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## Action Taken to Boost Donor Rate in Croatia

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### 1. Introduction

Over the last 50 years, organ transplantation has become a widely accepted and successful treatment method that has provided the best therapeutic benefit for more than one million people worldwide (Council of Europe Consensus document, 1999). Due to the outstanding results and success of transplant medicine, there has been a dramatic increase in waiting lists after the 1980-ies. At the same time, the number of organs available for transplantation does not nearly match the demand. Organ shortage has led some countries to find an alternative in living donation, but in most European countries, deceased donation is recognised as the most appropriate source of organs for transplantation. Deceased donation is primarily based on donation after brain death. It has been estimated that no more than 1% of deceased persons and no more than 3% of people who die in the hospital fall into this category (Matesanz & Dominguez-Gil, 2007). Although the number of potential brain-dead donors is limited due to that fact, there is evidence showing that organ shortage is not primarily the result of a lack of suitable donors but, rather, the result of the failure to accurately identify them, obtain the consent, and procure the organs (Matesanz & Miranda, 2002). Partial strategies in many countries have resulted in mild or transient increases in organ donation or even no improvement at all (Hou, 2000). However, several successful models and strategies exist which can serve as guidance to countries attempting to increase their donor rates; the “Spanish Model” is definitely one of the most widely acknowledged. Recently, Croatia has risen to a role model status which other countries might like to follow and replicate. This paper illustrates actions taken in Croatia to increase the donor rate, and highlight the great achievements that recently ranked Croatia among world leaders in organ transplantation and donorship.

### 2. How does Croatia compare with other countries?

Remarkably, only 10 years ago Croatia was at the tail end of Europe with a (effective) donor rate of only 2.7 per million population (pmp). Over the last ten years the number of donors has multiplied ten times over and the (effective) donor rate has increased from 2.7 to 28 pmp (Fig.1.)

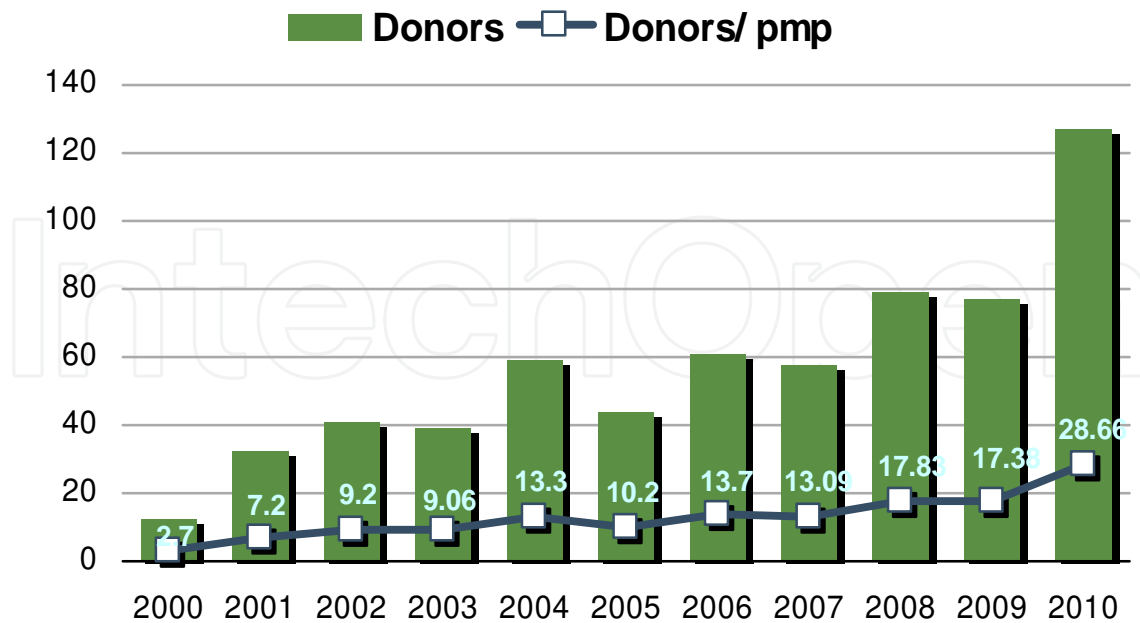


Fig. 1. Number of effective Donors/effective Donors per million in Croatia from 2000 to 2010

### Number of transplanted organs – deceased and living donors

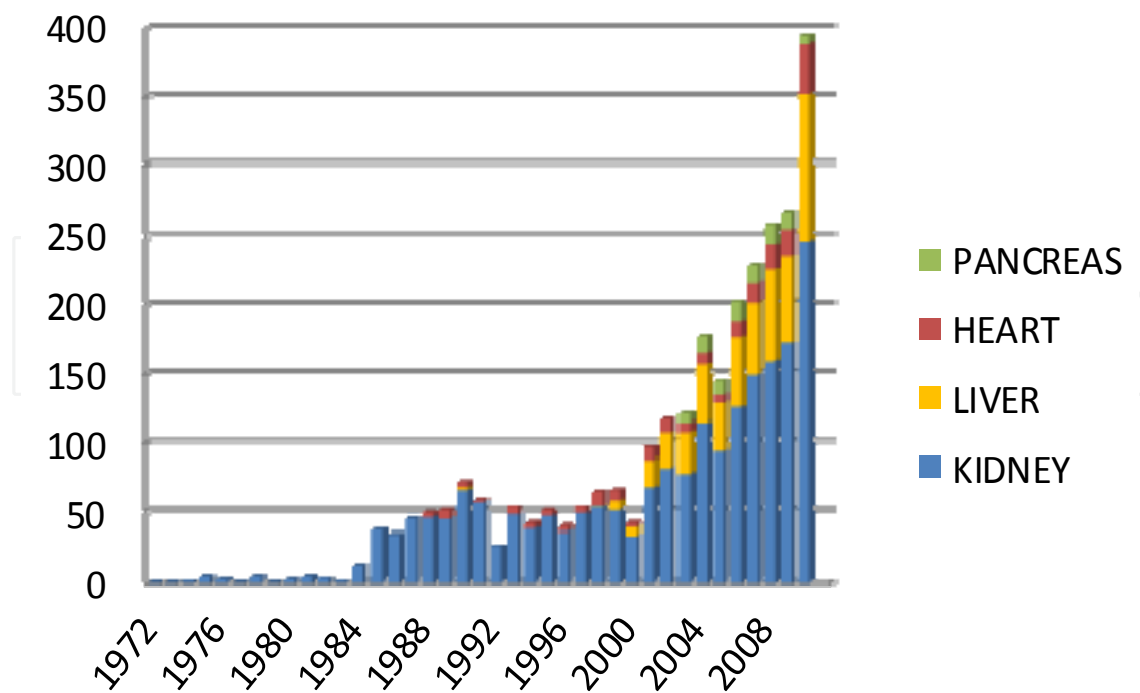
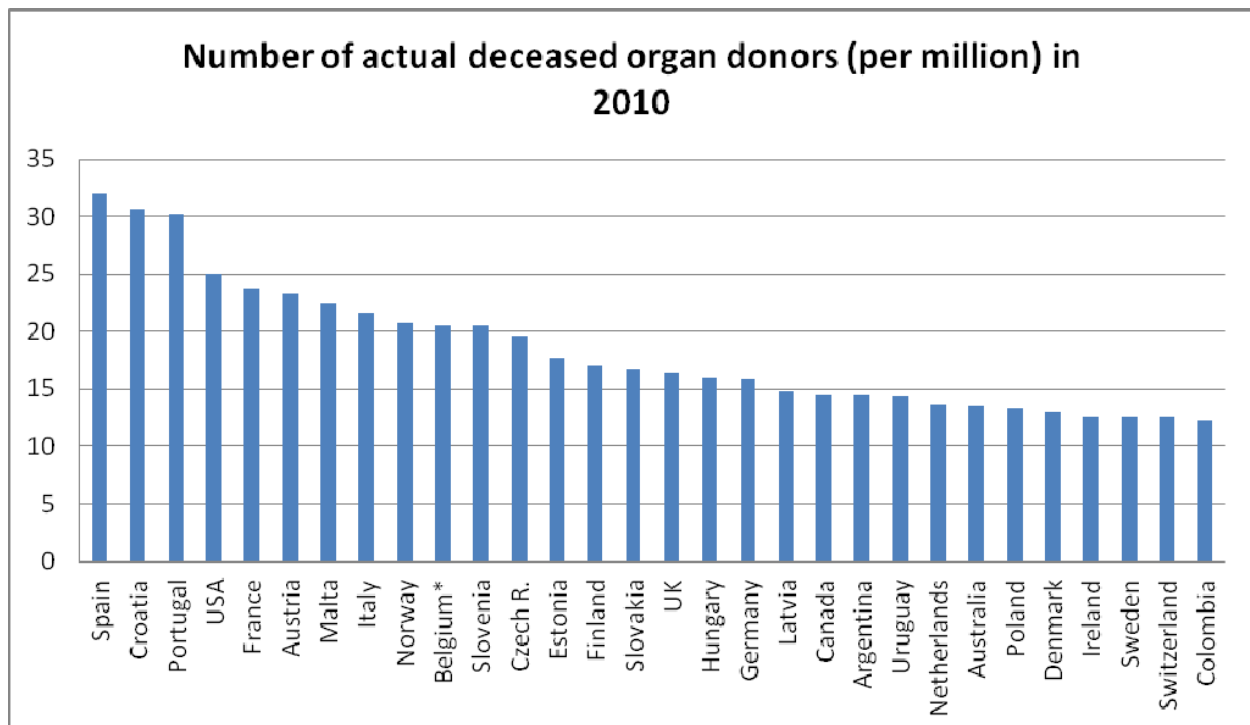


