Type D: Fully integrated multilateral allocation

The fully integrated multilateral cooperation scheme, similar to type C organisations, employs a common waiting list and is responsible for the organ allocation. Yet, the respective national procurement systems do possess a certain autonomy in designing their donation systems (allowing, for instance, for differences in consent systems, etc.). However, imbalances between the member countries are generally tolerated (see Fig. 4; this may differ from organ to organ). The best example for this kind of cooperation also illustrates how special and unique this kind of cooperation is: The UK’s “National Health Service – Blood and Transplant” (NHS BT) serves as the head institution that supervises the several transplant programmes across all of the UK and their devolved administrations (such as England, Wales, Scotland, and Northern Ireland). This is especially interesting as Wales’ and Scotland’s transplant systems differ slightly from the other administrations’ systems,

thus exemplifying the unique institutional and legislative circumstances under which such a system – transgressing national boundaries – may exist.

These abstracted types of transnational allocation cooperation usually do not appear separately from one another: For instance, the UK is one of the financiers of the FOEDUS EOEO-scheme, yet according to CARELLA et al. (2017), has not used the system between 2015 and 2017. However, there is a bilateral cooperation between the NHS BT and the Republic of Ireland. Other countries, such as Bulgaria, take part in the FOEDUS EOEO-scheme and have had bilateral agreements with Eurotransplant (specifically with the Vienna hospital in matters of lung transplantation). Often there are formal bilateral agreements in place (e.g. between Malta and Italy), despite one of the countries taking part in type A and/or type-B schemes.

As a matter of fact, transnational cooperation is a field in becoming as increased IT-capacities, new medical possibilities in the perfusion of deceased-donor-organs and more and more homogenised legislations (e.g. due to the EU’s efforts; see EU 2010) provide the grounds to consider more cooperation in the face of what is perceived to be an imbalance between patients in need of a substitute organ and a lacking supply for that (see e.g. MIGGELBRINK et al., p. 18f.)

