

International approaches to organ donation reform

Introduction

The incentive for systemic reform of organ and tissue donation has arisen internationally because of the increased incidence of end stage organ failure and the corresponding growth in need for transplants. Several countries have responded to this challenge by implementing strategies to increase organ and tissue donation and now have well established reform models¹. The key elements of these reform models that have now been adopted by Australia are:

1. An appropriate legal and ethical framework;
2. A national coordinating body;
3. Hospital-based clinical donation specialists;
4. Specialist training for clinical staff in management of the deceased donation process and family donation conversations;
5. Implementation of a clinical governance framework that supports quality assurance and audit of hospital clinical practice and governance of the donation process;
6. Financial support to donor hospitals to ensure that costs related to donor management are not a barrier to donation;
7. Media engagement and national community awareness and education; and
8. International cooperation to share best practice.

International efforts to promote collaboration have been taken up by governments and professional bodies to set the framework for ethical and clinical reform models and provide for equity, quality and safety in organ and tissue donation for transplantation. The international governmental response has resulted in the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation (updated, 2010) which apply to both living and deceased donation and contain 11 principles to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissue and organs for therapeutic purposes.²

The professional response to the challenges presented by an increasing demand for organ and tissue donation for transplantation has been led by the Transplantation Society in association with other international professional societies and culminating in the Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2008).³ The Declaration was a response to increasing reports of organ commercialism which targets vulnerable populations. The Declaration proclaims that the poor who sell their organs are being exploited whether by richer people in their own countries or by transplant tourists abroad. Transplant tourists also risk harm through unregulated and illegal transplantation.

A further joint initiative between governments and professional organisations is the Resolution of Madrid (2010) which calls for all countries to strive towards self-sufficiency, both by increasing organ donation activity and by efforts to reduce the burden of end-stage organ failure. The Madrid Resolution urges:

1. National capacity management (such as an appropriate healthcare infrastructure and workforce);

1 International practices of organ donation: C Rudge, R Matesanz, F L Delmonico and J Chapman; British Journal of Anaesthesia 108 (s1): i48-i55 (2012).

2 <http://www.who.int/transplantation/en/>

3 <http://www.who.int/transplantation/en/>

2. National regulatory control (through adequate legislation for declaration of death, consent, organ procurement, fair and transparent allocation and penalties for organ trafficking and commercialisation); and
3. National authorities to lead normative change so that all levels of society share a collective responsibility for donation after death, contributing to the common good of transplantation for all.

The attached fact sheets describe the national reform effort in three leading countries for organ and tissue donation reform: Spain, Croatia and Portugal. They have been developed and co-authored by the Organ and Tissue Authority (OTA) with the relevant national authority or ministry in each country.

Themes

These three countries have adopted similar models over different timeframes. Direct comparisons between countries in terms of progress is difficult because there are differences in health care systems, population size, community attitudes and their relative starting points. However, the key lessons for Australia to be learnt from these leading countries are:

1. Foundational effort prior to the national reform model.

The three countries each had an established network of donation specialists with a common sense of purpose for some years before a concerted effort to change clinical practice. There were staff in place in each hospital before they systematically changed practice across intensive care units, critical care and hospital governance. For example, Spain commenced the appointment of transplant coordinators in 1985, before the establishment of their national coordinating body (ONT) in 1989. In Croatia, the hospital teams were established over 1998-2000 and the National Transplant Coordinator was established in 2001. Portugal implemented three iterations of the national reform model progressively over time, refining their models for national, regional and hospital – based coordination of organ and tissue donation practice.

