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Current status of transplantation and organ donation in the Balkans – Could it be improved through the South Eastern European Health Network (SEEHN) initiative?

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Organ transplantation today

After the first successful kidney transplant performed in 1954, over the past 50 years organ transplantation has become an established worldwide practice. It is now considered the most cost-effective treatment for end-stage renal failure [1]. Organ transplant recipients have improved quality of life, capacity for work and reduced overall medical costs which result in significant public health benefits. In addition, patients who received a deceased donor transplant had reduced risk of mortality compared to those who remain on the transplant waiting list based on long-term follow-up [2]. There is also an increased mortality risk with increasing dialysis times before transplantation, due to a higher infection rate on dialysis and worsened cardiac risk status of the recipient [3,4]. Thus, it seems that a significant benefit in terms of both patient and allograft survival may be obtained primarily through a pre-emptive transplantation [5]. Indeed, even in patients with very brief dialysis duration (0 to 6 months), there is a significant reduction in cardiovascular mortality for those patients who received a pre-emptive transplant [6]. Regardless of the data clearly showing patients' benefit from transplantation, there is a widespread recognition that the growing gap between organ supply and demand will continue into the foreseeable future, thereby limiting this life-saving therapy unless action is taken.

In an effort to increase the number of organs for transplantation, living donor (LD) transplantation from unrelated [7], expanded criteria [8] and ABO incompatible (ABOi) donors have been introduced over the last few decades [9]. However, the employment of these advanced methods of organ transplantation as "medical miracle" in the twentieth century seems to be beneficial only for the vast majority of patients living in more highly developed areas of the world. In developing countries, even some of the ethical and practical dilemmas of the wait listing and organ allocation may be solved through the recent concept of matching the projected longevity of the allograft with the projected longevity of the recipient [10]. The current state of transplantation as an effective medical treatment in developed countries poses an intriguing question. How can this outstanding method of treatment be further expanded for patients, and offered to those in countries around the world with less developed health care systems?

Organ transplantation in the SEE countries of Balkans

Although transplantation should be an universal human right as the best treatment option in patients with chronic kidney disease equally distributed all over the world, it seems that the healthcare systems and professionals in developing countries fail to successfully enable this therapeutic practice. There are several reasons for the lack of progress in the Balkan region, which are not always easy to understand. Data on the topic in the public domain are insufficient, sometimes rather confusing, and inappropriately reflects the actual situation, predisposing speculations not based on facts. Reasonably, there are problems emerging from the economic deprivation in these developing countries, and the very modest expenditure on public health care has translated into poor transplantation activity, even lower than 10 per million population (pmp) compared to approximately 50 transplantations pmp in more developed

countries. However, it is not only the economic constraint which affects donation and transplantation programs, but also the lack of appropriate organization (such as national transplant organization and/or competent Authority), legislation, public awareness, education and motivation for organ donation, as well as the small number of well trained, skilled and competent procurement and transplantation teams, and hospital transplant coordinators, all of which are considered as prerequisites for the successful deceased donation and transplantation program [11]. Thus, the global organ shortage which is even more prominent in the Balkans, where deceased donor transplantation has not yet been sufficiently developed, is in fact a composite mixture of a several objective weaknesses of the healthcare system in SEE countries already burdened by poor socio-economic conditions and post war political situations. In addition to the subjective factors such as unmotivated professionals reluctant to put an effort into improving the current situation.

More specifically, the regional cultural conflicts of the past have consistently overwhelmed public health care structures diverting focus from the primary health care level and highly complex sophisticated medicine and the required attention necessary to address the current regional condition of transplantation medicine and organ donation. Thus, the Homeland War in Croatia (1991-1995) had a wide ranging impact on the country's public healthcare system prioritizing the organized care of traumatized war victims. In the following period, Croatia and other neighboring countries (Bosnia and Herzegovina, Serbia) began to slowly create viable post war national healthcare systems where basic needs and infrastructures were being rebuilt. At the beginning of 21 century in Croatia it became evident that it was extremely important and reasonable to support development of previously neglected high level programs such as transplantation, in line with the internationally accepted standards. At that time, transplantation medicine was declared as one of the political and strategic goals incorporated into the Croatian health care policy. However, only ten years later, Croatia achieved great success, ranking as the world leader in the number of kidney and liver transplantation in the world in 2010 (CITATION ONT OR COUNCIL OF EUROPE).