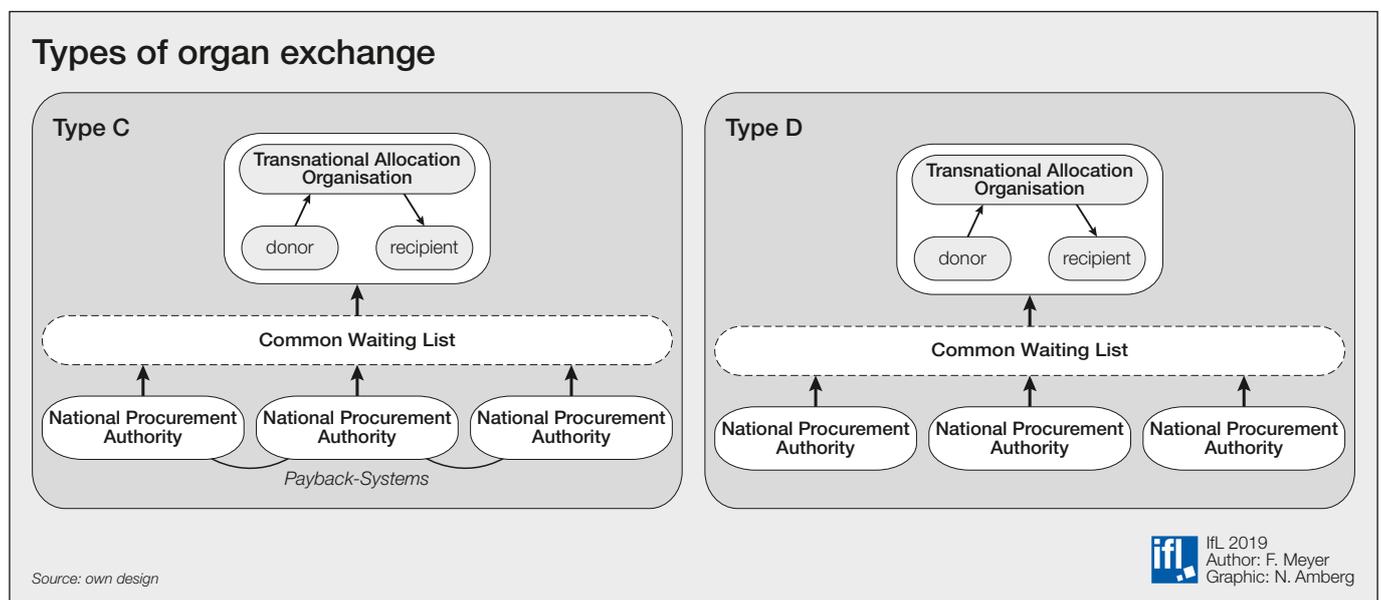


Fig. 4: Allocation cooperation – Type C and D

The complexity of transnational cooperation in organ allocation

In matters of transplantation and organ donation, a complex web of subnational, national and supranational competencies and responsibilities exists. For instance: Although the European Union has issued several directives on the matter of transplantation (e.g. EU 2010), article 168 of the Treaty on the Functioning of the EUROPEAN UNION (2009) set up the legal basis for “measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives”. This means that differences regarding consent systems, waiting list management, allocation and death diagnostics are not covered and, thus, remain under national legislation. However, an international consensus has been established banning organ donation without the donor’s consent (WHO 2010b). Furthermore, the Council of Europe holds competencies in matters of regulating the quality and safety of transplanted organs and clinical practices and regularly issues guides (e.g. EDQM 2016). As a consequence, the EU concentrated on setting common standards and making the respective systems compatible (see EU 2008, EU 2013, EU 2017). Furthermore, research projects such as ACCORD and FOEDUS aimed at increasing collaboration in transplantation among EU member states.

Yet, there seems to be a limiting extent to which international cooperation is desired: Even the type-D organisation scheme – the fully integrated allocation system of UK’s NHS BT – allows for differences in the respective legislation of the devolved administrations of e.g. Scotland or Wales: For instance and in contrast to England or Scotland, a presumed or deemed consent system for organ donation in Wales came into effect in 2015 (see NATIONAL ASSEMBLY FOR WALES 2013). This differed from the UK’s common Human Tissue Act from 2004, and also from Scotland’s own Human Tissue (Scotland) Act from 2006. Again, whereas transplantation and allocation are transnationally organised and regulated, organ donation

shows significantly different approaches even within common exchange schemes. However, allocation itself remains rather untouched by these differences.

For type-A and type-B exchange schemes, such differences do not matter much as the common basis for the exchange has usually been set up by EU-guidelines and organ and tissue safety. Sometimes, further standards for tissue typing and a certification programme of reference laboratories are agreed on. However, as international allocation is not conducted, common quality standards already facilitate optional organ exchange.

In contrast, partially integrated type-C organisations such as Eurotransplant and Scandiatransplant, on the one hand, need to incorporate the various national legislations and medical capabilities into one common scheme, while – on the other hand – setting up minimum standards in other fields. For instance, setting up certified laboratories is mandatory for member states to allow for a legitimate allocation that is compatible with all member states. Yet, they may employ very different organ donation schemes with regard to the consent system, the financial support for donation-specialised personnel in hospitals, etc. This may lead to some strain on the system as donation rates amongst Eurotransplant member states range from 5.2 donors pmp (Luxemburg) to 39.5 donors pmp (Croatia), and the employed payback systems for cross-border organ exchange (e.g. in high urgent cases) have to uphold the balance whilst – with higher disparities – not being able to fully achieve this.

Another difference concerns the principles for death diagnostics that may also differ from country to country: In general, most countries employ the brain (stem) death diagnosis, setting up different diagnostic regimes to determine whether a patient has suffered fatal irreversible brain damage so that – given that such patients are usually treated in an Intensive Care Unit (ICU) and are ventilated – a so called dbd(donor after brain death)-donation may be planned. However, some countries further conduct dcd-(donor

after circulatory death)-donation: Here, organ donation may take place under uncontrolled (e.g. in emergency-departments) or controlled (in ICUs) circumstances after assisting machines have been switched off and consent has been determined. However, the latter raises different ethical questions and is considered more resource-intensive. As a consequence, Eurotransplant does not allocate dcd-organs to countries where dcd-donation is not conducted for whatever reason (see EUROTRANSPLANT 2017, p. 7).

