### REVIEW

# Spanish experience as a leading country: what kind of measures were taken?

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benchmarking, donation, expanded criteria donors, organ transplantation.

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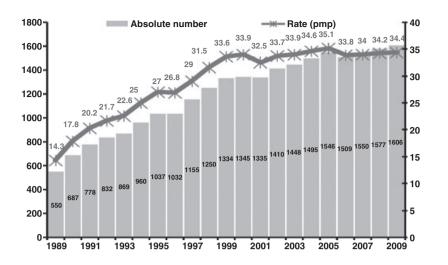
#### Summary

A recent call for self-sufficiency in transplantation issued by the WHO faces variable worldwide activity, in which Spain occupies a privileged position, with deceased donation rates of 33-35 per million population (pmp) and 85 transplants pmp. An evaluation of current challenges, including a decrease in deaths because of traffic accidents and cerebrovascular diseases, and a diversity of cultures in Spain, has been followed by a comprehensive strategy to increase organ availability. Actions include an earlier referral of possible donors to the transplant coordination teams, a benchmarking project to identify critical success factors in donation after brain death, new family approach and care methods, and the development of additional training courses aimed at specific groups of professionals, supported by their corresponding societies. Consensus documents to improve knowledge about safety limits for organ donation have been developed to minimize inappropriate discarding of organs. Use of organs from expanded criteria donors under an 'old for old' allocation policy has resulted from adaptation to the progressive decline of optimal organs. National strategic plans to deal better with organ shortage, while respecting solid ethical standards, are essential, as reflected in the WHO Guiding Principles and the Istanbul Declaration on Organ Trafficking and Transplant tourism.

The World Health Assembly (WHA) recently adopted Resolution WHA 63.22, urging Member States 'to strengthen national and multinational authorities and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protect the welfare of living donors with appropriate health-care services and long-term follow-up' [1]. The Resolution was adopted 2 months after participants at the 3rd World Health Organization (WHO) Global Consultation on Organ Donation and Transplantation (Madrid, Spain, March 2010) called for governments to progress toward the concept of self-sufficiency in transplantation and therefore cover the needs of their patients by using resources within their own population and by decreasing the burden of chronic diseases, leading to the need of a transplant and consequently increasing organ availability.

Initiatives relating to this matter are to have a solid ethical basis and respect the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation [2], and the Declaration of Istanbul on Organ Trafficking and Transplant Tourism [3].

The call to address the transplantation needs of a particular population is worth highlighting in a diverse global landscape where huge disparities exist between the countries in terms of donation and transplantation activities. Deceased donation is an essential element of the selfsufficiency paradigm, from which the number of donors, but also the number of organs recovered and transplanted *per* donor should be maximized. An inability to address transplantation needs and disparities in donation, added to the unequal distribution of wealth in the world, represent the root causes for many patients dying or having a poor quality of life and for unacceptable practices, such



**Figure 1** Deceased donation activity in Spain. Absolute number and rate (donors pmp). Years 1989–2009. Source: Organización Nacional de Trasplantes database.

as organ trafficking and transplant tourism [4]. Deceased donation ranges from nonexistence in many countries throughout the world to rates of over 30 donors *per* million population (pmp) [5].

In this scenario, Spain occupies a privileged position, with the highest deceased donation rates ever recorded for a large country, and maintained at 33-35 donors pmp in recent years. With around 14 donors pmp at the end of the eighties, activity in Spain was at the mid-low position when compared with other European countries (Fig. 1). The increase in deceased donation, and consequently in the number of solid organ transplants, resulted from the implementation of a set of measures, mainly of an organizational nature, altogether internationally named as the Spanish Model of Organ Donation and Transplantation [6,7]. These measures were adopted after the Spanish National Transplant Organization (ONT) was created in 1989. The ONT was conceived as a technical agency of the Ministry of Health in charge of overseeing donation and transplantation activities in the country. Results of the Spanish Model do not result from the adoption of what we could consider 'classical' measures of dealing with organ shortage. Promotional campaigns or the development of particular tools to facilitate donation wishes recorded during lifetime are not part of a system that has been based on two basic principles: organization and continuous adaptation to change.

# The Spanish model of organ donation and transplantation

#### The background

Measures implemented in the country were based on an appropriate healthcare, legal, and technical background. Our healthcare system is a public one with a universal coverage of the population, which means the principle of reciprocity is entirely applicable to daily situations. Technically, the country was dependent on extraordinary, prepared, enthusiastic, innovative, and motivated transplant teams. The Spanish *Transplantation Law* was first enacted in 1979, and contained the basic elements of any transplantation law [8]. An opting-out system for consent to donation has been in place since then in Spain. However, the presumed consent policy is not strictly applied in practice; relatives are always approached and still have the final veto [9]. Political competencies in the country are transferred to 17 autonomous regions, so any national initiative has to reach an inter-regional consensus, and this also applies to the field of donation and transplantation.