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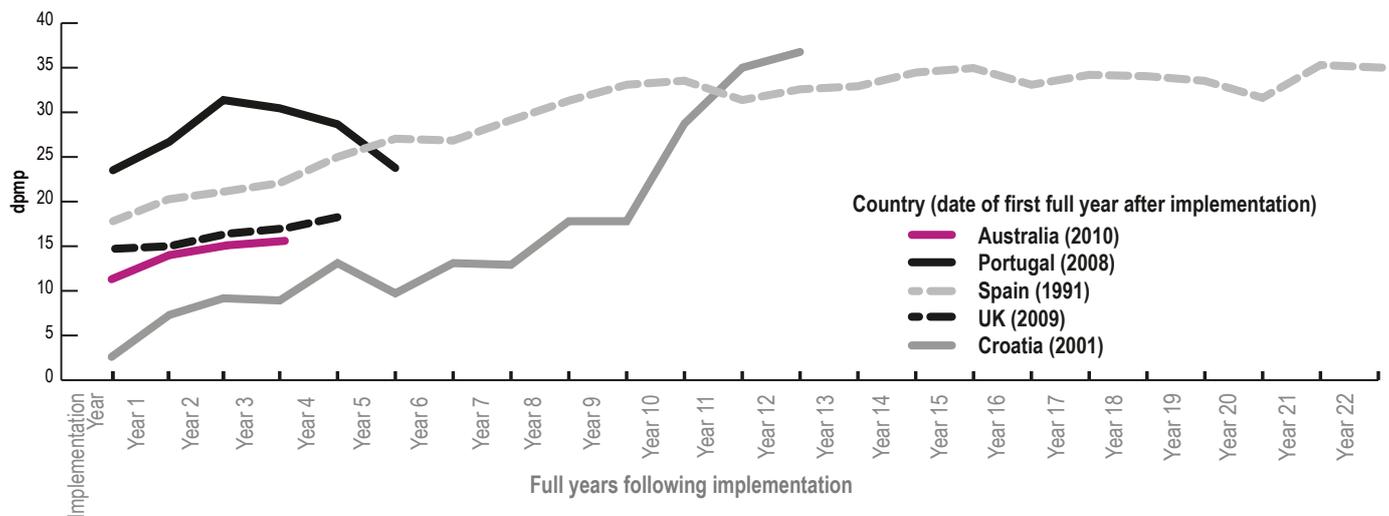
2. A methodical and sustained approach to clinical practice reform.

All three countries demonstrate a sustained increase in donation outcomes over a number of years to reach world-leading rates. The growth trajectories illustrate the cumulative impact of organisational reform and professional training to change end of life care and donation practice at the hospital level. A central role is played by the national coordinating authority to drive consistency of practice and address variation in practice. The National Transplant Coordinator in Croatia, Dr Mirela Busic says their extraordinary results in recent years are due to “sustained efforts and gradual implementation of the whole set of organisational measures supported and facilitated by the Ministry of Health. The team work and dedication of

the many professionals involved has been one of the keys that has enabled such astounding results in Croatia”. The national coordinating bodies of both Spain and Portugal reiterate the need to implement a coherent suite of measures to achieve a sustained increase.

3. Growth is progressive and cumulative.

Each of the world leading countries shows that sustained effort to fundamentally change donation clinical practice is effective. While the change is revolutionary, the growth is progressive. Each country has changed its end of life care practice to better identify and support families when the rare opportunity for potential organ donation arises. The resulting growth in organ donation outcomes is shown in the figure below:



Source: Australia and New Zealand Organ Donor (ANZOD) Registry, International Registry of Organ Donation and Transplantation IRODAT November 2013

Australian Approach

Australia is currently in its fourth full year of reform and has achieved promising early growth in donation and transplantation outcomes. The improvement to date demonstrates the impact of the key measures that have been implemented in Australia since 2009:

- A network of donation specialists has been established in 72 hospitals across Australia to change donation practice – the Donatelife Network;
- International best practice clinical training has been provided to more than 600 intensive care and critical care specialists in the conduct of the family donation conversation to support families to make an enduring decision when the opportunity for donation arises;
- Reporting and auditing of organ and tissue donation practice has been enhanced and embedded across the hospitals in the Donatelife Network;
- Implementation of public education and awareness of the importance of family discussion resulting in significant improvement in family discussion levels.

