Thieme

Organ Donation Worldwide, Successful Transplantation Models and the Transplant Procurement Management Model

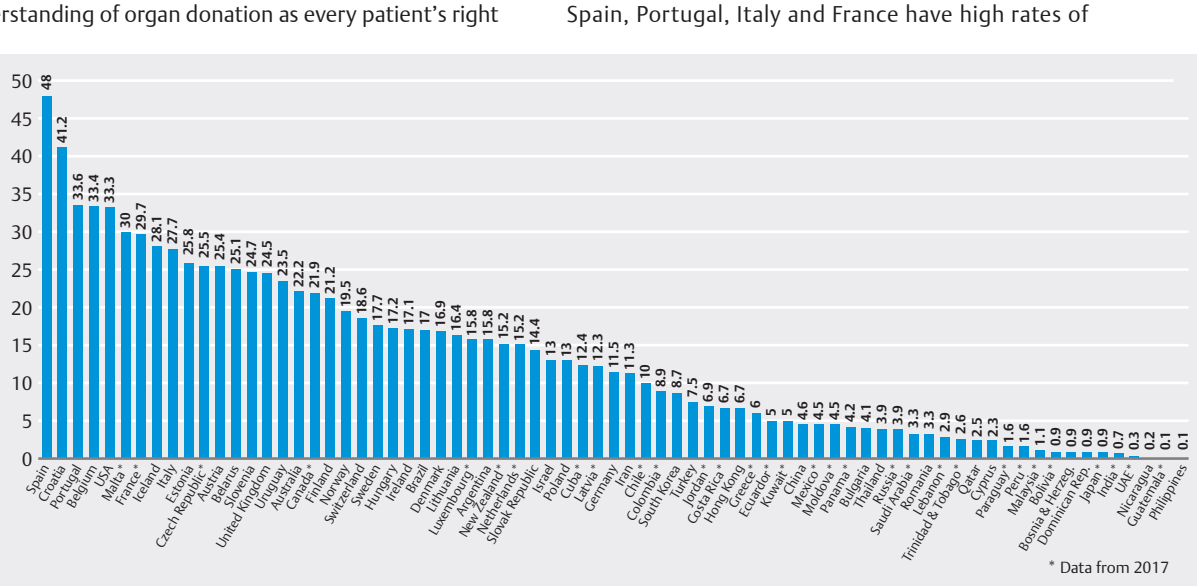
SUMMARY

Transplantation is one of the most used "gold-standard" treatments and is carried out in 111 countries. However, even though there are more than 130 000 solid-organ transplantations performed annually worldwide, there are not sufficient organs available for all patients on the waiting list. Organ donation rates vary widely between countries, with Spain having the highest rate in international comparison. The Spanish organ procurement system is a major factor contributing to the high organ donation rates, and has been rolled out successfully in other countries. To identify potential donors and ultimately to increase organ donation, dedicated organ procurement units and professional training for the healthcare professionals involved are crucial for a successful transplant procurement management.

Some 135 860 solid-organ transplantations (kidney, liver, heart, lung, pancreas, small bowel) were performed in 2016, of which 89 823 were kidney transplants, followed by 30 352 liver transplants. Forty percent of all kidney transplants and 20 % of liver transplants are performed with organs from living donors [1]. It is estimated that this represents less than 10 % of global transplant needs. Long times spent on the waiting list may result in patients deteriorating or dying before transplantation is available. The primary concern therefore is a sufficiency of available organs for transplantation.

The World Health Organization (WHO) has stated that each country should be responsible for meeting its transplantation needs, i.e. for achieving self-sufficiency in organ donation, and that donation from deceased donors should be the primary source of organs [2]. An understanding of organ donation as every patient's right is the first step in working towards the goal of self-sustainability in organ donation. Transplantation activity varies widely across countries: it is more developed among the countries of North America, Europe, and Australia than in the rest of the world. There are countries with a transplantation rate of 50 transplants per million population (PMP) or more, led by Spain with more than 100 transplants PMP [1]. Transplantation activity correlates directly with the number of donors and the availability of organs for transplantation, so low numbers of transplantations are largely linked to low donation rates. ▶ **Fig. 1** shows deceased organ donation rates (PMP) worldwide.