#### Main elements of the Spanish Model

The core principle of the Spanish Model is a systematic and organizational approach to the process of deceased donation. Donation after brain death (DBD) remains the main source of organs for transplantation. The main elements of the Spanish Model have been described previously (Table 1) [6,7]. In summary, coordination of donation activities has been conceived and structured at three different but interlinked levels: national (ONT), regional (17 regional coordinations), and hospital. The first two levels act as an interface between the technical and the political strata and act in support of the process of deceased donation. Any national decision on donation and transplantation activities is agreed upon by the Transplantation Commission of the Health Inter-territorial Council, which comprises the ONT as chair and the 17 regional coordinators. The hospital level of coordination is represented by a network of officially authorized procurement hospitals that are directly in charge of effectively developing the deceased donation process. This  
 Table 1. Main elements of the Spanish Model of Organ Donation and Transplantation.

Transplant coordination network at three levels: National, regional, hospital.

Special profile of Transplant Coordinators

Medical doctors, mainly critical care physicians, supported by nurses.

Part-time dedication to the transplant coordination activities Independence from the transplant teams. Appointed by and

reporting to the hospital medical director

Main objective: deceased donation. Progressively more involved in: promotion, training and education, relation with the mass media, management of resources, research

Transplant Coordinators inside the hospitals.

Central Office (ONT) as a support agency.

Quality Assurance Program in the deceased donation process:

continuous clinical chart review of deaths at critical care units of procurement hospitals. Two phases: internal and external audit.

Great effort in medical training through different type of courses. Targets: transplant coordinators, intensive care physicians and nurses, emergency and urgency physicians and nurses, other health care professionals.

Close attention to the mass media with a special communication policy.

Hospital reimbursement for donation activities.

network has grown from less than 20 hospitals in 1989 to 118 in 1992, a rapid evolution that reflects the significant efforts made by the system and the political support received in its initial years. The network has continued to increase with 170 hospitals involved in 2009.

The figure of the transplant coordinator (TC) appointed at each procurement hospital has been considered a key element of our model. The initiative of designating key donation persons, or TCs, responsible for developing a proactive donor detection program and effectively converting potential into actual donors has progressively been replicated in several other countries. However, TCs in Spain have a unique profile, conceived to facilitate early identification and referral of possible donors. Transplant coordinators are in-house professionals and members of staff of the procurement hospital concerned. They are nominated by and report to the medical direction of the hospital, and therefore do not report to the transplantation team. Most of the TCs are involved in donation activities on a part-time basis, which enables them to be appointed even at hospitals with low deceased donor potential. Notably, a majority of TCs are critical care physicians so their daily work is carried out precisely in those units where 11-12% of deaths occur in persons with a clinical condition compatible with a brain death diagnosis [10].

The ONT acts as a supporting agency to the network of procurement hospitals. It is not exclusively an organ-sharing office. The support provided by ONT and some regional offices is particularly important for small hospitals, which are frequently unable to develop the whole process of deceased donation on their own.

The Quality Assurance Program in the Deceased Donation Process has become an essential tool for the system [11,12]. So far focused on DBD, the program aims to monitor deceased organ donation potential, evaluate performance, and identify key areas for improvement. Already in place for over 10 years, the program is based on a continuous clinical chart review of all deaths occurring in critical care units (CCU) of procurement hospitals. The program includes an internal audit performed by TCs within their hospitals and an external audit carried out by expert TCs belonging to a region different to the one the evaluated hospital belongs to. External audits are performed at the request of regional transplant coordinators.

Training is an essential component of the model. Regular courses focused on the entire process of deceased donation and on some of its particular phases have been aimed at all directly or indirectly involved professionals. Since 1991, over 11 000 professionals have been trained through these courses in Spain that are now reproduced in many other countries [13]. The objective of constructing a positive social climate toward donation and generating society's trust in our system has been achieved through close work with the mass media [14,15]. The communication policy of ONT and its network is based on four basic principles: i) A 24-h telephone line available for consultation; ii) Easy and permanent access to the media; iii) Connection with journalists built through dedicated meetings aimed at learning about mutual needs; iv) Delivery of messages with no intermediaries. These measures have led the media to handle information about donation and transplantation appropriately. Finally, as with any other medical activity performed within the public health care system, hospitals are reimbursed for their donation and transplantation activities. The corresponding regional health authorities allocate a specific budget to cover both human and material resources needed for the effective development of these activities at every hospital [16].

#### Replication of the Spanish model in other countries

The features of the Spanish Model can be reproduced in other settings as long as a set of conditions are fulfilled [17]. The adaptation of this organizational approach to other countries and regions in the world has been accomplished with variable results. A successful example is that adaptation experienced by the region of Tuscany, in Northern Italy, which resulted in a sustained increase in deceased donation activity, reaching levels of over 40 donors pmp [18]. More recently, Croatia and Portugal have adopted the model insofar as a national transplant agency, a network of procurement hospitals and the in-house figure of the medical TC is concerned. As a result, from 2006 to 2009 both countries have increased their deceased donation rates in 37% (from 12.9 to 17.7 deceased donors pmp) and 54% (from 20.1 to 31 deceased donors pmp), respectively.