Unfortunately, other countries in the region which had similar political and socioeconomic situations are still lacking in their basic infrastructure needs, not even mentioning the issue of an underdeveloped and complex transplant program.

Development of transplantation program as prevention of organ trafficking

The lack of developed national transplant systems should be perceived as an extremely important missing prerequisite for prevention of any illegal transplant tourism. Indeed, in contrast to the reported recipients trying to get paid transplants as early as possible, even in an organised transplant system such as in US [15], the reason why Balkan recipients are sometimes even selling their houses to buy a kidney is due to the absence of deceased donor transplantation in their own countries, in cases when they have no potential for living related donation. In addition, this type of paid renal transplantation against all medical advice formerly from India, Pakistan and nowadays Egypt, has been associated with several medical and social problems [12,13]. Many surgical complications and invasive opportunistic infections increase the morbidity and mortality in this group of transplant recipients [14]. Expectedly, patients' one year and graft survival were found to be as much as 78% and 60%, respectively. Finally, the lack of information from the transplanting center regarding both donor and recipient and the associated, unacceptable risks on the graft and patient survival in unrelated, paid transplant recipients reinforces the standpoint that this practice should be entirely abandoned. More importantly, the accompanying complications and required treatment of these patients frequently incur substantial costs

in the healthcare expenditure, which should additionally be viewed as an argument in favor of developing each national transplant system.

WHO Guiding Principles on improving organ donation and transplantation and the international transplant community concept on self-sufficiency

In examining the currently under developed organ donation and transplantation programs prevalent in the Balkans, it is important to address the stance of the WHO and international community regarding paid organ commercialism. The problem of global organ trading has been recognised and the first concerns were expressed through the World Health Assembly (WHA) Resolution in 1987 [16]. Additional resolutions have been adopted, but significant progress has been achieved since 2004, when partnership, collaboration and a global consultation process had been established with the scientific community, professional transplant societies, and health authorities for a common global attitude towards transplantation [17]. To address the growing problems of organ commercialism and exploitation of poor vulnerable populations, the Declaration from the Istanbul Summit aims to reinforce the resolve of governments and international organizations to develop laws and guidelines to bring an end to wrongful practices and to preserve the nobility of organ donation [18]. Furthermore, the recently adopted WHA Resolution 63.22 urges Member States “to strengthen national and multinational authorities and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protect the welfare of living donors with appropriate health-care services and long-term follow-up” [19]. The Resolution was adopted immediately after the 3rd WHO Global Consultation on Organ Donation and Transplantation: Striving to Achieve Self-Sufficiency (Madrid, Spain, March 2010). This new concept of self-sufficiency in transplantation has been promoted as every nation’s responsibility to meet the needs of their patients by using resources within their own population and by decreasing the burden on public healthcare budgets from treating chronic diseases [20]. As a result of the Consultation, a comprehensive list of recommendations directed at governments, international organizations and healthcare professionals was devised on how to successfully and ethically meet the transplantation needs of patients. However, the implementation of these guiding principles, recommendations and directives on self-sufficiency in transplantation is the next and even more difficult step to successfully manage this complex issue.

South-eastern Europe Health Network (SEEHN) & Regional Health Development Centre - a part of the global transplant networking

With regard to the implementation of a concept of “self-sufficiency”, a Task Force Group composed of the professionals from The Transplantation Society (TTS) and the European Society of Organ Transplantation (ESOT) in collaboration with the International Society of Organ Donation and Procurement (ISODP) and the European Transplant Coordinators Organization (ETCO) has taken the initiative to address the organ donation and transplantation needs of each country within the South-eastern Europe (SEE) geographical region. The project is also supported by the collaboration of the WHO with Organización Nacional de Trasplantes (ONT), and the consultation of the Council of Europe (CoE) through the European Directorate for the Quality of Medicines and Health care (EDQM) and the European Commission.

