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Factors influencing the adaptation of the Spanish Model of organ donation

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Abstract Spain is the only existing example of a large country (40 million inhabitants) with a continuous increase in cadaveric organ donation for a period of over 10 years, and, in parallel, with an increase in the overall number of solid organ transplantations. A proactive donor detection program performed by well-trained transplant coordinators, the introduction of systematic death audits in the hospitals combined with a positive social atmosphere, adequate management of mass media relations, and adequate economic reimbursement for the hospitals accounted for this success. Some

regions of Italy, for example Tuscany, have successfully adapted this approach with excellent results. We can conclude that the “Spanish Model” can be partially or totally adapted to other countries or regions if basic conditions are guaranteed. An adequate and careful study of the local characteristics that influence organ donation directly or indirectly should be carried out before planning any specific action to improve organ donor rates.

Keywords Spanish model · Organ donation · Transplant coordinators · Tuscany

Introduction

The shortage of cadaveric organ donors imposes a severe limit on the number of patients who can benefit from transplantation, at the same time there is an ever-increasing demand for cadaveric solid organs all over the world. Partial strategies in many countries have resulted in small or transient increases of organ donation or even in no improvement at all [1, 2]. In the early nineties, Spain started an original integrated approach mainly designed to improve cadaveric organ donation [3, 4]. The Spanish National Transplant Organisation (ONT) was created in 1989 [5]. This resulted in a regional network of specifically trained, part-time dedicated and strongly motivated hospital physicians in charge of the whole process of organ donation [6, 7]. Since then, in Spain, organ donation has increased from 14 to 32,5 organ donors per million population in 2001,

an increase by 132%, by far the highest donor rate ever reached by a whole country [8]. This is the only existing example of a large country (40 million inhabitants) with a continuous increase in cadaveric organ donation for a period of over 10 years [9] and, in parallel, with an increase in the number of all solid organ transplantations (Table 1).

All the measures taken in Spain to improve cadaveric organ donation during the nineties are known at an international level as the “Spanish Model” of organ donation [9, 10] and have been extensively described in the medical literature. The questions however are: can this system be successfully transferred to other countries or regions? And if this be the case, is it to be totally or partially adapted? Under which conditions? How should it be implemented?

Below, I will try to describe the international experience of total or partial adaptation of the Spanish

Table 1 Organ donation and transplantation in Spain, 1989 compared to 2002

Activity	1989	2002
Organ donors	550	1410
Renal transplantations	1039	1410
Liver transplantations	170	1033
Hear transplantations	164	310
Total solid organ transplantations	1382	3608

Model, the reasons for failure or success, and the basic requirements for implementation in other countries or regions.

General considerations and methodology

For the purpose of this publication, I use data and definitions that have been agreed on by the Council of Europe for all its country members [8]. An organ donor is defined as “every potential donor transferred to the operating theatre from whom, at least, one solid organ has been retrieved” [8]. Other economic and population data have been obtained from “The Economist” [11, 12], Eurostat [13], Istat [14], The European Union of Medical Specialists [15], and local sources. All the organ donation and transplantation data refer to the year 2001, unless specified.

Basic principles of the Spanish Model

Although widely described in the medical literature [4, 6, 7, 9, 16], the results of the Spanish Model can only be understood within the perspective of a 10-year integrated approach to improving cadaveric organ donation. This approach includes an adequate legal, economic, ethical, medical and political background. It is clear that merely placing transplant coordinators in the hospitals cannot be considered effective. First and foremost, it is necessary to clearly define the most important factors of the success achieved in Spain, the requirements for the adaptation of this model to other region or countries, and the beneficial and detrimental structural factors.