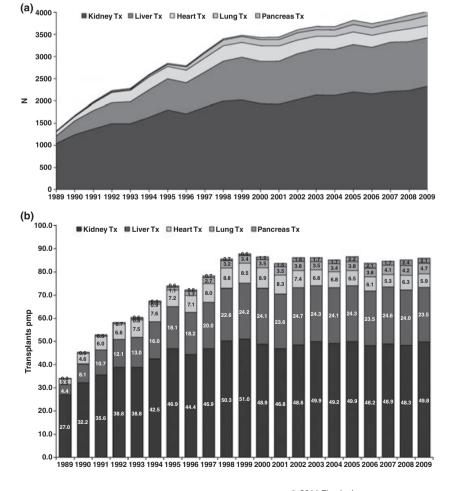
Efforts are underway in Latin America to implement the Spanish model in a manner that adapts to local circumstances through the *Iberoamerican Network/Council of Donation and Transplantation*. Some elements have been reproduced in Argentina, Brazil, Colombia, and Uruguay, precisely those countries leading the deceased donation activity in this area [19].

## Current challenges and opportunities for improvement

With around 4,000 solid organ transplants performed annually in our country (Fig. 2a), the transplantation

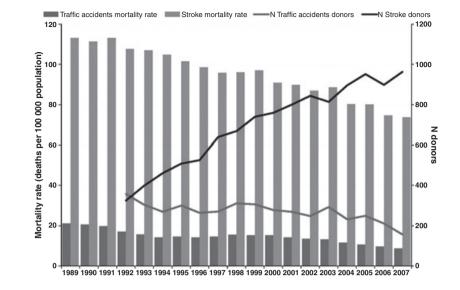
needs of our population are far from being adequately met [20]. Prevalence and incidence of end-stage renal disease (ESRD) patients under dialysis therapy in Spain is about 500 and 150 pmp, respectively [21]. With an estimated 20% of prevalent and 30–40% of incident patients being candidates for kidney transplantation, we would need to perform 150–160 kidney transplants pmp to meet needs, which greatly exceeds the approximately 50 pmp procedures performed annually (Fig. 2b). Of patients waiting for nonkidney transplants, 6–8% die each year in Spain [20]. This proportion is possibly an underestimation as a similar percentage of patients are withdrawn from the waiting list, in many cases because of a deterioration of their clinical situation.

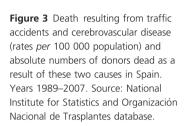
The inability to satisfy transplantation needs adequately is confronted by substantial epidemiologic changes combined with well-known modifications in the patterns of care of critical patients. Mortality as a result of cerebrovascular disease and traffic accidents has fortunately decreased in Spain through time, as represented in Fig. 3 [22]. Immigration has been an outstanding feature in the country in recent years, leading to a significant increase



**Figure 2** Solid organ transplantation (Tx) activity in Spain. Absolute numbers (Figure 2a) and transplant procedures pmp. Years 1989–2009. Source: Organización Nacional de Trasplantes database

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in the Spanish population mostly as regards young people (obviously with lower mortality rates), which might partially justify the stabilized rates of deceased donation. The percentage of the population in Spain born abroad has increased from 0.9% in 1991 to 12.1% in 2010 [22]. On the other hand, immigration has led to the current coexistence of a wide variety of origins, cultures, and religions with their particular experiences and views on death and organ donation.

Demand continues to exceed supply as donation and transplantation rates remain stabilized (Figs 1 and 2b). The current situation has prompted our system to examine whether the maximum deceased donation activity has been achieved. When comparing performance between regions and hospitals, profound differences can be observed in Spain. In 2009, deceased donation rates for the different regions ranged between 25.5 and 61 donors pmp (Fig. 4) [20]. Several regions have reached sustained levels of activity substantially exceeding 40 donors pmp. These differences suggest that there is room for improvement.

The Quality Assurance Program in the Deceased Donation Process has also offered undisputed evidence that better performance is still possible. Based on the internal audit, the national potential of DBD is estimated to be of around 40 donors pmp, with valuable data on areas for improvement in the process, as shown in Table 2 [10]]. However, the data provided by the external audit, with



**Figure 4** Deceased donation rates (donors pmp) in the Spanish regions for the year 2009. Source: Organización Nacional de Trasplantes database.