Further aspects which the algorithms of allocation in type-C organisations need to include are for example national or regional priorities according to which the organ (or one of the two kidneys) may be reserved for recipients in the catchment area of the explantation-hospital, etc. This relates to the hospital structure in the respective member states: Countries in which only one hospital with a transplantation programme exists apply different national guidelines than countries with several hospitals. Other differences, e.g. in the case of Eurotransplant, may include:

- various forms of cooperation between hospitals in specific regions within/between member states and country-specific guidelines on whom to enrol in waiting lists,
- accounting and reimbursement principles for the hospitals,
- regulations on when a patient can be a recipient (e.g. based on different required time span of residency),
- procedures of notifying the respective national institutions in cases of misconduct or criminal behaviour,
- the extent to which penalties can be imposed,
- bonus points for kidney patients who have donated one of their own kidneys in the past.

Such differences result from different national health systems, different procedures in criminal law or different opinions in the respective national medical councils who decide on clinical practices (see Meyer forthcoming). Yet, the more international cooperation in transplantation

medicine becomes common, the more likely may be claims for further harmonisation to level these differences.

Organ donation and transplantation: A case of hesitant upscaling

While this article has not set out to make an argument for or against further transnational cooperation or harmonisation in terms of regulation, it nevertheless aimed to provide an overview of current ways to facilitate legal organ exchange. Furthermore, the article aimed to highlight the obstacles for such endeavours.

In conclusion, transplantation and organ donation have been subject to remarkable processes. In the pioneer years of transplantation medicine in the early 1960s, cooperation happened rather between clinicians and did not involve the exchange of organs:

“Donors were sought only in the hospitals pioneering transplantation, and none were initially obtained elsewhere, not only because of the need for speedy grafting but also because other hospitals were uninterested in participating in such efforts. Exchange of kidneys with the other scattered and distant transplant units was not considered” (HAMILTON 2012, p. 283).

Yet with medical progress, technological advancements and increasing success of transplant procedures, national organ exchange between hospitals and later on between countries within organisations such as Eurotransplant became possible and legally domesticated. However, a heterogeneous collage of organisations and ways to facilitate cooperation can still be found. At the same time, donation rates differ remarkably as well.

This unfortunately coincides with higher capabilities for individual mobility and growing socio-economic disparities on a global scale, thus making the field of organ donation and transplantation medicine a focal point of homogenising the respective regulatory frameworks. However, this is a political field in becoming and nation states and their heterogeneous

ways of cooperating in terms of organ allocation have remained the primary scale on which transplantation and organ donation is regulated. The extent to which a transnationalisation is tolerated and national responsibilities are transferred to common organisations, from the current point of view, will most probably not change considerably on the short-run (not even in the EU).

On the one hand, such findings reify the notion that the nation state resists attempts of upscaling and remains the bearer of social welfare policies. On the other hand, this is a field in which four key developments converge:

1. The EU is proactively shaping certain aspects of transplantation (e.g. quality standards for tissue and organs) and thus leads to a harmonisation of institutions and practices. Other actors (e.g. WHO, Council of Europe) have gained importance, for instance by being vocal about ethical or quality standards.
2. Furthermore, medicine is a field in which mobility and the proliferation of knowledge have long been common. The inception of cooperation schemes by hospitals and clinicians can be considered a logical continuation. International educational programmes e.g. for transplant coordinators (e.g. the Spanish TPM-programme) further put emphasis on the proliferation of best practices that, de facto, leads to a further harmonisation of practices in this field.
3. Medical and technological progress has advanced the possibilities in transplantation (e.g. in machine-perfusion of donated organs, increased ischemia times). Other innovations include the ability to process large amounts of patients' data to match for the best results in the face of a possible organ rejection. This creates possibilities for cooperation by bundling donor- and recipient pools, yet also creates pressure to keep up with the latest developments.
4. This pressure is fuelled by the fact that a so-called organ shortage is nowadays widely proclaimed, meaning an asymmetry between a relatively small number of available donor organs and

a relatively large number of terminally ill patients requiring a substitute organ. Keeping up with these needs also means preventing widespread organ trafficking in the face of prevalent global wealth disparities.