Fig. 2. Total number of transplanted organs in Croatia (1972–2010) from deceased and living donors

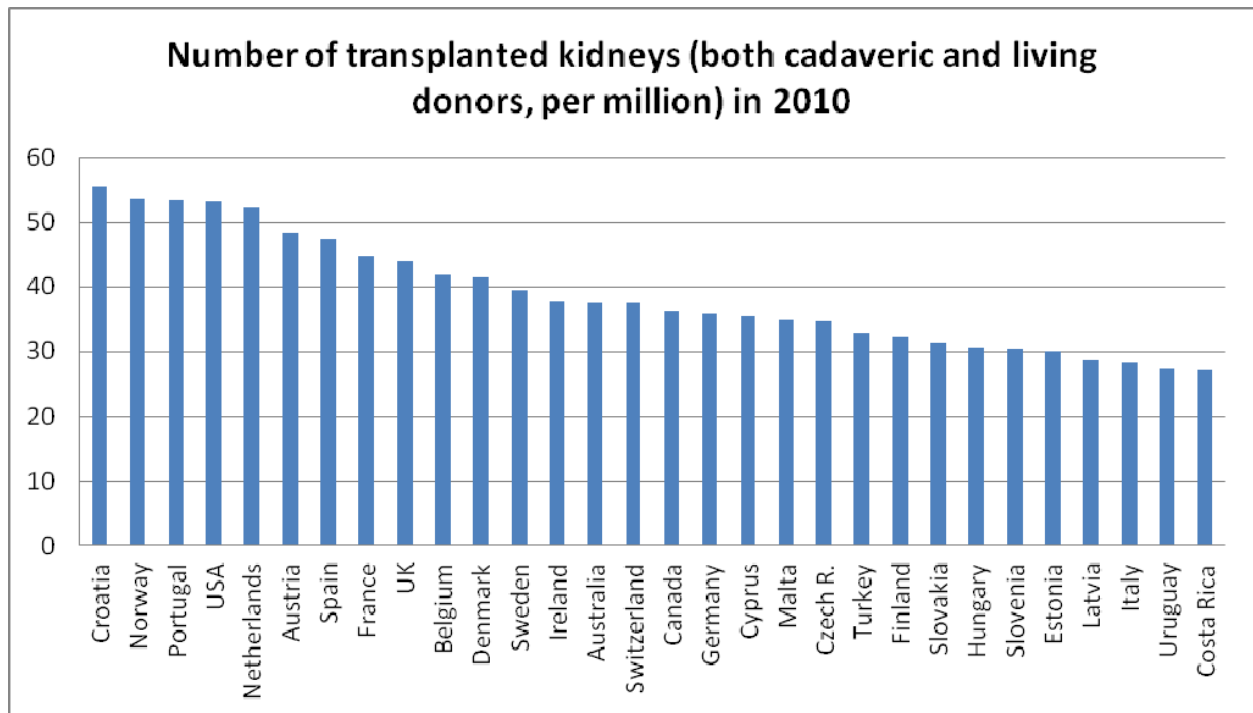
While in recent years the number of donors has been stagnating or only slightly increasing by 2% per year on average in Europe, last year Croatia burst its own annual number of donors and overall number of transplantations, increasing both by 64% and 54 % respectively (Fig. 2.), thus positioning Croatia at the top of the world's transplantation scene. Similar success was recorded only in Spain and Portugal, while many other highly developed countries (such as the Netherlands, the United Kingdom, and Norway), which traditionally rely on living and donation after circulatory death (DCD), significantly lagged behind Croatia, both in deceased and overall donor and transplantation rate. More specifically, when comparing the international data for 2010 (The Transplant Newsletter of the Council of Europe, 2011), a wide range of organ donation rates among countries is still observed. The world leader Spain had the highest actual donor rate (32 pmp), followed by Croatia and Portugal (30,2 and 30,1 pmp) (Fig. 3).



\*Source; Newsletter Transplant of the Council of Europe 2011

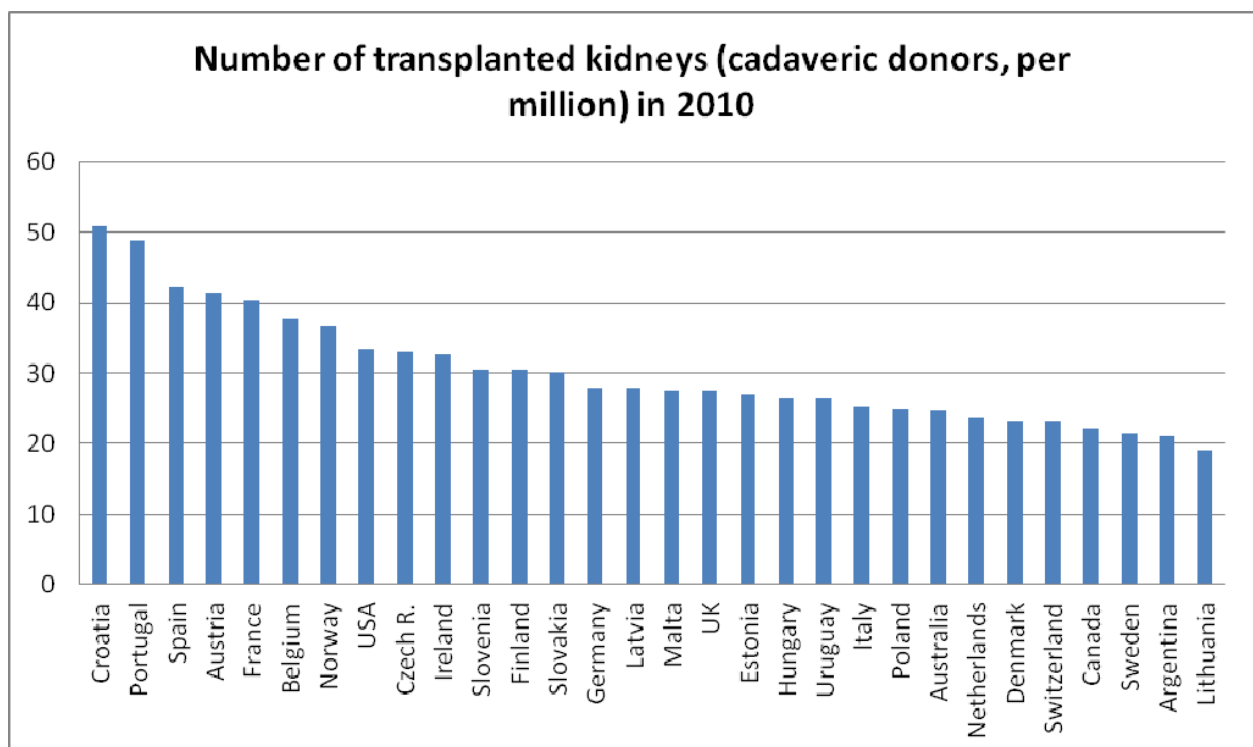
Fig. 3. Number of deceased organ donors/per million in 2010

The Republic of Croatia ranked first in the world in the number of transplanted kidneys (overall and deceased) (Fig. 4., Fig. 5.), and the number of transplanted livers per million people (Council of Europe, 2010) (Fig. 6.). At the same time, along with Austria, Croatia ranked second in the heart transplant rate (Fig. 7.). If we compare the total transplant rate, Croatia ranked third in the world; only the United States and Austria reported a higher total number of transplantation performed per million populations due to high number of lung transplants (Fig. 8.).