Table 2. Data from the internal audit of the Spanish Quality Assurance Program in the deceased donation process. Years 1999–2008.

|   | 1999  | 2000  | 2001  | 2002  | 2003  | 2004  | 2005  | 2006   | 2007   | 2008   |
|---|-------|-------|-------|-------|-------|-------|-------|--------|--------|--------|
| General data  |       |       |       |       |       |       |       |        |        |        |
| Hospitals (n)   | 62    | 68    | 96    | 108   | 107   | 109   | 109   | 122    | 123    | 124    |
| Hospital deaths (n)   | 62071 | 59198 | 64745 | 92033 | 99194 | 92149 | 98560 | 100163 | 110289 | 109283 |
| CCU deaths (n)  | 11360 | 13012 | 12676 | 18708 | 19633 | 18072 | 17360 | 18409  | 20445  | 20196  |
| Brain deaths (n)  | 1436  | 1571  | 1768  | 2187  | 2220  | 2204  | 2304  | 2354   | 2343   | 2478   |
| Actual donors (n)   | 696   | 722   | 868   | 1100  | 1185  | 1263  | 1267  | 1365   | 1359   | 1453   |
| Losses in the process                                       |       |       |       |       |       |       |       |        |        |        |
| % B.D. not referred to<br>coordination unit                 | 3.5   | 3     | 3.1   | 3.6   | 2.5   | 2.8   | 4.2   | 5.3    | 1.5    | 1.5    |
| "Gaps" in the process                                       | 1.9   | 1.7   | 1.2   | 1.4   | 1     | 0.7   | 1.7   | 0.6    | 0.7    | 0.85   |
| % Medical Contraindications/B.D.<br>(not referred included) | 27.9  | 30.2  | 29.4  | 29.1  | 29.3  | 27.7  | 27    | 25     | 23.9   | 22.3   |
| % Maintenance problems/B.D.<br>(not referred included)      | 5     | 3.7   | 3.8   | 3.1   | 3.2   | 2.7   | 3.1   | 2.1    | 2.7    | 3.3    |
| % Family refusals/B.D.                                      | 15.1  | 16.6  | 14.9  | 14.1  | 11.7  | 10.5  | 11.4  | 12.6   | 13     | 13.5   |
| % Judicial refusals/B.D.                                    | 0.1   | 0.4   | 0.4   | 0.6   | 0.3   | 0.2   | 0.1   | 0.2    | 0.3    | 0.1    |
| % Uncompleted BD diagnosis/B.D.                             | 0.3   | 0.2   | 0.1   | 0.1   | 0.2   | 0.05  | 0.1   | 0.1    | 0.3    | 0.1    |
| % Lack of recipient/B.D.                                    | 0.5   | 0.5   | 0.7   | 0.9   | 0.5   | 0.5   | 1.1   | 0.6    | 0.3    | 0.8    |
| % Organizational Problems/B.D.                              | 0.6   | 0.6   | 0.4   | 0.5   | 0.4   | 0.3   | 0.4   | 0.8    | 0.7    | 0.4    |

15 292 deaths in CCU audited between 2001 and 2008, are particularly noteworthy. Of 2,017 persons with a clinical condition consistent with brain death identified in the clinical chart review, 6% were never referred to the TC system and 24% were deemed medically unsuitable for donation by TCs, although in 12% of these latter cases, medical contraindications were considered inappropriate by external observers. Hemodynamic instability leading to an early cardiac arrest and refusals to organ donation were the reasons behind 2% and 13% of losses, respectively.

In this challenging scenario and having identified opportunities to increase donation and transplantation activities, a national comprehensive strategic plan aimed at increasing deceased donation to a feasible objective of 40 donors pmp was conceived for upcoming years, along with a strategy aimed at promoting the offer of live donation as an alternative therapy for patients with ESRD, mostly in a preemptive fashion [23]. Actions under development to yield this level of activity are summarized below.

# Optimizing the process of DBD and promoting an earlier referral of possible donors

Early identification and referral to the CCU of persons with a devastating brain injury can substantially modify deceased donation potential. In recent years, a group of hospitals has reached an outstanding performance of over 60–70 donors pmp. This level of activity challenges previous analyses of deceased donation potential in Spain [10]]. However, former estimations of DBD potential were focused on the CCU. Many factors determine the number of persons who finally die with a devastating brain lesion within a CCU [24]. Although some of these factors are not easily modifiable, such as the availability of critical care resources, admission criteria to the CCU is acknowledged as a variable but modifiable factor, very much dependent upon the level of professional knowledge and ownership of the deceased donation activity. Excellent performer teams have, in fact, promoted the early identification and referral of possible donors from outside of the CCU to the critical care team and the TC staff. This already apparent critical success factor, to be detailed further within the context of an ongoing benchmarking strategy, prompted our system to promote inter-institutional cooperation between ONT and the Spanish Society of Urgency and Emergency Care [Sociedad Española de Medicina de Urgencias y Emergencias (SEMES)] [25]. Likewise, cooperation with the Spanish Neurology Society [Sociedad Española de Neurología (SEN)] has also been initiated, mostly through the recently emerging stroke units. Both cooperative initiatives are resulting in co-promoted training programs specifically designed for the aforementioned professionals and seeking their in-depth knowledge about deceased donation and active participation in the early identification and referral of possible donors.