Thus, organ donation and transplantation medicine serve as examples of *hesitant upscaling*: On the one hand, the harmonisation of regulations and the implementation of proliferated best practices seems to be a logical conclusion given the widely available information of performance, success rates and the wealth-disparity-related incentives for transplant tourism. Yet, welfare systems have thus far resisted moving more responsibilities towards the European level. And as of now, there is no European initiative in sight that may alter the landscape of transplantation cooperation in Europe considerably.

Undoubtedly, transplantation and organ donation will remain a contested field where medical and technological capabilities, legal requirements, ethical considerations and existential individual needs clash. The question whether to shift the power of regulation away from singular states towards larger legislation bodies will most probably remain a topic for a long time, given that the surrounding circumstances (e.g. wealth disparities, increasing life span and widespread lifestyle diseases such as diabetes) are unlikely to change dramatically for some time. Cooperation in terms of transplantation in Europe is therefore to be considered a field in becoming; it has emerged on the grounds of conflicting medical needs, medical capabilities and sedimented notions of national primacy in health care. It flourishes on the grounds of medical progress, success and promises of patient equality. Yet, it is also closely entwined with how transnational bodies in Europe are able to persist and, maybe, will be able to broaden their scope to the field of health care as well.

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Резюме

ФРАНК МЕЙЕР

Обмен органами: транснациональное сотрудничество в области трансплантации и донорства органов в Европе

Несмотря на растущую транснациональную гармонизацию широкого спектра политических сфер в Европе, системы здравоохранения по-прежнему в первую очередь регулируются и приоритизируются на национальном уровне. Данная статья описывает текущее состояние транснационального сотрудничества для конкретного случая донорства органов и трансплантационной медицины в Европе, области, в которой еще с конца 1960-х годов создавались различные формы взаимодействия, необходимые для его успеха. Однако, согласно основному аргументу, на опыте данного сотрудничества не было создано единого режима европеизированных обязанностей, а скорее возник неравномерный коллаж из разных способов регулирования донорства и трансплантации органов. Соответственно, данная статья разрабатывает обзор и типологию существующих в настоящее время форм сотрудничества, а также обсуждает препятствия для дальнейшей гармонизации в этой области на основе обширных эмпирических исследований более чем в 30 европейских странах.

Донорство органов; трансплантация; транснациональный; регулирование; Европейский союз; масштаб; обмен органами

Résumé

Échange d'organes: la coopération transnationale pour les transplantations et les dons d'organes en Europe

Malgré la poursuite de l'harmonisation transnationale de nombreux domaines politiques en Europe, les systèmes de santé sont, aujourd'hui encore, principalement à vocation nationale et réglementés à l'échelle nationale. L'article illustre la situation actuelle de la coopération transnationale pour le cas particulier du don d'organes et de la transplantation en Europe, un domaine dans lequel il existe différentes formes de collaboration depuis la fin des années 1960, ces dernières étant essentielles à sa réussite. Néanmoins, selon l'argument principal, aucun régime uniforme de responsabilités européanisées n'a vu le jour sur la base de ces expériences de coopération. Il s'agit plutôt d'un collage non uniforme des différentes façons de réguler les dons d'organes et les transplantations. Par conséquent, l'article dresse un aperçu et une typologie des modes de coopération actuellement établis et examine, sur la base d'études empiriques extensives menées dans plus de 30 états européens, les obstacles pouvant empêcher la poursuite d'une harmonisation dans ce domaine.

Don d'organes; transplantation; transnational; réglementation; Union européenne; échelle; échange d'organes