Looking for an official form of organisation to facilitate the implementation of the initiative, it was considered that the South-eastern Europe Health Network (SEEHN) operating under the Regional Cooperation Council, successor to the Stability Pact for South-eastern Europe, establish a regional form of organisation through its newly designated Regional Health Development Centre (RHDC) on Organ Donation and Transplant Medicine in Croatia (Zagreb). The function of SEE Health Network RHDCs is outlined in the SEE Health Network Memorandum of Understanding, 2009 (IF AVAILABLE ON WEB PUT THE CITATION). RHDCs serve as a centre for facilitating dissemination and exchange of good practices, knowledge, expertise and experience within SEEHN countries: Albania, Bosnia & Herzegovina, Croatia, Macedonia, Moldova, Montenegro, Serbia, Romania, and Bulgaria. The RHDC Croatia was considered to be a good base for long term regional cooperation in the field of organ donation and transplantation based on Croatia's success in the field over the last 10 years. Namely, it was perceived from the available data, that transplantation medicine in SEE is still lagging far behind other EU countries due to a lack in organization and internal infrastructure necessary to support such high level programmes. Since the transplant program in Croatia made a huge leap forward in the last few of years, setting up the RHDC was intended to serve as a competent regional resource centre assisting SEEHN countries in their close collaboration with national health authorities in improving the complex transplant interrelationships. The Centre has been designed to operate in full compliance with WHO and CoE guiding principles, European legislation and in line with the SEEHN basic objectives as increasing awareness, exchange information and knowledge, training assistance, education and implementation of the action plans created, based on specific country needs, and networking the region geographically to improve interstate (interministerial) collaboration in organ donation and transplantation.

The first meeting of the RHDC Croatia in its role as regional support center for SEEHN partner countries was held in Zagreb on February 22nd, 2011, and was aimed at defining and finalizing the operational tool for assessment of specific country needs, as well as agreeing on the next steps from their individual forthcoming action plans. Thus, representatives from Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Greece, Kosovo, Macedonia, Moldova, Montenegro, Romania, Serbia, and Slovenia were invited to participate in this action convening the second meeting of stakeholders on May 27-28, 2011, in Skopje, Macedonia. The objective was to bring together representatives from the Ministries of Health and Professional Organizations for the first ever formal exchange of information, data, and experience amongst these countries, and to assist in the collaboration between professionals and their health authorities in achieving living and deceased donation and transplantation best practices, accomplishing the aforementioned resolutions and directives. Data from a predefined questionnaire on the current status on transplantation and donation activity in each country were reported at the meeting on May 27th - 28th and is presented in Fig. 1-3 and Table 1.

What can we learn from the present data? Looking for the number of performed kidney transplantations/pmp, Croatia is the leader with 56, followed by Slovenia (30.5). Serbia (13.2), Romania (10.7) and Bulgaria (7.1), while the Bosnian Federation (Bosnia & Herzegovina) and Macedonia with (5.7) pmp are lagging far behind with an underused and depreciated transplant program. Macedonia has only a LD program without any progress towards deceased donation in the last 2 decades, unlike Albania, Moldova and Montenegro who do not even have an established LD program. All in all, we may stratify 3 groups of countries in the Balkans: the excellent transplant programs in Croatia and Slovenia, insufficiently developed deceased donor program in Serbia, Romania and especially Bulgaria and Bosnian Federation, and finally countries urged for improving or even establishing a national transplant program such as Macedonia, Albania, Moldova and Montenegro.

When we look at the deceased donation/pmp, only Croatia and Slovenia fulfill the required minimum of 10 DD/pmp, i.e. 28.9 and 20.5, respectively, and have already joined Eurotransplant. The question arises as to where the weaknesses lie in other countries? The number of transplant centers should not be considered a cause since Slovenia has realized a successful program through operation of only 1 transplant center, also emphasizing the existence of appropriate legislation in all SEEHN member countries. However, in comparison with those successful models, the observed deficiency can be attributed to the lack of proper organisational infrastructure which lies within the absence of Competent Authority or National Transplant Coordinator/body, regular public education, established registries, transplant waiting list management and hospital coordinators. Hence, all listed seem to be essential priorities for those countries in need of improving their programs. Finally, the continuous training in procurement and transplantation medicine, with an allocated central budget funding provision per each deceased donation are also considered as key factors for success in organ donation and transplantation and should be as such recognized by each country's health authority.

Based on the all above mentioned data specific steps for SEEHN countries were defined with support of the RHDC Croatia: 1) support implementation of legislation in harmony with EU guidelines; 2) provide means for educational assistance for professionals (esp. in brain death, and for transplant surgeons); 3) assess and procure necessary equipment; 4) strengthen infrastructure (through personalized relationships and collaborative efforts of RHDC Croatia with the assistance of professional societies (e.g TTS) in terms of composition of a national coordinative body, appointment of hospital transplant coordinators, and acknowledged reimbursement to the donor hospitals by the national health fund, etc.