The next steps in reform in Australia will set a new threshold for growth. The initiatives now underway are:

- Implementation of a clinical governance framework to support and guide hospital staff in the provision of quality organ and tissue donation services within the Australian health system;
- Implementation and evaluation of the effectiveness of the national Professional Education Program on family donation conversation and its impact on consent rates for organ and tissue donation;
- Implementation of an electronic donor record to improve the accuracy, reliability, efficiency and transparency of the organ and tissue donation process;
- Implementation of eye and tissue donation reform;
- Implementation of a nationally coordinated Indigenous Australian and culturally and linguistically diverse audiences communication and engagement plan.

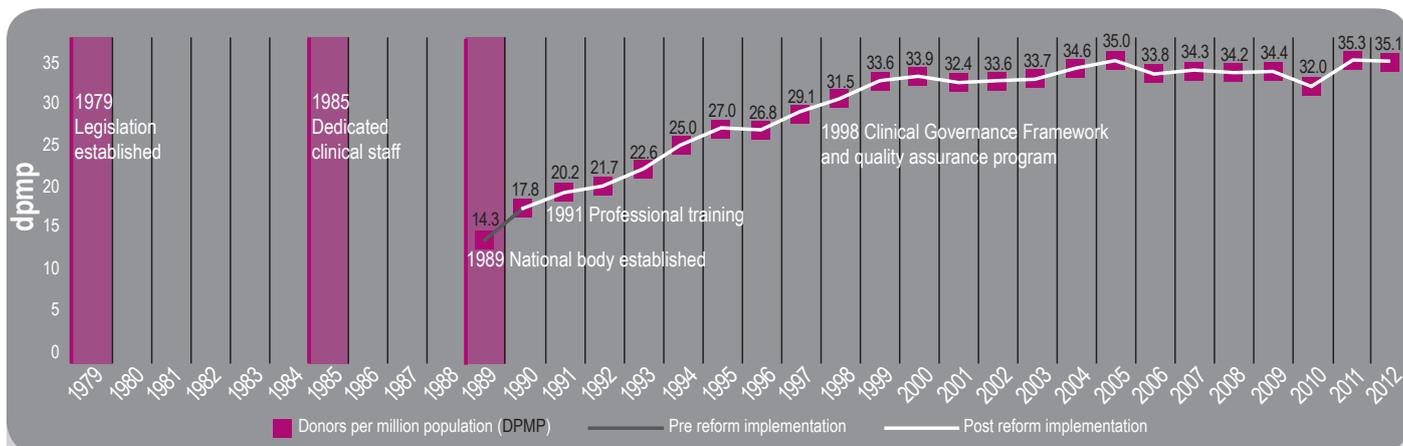
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Organ donation reform in Spain



Source: International Registry of Organ Donation and Transplantation website (November 2013)

National reform in organ donation

Spain is widely acknowledged as a world leader in organ donation. Spain has developed the Spanish Model of Organ Donation and Transplantation which has been adapted in many other countries according to their health care systems, population size, community attitudes and relative starting points for organ donation reform. The main elements of the Spanish Model of Organ Donation and Transplantations are:

1. Transplant Coordination Network at three levels: national, regional and hospital;
2. Special profile of Transplant coordinators (Medical doctors- ICU physicians, supported by nurses);
3. Transplant coordinators inside the hospitals;
4. Central Office (ONT) as a support agency;
5. Quality Assurance Program in the Deceased Donation Process;
6. Medical Training in entire process of deceased organ donation;
7. Close attention to the mass media with special communication policy; and
8. Hospital reimbursement for donation activities.

This fact sheet describes the progress of national organ donation reform in Spain. Spain has a population of 47.2 million and supports an organ donation network of 170 hospitals.

Transplant Coordination Network at three levels: national, Regional and Hospital

The organ donation and transplantation network should be designed having regard to a country's political system and the organisation of its health system.

Donation activities in Spain are coordinated at three different levels; at a national level (ONT), 17 autonomous regional coordinators and at the hospital level. The ONT and regional coordinators provide the link between policy and technical processes and all national policy initiatives require inter-regional consensus. At the hospital level, each procurement hospital is directly in charge of developing an effective donation process.

Special profile of Transplant coordinators (Medical doctors- ICU physicians, supported by nurses)

Spain has defined very specific requirements for its Transplant Coordinators.