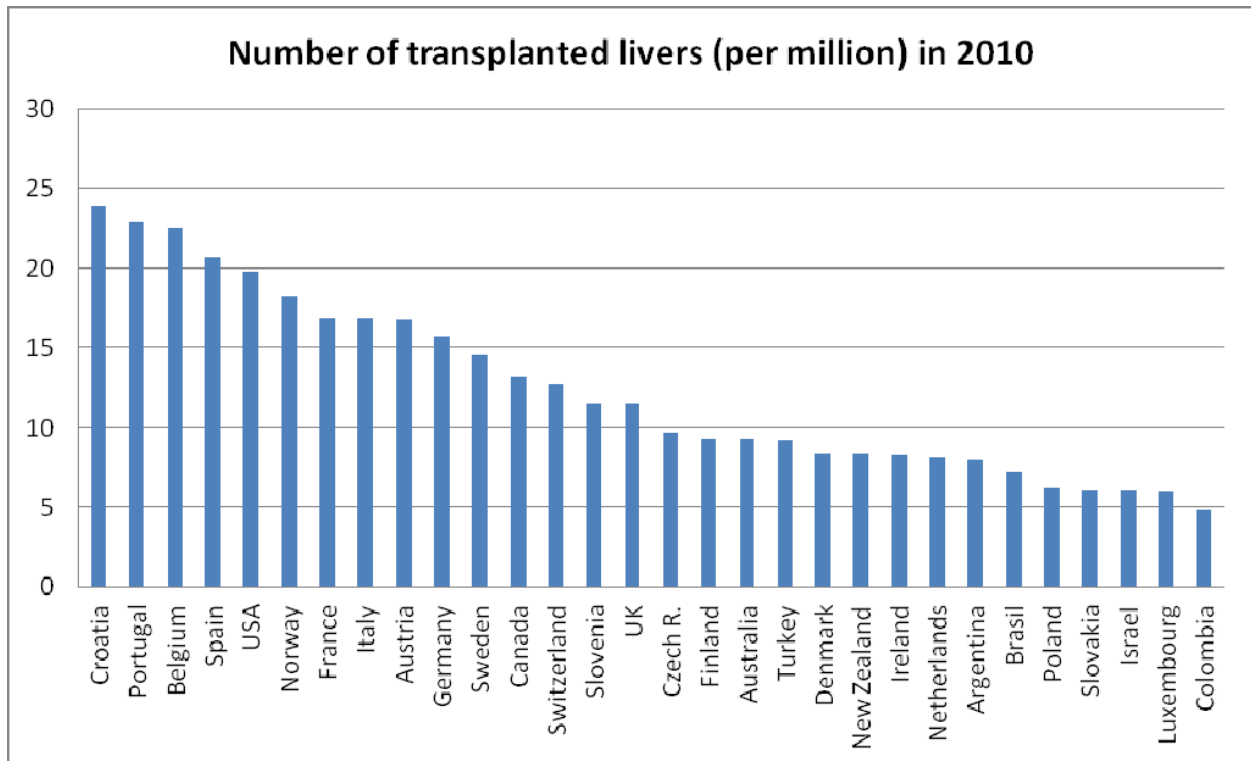
Source: Newsletter Transplant of the Council of Europe 2011

Fig. 4. Number of total transplanted kidneys (cadaveric and living donors) per million in 2010



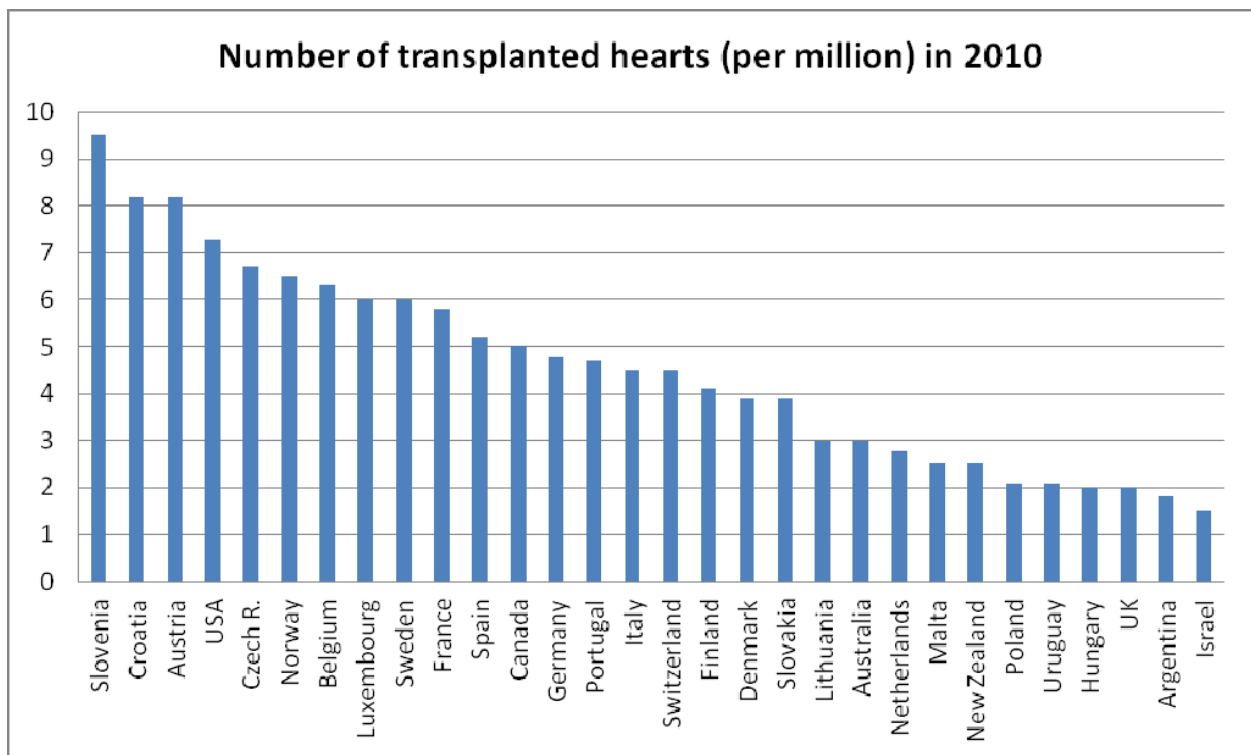
Reference: Newsletter Transplant of the Council of Europe 2011

Fig. 5. Number of transplanted kidneys (cadaveric donors) per million in 2010



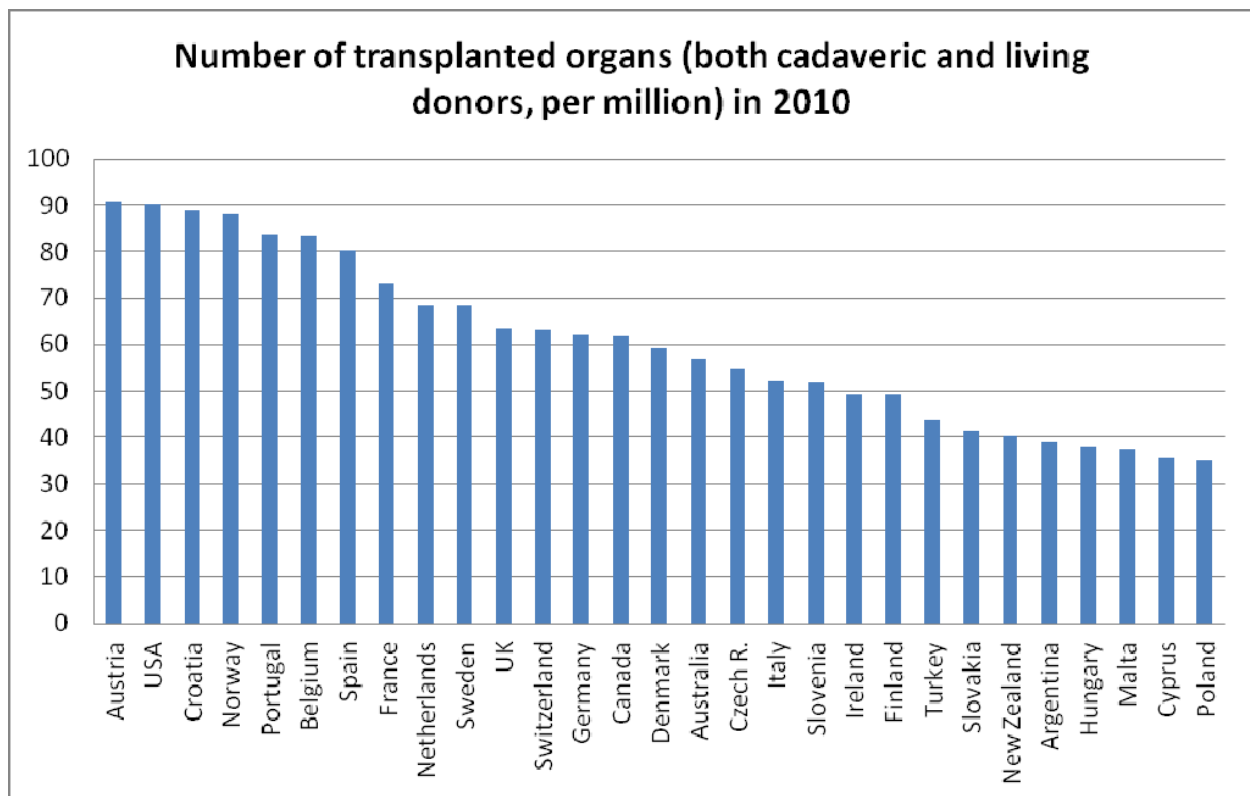
Reference: Newsletter Transplant of the Council of Europe 2011

Fig. 6. Number of transplanted livers (cadaveric and living donors), per million in 2010



Reference: Newsletter Transplant of the Council of Europe 2011

Fig. 7. Number of transplanted hearts/per million in 2010



Reference: Newsletter Transplant of the Council of Europe 2011

Fig. 8. Number of total transplanted organs (cadaveric and living donors) per million in 2010

Even being the newest Eurotransplant (ET) member, in comparison with other ET member countries, Croatia ranked first in the total transplant and donation rates in 2010, and had the highest percentage of multiorgan donors (85.5%) (Table 1.).

