



## The 40 Donors Per Million Population Plan: An Action Plan for Improvement of Organ Donation and Transplantation in Spain

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### ABSTRACT

**Introduction.** Spain has been showing the highest rate of deceased donor organ recovery in the world for a whole country, namely, 33–35 donors per million population (pmp) during the last years. This activity is attributed to the so-called Spanish Model of organ donation, an integrated approach to improve organ donation since the start of the Organización Nacional de Trasplantes (ONT) in 1989. However, in 2007 there were 7/17 regions with >40 donors pmp and a marked regional variability. Thus, ONT has set a large-scale, comprehensive strategy to achieve a substantial improvement in donation and transplantation in Spain in the coming years: The 40 Donors pmp Plan.

**Purpose and Scope.** The overall objective is to increase the average rate of deceased donors to 40 pmp between 2008 and 2010. The areas of improvement, specific objectives, and actions have come from deep reflection on the data and the material generated from multidisciplinary discussions and open consultation with the donation and transplantation community.

**Key Areas Selected for Action.** Detection and management of brain-dead donors, with 4 specific subareas: access to intensive care units, new forms of hospital management, foreigners and ethnic minorities, and evaluation/maintenance of thoracic organ donors. Expanded criteria donors, with 3 subareas: aging, donors with positive tests to certain viral serologies, and donors with rare diseases. Special surgical techniques. Donation after cardiac death.

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**S**INCE the first successful kidney transplant in 1954,<sup>1</sup> solid organ grafting is now recognized as an established therapy, which has been improving continuously. However, owing to the outstanding results achieved, organ transplantation has also become a victim of its own success, through the generation of a chronic imbalance between demand and availability of organs. Whereas the number of patients on waiting lists has been increasing, the number of donors or organs available for transplantation has either not or insufficiently rising, resulting in longer waiting times for patients, who deteriorate or even die while awaiting the necessary organs. For instance, among European Union (EU) countries over a 17-year period, the number of patients included annually in waiting lists for kidney transplantation per million population (pmp) increased by >29.1%, whereas the annual number of kidney transplant procedures was hardly augmented by 16.6% (Fig 1).

Spain has the highest rate of deceased organ donation ever reported for an entire country; it has been sustained

for years. The Spanish success with regard to donation and transplantation has been nationally and internationally attributed to a unique organizational model, the so-called Spanish Model for Organ Donation and Transplantation, or in short, the ‘Spanish Model.’ Since the creation of the Organización Nacional de Trasplantes (ONT) in 1989<sup>2</sup> and the simultaneous development of a coordination network of highly motivated in-hospital medical doctors in charge of the donation process<sup>2,3</sup> organ donation and transplantation activities have strikingly increased in Spain.<sup>4,5</sup> With regard to donation in particular, the rates have moved from 14.3 donors pmp in 1989 to 33–35 donors pmp in recent years<sup>6</sup> (Fig 2). The Spanish Model has been successfully imple-

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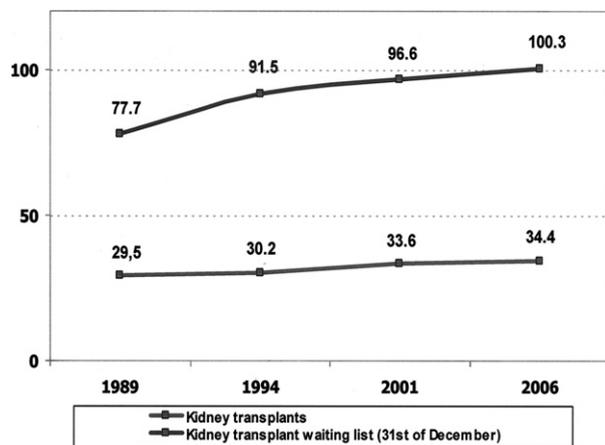
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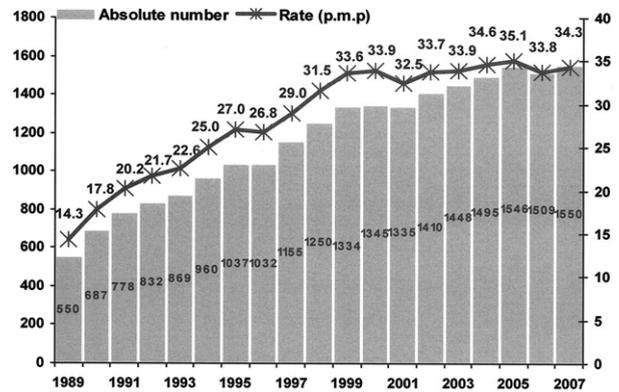
mented in other countries and regions of the world. A significant example is the Italian region of Tuscany, where the rates of donation went from 10 to 40 donors pmp between 1997 and 2006.<sup>7,8</sup> The Spanish Model has also been adapted to the reality of many Latin American countries, through the *Consejo Iberoamericano de Trasplantes*, resulting in remarkable results: Uruguay has reached 25.2 donors pmp in 2006, a level of donation similar of that of the United States or Argentina, where a 2-fold increase in the organ donation rate has been evident in a 3-year period; likewise, donation rates have risen significantly in recent years in countries like Colombia, Chile, and Cuba.<sup>9</sup>