The points that define the Spanish Model are:

1. The transplant coordination network operates on three levels: national, regional and in the hospital.
2. The two first levels, nominated and paid for by the national and the regional authorities are real interfaces between the political and the professional levels. All technical decisions regarding transplantation are reached by consensus in a regional council formed by the national and the regional executives.
3. The third level, the hospital co-ordinator, is a medical doctor assisted by nurses in the large hospitals. He preferably works on a part time basis and is located inside the hospital. The coordinators are nominated by, and report to, the hospital director (not the head of the transplant units), although they are functionally linked to the regional and national coordinators [16].
4. Most hospital coordinators are anaesthesiologists/intensivists, meaning they participate actively in organ donation. Part-time dedication allows them to continue their previous profession while being present, even in the smaller hospitals.
5. Continuous brain death audit is performed by the transplant coordinators [17, 18, 19].
6. The central office of the ONT acts as the support agency in charge of organ sharing and transport. It manages waiting lists, transplant registries, statistics, and provides general and specialised information and action to improve the whole process of organ donation and transplantation. As a significant percentage of organs is retrieved in small hospitals without neurosurgery, (up to 15% in the national 2001 brain death audit [19], regional and national offices give external support to those centres where the whole process cannot be performed.
7. A great effort in continuous medical training and education for new and old transplant coordinators, financed and directed by the central health administration, has been made. Development of various training programmes for health professionals, specifically dedicated to each step of the process, i.e. donor detection and management, legal aspects, the family approach, organisational aspects, and management of resources, has been promoted.
8. Hospital reimbursement by the regional or national health administrations, funding adequately the procurement and transplant activity [18] is required, otherwise sustained procurement activity, especially that of small non-university and non-transplant hospitals becomes practically impossible.
9. Much attention is devoted to implementing the mass media optimally and to improving the level of information of the Spanish population on these topics. A 24-h transplantation hot-line, periodical meetings of journalists and opinion leaders, communication training courses for hospital and regional coordinators, and management of adverse publicity combined with adequate and systematic spread via the media to the medical and lay community [20, 21] have been implemented.
10. An adequate legal background, technically similar to that of other western countries [22]: definition of brain death, organ retrieval after obtaining family consent, no compensation for donated or grafted organs. Spain theoretically has a presumed consent

law, but from a practical point of view, family consent is always solicited, and the wishes of the relatives are always respected, as it is practised in almost all EU countries. The rate of refusal by families has remained stable between 20% and 25% during the last years [9, 17, 22]. It is clear that the increase in organ donation during the nineties cannot be attributed to any change of the Spanish legislation, which has remained unmodified since 1979.

These measures are more far-reaching than merely placing transplant coordinators, and they are not easy to link. Furthermore, the results can vary greatly according to structural differences of a country, or if any single measure is stressed. The measures should be regarded as examples to be considered when trying to adopt this model.

Factors influencing the adaptation of the Spanish Model

A *sine-qua-non* prerequisite is a public national health system with full coverage of the population [18]. Organ donation can hardly be a concern for private medicine, although this is not the case for transplantation. Consequently, the development of a national program like the Spanish one needs a public health background. This does not mean that the model cannot be implemented in parts in selected hospitals or regions. It has been done in some Latin American countries [23, 24], but the complete model was not adapted. The fragmentation of health care imposes further difficulties on the development of an integrated system.

Economic resources dedicated to health care are usually measured as a percentage of the gross national product [11, 12], or, more graphically, in \$/inhabitant per year (Fig. 1). As stated before, the ratio between

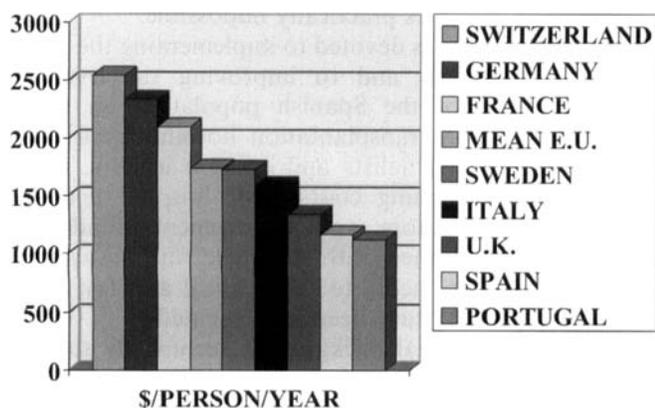


Fig. 1 Health expenditures per person (US\$) in selected European countries during 1997

public and private funding is also relevant when considering the adaptation of the Spanish Model. Spain is in the middle-to-low range of western countries in terms of the first index, but clearly in the lower range of EU countries for the second one. Nevertheless, adequate funding is necessary. There is a minimal level under which it is not possible to develop such a system. Transplantation cannot be considered a luxury treatment for only the richest countries. The most important economic factor is by far reimbursement for organ procurement and transplantation, based on the local estimated costs of the hospitals.