The United States has an average rate of 30 donors PMP; in Europe this average is around 20 donors PMP. However, even within Europe, there are notable differences among the countries: Mediterranean countries such as Spain, Portugal, Italy and France have high rates of



▶ **Fig. 1** Worldwide deceased organ donation rates per million population (PMP) 2018 [5].

CONVERSION RATE

Potential numbers of donors from deaths in hospital can be estimated as follows:

- 3–5 % of patients dying in hospital
- 10–15 % of all patients dying in ICUs
- 8 % of patients dying in the emergency room, including those dying in ER who are not registered to the hospital.

In addition:

- 5 % of cardiac patients dying outside hospital can be considered as potential uncontrolled DCD.

After all clinical donation steps have been followed, together with donor/organ evaluation and family consent, the overall conversion rate should be between 50 and 75 %.

donation, whereas others such as Holland and Germany have low rates of donation and consequently are lacking in organs available for transplantation [4].

Currently only 0.05 % of all deaths are converted into utilized organ donations. Given that 10 times more organs than at present are needed to reach the global needs for transplantation, each country needs to convert 0.5 % of all deaths into utilized donors. ▶ **Fig. 2** shows the differences worldwide in the approach towards self-sufficiency in organ donation.

Some countries – such as Japan, China, and Germany – have large numbers of deaths per year but only a low number of these converted to donors as shown by the ratio of donors/deaths of 0.1 % or even less. USA, Australia, and Belgium achieve better rates, between 0.3 and 0.4 %. At the top of the table, Spain has a conversion rate of 0.49 %, almost equal to what is needed for self-sufficiency. The reasons for very low donation rates in countries like Germany and South Korea that have advanced economies and very good transplantation skills need to be identified. It seems likely that this is due to the organization of the transplantation systems in those countries and this point needs to be analysed and discussed.

A successful model for organ donation and the role of the transplant procurement management team

The transplant procurement management (TPM) team plays an important role in organ donation, providing a powerful tool to help identify ways to increase the number of organs and tissues available to be transplanted and address the challenge of sustainable organ donation programmes. TPM is regarded as a distinct and separate discipline [3].

Spain, and in particular Catalunya [6], has had some of the highest organ transplantation rates per million population over the last 25 years; as a result, the waiting list has been almost flat for many years. The number of kidneys transplanted per year in Spain has increased from 1300 to more than 2900. Specifically, in 2018 in Spain

Country	Deaths/Year	Deceased Donors/Year	% Donors/Death/Year	Country	Deaths/Year	Deceased Donors/Year	% Donors/Death/Year
India	9 466 889	875	0.009	Sweden	94 385	181	0.192
Japan*	1 239 224	112	0.009	Finland	55 927	117	0.209
Cyprus	8412	2	0.024	Argentina	335 206	701	0.209
Romania	257 485	65	0.025	Iran	440 031	923	0.210
UAE*	11 538	3	0.026	Switzerland	69 660	158	0.227
Bulgaria	102 334	29	0.028	Norway	42 978	104	0.242
Russia*	1 920 476	572	0.029	Ireland	33 449	99	0.242
China	11 077 512	6346	0.057	Uruguay	31 671	77	0.243
Latvia*	32 654	24	0.073	Slovenia	20 811	51	0.245
HK – China	54 821	50	0.091	Brazil	1 399 274	3531	0.252
Saudi Arabia	109 201	99	0.091	Italy	653 590	1681	0.257
Germany	949 401	955	0.101	Israel	43 810	113	0.258
Turkey	487 543	598	0.123	UK	611 989	1619	0.265
Poland	403 417	498	0.123	Austria	85 296	229	0.268
Hungary	125 769	168	0.134	Portugal	109 768	344	0.313
South Korea	323 934	449	0.139	Croatia	52 954	169	0.319
Slovakia	53 906	78	0.145	Australia	171 332	554	0.323
Netherlands*	152 054	244	0.160	Belgium	112 236	381	0.339
Denmark	54 028	100	0.185	USA	2 699 903	10 721	0.397
Belarus	125 764	238	0.189	Spain	453 846	2241	0.494