The appropriate development of DBD requires the undisputed prominence of critical care physicians who should be made aware of their responsibility in the process and be made to understand donation as a part of end-of-life care and as an additional medical service provided by CCU. This concept was the clear basis for the specific professional background of TCs in our country, who are mainly critical care physicians. This situation was made possible because of the existing solid cooperation between ONT and the *Spanish Society of Critical Care Medicine and Coronary Units* [Sociedad Española de Medicina Intensiva Crítica y Unidades Coronarias (SEMIC-YUC)]. As a result of this cooperation, additional training courses covering all the steps of deceased donation aimed at critical care doctors during their residency period have been developed. This effort represents the consolidation of today's situation and a commitment to the near future.

Inappropriate hemodynamic maintenance of the potential donor represents an obstacle to the process of DBD that may lead to the loss of the donor and/or to specific organs being deemed unsuitable for transplantation. Thoracic organs are particularly susceptible to damage as a result of inappropriate maintenance. This particular barrier has been dealt with through the development of a *National Protocol for the Maintenance of the Thoracic Organ Donor*, developed by an *ad hoc* group of experts and ONT [26]. Previously mentioned training efforts and wide dissemination of this *National Protocol* among TCs and critical care physicians is underway. Impact of these measures on the availability of thoracic organs is yet to be analyzed.

Twenty-five percent of persons dying in conditions consistent with brain death are not considered medically suitable for donation in our country. Although safety of the process is an unquestionable professional standard, a scientific analysis of the risks should deeply guide decisions about transplantation at a moment of shortage. ONT has a 24-h medical team available for TCs to ask for a second opinion regarding the evaluation of potential donors. National Consensus Documents on the evaluation of organ donors to prevent the transmission of neoplasic diseases and with regards to infections have also been important elements in meeting this need [27,28]. Notably, the first of these documents has served as a solid basis for the Consensus Document on donor neoplasias recently released by the Committee of Experts on Transplantation of the Council of Europe, which has become an international professional point of reference [29]. Moreover, to define safety limits in the use of organs for transplantation clearly, a national specific registry on the follow up of recipients transplanted from nonstandard risk donors has been developed by ONT [30]. Information provided by this registry will indeed contribute to increase the level of evidence for the transplantation of these organs.

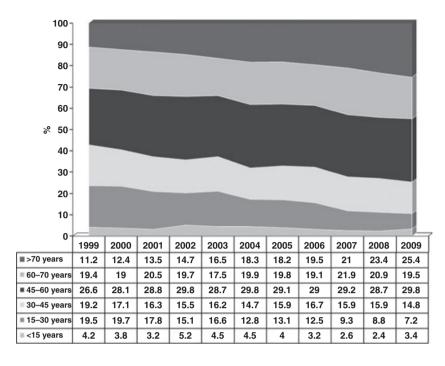
Training, as well as the aforementioned communication strategy, has once again formed the key activity for handling refusals to organ donation. Our network has

embarked on courses for family care and bad news communication aimed at all health care professionals and those actively participating in the family interview for organ donation. These training courses include donation as a component of the course, but not as the unique feature. Efforts have been made to understand how minorities and different cultural and religious groups deal with death and to learn about their attitudes toward organ donation. Dedicated workshops for representatives from these groups and TCs have provided the opportunity to learn about donation and provide a positive image of our system to the former. Meanwhile, TCs receive exclusive guidance about how to proceed with family approach and care when the relatives of a deceased person have particular informative and support needs. The potential of cultural mediators is further being explored by some of the TC teams. Specific meetings with other groups, such as jurists or the media, compound a national strategy to increase the rate of consent to donation.

Finally, a specific project aimed at identifying critical success factors in the process of DBD is currently underway [31]. For the purpose of this project, information collected from the *Quality* Assurance Program by procurement hospitals during a 5-year period, combined with an analysis of ICD-9 codes known to represent main causes of brain death have enabled the construction of specific indicators representing performance in three different phases of the DBD process: i) Identification and referral of possible donors from outside of the CCU; ii) donor identification, evaluation, and maintenance inside the CCU; iii) obtaining consent to proceed with organ donation. Several hospital factors have been identified as significantly affecting the value of the selected indicators. By taking into consideration these factors, we have been able to identify hospitals with an excellent performance for each of the previously summarized phases. Information gathered from face-to-face visits to these hospitals following a predesigned questionnaire by an ad hoc group of experts is now enabling the description of factors leading to successful results. Adapted implementation of these practices is expected to help other procurement hospitals to improve progressively performance in the DBD process.