EUROTRANSPLANT COUNTRY	POPULATION	DONORS 2009	DONORS 2010	DONOR RATE 2009	DONOR RATE 2010	TREND	% MULTI ORGAN 2010
AUSTRIA	8,357	212	189	25.36	22.61	-10.84%	76.7%
BELGIA	10,827	276	263	25.49	24.29	-4.70%	74.9%
CROATIA	4,443	77	127	17.15	28.67	+67.17%	85.5%
LUXEMBURG	0.502	0	3	0	5.97		100%
NETHERLANDS	16,065	215	216	13.38	13.44	+0.4%	68.5%
GERMANY	82,329	1196	1271	14.52	15.45	+8.42%	83.2%
SLOVENIA	2,054	33	40	16.06	19.47	+21.2%	80.0%
EUROTRANSPLANT	124,623	2009	2109	16.12	16.92	+4.96%	77.5%

\* Source: Eurotransplant Internation Foundation Annual Report 2010

Table 1. Eurotransplant members; Donor/transplantation rate 2009/2010

Moreover, in 2011 this trend continues and there is an additional increase of 29.5% in the donor rate in Croatia, for the first 6 months of 2011 alone.

### **3. The history of Croatian deceased organ donation and transplantation system development**

Croatian transplantation medicine has a long history of 40 years which has blossomed into a modern transplantation practice that successfully keeps pace with the development of all contemporary transplant surgery techniques and immunosuppressive therapy. The first kidney transplantation was performed in 1971, only 17 years after the first successful kidney transplantation in the world which occurred in 1954. The first heart transplantation in Croatia was performed in 1988, and only two years thereafter the first liver transplantation. Even as early as the 1980-ies, during the time of former Yugoslavia, the professional community felt the need to establish an umbrella organization for a transplant programme (Jugotransplant/later Crotransplant). Although for a long period of time the initial enthusiasm and development of transplant surgery techniques were not accompanied by appropriate organizational measures. Political and historical circumstances during the Homeland War (1991-1998) additionally prevented the progress and advancement of transplantation medicine during that period; all transplantation activities were brought to an almost complete halt due to moral and ethical implications. As a result, the liver transplant programme only became established as of 1998.

Originally conceived in the 1980-ies, the goal of such an "umbrella" organisation, was to provide logistical support to donor hospitals, procurement and transplantation teams, coordinate cooperation, maintain and monitor waiting lists, and carry out organ allocation in a transparent manner and in accordance with the defined criteria. The historical and political circumstances at the time (the disintegration of the former Yugoslavia and the Homeland War) did not favour such a development though. After the disintegration of Yugoslavia and the onset of Croatia's independence, the health policy searched for priorities in other areas of the health care system that had suffered the greatest losses during the war. Even so, immediately following the end of the Homeland War, there was an attempt at improving the donor rate by following the "Spanish Model". The first concrete step was taken by the adoption of the Minister's Instruction in 1998, 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 (Ministry of Health of the Republic of Croatia, 1998). The basic objective was to increase the organ donation and transplantation rate in the Republic of Croatia to that of other average developed European countries. The Instruction proposed the following measures for the realization of this objective:

- defining the structure (organisation) for the implementation and monitoring of the deceased donation and transplantation programmes
- organising procurement teams
- increasing diagnostic equipment availability in hospitals for determining brain death
- allotting funds for the transplantation programme
- planning and providing additional training for professionals (including training programmes regarding the psychological aspects of the family approach)



- initiating organ donation and transplantation promotion activities for public awareness
- legally recognized brain death criteria.

The gradual implementation of these measures enabled a sustained and continuous increase in cadaveric organ donations over the last 10 years. It has been followed in tandem, by an increase in the overall number of solid organ transplantations and development of new surgical techniques; in 2003 multi-organ kidney- pancreas, liver- kidney, and the transplantation of the small intestine. Additionally in 2007 Croatia became a full member of Eurotransplant and Croatian transplantation medicine has since been successfully representing a part of the integrated health care system reflective of the overall EU health system.

### **3.1 The condition of the organ donation and transplant program ten years ago**

Only ten years ago, the professional community, political establishments, health institutions and public perceptions hit a wall. After almost 30 years of practice the transplant programme was almost completely shut down due to organ shortage. The long waiting list discouraged patients and the public. The media then reported the crushing status of Croatia's transplantation programme which when compared to similar European countries, was at the tail end of Europe, especially concerning donor rates (Fig. 2.). The future of the entire programme was at stake and the outlook was very bleak.

The lack of appropriate structure (e.g. organisation) and health administration support, coupled with faulty legislation and vague organ allocation criteria presented only some of the problems which further jeopardized the programme.

From an ethical perspective, and probably the most sensitive process of organ distribution was additionally burdened by the organ shortage, resulting in the "desperate " behaviour demonstrated by transplant centres aggressively determined to fight for the lives of "their own" patients, without taking an objective stance towards the clinical status and urgency of a possible recipient from other centres. On the other hand, the long and outdated waiting list led to frequent rejection of potential candidate patients for transplantation as being clinically unsuitable, due to their outdated or incomplete pre-transplant evaluation results. In 2000, there were approximately 900 patients on the national kidney waiting list and the average waiting time for a kidney transplant ranged between 7 and 15 years. In addition to long-term and overwhelming organ shortage, the principle frustration and weakest point moving forward at that time was the lack of appropriate central organization to comprehensively and competently manage the overall implementation and supervision of the programme.

### **3.2 Action taken to increase donor rate between 2000 to 2010**

Since 2000, different actions have been taken on three levels which have been successfully and gradually implemented and have subsequently led to the continual increase in the donor rate in Croatia. The "key" to Croatia's success, similar as in Spain, is an integrated approach and set of initiatives designed and facilitated by the National Transplant Coordinator, to strengthen all components of the organ donation and transplantation processes; a strategy that clearly articulates jurisdiction, responsibilities and accountabilities at three levels: national, hospitals and public/individuals (Table 2.).

National level (at the Ministry of Health)
<ul style="list-style-type: none"> <li>National Transplant Coordinator appointed at the Ministry, year 2000, responsible for the National Transplant Programme planning, monitoring and implementation</li> </ul>
<ul style="list-style-type: none"> <li>National 24 hour "duty coordination office" established at the Ministry with part-time employed Transplant Coordinators-medical students, doctors) and the following tasks:           <ul style="list-style-type: none"> <li>Keeping a National Non-donor Registry</li> <li>Keeping a National Waiting list (later assigned to Eurotransplant in 2007)</li> <li>Coordinating the donation process and providing logistical support to procurement teams and donor hospitals</li> <li>Supporting and auditing the organ allocation process (partially assigned to Eurotransplant beginning in 2007) and exchange of organs</li> <li>Keeping the Registers of Donors and Transplanted Patients (follow up)</li> <li>Processing and keeping overall data on donation and transplantation</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>2003 National Training programs for intensive care unit (ICU) doctors and hospital coordinators were launched</li> </ul>
<ul style="list-style-type: none"> <li>2003/04 International cooperation (exchange of livers for high urgent patients) established with Italy (Nord Italia transplant/Centro National Trapinati)</li> </ul>
<ul style="list-style-type: none"> <li>2004 New transplant legislation adopted</li> </ul>
<ul style="list-style-type: none"> <li>2006 New Financial model implemented (Reimbursement to donor hospitals)</li> </ul>
<ul style="list-style-type: none"> <li>2006/7 International cooperation established- Eurotransplant membership</li> </ul>
<ul style="list-style-type: none"> <li>2002-2010 External "audit"/inspection (Quality assurance programmes in the deceased donation process), started</li> </ul>
<ul style="list-style-type: none"> <li>As of 2004-Procurement of hospital equipment for the purpose of diagnosing brain death / funds from the Ministry</li> </ul>
Hospital level
<ul style="list-style-type: none"> <li>In-house transplant coordinators appointed in each hospital with ICU, and supported by the Ministry, started in year 1998</li> </ul>
<ul style="list-style-type: none"> <li>Training Programme for Coordinators and ICU doctors, provided by the Ministry of Health (national Training Course or international Transplant Procurement Management)</li> </ul>
<ul style="list-style-type: none"> <li>Donor Quality Programme (donor action implemented in some hospitals as pilot project)</li> </ul>
<ul style="list-style-type: none"> <li>Donor family psychological support /reimbursement of funeral/transport costs</li> </ul>
Public level
<ul style="list-style-type: none"> <li>National public awareness campaign 'New Life as a Gift' launched 2005</li> </ul>
<ul style="list-style-type: none"> <li>Since 2006, Croatia has inaugurated an official National Donor Day           <ul style="list-style-type: none"> <li>Celebration of European Donor Day (EDD);               <ul style="list-style-type: none"> <li>Various activities aimed to increase public awareness/ every year</li> <li>2010 as associated partner in EU funded EDD project</li> </ul> </li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Close cooperation with patient support groups and Non-government organisation (NGO):           <ul style="list-style-type: none"> <li>Croatian Donor Network (Donor Card)</li> <li>Association of Transplanted Patients</li> <li>Association of Dialysed Patients and Transplanted Patients</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>Media cooperation ongoing</li> </ul>

Table 2. Actions taken on three levels to improve donor rate

At the same time, its implementation had been strongly supported by the National Transplant Coordinator (NTC) representing the Ministry of health (i.e. health administration). Health professionals had been provided with a different kind of support in order to obtain the strategic goals – the first being primarily to increase the deceased organ donor rate. The following text describes in detail only some of the measures which have played a key role in the "phenomenon" which has occurred in the Croatian transplant programme.

#### **4. The introduction of a key role - National Transplant Coordinator (NTC)**

The introduction of the position of National Transplant Coordinator at the Ministry of Health and Social Welfare in 2000, i.e. a medical doctor full-time employed at the Ministry for the purpose of improving the transplantation system, represented a milestone and turning point in the programme. The introduction of the position of NTC precisely within the Ministry of Health and Social Welfare resulted in a solution of crucial importance for the increased number of donations and transplantations in Croatia.