Whereas in absolute terms the number of deceased donors has been rising gradually, the annual donation rates (donors pmp) have remained over the last years, at similar levels because of the simultaneous increase in the population.<sup>6</sup> A thorough analysis of the situation, which was performed by the ONT in 2006, revealed that, far from a unique explanation, several factors were involved in stabilization of the organ donation rates.

First, the impressive reduction in traffic mortality in recent years has shown an effect on donation activity as well as on the donor profile. Owing to this reduction, stroke has replaced trauma as the main cause of brain death, and the mean age of donors has increased gradually. As an immediate consequence, donors are increasingly growing more complex and less effective in terms of number of recipients transplanted, particularly with organs affected negatively by age. Second, the huge regional variability in donation activity observed, ranging between 17.4 and 74.2 donors pmp in 2007, with 7 regions exceeding 40 donors pmp in the same year (Fig 3), suggesting that there is room for improvement.<sup>10</sup>



**Fig 1.** Evolution in the amount of patients included annually in waiting lists for a kidney transplant pmp versus evolution in the annual amount of transplanted patients pmp between European Union countries from 1989 to 2006. Data adapted from the Council of Europe. International Figures on Organ Donation and Transplantation, Newsletter Transplant.

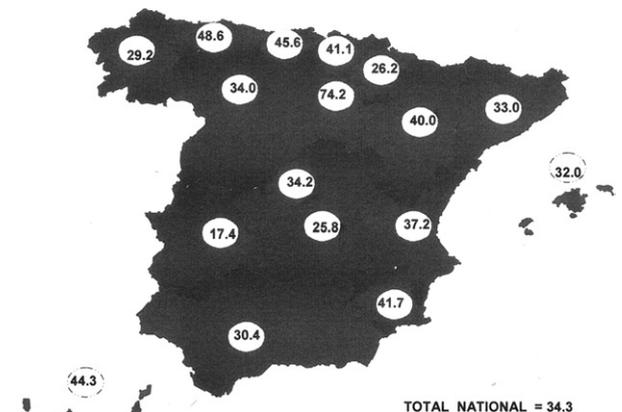


**Fig 2.** Total amount of cadaveric organ donors and donation rate from cadaveric donor pmp by year in Spain, 1993 to 2007. Annual Report on Donation and Transplantation activity—2007. (Data available at [http://www.ont.es/Estadistica?accion=2&id\\_nodo=19&id\\_estadistica=68&perfil=](http://www.ont.es/Estadistica?accion=2&id_nodo=19&id_estadistica=68&perfil=). Accessed December 22, 2008.)

This scenario has led the ONT to establish a bold comprehensive strategy for a substantial improvement in donation and transplantation activity in Spain in the coming years. The expected result of this large-scale action plan is an increased rate of donation and of available transplanted organs. This ambitious strategy pursuing change to keep on improving has been named the 40 Donors pmp Plan. This paper sought to describe the current progress of this ongoing process, to provide a rationale behind each key area for improvement and to outline some of the future actions.