Figure 2 shows the number of doctors available in every country [11, 12] and their average basic annual salary [15]. It is easy to understand that a system like the Spanish one, based on a network of medical doctors would be very difficult or very expensive to implement in countries like the U.K., with a very low index of physicians/1000 inhabitants, in the USA or in European countries with very high incomes for the doctors.

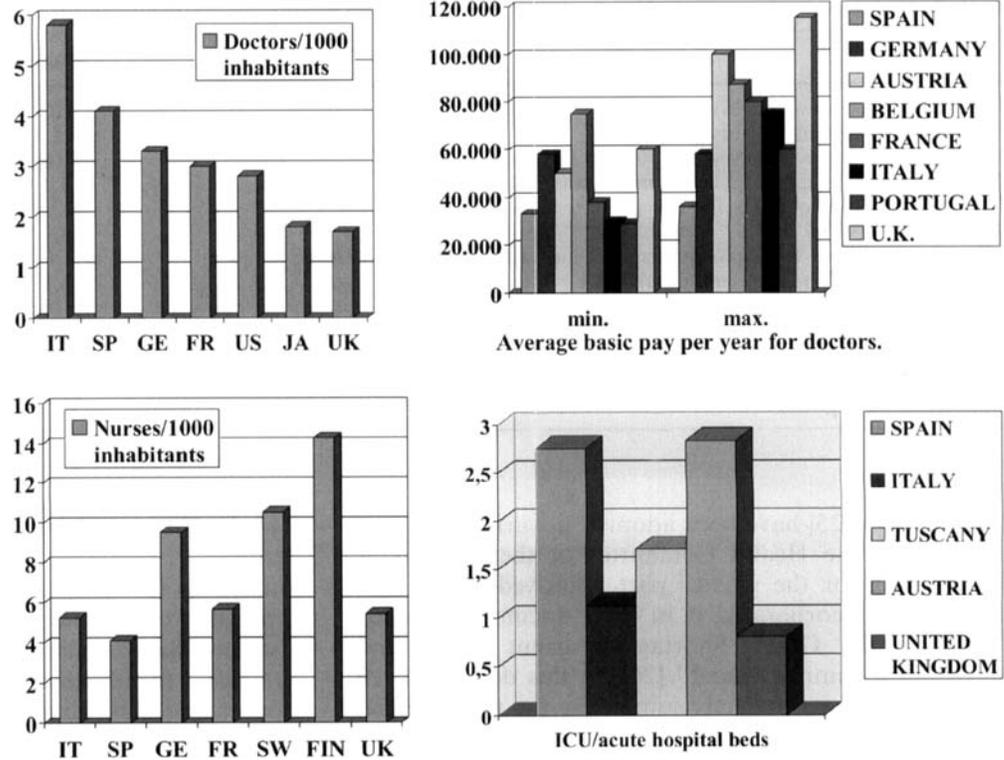
The Spanish (and the Italian) situation is probably the most adequate because there are many doctors with low basic pay, but with the prospect of a significant increase linked to objectives. A low number of doctors with high incomes not linked to objectives, but to the concept of "availability" is probably the most inappropriate scenario. The number of nurses is also relevant [11, 12] (Fig. 2), not only for their potential as coordinators, but also for the availability of ICU beds (see later). More important than absolute figures or the index per 1000 inhabitants seems to be the ratio between nurses and acute public beds, as the best assessment basis for the available care for potential donors.