The Minister at the time (as well as all Ministers thereafter, together with State Secretaries) had offered their unconditional support to the NTC, giving her "free" hands in planning and implementing measures to improve the program. Having that support, the NTC started work using all available legal instruments and the political strength of the Ministry to achieve the programme goals set forth and to introduce necessary, often "painful" changes within the health system. It is also important to point out that the existing condition of the programme was devastating and, at best described, chaotic. At that time the donor rate in major university hospitals was at an all time low, while general (county) hospitals were completely inactive. The NTC's enthusiasm, persistence, dedication and autonomy in work, and constant availability outside regular working hours had proven to be crucial in linking individuals, teams and institutions into a cooperative and harmonious whole during the initial stages of work. Such an approach encouraged the formation of a positive environment and long-term collaborative trust between professionals and the health administrations, which in the eyes of the professional community was a synonym for the "unpopular" political, rigid, slow and inefficient bureaucratic system. The wide authoritative power granted to the NTC in addition to great enthusiasm and commitment of many coordinators, procurement teams, health (co)workers and individuals enabled the beginning of implementing measures following the example set forth and recommended in a European consensus document: Organ shortage: current status and strategies for improvement of organ donation (Council of Europe, 1999). By initiating close cooperation and direct communication with hospital transplant coordinators, the NTC's commitment and engagement, in tandem with the authority of the Ministry encouraged swift and efficient solutions for problems coordinators were facing, (particularly at the beginning stages of establishing the donor programme in hospitals). Simultaneously, in a dialogue with hospital managers, the NTC continued strengthening the role and authority of hospital transplant coordinators. The entire system during that period was changed by the newfound enthusiasm of many health workers as well as that of national and hospital transplant coordinator and their co-workers who worked without any financial compensation or totally inadequate financial compensation.

In close collaboration with Referral Centre for Neurovascular Disorders of The University Hospital Centre «Sestre milosrdnice», the NTC began promoting the widespread use of hospital applications (e.g. TCD and EEG) as methods used for confirming brain death. In conjunction with systematic training for the neurologists provided by the Referral Centre, the National Transplant Coordinator carried out a plan beginning in the year 2004 to acquire (TCD and EEG) hospital equipment for qualified hospital personnel. Each year selected hospitals were outfitted (by the Ministry) with the technical diagnostic equipment necessary for use in confirmation of brain death, and overall support for multi-organ and tissues explantation. Continuous improvement in education and hospital technical equipment for diagnosing brain death has been one of the measures that has enabled a 100% increase in the number of explantation centres (e.g. donor hospitals) over the last 10 years. Nowadays almost 70% of hospitals with acute beds are donor hospitals e.g. hospitals which are able to independently complete all steps of the donation process, from donor identification to its conversion into an actual/effective donor.

In 2002/2003 external audits, based on classic health inspection supervision, were performed at the five major hospitals with the aim of detecting patients' actual brain death rate occurrence and reasons for loss of donors. Inspection supervisions later grew into a form of expert-motivational supervision, which proved to be a more efficient and better accepted method of cooperation with hospitals. Upon completion of supervision followed an evaluation of rationale, corrective measures and the proposed deadline for their implementation. Such concept of supervision was based on retrospective analysis of "lost" donors, modelled after the Spanish Donor Quality Assurance Programme, the methodology of which was later described in detail in an EU project funded by the European Commission under the title DOPKI (Improving the Knowledge and Practices in Organ Donation, 2007).

It was evident that most of the hospitals were missing protocols, guidelines and criteria for each of the steps of the donation process. Very few professionals were additionally trained and skilled in communication, the family approach, or donor management at the time. Therefore, in 2002/2003 the NTC initiated preparation of new legislation along with a set of protocols and algorithms, e.g. of significant importance being donor detection and reporting the death of persons eligible as donors, that had been identified in the "Ordinance on the Reporting Procedure of the Death of Persons Eligible as Donors of Parts of the Human Body for Therapeutically Oriented Transplantation" (Ministry of Health of the Republic of Croatia, 2005).

Different training modules and programmes have been designed and launched in close collaboration with the Croatian Donor Network, panel of national experts, internationally recognised transplant managers and Non-government organisation (NGOs). Specific training modules were designed according to donor hospital objectives and combined with motivational one-day visits to the hospital. In recent years training programs were successfully extended with licensed or EU funded training modules (such as TPM, ETPOD etc.) Direct contact and visits to hospitals with training programmes adapted towards the specific problems of the hospital have remained to this day to be one of the most efficient and preferred forms of cooperation between the NTC and hospital institutions. Along with the set of protocols/ordinances and guidelines set up in regard to the donation process, the NTC had initiated the standardization of work-up protocols and criteria for admittance of

patients to waiting lists; in 2005/6, in cooperation with a panel of experts, national guidelines (Ministry of Health and Social Welfare, 2006) for kidney transplantation were prepared and a complete re-evaluation of patients on the waiting list carried out, in line with the defined standard set of tests (Ministry of Health and Social Welfare 2006). Furthermore, criteria for the organ allocation and National Waiting List management were regulated by the "Ordinance on the Criteria for the Allocation of Parts of the Human Body and the Method of Keeping the National Waiting List" (Ministry of Health, 2005).

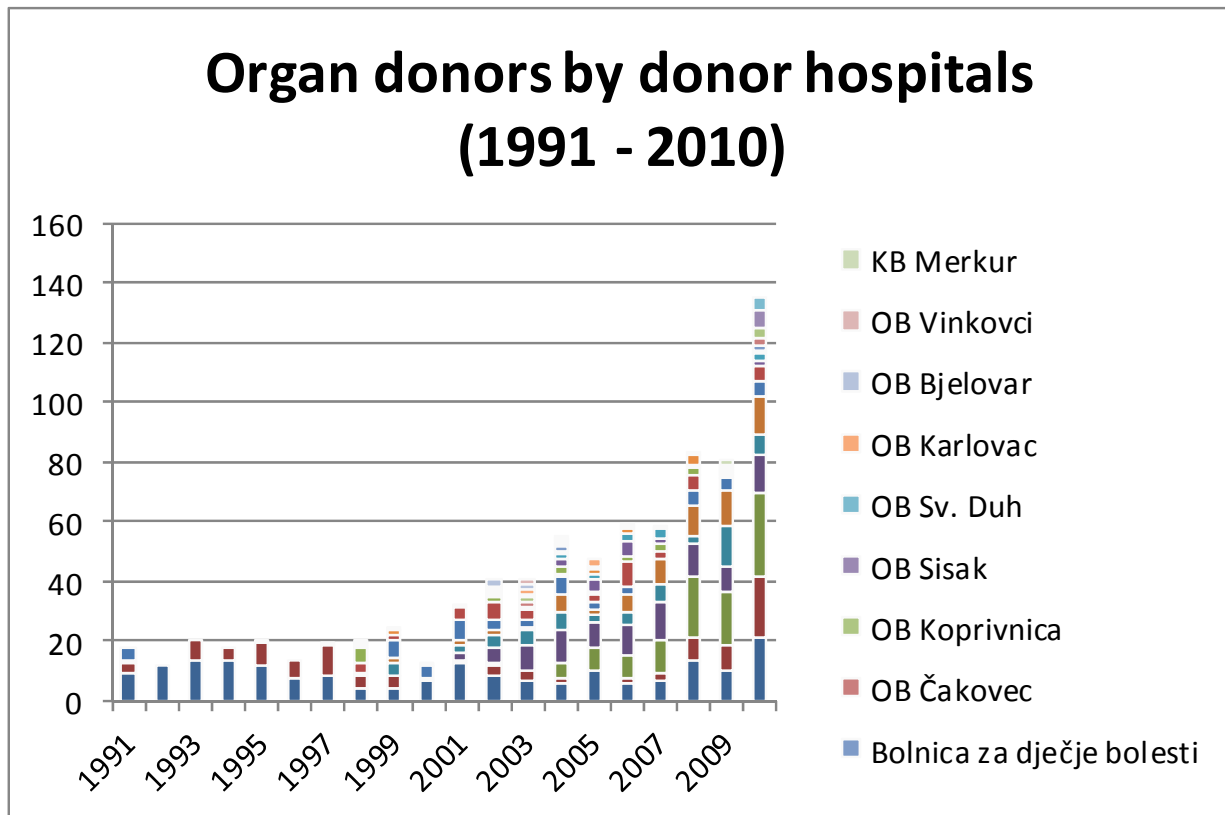
Up until 2007, the NTC most often single-handedly organized the "round-the-clock" duty office for coordination of donor referrals, organ sharing, and procurement and transplant activities, in addition to numerous other tasks during regular working hours. Due to an employment freeze in the work force, the NTC single-handedly (with occasional short-term help from colleagues and co-workers) performed all tasks which, pursuant to the Recommendation of the Council of Europe on National Transplant Organisation (NTO), should have been under the jurisdiction of the National Transplant Organisation, i.e. an entire team of people. In 2007, the Transplantation Department was established at the Ministry as a surrogate for a National Transplant Organisation, although unfortunately, with limited scope of authority and insufficient technical capacities. Today, however, the Department has three full-time employees (a psychologist and 2 physicians) and six additional contracted transplant coordinators, mostly fifth and sixth year medical students to fulfill the required needs of maintaining a 24-hour office for referrals of potential donors, coordination and monitoring of all donation activities, and exchange of organs with Eurotransplant member countries.