< 0.1 > 0.1 > 0.3 > 0.4

* Data from 2017

▶ **Fig. 2** Departure from self sufficiency of various countries (global self-sufficiency requires 0.5 % donors/death/year) [5].

the rate was 70 kidney transplants PMP [7] and in Catalunya 100 [8]. In comparison, there are now more patients living with a transplanted kidney than on dialysis in Catalunya. This is important because patients enjoy improved quality of life from transplantation, and in addition transplantation is also more favourable economically for the overall healthcare system.

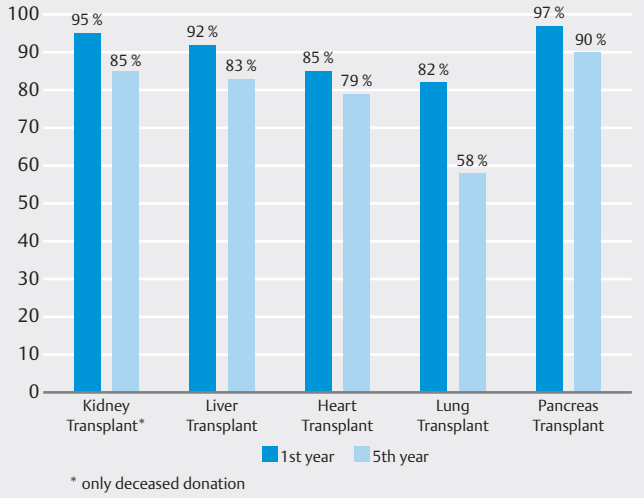
A system for organ procurement was implemented first in Hospital Clinic of Barcelona in 1985 and then extended to all of the Catalunya region during the following years and to all of Spain as of 1989. The TPM hospital team is independent from the transplantation team and is concerned only with donation. The key to the success of the system is that, unlike other models, such as the Organ Procurement Organizations (OPO) in the USA, the TPM is based inside the hospital and is on alert for identification of potential donors.

The TPM team's responsibility is

- First to identify any and all possible donors: all persons who die in the hospital and where in the hospital these deaths occur.
- To evaluate which of these possible donors are suitable for organ donation.
- Then to approach the family in order to discuss organ donation and to maintain regular communication with them about the organ donation process.
- Finally, to take care of all the procedures needed to allocate and transplant the organs of these suitable donors to the recipients.

The process is the same for both donation after brain death (DBD) and donation after circulatory death (DCD) [9]. The TPM is also responsible for having in place in the hospital the procedures necessary to fulfil this role and the team is trained to ensure that the appropriate steps are always correctly implemented. The TPM team is also involved in the living donation programme. They are regarded as the donor advocate guaranteeing the social, administrative, protection and transparency aspects of kidney and liver donors [3].The increased donation activity can be ascribed to the success of the TPM model and the number of TPM teams in existence. When this programme started in Spain in the 1980s, there were 20 "pioneer" teams – now there are 188 TPM teams in hospitals across the country [10].

Over time, there have also been changes of which healthcare professionals are involved in the donation process. In the 1980s and 1990s most activities were undertaken by nephrologists, but nowadays the majority of those involved are from the intensive care unit (ICU), anaesthesiology, and emergency areas (EA). In Spain, this has made a big difference. These senior doctors with background from intensive care, EA, and neurosurgery are the ones caring for the critically ill patients and now some of them are also part- or full-time dealing with the process of donation. Thus, care for donors is included in the process of end-of-life care.



▶ **Fig. 3** Survival of transplant patients in Catalunya 2017 according to organ [11].

Over 50 % of donors are older than 60 years and 30 % are more than 70 years old; the organs of these donors have good function and have been used for recipients who are older than 20 years. Although the criteria for donation have been extended by age and by cause of death and the standard-criteria donors represent only 15–20 % of the total, comparison of survival data between the 1980s and nowadays shows that the results are improved.