The number of acute beds and ICU facilities available

It is not easy to compare the number of acute beds (i.e.: hospital beds not dedicated to chronic patients) as the calculation method varies from country to country. Furthermore, modern medicine tends to reduce these facilities as far as possible and to use day-care hospitals, ambulatory surgery, and so on. Official national statistics often reflect total hospital facilities including those of chronic patients that are not relevant for organ donation. The same can be said with respect to ICU facilities when trying to compare data. From a practical point of view, mechanical ventilation seems to be the crucial factor characterising an ICU bed as suitable for organ procurement.

Among the various data relevant for organ donation, the number of ICU beds per million population and the ratio between ICU beds and total acute beds seem to be most relevant. [17, 18]. Differences between the countries (Fig. 2) can explain some of the difficulties encountered when detecting potential donors and caring adequately

Fig. 2 Structural data that can influence organ donation in selected countries. *Upper left* Medical doctors per 1000 inhabitants. *Upper right* Average basic pay per year for doctors. *Lower left* Number of nurses per 1000 inhabitants. *Lower right* ratio ICU beds/ acute hospital beds



for them, until the full process of brain death diagnosis and organ procurement is completed.

Age distribution of the population

The results of an integrated approach like the Spanish one to increase cadaveric organ donation show an expansion of the organ donor pool due to the acceptance of older and more difficult donors [2, 10]. The percentage of Spanish donors over 60 years rose during the last ten years from 10 to 33,9%, significantly higher than those reported by other European countries. Likewise, as is now the case in other European countries, most organ donations are due to cerebral bleeding, while traffic deaths accounted just for 21,3% of all donors during 2001.

So, differences from one country or even region to another in terms of age distribution of the population (Fig. 3) can explain relevant differences in organ donor potential. These age differences are explained by, and are also the consequences of epidemiological data (cerebral bleedings, tumoral deaths, etc.). All these and other data, together with the number of road accidents form a clear definition of the basic state of a country or region, which is necessary when considering an approach like the Spanish Model. In Table 2, the structural indices of Spain, Italy and the region of Tuscany are compared. There are some other relevant factors which are not so

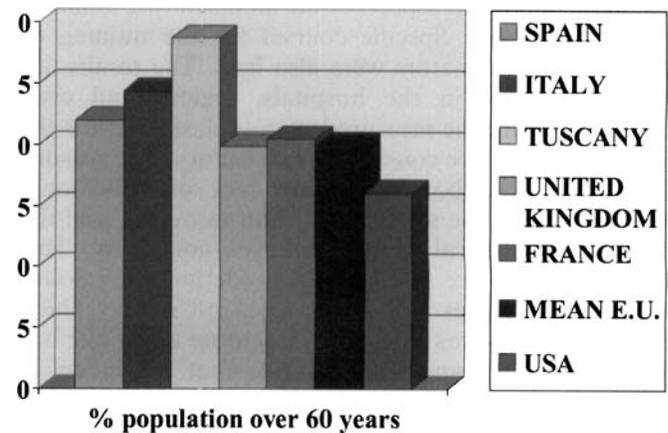


Fig. 3 Percentage of the population over 60 years in selected countries/regions

easy to standardise, such as the concentration or dispersion of the population, the access to TAC and neurosurgery facilities, but are nevertheless highly relevant for a specific situation of organ donation.

Some experiences adapting the Spanish Model

Many partial aspects of the Spanish Model, especially those related with the training of transplant

Table 2 Comparison of structural data that can influence organ donation, corresponding to Spain, Italy and Tuscany

	Spain	Italy	Tuscany
Population over 60 years (%)	22	24,37	28,7
Mortality/100.000 inhabitants per year	915,7	983,5	1176,9
Mortality due to cerebral bleeding/100.000 inhabitants per year	96,8	123,5	170,2
Mortality due to accidents/100.000 inhabitants per year	33,3	46,8	52,2
Mortality due to neoplasias/100.000 inhabitants per year	227,5	268,5	337,5
Tumoral deaths (%)	24,9	28,5	28,7
Acute hospital beds/1000 inhabitants (Not included facilities for chronic patients)	2,4	5,33	4,83
Intensive care unit beds/million inhabitants	66,3	60,4	73,4
I.c.u./acute hospital beds (%)	2,76	1,13	1,71
Medical doctors/1000 inhabitants	4,1	5,8	
Nurses/1000 inhabitants	4,1	5,23	
Nurses/acute hospital bed	1,7	0,98	
Organ donors pmp 2001	32,5	17,1	30,7