The model of employment and organization of a 24-hour coordination system at the Ministry presented a big challenge for the civil service which was already stigmatized by the employment ban, non-stimulating salaries, slow administrative procedures and inability to reward its employees. Nonetheless, a successful temporary solution was found in "flexible" models of employment utilizing medical students and interns (part time contracted). The organization of the national coordination Department within the Ministry represented an economically rational substitute to contemporary NTO/agency models. At the same time, however, the work and operability of such a model (organisational unit of the Ministry) were and have been to a large extent limited by slow administrative procedures of the state administration, whose office operations, operational and technical equipment have not been suited to meet the need of a modern transplantation system (24-hour on-call duty, operational and financial interconnectivity of the entire healthcare system, swift and standardized communication, highly specific procedures, flexibility in emergencies, operative independency, appropriate authority in adopting decisions on an international level). The manner of operation of state administration and the principles of good administrative practise are in essence contrary to the principles of good "coordination" practise and consequently affect the manner of operation of national transplant organisations.

## **5. Network of Hospital Transplant Coordinators (HTC)**

The second key element and important backbone of Croatia's organisational model is a network of in-house hospital transplant coordinators, consisting of physicians, mostly anaesthesiologists, employed full time in intensive care units in hospitals, who perform

coordination in addition to their other job duties. Each acute hospital has an in-house coordinator (hospital transplant coordinator - HTC), i.e. a key donation person responsible for donor identification, management and realization of organ and tissue donation. The role of HTC has proven crucial in the early detection of each potential donor and its conversion into effective donor. Due to the complexity of the donation process in and of itself, the HTC's additional engagement was necessary outside the "routine" job duties and working hours. This included motivation, enthusiasm, training, communication and organisational skills and the creation of a positive attitude within the working community, i.e. hospitals and ICUs. The hospital in-house transplant coordinators network in Croatia consists almost exclusively of intensive care specialists (not necessarily the heads of intensive care units), whom, by the proposal of the hospital director, are appointed to the position by the Minister from the existing human resources of the hospital. Such profile of highly trained, skilled and motivated coordinators, mostly ICU doctors had proven to be another key factor for success of the donation programme in Croatia as well as in Spain (Salim et al., 2007).



Reference: eNTM - <http://transplantacija.mzss.hr/eNTMV2/>

Fig. 9. Number of organ donors by donor hospitals (1991 - 2010)

Proof of this is particularly evident in many Croatian hospitals (Fig. 9.) (University Hospital Centre "Sestre Milosrdnice", University Hospital Centre Rijeka, Varaždin General Hospital, Sisak General Hospital, University Hospital Dubrava), which only, after appointing highly trained coordinators with professional authority, have witnessed multiple growth in donor rates.

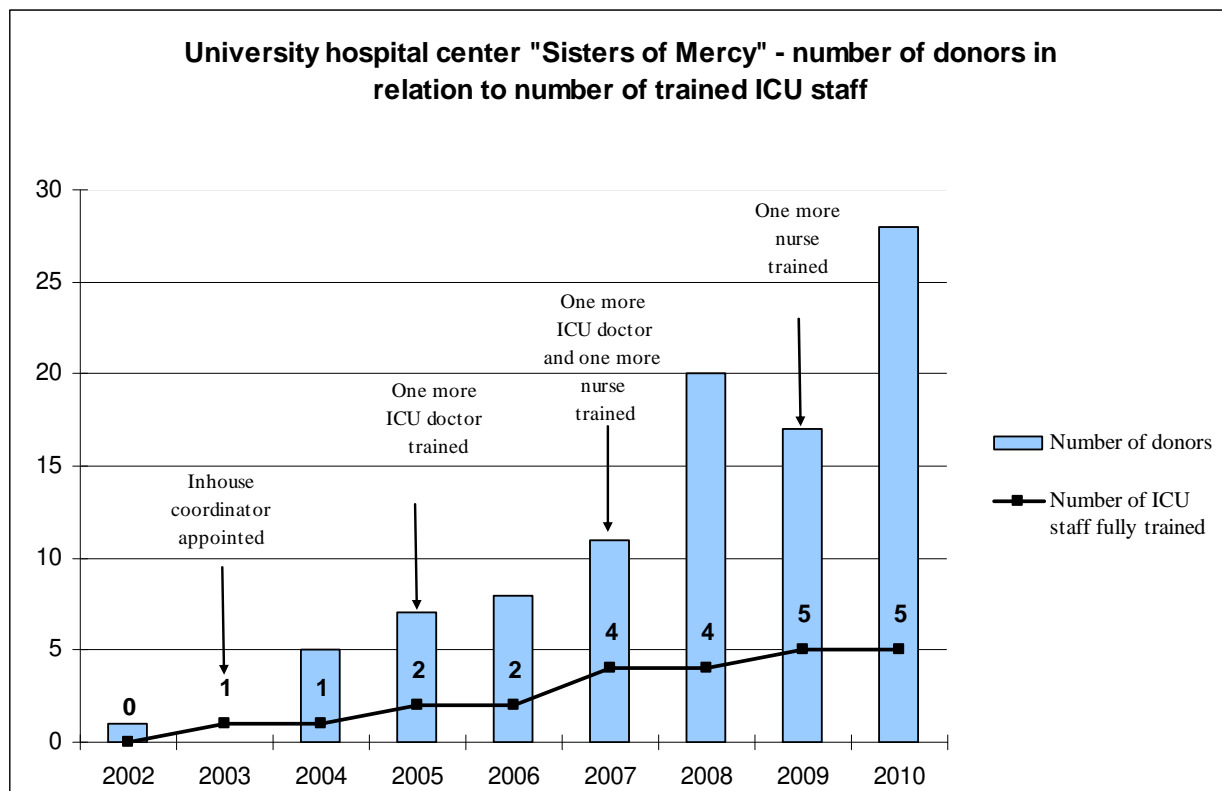


Fig. 10. Numbers of donors in University hospital centre Sestre Milosrdnice

Those highly trained hospital coordinators played a crucial role in creating a positive attitude among health care workers in intensive care units, and the implementation of good intensive care practice, i.e. care for the donor as continuation of care for the dying patient (Fig. 10.). Namely, the intensive care units staff in Croatia, like in most of countries, had and still are traditionally trained in patient care and dying patient care, but not necessarily in organ donor care. Consequently, brain death is frequently seen as a situation in which any further therapy e.g. donor maintenance is not needed. This represents the moment when the decision to continue invasive "monitoring" and therapeutic maintenance for the purpose of potential donorship, is crucial, but unfortunately in practice very often not made. (Van Gelder et al., 2008). Retrospective analysis carried out in Belgium shows that precisely such denial of therapeutic support of the dying patient is the most frequent reason for donor under detection (Van Gelder et al., 2007). The Spanish Model uses an opposite approach, which Croatia has followed and is highly successful mostly because organ donation (organ donor care) has been integrated into intensive care therapy, rather than being superimposed into it. In that way, the decision to continue of care for the dying patient (care for the purpose of organ donation), must be always made no matter what circumstances are presented by the shortage of funds or human resources. All of this reinforces the extraordinary importance of in house transplant coordinators as the key donation person responsible for the implementation of a pro-active approach, i.e. a timely detection of potential donors, clearly defined algorithms for their optimum care and unique donor treatment methodology within all intensive care units and emergency departments.

## 6. Financial incentives

The therapeutic promise of transplanting organs from cadaveric donors, as envisioned by the pioneers of transplantation, (Starzl, 1992) has never been realized because the demand for cadaveric organs has far exceeded the supply. In the year 2000 several possible financial incentives for deceased organ donation (such as payments, tax benefits, funeral reimbursement, and charitable contribution) were considered in the United States to determine whether any of these approaches could be used as an ethically acceptable model for a pilot trial to increase donation. The ethical methods outlined in the Table 3. (Delmonico, 2004) were developed so that they could be applied to any proposal to elucidate its propriety.