PURPOSE AND SCOPE

As a general objective, the 40 Donor pmp Plan seeks to increase the average rate of deceased donors to 40 pmp



**Fig 3.** Donation rates (pmp) in Spain in 2007 (national and regional rates). Annual Report on Donation and Transplantation activity—2007. (Data available at [http://www.ont.es/Estadistica?accion=2&id\\_nodo=19&id\\_estadistica=68&perfil=](http://www.ont.es/Estadistica?accion=2&id_nodo=19&id_estadistica=68&perfil=). Accessed December 22, 2008.)

between 2008 and 2010. It should be noted that living donation activity would also be further augmented.

The areas of improvement, the goals, and the actions are all integrated within the framework of the 40 Donors pmp Plan, based upon a deep reflection of analyzed data and material generated from multidisciplinary conferences and discussions at symposia organized ad hoc by the ONT as well as open consultations to the Spanish donation and transplantation community between December 2007 and February 2008. The rate of 40 donors pmp was selected as a demanding (but feasible) objective, because several autonomous communities have already reached this rate.

In the first stage, we identified, carefully analyzed, and selected several areas of improvement, according to certain characteristics such as feasibility, expected impact on the donation pool, or improvability. All areas have been considered equally important, because all are expected to yield a positive effect on donation and transplantation. They are being approached in parallel by various working groups. A second stage, consisting of specific actions and activities, has been detailed in the documents of the action plan. The effect of actions and activities will be assessed as well as the action plan as a whole.

#### KEY AREAS FOR ACTION

The identified and selected actions for improvement for this action plan are as follows.

##### Detection and Management of Brain-Dead Donors

Optimization of the process of brain death donation is of paramount importance. However, detection and management is a complex process, so for a more systematic approach, several elements must be borne in mind separately.

*1. Access to Intensive Care Units.* As succumbing outside of an Intensive Care Unit (ICU) bed practically removes the possibility of becoming a real donor, admission to an ICU seems to be among the most important limiting factors for donation. The variability in admission to an ICU of conditions potentially evolving to brain death may explain the considerable differences in donation between hospitals. Hence, we must ascertain determinants of access to an ICU versus the alternative sites of referral. Possible determinants of ICU access, including epidemiologic differences in the assigned population, availability of beds, as well as awareness of or willingness to participate in the donation process, are being studied by our group. In this sense, as an action, the ONT and the Sociedad Española de Medicina de Urgencias y Emergencias (SEMES [Spanish Society of Emergency Care]) have initiated a cooperative process to improve the awareness and participation of emergency staff in the donation process. Likewise, hospital stroke units, which every day are more common in Spain, are potential donors sources. Therefore, cooperation between such units and ICUs, for training staff on the donation process or for detection of potential brain dead donors, is of key impor-

tance to prevent losses due to the flow of critical patients through the hospital.

*2. New Forms of Hospital Management.* Hospitals within the public system have for years constituted the source of the great majority of donors in Spain. However, there is now a trend to new forms of hospital management with potential impacts on our donation and transplantation activity. Although in some regions, new privately operated small public hospitals have been incorporated into the system; others may show higher activity among privately funded hospitals. New, privately operated hospitals, as part of the public system and regardless of its type of management, must be treated similar to the rest with equal expectations. Privately funded hospitals, often highly equipped, have not been as involved in the donation activity as the public ones, probably because of a lack of awareness and common interests. In this sense, a comprehensive strategy for the involvement of private centers has been developed in the Balearic Islands, which might be considered as a reference.

*3. Foreigners and Ethnic Minorities.* These culturally different groups should not be left out of the donation process. Consequently, identification of their needs is crucial. Although generosity is common to all cultures, linguistic and cultural differences as inherent barriers should be investigated and overcome. In this regard, the presence of cultural mediators, appropriately trained on donation and transplantation issues, is considered essential, as they facilitate communication with relatives and provide them with support in times of grief.

The import of nonprevalent diseases into the host country might be taken into consideration here, although it is not exclusive to this group. However, because of the current phenomenon of global mobility, which is likely to expand, decisions regarding imported diseases are increasingly made in the procurement and transplantation sphere. This area requires the incorporation of methods to support the decision making process, such as risk management methods or periodically updated guidelines searching to prevent unintended disease transmission as well as unnecessary waste of organs.