The role of a Transplant Coordinator in Spain is unique in that it was conceived to facilitate early identification and referral of possible donors. Transplant Coordinators are professional staff members of a specific procurement hospital and are appointed by, and report to, the medical executive of the hospital, rather than the transplantation team. The majority of Transplant Coordinators in Spain are critical care physicians (intensivists), so their daily work is carried out in units where a large number of potential donors are realised. The transplant coordinators are supported in their role by nurses.

Transplant coordinators inside the hospitals

It is critical that each hospital has the capacity to manage organ donation. Spain commenced the appointment of Transplant Coordinators in 1985, before the implementation of the ONT. Spain employs Transplant Coordinators in 170 hospitals that are responsible for donor identification, management of organ and tissue donation, in addition to their regular job duties. They are supported in their work by the staff from the ONT.

Developed with the assistance of:

National Transplant Organization (ONT) Madrid, Spain
DTI Foundation (Donation and Transplantation Institute) Barcelona, Spain

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Organ donation reform in Spain

The appointment of the Transplant Coordinators at each procurement hospital is a key element of the Spanish model. The initiative of designating key donation positions responsible for developing a proactive donor detection program (which effectively converts potential into actual donors) has progressively been replicated in other countries.

Central Office (ONT) as a support agency

The *Spanish National Transplant Organisation* (ONT) was established in 1989 as the responsible agency of the Ministry of Health to oversee donation and transplantation activities. The current Chief Executive Officer is Dr Rafael Matesanz. The ONT acts as a supporting agency to the network of procurement hospitals, and together with the *Regional Catalan Organisation*, forms the *Spanish Model of Organ Donation and Transplantation*, which provides the organisational framework for reform in Spain.

Quality Assurance Program in the Deceased Donation Process.

It is important that organ and tissue donation specialist staff and their clinical colleagues operate within a structured clinical governance framework that articulates the objectives, actions, results and measures required for an effective organ and tissue donation system to operate in hospitals. A component of this framework is an audit of all deaths in the hospital is conducted to identify any missed donation opportunities and to provide quality assurance feedback to the system.

Spain commenced a quality assurance program in the deceased donation process in 1998 to monitor deceased organ donation potential, evaluate performance and identify key areas for improvement. The quality assurance program is based on a continuous clinical chart review of all deaths occurring in critical care units of procurement hospitals. The program includes an internal audit performed by Transplant Coordinators within their hospital, and an external audit conducted by expert Transplant Coordinators from other regions.

Medical Training in entire process of deceased organ donation.

It is imperative that all healthcare professionals be trained in deceased organ donation for transplantation. In Spain, a special emphasis is placed on the staff directly involved with organ donation to ensure they are appropriately trained in all steps of the donation process.

In Spain this professional training was first made available to clinical staff in 1991 and it is mandatory that all Spanish doctors specialising in intensive care must attend specific deceased organ donation for transplantation training.

Spain is also considered to be a world leader in training delivery. The Transplant Procurement Management (TPM) educational program in organ and transplant coordination is academically endorsed by the University of Barcelona and are recognised as the international benchmark for training within the organ donation and transplantation community. The program promotes knowledge transfer and development of professional competences in organ donation as key factors to maximize donor potentiality and conversion rates.

Close attention to the mass media with special communication policy.

In order for organ and tissue donation rates to improve, in addition to changing clinical behaviour it is necessary to educate the public about donation and the processes by which you can become a donor or support a family member's wishes.

In Spain, there is no convincing data demonstrating the relationship between advertising campaigns and a sustained increase in the rate of donors. It has been observed to be episodic and without continuity and at a high cost to benefit ratio. Since the creation of the ONT in 1989 until the present day, the donation rate has increased by almost 250% without significant advertising campaigns.

The communication policy of the ONT and the network is based on four principles:

- i) A 24-hour 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; and
- iv) Delivery of messages with no intermediaries.