<ul style="list-style-type: none"> <li>• It should preserve the concept of the organ as a donated gift</li> <li>• It should convey gratitude for the gift</li> <li>• It should not subvert or diminish the current standard of altruism</li> <li>• It should not be an excessive inducement that would undermine personal values and alter decision-making solely to receive the compensation</li> <li>• It should preserve voluntariness (e.g. so that a family member is not coerced to donate by the will of another family member solely to receive the compensation)</li> <li>• It should not lead to a slippery slope that fosters the sale of live human organs</li> <li>• It should honour the deceased (i.e. it should not dishonour the merit of an individual's life by assigning a monetary value for the individual's organs)</li> <li>• It should respect the sacred nature of the human body by not intruding or tampering without specific permission</li> <li>• It should serve the public good by maintaining the current public perception of organ donation as good</li> <li>• It should maintain public trust by the following: not altering patient care by premature life support withdrawal from the person who might donate and not placing transplant recipients at increased health risk by jeopardizing the integrity of the organ pool.</li> </ul>
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Table 3. Recommended characteristics of a proposal to provide financial incentives for deceased donation

Finally, a panel of experts concluded that reimbursement for funeral expenses fits within the guidelines and maintains the standards established by the ethical methods (Delmonico, L.F 2004). The importance of allotting funds for a transplant programme had already been recognized in Croatia in the late 1990-ies when the obligation to secure additional funds for the payment of the following was adopted by the Instruction of the Minister (Ministry of Health of the Republic of Croatia, 1998):

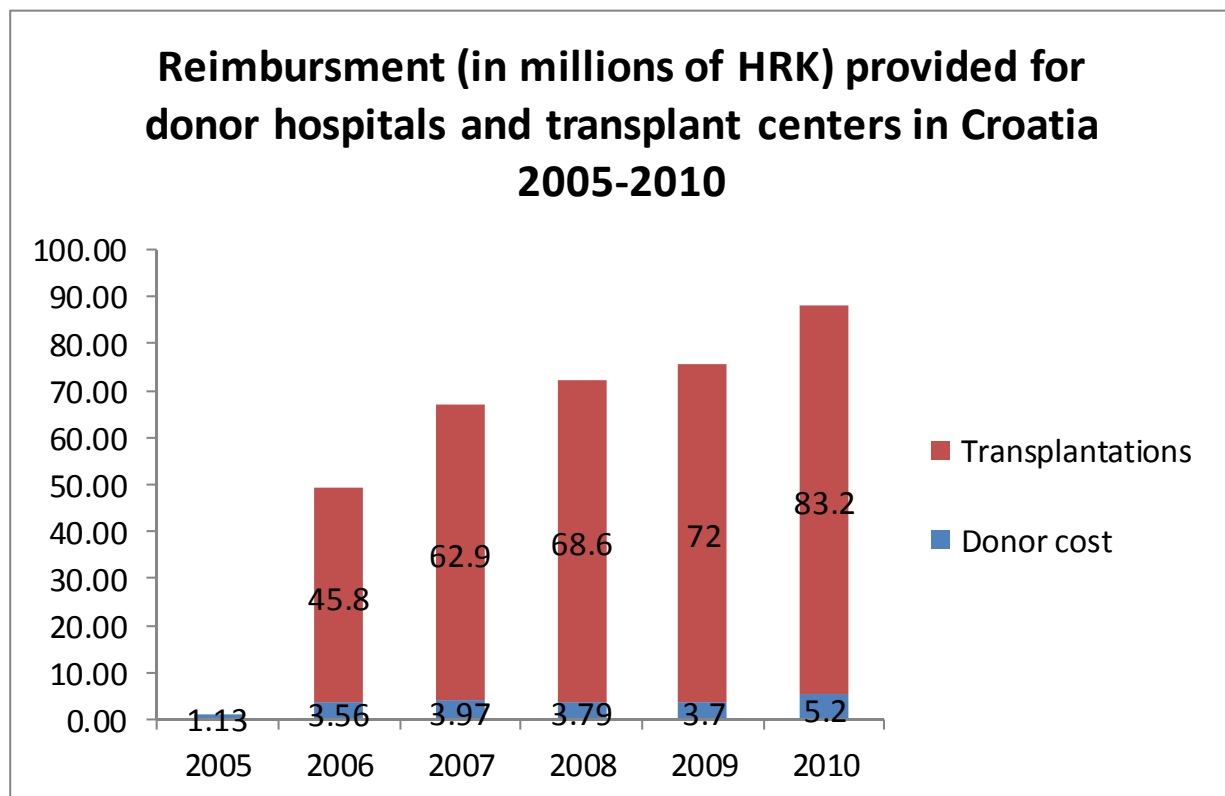
coordinator preparedness, procurement teams preparedness, preparedness of employees in centres for tissue typing, reimbursement of donor management and transplantation services costs, reimbursement of transport cost of the body of the deceased after organ donation.

Similar to the United States, reimbursement of transport cost of the body of the deceased organ donor has been implemented as the only ethically acceptable incentives on the donor side. Although there is no evidence that this kind of approach helps families to make their decision towards donation, it has been reported from HTCs that sometimes it might positively influence the family's decision. Even though such an incentive measure is



definitely welcome, it does not play a crucial role in increasing donor rates. Reimbursement of donor preparation cost above the hospital budget limit, is considered to be by far the most important economic incentives (Matesanz et al, 2009). This is understandable, keeping in mind the fact that most hospitals are chronically underfunded and that financial disincentives are given at the costs of donor management and organ retrieving procedures. Furthermore, as most hospitals are neither dedicated transplant nor dialysis centres, there is no infrastructural support or financial incentive (such as removing patients off dialysis) to identify donors and procure organs.

Yet in the years preceding 2006, most donation activities in Croatia had been based on the enthusiasm and initiative of a few individuals who performed job duties outside regular working hours and without appropriate compensation or any compensation at all. A period of eight years was required to fully implement the set of financial incentives as adopted in 1998. Nowadays transplantation procedures and donor preparation are regularly contracted and reimbursed under a special state budget item, independent of the hospital budget limits. The cost of transplantation procedures and donor preparation are reimbursed by the HZZO (Croatian Health Insurance Institute) according to the DRG (Diagnosis Related Groups) system. The amount of HRK 70,000-350,000 is reimbursed to the transplant centre depending on the complexity and type of transplantation procedure. At the same time, donor hospital receives HRK 40,000-55,000 for donor preparation and realization, depending on donor category (multiorgan, organ or tissue donor). This amount is allocated for the coordinators' extra work salary, cost of brain death diagnostics and donor evaluation tests.



Source: HZZO report

Fig. 11. Reimbursement costs for donor hospitals and transplantation centres

## 7. International cooperation - Eurotransplant membership

International cooperation is recommended by the European Commission as being desirable for increasing the donor rate and harmonising the level of transplant availability among countries (European Commission June 27, 2006). Soon after 2000, due to organ shortage and the implementation of new transplant techniques it has become more evident that Croatia must find a solution for a specific group of patients (highly urgent, highly sensitised and children) and increase the chances for a timely procurement of organs for highly urgent patients and of finding a compatible organ for highly sensitized patients.

From the very beginning, Italy was considered as a good potential partner for several reasons: a neighbouring country, with developed transplantation medicine, high donor rate and the necessary organisational infrastructure, short distance, and historically based long-term cooperation and exchange of experts in the field of transplant medicine (Veneto Region and Istria and Rijeka). Underscoring the beginning of cooperation was the political significance that such regional cooperation represents, as well as unconditional support from the Italian National Transplant Organization. Following a short negotiation, a cooperation model was agreed upon which met the needs of the Croatian most endangered patient group (high urgent liver recipients). In 2004, a bilateral Agreement between the Italian National Transplant Centre and the Ministry of Health and Social Welfare of the Republic of Croatia was signed. The agreement defined the exchange of livers for high urgent patients, based on reciprocity, i.e. on "zero" balance of received and exported organs between Italy and Croatia. The cooperation resulted in a reciprocal benefit for 6 urgent patients (3 in Croatia and 3 in Italy) who received liver transplant in time to save their lives. In 2005, the extension of bilateral cooperation was discussed between an Italian and Croatian group of experts, with the aim of improving the chances for transplantation for a larger group of patients; paediatric recipients, sensitised kidney recipients, and combined transplants. Simultaneously, in light of the increasing donor rate (which presented one of the prerequisites for Eurotransplant membership), an idea arose at the Ministry for potential membership in Eurotransplant as one of the strategic goals of Croatian health policy. The feeling of historical affiliation with the West and the world view of developed countries, as well as current foreign policy efforts in Croatia's EU accession had made membership in Eurotransplant (international organization coordinating organ allocation among Austria, Germany, Slovenia, the Netherlands, Luxemburg and Belgium) one of the strategic goals of the Croatian health policy at that time. This goal, unlike many others, had from the very beginning been wholeheartedly supported by the professional community and the general public. The reason could be explained by the fact that Eurotransplant has a reputation of being one of the most prestigious international organizations with a long running tradition and expertise in organ allocation based mostly on the HLA match (of kidney allocation) and other well defined criteria. Namely, ethical dilemmas and a primary concern of the public had always focused on how to provide equal access and secure fair distribution of organs. Croatia, at that time, with its existing allocation system could hardly guarantee such high autonomy and consistency as a politically independent, international organisation, whose core business centered around an IT program for organ allocation. In 2006 Croatia became a Eurotransplant candidate member, and one year later a full Eurotransplant member. It was one of the recent accomplishments that positively influenced Croatia's National Transplant System resulting in quality improvements on several different levels; first of all the lack of a "traditional" central organization (in regards to sharing offices) was successfully overcome -

Eurotransplant membership gave Croatia a more transparent, objective, efficient and firmly structured system of organ distribution. Today, precisely this segment, which is the most sensitive towards the public, represents the most important reference and anti-corruption measure which guarantees transparency and focuses on maintaining long-term trust of the public and donor families in the health system.

Besides improving the allocation system, Eurotransplant membership had an indirect "motivational" effect on the professional community, and HTCs in particular. Namely, the loss, i.e. rejection of "marginal" organs as unacceptable or even rejection of good quality organs, used to be a "privilege" of our transplant centres, which often resulted in revolt and dissatisfaction of hospital transplant coordinators. In what was no doubt an attempt to find "ideal" organs for their recipients, transplant teams often rejected marginal organs, as unacceptable, even in times of organ shortage. Upon joining Eurotransplant, this practice as a result from a "monopolistic" position and lack of competition (in cases where only one TX centre existed) and a lack of any kind of supervision over ethical justification of such decisions, almost completely disappeared. Today, the acceptance and utilization of organs by Croatian donors fits into the Eurotransplant average (Table 4.) providing additional enthusiasm and representing an indirect incentive measure to all those caring for the donor.