*4. Maintenance and Evaluation of Thoracic Organ Donors.* Aging has a direct, negative effect on the availability of thoracic organs. The increasing mean age of Spanish donors calls for a series of measures to minimize these losses:

1. Lung procurement requires particular measures during donor maintenance. A national consensus document has already been developed by a multidisciplinary group of experts. Disseminating it to promote its full adoption will likely be the next step.
2. The heart transplantation rate has shown a 2.3% decrease in Spain in 2005, whereas donation and transplantation activity was growing for other organs reaching historic records.<sup>11</sup> A number of hearts with good function before brain death are discarded in Spain mainly owing to an history of heart disease or

of ventricular dysfunction. Specifically, the latter has been shown to account for 30% of the exclusions.<sup>12</sup> Two important considerations should be borne in mind: First, most dysfunctions are secondary to brain death and may be reversed; and second, heart function is usually assessed by ultrasonography, a technique with high interobserver variability. The general use of diagnostic techniques that provide accurate, stable, and observer-independent results seems crucial to avoid heart loss; otherwise, the timely use of ultrasonography-based methods should be performed by highly experienced staff.

3. Preservation: Enlarging the objective of avoiding any loss of thoracic organs, further research or technical advances on preservation, must be assessed, and supported, if appropriate.

#### Expanded Criteria Donors

The points considered when assessing this area have been the following.

1. *Aging.* The utilization of kidneys or livers coming from aged donors is variable between Spanish teams. With regard to kidneys, the utilization of aged organs makes more sense in elderly than in young recipients, given that graft survival is expected to cover the life expectancy. However, as for livers, an existing belief contrary to the validity of organs from aged donors must be overcome. In this sense, a review seems to be required of the indications and criteria for their use.

2. *Donors With Positive Tests to Certain Viral Serologies.* There is great variability, difficult to explain, in transplantation of organs from donors with positive serology for certain viral agents. Centers performing such practices achieve good results based on a correct assessment of the donor, an appropriate selection of the recipient, and an individualized therapeutic approach. Increasing the belief of various teams in the usefulness of these organs should probably be the first step.

3. *Donors With Rare Diseases.* Careful consideration of each potential donor is required for cases with certain conditions, such as acute intoxications, cancer or related history, and rare diseases. The mentioned conditions require us to pool and review the experiences accumulated by specific registries, as a basic tool to developing and update consensus documents for the decision making process.

#### Special Surgical Techniques

The use of surgical techniques developed as alternatives to increase the pool of donors have varied among centers. Furthermore, considering the whole country, our activity differs from that described in neighboring countries.

With regard to the split technique for liver transplantation, activity has shown to be considerably lower in Spain than that observed in other countries as Italy, United Kingdom, France, or Germany.<sup>9</sup> The same consideration applies to double-kidney transplantation with organs coming from expanded criteria donors as well as domino liver

transplantations, although this latter possibility is dependent on the prevalence of certain diseases, such as familial amyloidotic polyneuropathy.

#### Donation in Cardiac Death

Donation after cardiac death (DCD) represents 5% of all activity in Spain,<sup>9</sup> mainly based on Maastricht types I and II. An equipped, trained, and motivated nonhospital emergency organization is the key to undertake the complexity of DCD, particularly “uncontrolled” donation. This need explains why a small number of centers represent the great majority of the Spanish non-heart-beating activity. One center in particular has shown an exceptional performance of the hospital and the nonhospital emergency organization, accounting for >65% of these donors. Despite such complexity, DCD is becoming a real source of organs for transplantation. Over a 12-year period, 814 renal, 75 liver, and 28 lung transplantations were performed in Spain with organs procured from non-heart-beating donors. Because of the outstanding results, replicating this program in other areas seems promising, regardless of the difficulty for its development.

As it has been since its foundation, the ONT as well as the Spanish transplantation community are concerned to provide those individuals who are in need with the best possible solid organ transplantation. The 40 Donors pmp Plan has been addressed to boost donation and transplantation activity in Spain; it is already considered to be international reference.

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