However, Spain also utilises the media to promote organ donation through the dissemination of positive news. Each year Spain conducts a training seminar in organ donation which is aimed at journalists to provide first-hand information about organ donation and transplantation processes. These principles have led the media in Spain to handle information about donation and transplantation appropriately.

Hospital reimbursement for donation activities.

Organ donation is more likely to occur when the hospital is funded in some way for the additional costs associated with organ and tissue donation e.g. tissue typing, intensive care bed and staffing, operating theatre and staffing costs.

In Spain, the authorities allocate a specific budget to fund the human and material resources needed for donation management at every hospital.

Spain is the only example in the world of a middle size country (47 million people) with a sustained increase in organ donation during more than 20 years. An adequate organization is in fact the only means to increase deceased donation activity in a sustained way. This is the whole philosophy of what has been internationally known as the Spanish Model of Organ Donation, a model that has led Spain to lead the world in organ donation since 1992.

The figure of the transplant coordinator, the central office in support of all the process of organ donation, great effort in training and education, close attention to the media, and reimbursement to the hospitals are the measures that, altogether and appropriately integrated, constitute this model. If some basic conditions exist, the Spanish Model of Organ Donation can be successfully reproduced in other countries or regions in the world.

Dr. Rafael Matesanz

Spanish National Transplant Organisation

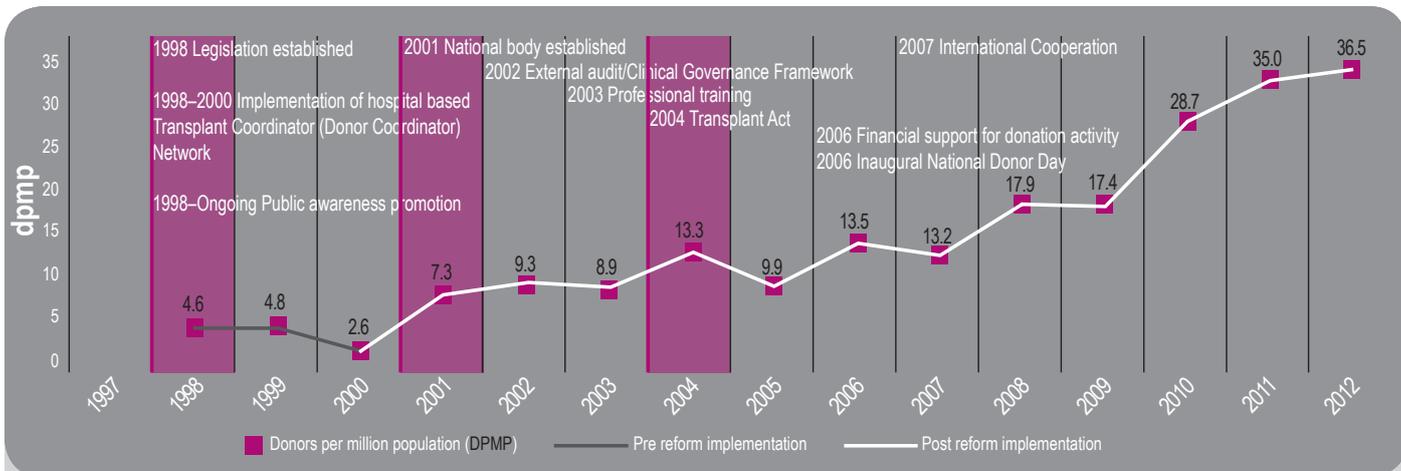
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An Australian Government Initiative

Organ donation reform in Croatia



Source: International Registry of Organ Donation and Transplantation website (November 2013)

National reform in organ donation

It is not possible to draw direct comparisons between countries in terms of their progress in organ donation reform, as there are many differences between health care systems, population size, community attitudes and the relative starting points for national organ and tissue donation reform. However, there are a number of key elements for reform which are usually seen in successful national organ donation reform initiatives. They are:

1. An appropriate legal and ethical framework;
2. A national coordinating body;
3. Hospital-based clinical donation specialists;
4. Specialist training for clinical staff in management of the deceased donation process and family donation conversations;
5. Implementation of a clinical governance framework that supports quality assurance and audit of hospital clinical practice and governance of the donation process;
6. Financial support to donor hospitals to ensure that costs related to donor management are not a barrier to donation;
7. Media engagement and national community awareness and education; and
8. International cooperation to share best practice.