KIDNEYS (2010)				
	ET	ET (%)	Croatia	Croatia (%)
Reported	4261	100 %	268	100 %
Offered	4182	98.1 %	263	98.1 %
Accepted	3925	92.1 %	246	91.8 %
Transplanted	3737	87.7 %	232	86.6 %
HEARTS (2010)				
	ET	ET (%)	Croatia	Croatia (%)
Reported	946	100 %	41	100 %
Offered	938	99.2 %	40	97.6 %
Accepted	750	79.3 %	35	85.4 %
Transplanted	631	66.7 %	33	80.5 %
LIVERS (2010)				
	ET	ET (%)	Croatia	Croatia (%)
Reported	1998	100 %	126	100 %
Offered	1996	99.9 %	126	100 %
Accepted	1955	97.8 %	125	99.2 %
Transplanted	1670	83.6 %	107	84.9 %
PANCREAS (2010)				
	ET	ET (%)	Croatia	Croatia (%)
Reported	944	100 %	38	100 %
Offered	920	97.5 %	38	100 %
Accepted	573	60.7 %	17	44.7 %
Transplanted	273	28.9 %	8	21.1 %

(ET Annual report 2010)

Table 4. Organ loss in 2010 – Eurotransplant average (ET) versus Croatia

Furthermore, in the field of immunogenetics, Croatia has made huge strides and significant progress in quality improvement, since this was an extremely important Eurotransplant requirement relating to the allocation criteria based on HLA matching.

Specifically, accreditation issued by the European Federation of Immunogenetics (EFI) for at least one laboratory for tissue typing was one of several prerequisites for ET full membership. The Tissue Typing Institute of the University Hospital Centre Zagreb, as the reference tissue typing centre met the requirement in May 2007, thus becoming the first Croatian medical laboratory with European accreditation. The tissue typing lab in Rijeka, although founded back in 1969, did not meet accreditation standards due to a lack of space, staff and methodological work standards. However, over the course of the next two years, and with financial and administrative support from the Ministry, the laboratory was successfully adapted, and finally met the accreditation criteria in September 2008. Currently it is the only EFI accredited centre for tissue typing in Croatia other than Zagreb.

High standards of immunogenetic testing are also required by specific Eurotransplant programmes, such as the "acceptable mismatch (AM) programme" intended for highly sensitized patients (PRA <85%). The programme offers a unique approach to the problem of highly immunized patients and significantly increases their otherwise slim chances of finding an appropriate kidney. It requires an extensive immunogenetic work-up which defines all HLA alleles for which HLA antibodies have not been created. In the case of an offered organ with precisely these antigens, the organ has to be primarily allocated to a patient from the AM programme.

There are numerous other benefits derived from Eurotransplant membership, such as a group of "high urgent" patients whose chances of a timely receipt of organs have been dramatically increased by ET membership.

## 8. Legislation

There are several legislative options for regulating organ donation and transplantation. Presumed consent represents one of the strategies aimed towards increasing cadaveric organ donation. In countries with presumed consent, citizens' organs are procured after their death, unless a person has specifically requested to be a non-donor. Advocates of the presumed consent approach might say that it is every person's civic duty to donate their organs once they no longer need them (i.e. after death) to those who do. People against presumed consent would argue that to implement this policy, the general public would have to be educated and well informed about organ donation, which would be difficult to adequately achieve (Hill DJ, Palmer TC, Evans DW 1999). Such presumed consent, also known as the opt-out system, is applied in over 20 European countries (Horvat, 2010). Croatia, alongside Spain, Belgium, Austria and Portugal, belongs to the group of European countries with presumed consent and the highest rate of cadaveric donors. In Croatia presumed consent has been implemented since 1988, based on the presumption of high social responsibility, transplant awareness and solidarity of our citizens and through today has remained a constant and basic value of our transplantation legislation. The new "Act on Explantation and Transplantation of Human Body Parts for Medical Treatment Purposes" (Official Gazette 177/204), adopted in 2004 together with a series of implementing by-laws, defined in detail the ethical, professional and organisational standards for organ explantation and transplantation in accordance with the most recent European Guidelines /Recommendations and Convention (*Guide to safety and*

*quality assurance for organs, tissues and cells/ Biomedicine Convention*). The modern legal framework was one of the prerequisites for accession to Eurotransplant and the European Union. With the amendments to the Act in 2009, the Croatian legislative framework was successfully harmonised with the EU tissues and cells directives (Directive 2004/23/EU, Directive 2006/86/EU, Directive 2006/17/EU) and the benchmarks from the negotiation Chapter 28 (Consumer Health and Protection) have been successfully fulfilled (*Government of the Republic of Croatia, January 2011*). In July 2010, the EU adopted the Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation, binding all member states, and Croatia, to harmonise their national legislation with the Directive by July 2012 at the latest. Currently, the only major shortcoming of our legislation is the lack of provisions on organ donation after cardiac death. For this reason, harvesting organs from non-heart beating donors is not possible. Donation after cardiac death (DCD) constitutes a large share of the donor pool in countries such as the Netherlands (over 40% of cadaveric donors) (Moers et al, 2010), and in the United Kingdom (about 35% of the donors), whereas in Spain DCD accounts for only 5% of the share of cadaveric donors, mostly based on Maastricht type I and II. (Matesanz et al, 2009).

## 9. Regional cooperation and leadership in South Eastern Europe

Transplantation medicine in most South East European countries is still nonetheless presently very underdeveloped. Little data are available and few transplants are being performed when compared to other European Union countries. Meanwhile, Croatia has made a huge step forward in the last decade while other countries in the region lack the organisation and internal infrastructure necessary to support such high level programmes. Dissemination of successful Croatian strategies and acquired experience could be essential in supporting other South Eastern European (SEE) countries in the development of a deceased organ donation and transplantation program as one of the prerequisites for furthering health and socioeconomic progress in the region. SEE Health Network (SEEHN) (institutional forum set up in 2001 under the patronage of the WHO Regional office for Europe), supplied a political and legislative framework for the designation of several regional health centres, each of them specifically focusing on some public health field. In February 2011, the Republic of Croatia was officially inaugurated as the SEEHN Regional Health Development Centre on Organ Donation and Transplant Medicine, aiming to support the development of an efficient system of organ donation and transplantation in South Eastern European countries through long-term cooperation. At the 1st RHDC meeting held in Zagreb, the role, objectives, functions and collaborative partners of the newly designated RHDC were presented. National focal points (NFPs) were introduced as the RHDC liaison persons representing national health authorities of SEE Health Network region countries (Albania, Bosnia and Herzegovina, Bulgaria, the Republic of Croatia, the Republic of Moldova, the Republic of Montenegro, Romania, the Republic of Serbia, and the FYR (Former Yugoslav Republic of Macedonia). NFP's committed to start regional cooperation in the field of organ donation and transplantation medicine.

## 10. Conclusions

Croatia is one of the few world countries which, with relatively modest funds, has managed to reach the top ranks of the world with its transplant programme. The Croatian Model as authored by Dr. Mirela Basic incorporates successful integration of different elements of the

„best“ European practices (the Spanish coordination model, the Eurotransplant allocation system, etc.) in the context of political and socio-economic circumstances of the Croatian health system (which had been severely burdened by war devastation and a post-socialist heritage). Sustainable increase in the donor rate can be attributed to the integrated and methodological approach in conjunction with a set of incentive measures, whose implementation was led by the NTC, always acting in support of the donation process as a whole and with the health professionals involved in organ donation and transplantation. Simultaneously, with the sustained development of the well structured and transparent system, enthusiasm, trust, and team work grew, while the ever present resistance, mistrust and prejudice gradually disappeared. The donation and transplantation programme in Croatia successfully linked institutions, individuals and health workers. Numerous benefits of the transplantation programme's success are reflected daily throughout the health system, in the eyes of the public, within politics, but most especially in the satisfaction of patients whose hopes and chances for a new life grow by the each day.

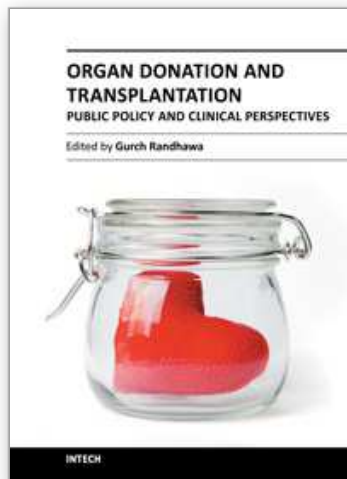
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## **Organ Donation and Transplantation - Public Policy and Clinical Perspectives**

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Transplantation has succeeded in prolonging the lives of those fortunate enough to have received the gift of a body organ. Alongside this life-saving development, there lies another sadder side to the story - there are not enough organs to meet the ever increasing demand. This not only places an increasing emotional and physical burden among the waiting patients and families but heaps a great financial burden upon health services. This book provides an analysis and overview of public policy developments and clinical developments that will hopefully ensure an increased availability of organs and greater graft survival. Medical, policy, and academic experts from around the world have contributed chapters to the book.

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