The hospital's role and responsibilities

In Spain, organ donation is explicitly part of the hospitals' social responsibility: as well as their roles in education, treatment, and prevention, they must also participate in the organization of the deceased donation process. Health care professionals must refer any potential organ or tissue donor to the TPM team or the person in charge of the donation process in the hospital. The ministry of health regulates the organ procurement and allocates the budget to the regions, and the regions organize the system in the hospitals in their area, making sure that funding for both transplanta-

tion and organ donation is adequate. The procurement unit can also cooperate with other so-called procurement hospitals (hospitals which often have donors) or referral hospitals (hospitals which occasionally have donors), which they can support on-site with the tasks of evaluation, validation, and retrieval. After completion of the ICU's procedures – the declaration of death, obtaining the family's consent, and evaluation of the organ – at the local hospital the body can be moved in the ICU ambulance to the procurement and transplantation hospital. After retrieval of the organ the body is returned to the family, usually at a funeral home. It is a matter of pride that so far no problems have been experienced with this procedure; families who agree donation are quite receptive to it because full respect is shown to the donor's family and they are assured that a recipient will be offered an organ of the best possible quality.

In general, as the organ procurement unit is an integrated part of the hospital organisation, this is also reflected in its having the same responsibilities as all other department: its functions include social responsibility, clinical aspects, research activities, educational activities, quality assurance, and overall management.

The DTI: its vision, international cooperation, and training

In most countries the allocation and transplantation systems are well-established and fairly well-organized. Problems that are encountered relate to the preceding procurement/donation system. It is important to implement an efficient procurement system from among the many different models.

The Donation and Transplantation Institute (DTI) is committed to helping countries and institutions to approach the goal of global self-sufficiency, ultimately saving millions of lives. In the last 20 years the DTI has developed several research projects, the majority in collaboration with the EU Commission. These help to improve practice and develop tools and skills involved in the donation procedure (▶ **Table 1**).

One of the most important tools in developing the deceased donation programme is training of the healthcare professionals involved in the process at the hospital level [12]. Key to the success of the model in Spain and its transfer to other countries is the implementation of the TPM training courses. To date, the DTI has trained more than 15 000 persons from 108 countries in Europe, North and South America, Asia and Africa, in both face-to-face and online training and at different levels of expertise from intermediate to advanced postgraduate diploma and masters courses. The objective of the training is to "create" experts in organ, tissue and cell donation for transplantation, building their competences and knowledge. This training programme is targeted to healthcare professionals involved in the donation and transplantation process, mostly working in critical care units, emergency departments and neurology, as well as in transplantation areas and tissue banking. Evaluation of the impact of the training indicates that it leads to improved donation rates. In Spain 1500 healthcare professionals have been trained and donation rates have increased from 20 PMP in 1991 to 48 PMP in 2018. Countries such as Italy, Portugal, France and Croatia where the courses continue to be delivered are also among the top European countries in terms of donation rates.

The success of TPM training has been demonstrated not only in Europe but also in countries with different cultures such as Iran, Thailand or China, where the TPM model has been rolled out successfully with training and the creation of organ procurement units or organ procurement organizations very similar to those in the Spanish TPM model. In Iran the donor rate increased from 0–11 PMP in less than 20 years (between 1999 and 2017). In China, which only recently abandoned the harvesting of organs from executed prisoners to adopt the western model, more than 6000 organ donations were realized in 2018.

A check-list for use when introducing or evaluating a TPM system would include at least the following:

- Establish a quality system with procedures, standards and protocols.
- Systematize the duties and responsibilities of the healthcare professionals.
- Assure training and certification of those professionals.
- Establish a registry and the transferability of the data.
- Meet quality controls, undertake external evaluation, and acquire accreditation.

For example, Hospital Clinic of Barcelona was accredited in 2012 through the ISO 9001 system and has been re-accredited up to the present. This is one of the first centres in Europe so accredited.

Comparative transplantation costs

As one of the units of the hospital, the procurement unit's budget is subsumed in the annual budget of the hospital. Dividing the annual costs involved in the donation process within the hospital, the transport costs,

▶ **Table 1** DTI projects and collaborations.