#### Fostering the use of expanded criteria donors

In the context of the fortunate progressive reduction in the number of deaths as a result of traffic accidents through the years, if criteria for organ donation had remained unaltered through time the deceased donation activity in our country would have dramatically decreased. However, our coordination and transplantation system has progressively adopted more flexible criteria for donor selection. As a result, the number of aged donors



**Figure 5** Age distribution of deceased donors in Spain. Years 1999–2009. Source: Organización Nacional de Trasplantes database.

has increased sustainably in Spain (Fig. 5). Simultaneously, the number of organ donors whose death is caused by traffic accident is decreasing, whereas the number of those dead because of a stroke is increasing (Fig. 3). In 2009, up to 45% of all deceased donors were aged 60 years or older, falling under the age criteria of expanded criteria donors as defined by the UNOS [32]. An 'old for old' allocation strategy was devised from the very beginning, whereby aged kidneys are preferentially allocated to aged recipients irrespective of HLA mismatch, as also performed in other European programs [33,34]. About 30% of the deceased kidney and 40% of the liver transplantation activity is based on the use of organs from donors aged  $\geq 60$  years, outstanding percentages compared with other European countries [35]. Discard rate of organs (organs discarded once recovered), mostly from expanded criteria donors, is still high [20]. Further analysis and work should lead us to conclude whether organ discard is based on objective factors determinant of post-transplant results.

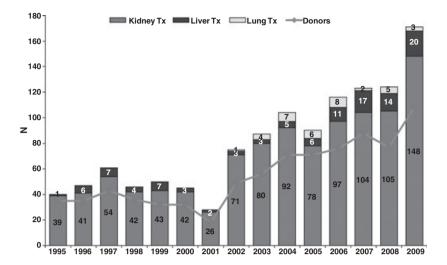
#### Promoting donation after circulatory death

Contrary to that described for other countries, Donation after Circulatory Death (DCD) in Spain has been classically focused on what the First DCD International Workshop, held in Maastricht in 1995, defined as categories I and II or uncontrolled DCD [36]. This particular type of DCD implies a very important logistical effort, both inside and outside of the hospital. Because of the degree of sophistication required, the activity was limited to three Spanish cities in recent years, after the pioneer experience at the *Clínico San Carlos Hospital* in Madrid [37]. Apparently, a cost-effective approach meant that these programs were not considered for cities with a population below 500 000 inhabitants. However, this approach is now under review after two programs established in smaller cities were recently developed, with a non-negligible activity. DCD is slowly but progressively increasing in Spain, as is the number and type of organs transplanted from these donors (Fig. 6). Uncontrolled DCD liver and lung transplantation has been added to the already consolidated kidney transplantation activity, with promising results [38–40].

Type III DCD has not been devised as an option in our country for many years. However, the system cannot ignore those cases where the withdrawal of futile treatment has been agreed upon with the relatives, and donation is not considered as a result of the lack of a national consensus, a developed legal basis or experience. A group of experts has recently been convened by ONT to build a consensus on type III DCD from an ethical and technical perspective. This group will also establish the guidelines for the creation of new uncontrolled DCD programs and exchange experiences aiming to increase donation and transplantation from programs already in place.

## Promoting live kidney donation as an alternative to the preemptive treatment of advanced renal disease

Live donation has remained a rather anecdotal activity in Spain, something to be understood in the global context



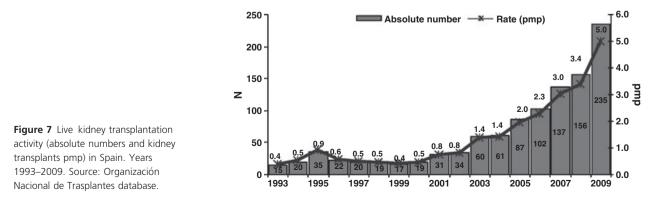
**Figure 6** DCD donation and transplantation in Spain (absolute numbers). Years 1995–2009. Source: Organización Nacional de Trasplantes database.

of a country with an emerging and soon robust deceased donation system during the nineties. Only a few highly experienced centers maintained a certain level of live kidney donation during those years. However, live kidney donation is an essential element in dealing with the transplantation needs of our population and particularly in a scenario where kidneys appropriate in nephron mass for young recipients are scarce. The evidence of excellent results of live kidney transplantation [41], the knowledge gained about the short-, mid-, and long-term safety of the donor when an appropriate framework of donor care is provided [42-44], as well as the incorporation of novel surgical approaches for donor nephrectomy have yielded a progressive change in the conception of live donation in the country, now devised as a need. This change occurred alongside changes in international institutions such as the Council of Europe, which progressed from restrictive principles [45] to the consideration of new strategies to increase the live donor pool, such as altruistic donation or kidney pair exchange [46].

Variable experience in live transplantation between centers, live kidney donation not being offered as an alternative for ESRD patients and ABO incompatibility or that

linked to a positive cross match are recognized obstacles in our system for live kidney donation [47,48]. Training courses aimed at multidisciplinary teams belonging to units that have started or are about to start a live donation program have already been developed. Transplant coordinators are being incorporated as figures facilitating the process and covering the informative needs of patients and their relatives. The Spanish Society of Nephrology and ONT have embarked on the construction of comprehensive professional guidelines to promote the offer of consistent information in a preemptive fashion. Cross-over donation recently became a reality in our country with a kidney pair exchange performed leading to two successful kidney transplants. A program for altruistic donation is under development, which combined with the cross-over donation program, will certainly lead to an increase in the possibilities of live kidney transplantation. As a result of all these initiatives, live kidney transplantation has increased, representing 10% of all kidney transplant procedures performed in the country in 2009 (Fig. 7).