This fact sheet describes the progress of national organ and tissue donation reform in Croatia. Croatia has a population of 4.3 million and supports an organ donation network of 33 hospitals. There are five transplant centres in Croatia.

Establishment of legislation

Organ donation must be supported by appropriate legislation which defines when organ donation can occur, how consent is to be obtained and how organ donation can be carried out in a legally and ethically acceptable manner.

Presumed consent was implemented in 1988. Since 1998, Croatia additionally introduced a Minister's Instruction, in which the objective, measures, and manner of implementation of the *Programme for Increasing the Number of Organ Donations in the Republic of Croatia* were defined. In 2004, the new *Transplant Act* together with a series of implementation by-laws were enacted.

Non donor registration has been implemented since 2004 and there are currently less than 3,000 Croatian citizens who have registered their wish not to donate. Regardless of the law the family is always approached to discuss the possibility of organ donation. This system represents a practical and efficient framework for the successful deceased organ donation program.

In 2012, a new *Transplant Act* fully harmonised with the *European Union Directive on Quality and Safety of Organs for Transplantation* was published. This legislation described in detail the ethical, professional and organisational standards for organ donation and transplantation in accordance with European Union requirements.

Developed with the assistance of:

Institute for Transplantation and Biomedicine
Ministry of Health
The Republic of Croatia



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Organ donation reform in Croatia

Establishment of a national coordinating body

The National Transplant Coordinator (Dr Mirela Basic) was appointed in 2001 following the announcement of the *Program for Increasing the Number of Organ Donations in the Republic of Croatia* in 1998 by the Croatian Ministry of Health (MoH). The Croatian Ministry for Health now employs six FTE of staff responsible for managing the implementation of the reform initiatives in the field of organs, tissues and cells, plus six contracted medical students maintaining a 24 hour duty coordination office.

Appointment of clinical staff dedicated to organ donation in each hospital

It is critical that each hospital with an intensive care unit has the capacity to identify potential organ donors, make an appropriate request for organ donation and facilitate the organ donation process. In Croatia there are 33 hospital (local) coordination teams (number depending on the size of the hospital and its donation potential) that are responsible for donor identification, management and realisation of organ and tissue donation, in addition to their regular job duties. They are supported in their work by the staff from the national coordinating body (MoH).

In Croatia the hospital based team of Transplant Coordinators were initially established from 1998–2000. Under the *Transplant Act 2004* appointment of the National Transplant Coordinator and the hospital based Transplant Coordinators was confirmed as a legal requirement with clear roles and responsibilities.

Provision of specialised training for health professionals including programs in requesting consent and managing family donation conversations

It is imperative that all staff involved in family consent conversations and organ and donation more broadly are well trained and competent in their practice.

In Croatia this professional training was first made available to clinical staff in 2003 and remains an ongoing priority, incorporated into the clinical governance framework.

Implementation of a clinical governance framework that supports quality assurance in organ and tissue donation service delivery, including hospital audit of all deaths for potential donors

It is important that organ and tissue donation specialist staff and their clinical colleagues operate within a structured clinical governance framework that articulates the objectives, actions, results and measures required for an effective organ and tissue donation system to operate in hospitals. A component of this framework is that an audit of all deaths in the hospital is conducted retrospectively to identify any missed donation opportunities and to provide quality assurance feedback to the system.

Croatia commenced hospital audits initially as an external quality assurance inspection process in 2002, which was gradually refined into a clinical practice improvement program and rigorous quality assurance process by 2010.

Financial support to donor hospitals to ensure that cost related to donor management is not a barrier to donation

Organ donation is more likely to occur when the hospital is funded in some way for the additional costs associated with organ and tissue donation e.g. tissue typing, donor evaluation and management, intensive care bed and staffing, operating theatre and staffing costs.