Project title and/or scope	Link or reference
Projects on living donation and treatment modalities of CKD	
European Living Donation and Public Health – EULID	http://www.eulivingdonor.eu/eulid/index.html
European Living Donor Psychosocial Follow-up – ELIPSY	http://www.eulivingdonor.eu/elipsy/index.html
International Conference on High Quality Practices in Living Donation – LIDOBS	http://www.eulivingdonor.eu/lidobsconference
Effect of Differing Chronic Kidney Disease Treatment Modalities and Transplantation Practices on Health Expenditure and Patient Outcomes – EDITH	https://edith-project.eu
Educational projects for healthcare professionals at European level and wider	
European Training Program on Organ Donation – ETPOD	http://www.etpod.eu/etpod.html; [13]
SEEDING LIFE Erasmus +	[14]
Training and social awareness for increasing organ donation – Eudonorgan	http://eudonorgan.eu
European-Mediterranean postgraduate program on organ donation and transplantation – EMPODaT	http://empodat.eu
Knowledge transfer and leadership in organ donation from Europe to China – KeTLOD	http://www.ketlod.cn
Organ Donation Innovative Strategy for South East Asia – ODISSeA	https://odisseaproject.eu
Projects on quality indicators	
European quality system in tissue banking – EQSTB	http://www.eqstb-sanco.org
European Quality System Indicators on Organ Donation – ODEQUS	http://odequs.eu; [15]

and the costs of surgeons and organ procurement by the number of organs gives the cost per organ transplanted per year. At Hospital Clinic of Barcelona in 2015, the cost per kidney or pancreas from utilized DBD was 7000 euro and the cost per liver from utilized DBD was 9000 euro. With regard to DCD donors, the total cost was 14 000 euro, taking into account an average of 1.3 organs utilized per case. With regard to a DCD donor, the costs per liver or kidney was 9000 euro. With an average of 1.3 organs utilized per case, the total costs of one DCD donor is 14 000 euro. There is a notable difference compared with e. g. the United States: In the USA the cost per donor is 81 000 USD and the cost per organ is 27 000 USD, taking into account an average of three organs transplanted per donor [Tom Mone; One legacy – OPO]. Other European countries with more expensive health systems than Spain's have comparable figures.

The take-home messages

The Spanish system works because of the knowledge and experience accumulated over many years and above all because of the motivation of the healthcare professionals involved. It is not easy to sustain motivation when dealing with donation after declaration of brain death.

Nevertheless, the results of this dedicated work are evident. Across all regions of Spain the donation rate is over 35 PMP and in some individual regions is over 50, 60 or even higher than 70 PMP. The consent rate in Spain as a whole is 85–87 %. The so-called Mallorca effect is of interest here: Germany has a donation rate of 11 PMP and a rate of consent to donation of 50 %; however, if a German citizen dies in Mallorca, they consent to donation to the same extent as the Spanish population – at a rate of over 85 %. (The same effect is observed in Malaga when analysing donation rates from United Kingdom citizens.) It can be concluded that international differences in comparative donation figures are not due to cultural differences but rather are attributable to how well-structured the donation systems are.

Self-sufficiency for each country should be based on knowledge of the total deaths in the country. If these are identified by an effective in-hospital organ procurement unit, this should make available sufficient organs for transplantation.

The number of donors in Germany is currently less than 1000; to achieve national self-sufficiency it should be at least 5000 (calculated from the German population and total deaths in the country).

The lesson that can be taken from the Spanish experience and the international roll-out of the TPM system is that donation process evolves from local to global and from the hospital to the government. Opportuni-

ties and advances are to be found mainly in the emergency area, the trauma centre and the intensive care unit, and these healthcare professionals should be engaged in organ donation. End-of-life care is part of the responsibility of those who work in these areas. The responsibility of the transplantation system is to support the development of hospital units responsible for the organ donation process so that they are enabled to facilitate the availability of enough organs for transplantation to all of the patients on the waiting list. That this is possible has been shown in the Mediterranean countries as well as in other cultures and countries around the world.

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