In summary, organization around the process of deceased donation is the key for success of the Spanish system. This approach has been totally or partially repli-



cated by other countries and regions resulting in a positive progression in the pursuit of self-sufficiency through deceased donation and transplantation. New challenges are to be confronted effectively by the system: the transplantation needs of our population are expected to increase, whereas the potential of donation might decrease in the upcoming years, particularly for DBD. Novel strategies to adapt to this changing scenario are being explored and implemented in Spain. Similar integrated plans defining objectives, exploring all those areas where improvement is possible and implementing actions tailored to the local needs are being developed by several other countries, as those belonging to the Latin American Network/Council of Donation and Transplantation. Finally, the pillars of a deceased and live donation program and the measures developed to increase organ availability should always respect basic ethical principles, which are solid elements of the Spanish Model per se.

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### References

- Sixty third World Health Assembly. Resolution 63.22 on Human Organ and Tissue Transplantation. Global Observatory on Donation and Transplantation website. Available at: http://www.transplant-observatory.org/Contents/ Library/Documents%20and%20guidelines/Documents0/ Documents%20and%20Guidelines/WHO%20Resolutions/ WHA63recen.pdf. Last access: June 2010.
- 2. WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Global Observatory on Donation and Transplantation website. Available at: http:// www.transplant-observatory.org/Contents/Library/ Documents%20and%20guidelines/Documents0/Documents% 20and%20Guidelines/WHO%20Guiding%20Principles/ WHOlegethgp.pdf. Last access: June 2010..
- 3. Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul. *Lancet* 2008; **372**: 5.
- 4. Joint Council of Europe/United Nations Study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs. Council of Europe website. Available at: Available at: http:// www.coe.int/t/dghl/monitoring/trafficking/default\_en.asp. Last access: June 2010.
- 2010 Report of the Global Observatory on Donation and Transplantation. Global Observatory on Donation and Transplantation website. Available at: http://www. transplant-observatory.org/Data%20Reports/ 2010%20Report%20final.pdf. Last access: June 2010.

- Matesanz R, Miranda B. A decade of continuous improvement in cadaveric organ donation: the Spanish model. *J Nephrol* 2002; 15: 22.
- 7. Matesanz R, Domínguez-Gil B. Strategies to optimize deceased organ donation. *Transplant Rev* 2007; **21**: 177.
- Matesanz R. Cadaveric organ donation: comparison of legislation in various countries of Europe. *Nephrol Dial Transplant* 1998; 13: 1632.
- 9. Matesanz R, Domínguez-Gil B. Pros and cons of a regulated market in organs. *Lancet* 2009; **374**: 2049.
- Programa de Garantía de Calidad en el proceso de donación. 2009 Report. ONT website. Available at: http:// www.ont.es. Last access: June 2010.
- Cuende N, Cañón JF, Alonso M, Martín C, Sagredo E, Miranda B. ONT Quality control programme for the donation process evaluation. *Nefrologia* 2003; 23(Suppl. 5): 28.
- 12. Guide of recommendations for quality assurance programmes in the deceased donation process. DOPKI website. Available at: http://www.dopki.eu. Last access: June 2010.
- Paez G, Valero R, Manyalich M. Training of health care students and professionals: a pivotal element in the process of optimal organ donation awareness and professionalization. *Transplant Proc* 2009; **41**: 2025.
- Matesanz R, Miranda B. Organ donation-the role of the media and public opinion. *Nephrol Dial Transplant* 1996; 11: 2127.
- 15. Matesanz R. The panorama effect on altruistic organ donation. *Transplantation* 1996; **62**: 1700.
- Matesanz R. Trasplantes de órganos, gestión y sistemas sanitarios. *Nefrología* 2001; 21(Suppl. 4): 3.
- Matesanz R. Factors influencing the adaptation of the Spanish Model of organ donation. *Transpl Int* 2003; 16: 736.
- Simini B. Policy and people: Tuscany doubles organ donation rates by following Spanish example. *Lancet* 2000; 355: 467.
- Costa AN, Simón i Castellvì JM, Spagnolo AG, *et al.* A colloquium on the congress "A gift for life. Considerations on organ donation". *Transplantation* 2009; 88(7 Suppl.): S108.
- 20. Yearly report on national donation and transplantation activities. ONT website. Available at: http://www.ont.es. Last access: June 2010.
- 21. European Renal Association-European Dialysis and Transplant Association. Annual Report 2007. Available at: http://www.era-edta-reg.org/files/annualreports/pdf/ AnnRep2007.pdf. Last access: June 2010.
- 22. Statistics National Institute. Available at: http://www.ine.es. Last access: June 2010.
- 23. Matesanz R, Marazuela R, Domínguez-Gil B, Coll E, Mahillo B, de la Rosa G. The 40 donors per million population plan: an action plan for improvement of organ

donation and transplantation in Spain. *Transplant Proc* 2009; **41**: 3453.