Croatia introduced this type of financial support for organ donation activity at the hospital level in 2006.

Implementation of a coordinated public awareness campaign to raise community awareness

In order for organ and tissue donation rates to improve, in addition to changing clinical behaviour it is necessary to educate the public about donation and the processes by which you can become a donor or support a family member's wishes.

In Croatia, this aspect of reform has been progressively introduced from 1998 and includes the establishment of an inaugural National Donor Day in 2006.

International Cooperation

It is important to share critical learning experiences between countries to maximise the improvements obtained by reform initiatives.

Croatia established international cooperation in 2007 when it joined Eurotransplant which positively influenced the organ allocation process and the overall Croatian transplant program.

The sustainable increase in the donor rate and the extraordinary results achieved in recent years in Croatia cannot be attributed to one single factor or measure.

It is rather, the result of sustained efforts and gradual implementation of the whole set of organisational measures supported and facilitated by the Ministry of Health.

The team work and dedication of the many professionals involved has been one of the keys that has enabled such astounding results for Croatia."

Mirela Basic, MD

National Transplant Coordinator
Institute for Transplantation and Biomedicine

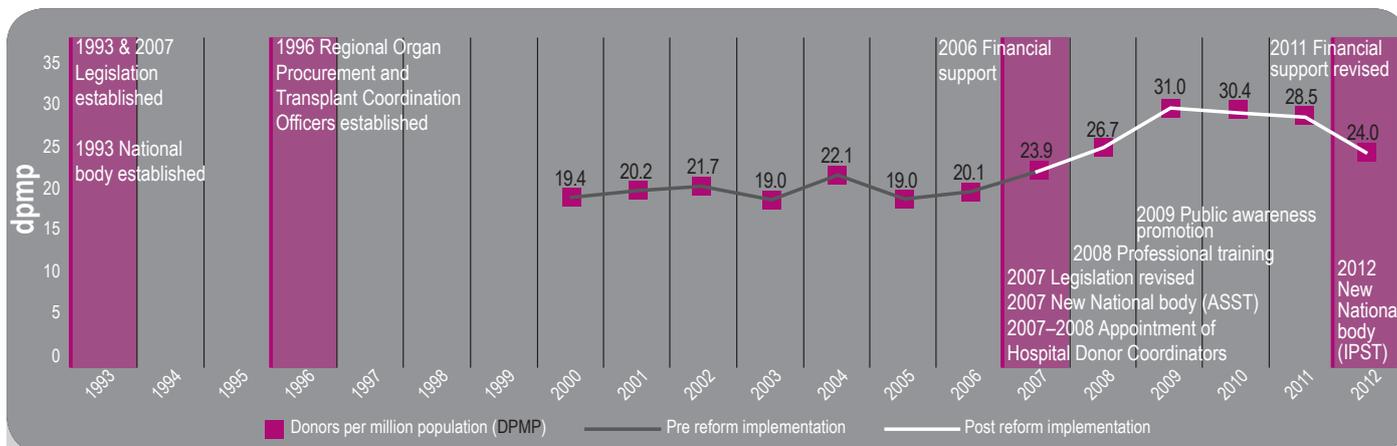
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An Australian Government Initiative

Organ donation reform in Portugal



Source: International Registry of Organ Donation and Transplantation website (November 2013)

National reform in organ donation

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1. An appropriate legal and ethical framework;
2. A national coordinating body;
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6. Financial support to donor hospitals to ensure that costs related to donor management are not a barrier to donation;
7. Media engagement and national community awareness and education; and
8. International cooperation to share best practice.

This fact sheet describes the progress of national organ donation reform in Portugal. Portugal has a population of 10.6 million and currently supports an organ donation network of 45 active donor hospitals.

Establishment of legislation to create an appropriate legal and ethical framework

Organ donation must be supported by appropriate legislation which defines when organ donation can occur, how consent is to be obtained and how organ donation can be carried out in a legally and ethically acceptable manner.

Portugal first enacted the *Transplantation Law* in 1993 which was later revised in 2007 to coincide with the new national coordinating body established the same year.