coordinators [25] have been adopted in various parts of the world. The Health Committee of the Council of Europe has for the greater part approved the of this model and incorporated it in their document entitled "Meeting the Organ Shortage: Current status and strategies for improvement" [26]. In this document, 19 recommendations perfectly summarise the more critical points of the model and the strategies for improvement.

In the nineties, Latin-American countries were the first to try to implement the Spanish Model [23, 24, 27, 28]. This was tried mainly by training professionals in the more important aspects of the model during 6-month periods in Spain. Specific courses for the training of transplant coordinators were also held. The results, although positive in the hospitals, regions and even countries where the measures were applied, can, for the greater part, not be considered satisfactory. The reasons have been described before: the lack of a National Health System, the scarcity of health resources, and the absence of political support or even continuity. This explains the failure to adapt the model in many South American countries. Local experience in Uruguay, Cuba and in limited areas of Brazil, Argentina and Chile has been very promising and confirms that the model is valid, if adequate support is provided by the health authorities.

In 1995, the South Australian minister for health, after contacting the Spanish executives, took the initiative to adapt some elements of the Spanish model [29]. The South Australian Organ Donation Agency (SA-ODA), in many respects similar to the Spanish ONT was established in 1996. In a recent report of the Australian situation, the National Director of Australian Donate Inc, the national coordinating body for organ donation and transplantation in this country summarised the situation [29].

The following elements of the Spanish Model were found suitable for adaptation by the Australian State Agencies:

- The location of donation teams in every donation hospital.
- Inclusion of at least one medically qualified person as a member of a donation team.
- Establishment of nationally consistent "best medical practices" for identification, management and care of donors and their families.
- National management of media relationship, emphasising consistent messages to the public.

The Australian state agency, which has replicated most elements of the Spanish Model (South Australia) enjoys the greatest improvement in cadaveric donation rates, double of the mean Australian donation rate. In contrast, the Agency (New South Wales) adopting fewest elements of the model continues to suffer poor cadaveric organ donation rates.

The Italian and the Tuscany experience

Italy is probably the country that has adopted most elements of the Spanish Model and worked most wholeheartedly in this direction. Consequently, Italy and Spain are the countries with the greatest increase in organ donation during the last ten years, indeed, they are the only countries with significant increases [8].

In the early nineties, the contacts between both countries at an organisational level started via Northern Italy Transplant, and in 1997, the region of Tuscany developed a system based in the Spanish Model [26], which is now in the phase of consolidation and has helped to raise the donor rate to more than 30 donors pmp during 2001. After approval of the Italian law in 1999 [31], a coordinating system similar to the Spanish one and operating at three levels, national, regional and at hospital level, was adopted. Italian transplant coordinators and Spanish specialists together took part in training courses courses, for example on on the mass

media [33] and the Spanish Quality Improvement Programme in Organ Donation [17, 25, 32]. This is now in the phase of implementation in Tuscany. Significant increases have been achieved throughout the country, especially in the northern regions, as Emilia-Romagna, Veneto and others.

Conclusions

Spain is the only example in the world of a large country showing a continuous improvement in cadaveric organ donation over a 10-year period. The Spanish Model shows that organ shortage is not due to a lack of

potential donors, but rather to a failure to convert many potential into actual donors. A proactive donor detection program performed by well-trained transplant coordinators, the introduction of systematic death audits in the hospitals, the combination of a positive social atmosphere, adequate management of mass media relations, and adequate economic reimbursement for the hospitals accounted for this success. This model can be partial or totally adapted to other countries or regions if basic conditions are guaranteed. An adequate and careful study of the local factors directly or indirectly influencing organ donation should be carried out before planning any specific action to improve organ donor rates.

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