- 24. Cuende N, Cuende JI, Fajardo J, Huet J, Alonso M. Effect of population aging on the international organ donation rates and the effectiveness of the donation process. *Am J Transplant* 2007; **7**: 1526.
- Matesanz R. Papel de los Servicios de Urgencias y Emergencias en la donación de órganos. *Emergencias* 2010; 22: 68.
- Protocol for the maintenance of the thoracic organ donor. Available at: http://www.ont.es/infesp/DocumentosDe Consenso/donantetoracico.pdf. Last access: June 2010.
- 27. Criteria to prevent the transmission of neoplasic diseases in organ donation. Available at: http://www.ont.es/infesp/ DocumentosDeConsenso/tumores.pdf. Last access: June 2010.
- Selection criteria of the organ donor regarding the transmission of infections. ONT website. Available at: http://www.ont.es/infesp/DocumentosDeConsenso/ infecciondonante.pdf. Last access: June 2010.
- 29. Guide to safety and quality assurance for the transplantation of organs, tissues and cells - 3rd Edition. Council of Europe website. Available at. http://book.coe.int/EN/ ficheouvrage.php?PAGEID=36&lang=EN&produit\_ aliasid=2153. Last access: June 2010:
- Garrido G, Matesanz R. The Spanish National Transplant Organization (ONT) tumor registry. *Transplantation* 2008; 85(8 Suppl.): 61.
- Domínguez-Gil B, Marazuela R, De la Rosa G, Coll E, Matesanz R. Benchmarking To Improve The Management Of Possible Donors inside The Critical Care Units. 2009 Organ Donation Congress. Abstract # 64.
- Port FK, Bragg-Gresham JL, Metzger RA, *et al.* Donor characteristics associated with reduced graft survival: an approach to expanding the pool of kidney donors. *Transplantation* 2002; 74: 1281.
- Frei U, Noeldeke J, Machold-Fabrizii V, et al. Prospective age-matching in elderly kidney transplant recipients–a 5-year analysis of the Eurotransplant Senior Program. Am J Transplant 2008; 8: 50.
- Arns W, Citterio F, Campistol JM. 'Old-for-old'-new strategies for renal transplantation. *Nephrol Dial Transplant* 2007; 22: 336.
- 35. State of the art on the use of expanded criteria donors in DOPKI countries. DOPKI website. Available at:

http://www.dopki.eu/dmdocuments/WP5\_ Statistical%20Report.pdf. Last access: June 2010.

- Kootstra G, Daemen JH, Oomen A. Categories of nonheart-beating donors. *Transplant Proc* 1995; 27: 2983.
- 37. Sánchez-Fructuoso AI, Marques M, Prats D, *et al.* Victims of cardiac arrest occurring outside the hospital: a source of transplantable kidneys. *Ann Intern Med* 2006; **145**: 157.
- Fondevila C, Hessheimer AJ, Ruiz A, *et al.* Liver transplant using donors after unexpected cardiac death: novel preservation protocol and acceptance criteria. *Am J Transplant* 2007; 7: 1849.
- Jiménez-Galanes S, Meneu-Diaz MJ, Elola-Olaso AM, et al. Liver transplantation using uncontrolled non-heart-beating donors under normothermic extracorporeal membrane oxygenation. *Liver Transpl* 2009; 15: 1110.
- 40. De Antonio DG, Marcos R, Laporta R, *et al.* Results of clinical lung transplant from uncontrolled non-heart-beat-ing donors. *J Heart Lung Transplant* 2007; **26**: 529.
- 41. Terasaki PI, Cecka JM, Gjertson DW, Takemoto S. High survival rates of kidney transplants from spousal and living unrelated donors. *N Engl J Med* 1995; **333**: 333.
- Delmonico FL. A report of the Amsterdan Forum on the Live Kidney Donor: data and medical guidelines. *Transplantation* 2005; **79**(Suppl. 6): S53.
- Segev DL, Muzaale AD, Caffo BS, *et al.* Perioperative mortality and long-term survival following live kidney donation. *JAMA* 2010; **303**: 959.
- 44. Ibrahim HN, Foley R, Tan L, et al. Long-term consequences of kidney donation. N Engl J Med 2009; 360: 459.
- 45. Conclusions of the 3<sup>rd</sup> Conference of European Health Ministers (Paris, 16-17 November 1987). Council of Europe website. Available at: http://www.coe.int. Last access: June 2010.
- 46. Resolution CM/Res (2008) 6, on transplantation of kidneys from living donors who are not genetically related to the recipient. Council of Europe website. Available at: http:// www.coe.int. Last access: June 2010.
- Domínguez-Gil B, Pascual J. Living donor renal transplantation in Spain: a great opportunity. *Nefrologia*. 2008; 28: 143.
- Valentín MO, Domínguez-Gil B, Martín Escobar E, Matesanz Acedos R. Not indicating live transplants is a poor practice. *Nefrologia* 2009; 29: 379.