Establishment of a national coordinating body

The *Organização Portuguesa de Transplantação* (Portuguese Transplant Organisation) was established in 1993 which created a regional structure of five regional coordination offices to work

together with transplant teams in hospitals. The Portuguese Transplant Organisation was replaced by the *Autoridade para os Serviços de Sangue e da Transplantação* (ASST) in 2007, run by the Portuguese Ministry of Health with a more defined structure and closer relation to the Ministry. In 2012, due to organisational changes in Portugal, the *Instituto Português do Sangue e da Transplantação* (IPST) was created by law and assumed the former ASST's competencies for the regulation and coordination of organs, tissues and cell donation and transplantation processes, as well as the European Projects and training programs. The Chief Executive Officer of the IPST is Prof Doutor Helder Trindade.

Portugal's national office now employs staff who are responsible for managing the implementation of the reform initiatives.

Developed with the assistance of:

Instituto Portuguese do Sanque e da Transplantação
Lisbon
Portugal



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Organ donation reform in Portugal

Employment of clinical staff dedicated to organ donation in each hospital

It is critical that each hospital has the capacity to identify potential organ donors, make an appropriate request for organ donation and facilitate the organ donation process. In Portugal, 45 doctors are employed as Hospital Donor Coordinators, with backup staff, in 45 active donor hospitals. These specialist staff are responsible for creating a 'donor culture' in donor hospitals to increase organ donation and transplantation nationally.

Prior to appointing Hospital Donor Coordinators in 2007 and 2008, Portugal had five Regional Coordinating Offices (established in 1996) to coordinate organ donation retrieval and allocation across 25 tertiary hospitals.

Provision of specialised training for health professionals including programs in requesting consent and managing family donation conversations

It is imperative that all staff involved in family consent conversations and organ and donation more broadly are well trained and competent in their practice.

In Portugal this professional training was first made available to clinical staff from 2008 as part of the organisational structure of the new national coordinating body. All staff employed as Hospital Donor Coordinators have received internationally recognised Transplant Procurement Management (TPM) training. TPM is an international educational program in organ and transplant coordination academically endorsed by the University of Barcelona in Spain.

Implementation of a clinical governance framework that supports quality assurance in organ and tissue donation service delivery, including hospital audit of all deaths for potential donors

It is important that organ and tissue donation specialist staff and their clinical colleagues operate within a structured clinical governance framework that articulates the objectives, actions, results and measures required for an effective organ and tissue donation system to operate in hospitals. A component of this framework is an audit of all deaths in the hospital is conducted retrospectively to identify any missed donation opportunities and to provide quality assurance feedback to the system.

Portugal is currently planning the method for conducting hospital audits as a quality assurance process nationally.

Financial support to donor hospitals to ensure that cost related to donor management is not a barrier to donation

Organ donation is more likely to occur when the hospital is funded in some way for the additional costs associated with organ and tissue donation e.g. tissue typing, intensive care bed and staffing, operating theatre and staffing costs.

Portugal introduced financial support for organ donation activity in 2006 and revised the funding model in 2011.

Implementation of a coordinated public awareness campaign to raise community awareness

In order for organ and tissue donation rates to improve, in addition to changing clinical behaviour it is necessary to educate the public about donation and the processes by you become a donor or support a family member's wishes.

Portugal has not previously implemented a national awareness campaign. The ASST national body has organised joint community events with the Catholic Church and patient organisations since 2009, and has worked with the media on general awareness of organ and tissue donation and transplantation activity.

A significant factor which influenced organ donation outcomes in Portugal was the re-organisation of the National Organ Donation and Transplantation Network, with the creation of the Hospital Donor Coordinator in each hospital.

Other factors contributed to the increase in donation rates such as the close collaboration between the Hospital Donor Coordinators and the National Coordinating Authority-IPST in implementing the Portuguese model of reform. An additional factor was the specialist training in organ donation and procurement provided to around 550 health professionals from 2009-2011 under European Training Program on Organ Donation Project as part of the European collaborative partnership on organ donation.

Instituto Portugueso do Sanque e da Transplantacao

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