Conclusion

The international transplant community, SEEHN, and WHO seem to have undertaken an important, timely and quite demanding action in the area of Balkans. The first step of assessing the specific country needs was a great success since professionals and health authorities gained official and current status of transplantation in their own countries as well as comparably to the region itself. To our best knowledge, this is the first official report of SEE countries on transplantation and organ donation which was a subject of many speculations and blurred public opinion until now. Only recognition and acknowledgement of the languishing organ donation and transplantation condition of the region could draw such attention and problem solving decisions. This has a much greater impact surely when arranged through or in presence of the international transplant community. Additionally, the information and experience gleaned from action and valuable help from the transplant societies and WHO stands to be deservedly recognized and acknowledged by the international community and transplant professionals as well. We hope to see as an outcome a stepwise increase in the number of deceased as well as living donor kidney transplantations in the future.

Finally, what are the defined priorities for the future? In countries where LD transplantation is absent or insufficient, transplant professionals should initiate to start or increase the program as an immediate and prompt action. Composing the official waiting lists, registries of transplant recipients and living donors should follow coupled with the composition of a few committed surgical teams, and a greater number of educated transplant nephrologists, which is perceived as a prerequisite for development of deceased donor transplant program. Here, the governmental support with necessary organizational and infrastructural investments to update the legislation, establish the national coordinative body, and hospital coordinators to raise public awareness on the number of potential deceased donors is ultimately recognized as essential.

At last, this report on donation and transplantation data from the region should also prompt health authorities in each Balkan country for the required support in achieving self sufficiency in deceased donation and organ transplantation through adoption of the positive experience from countries that already became successful.

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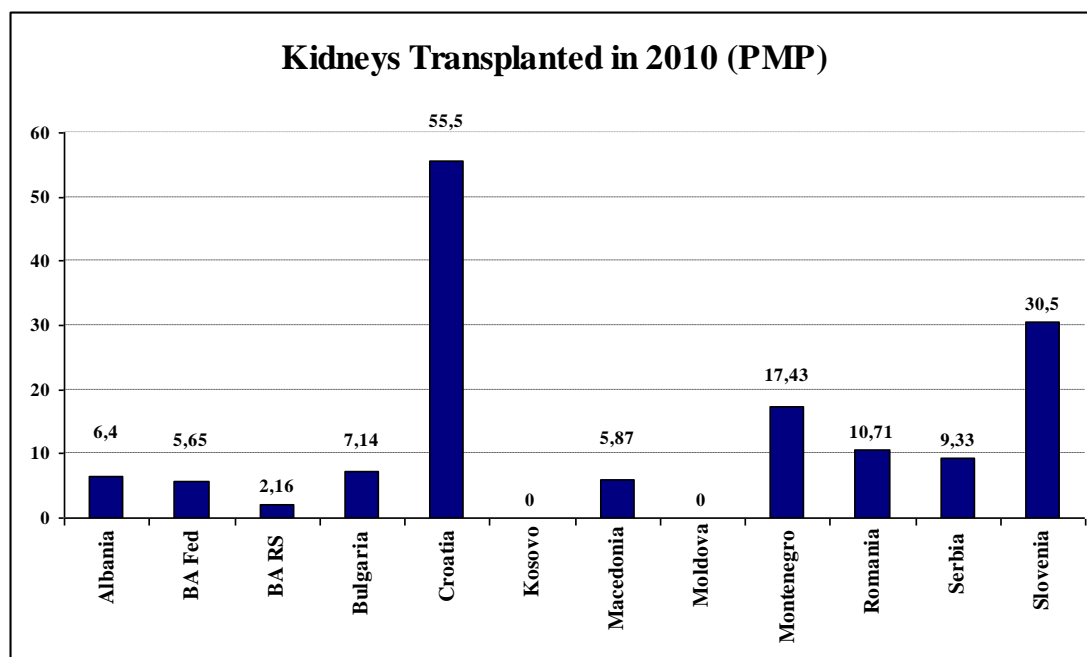


Fig. 1. Number of transplanted kidneys per SEE country regardless of the type and origin of transplantation.

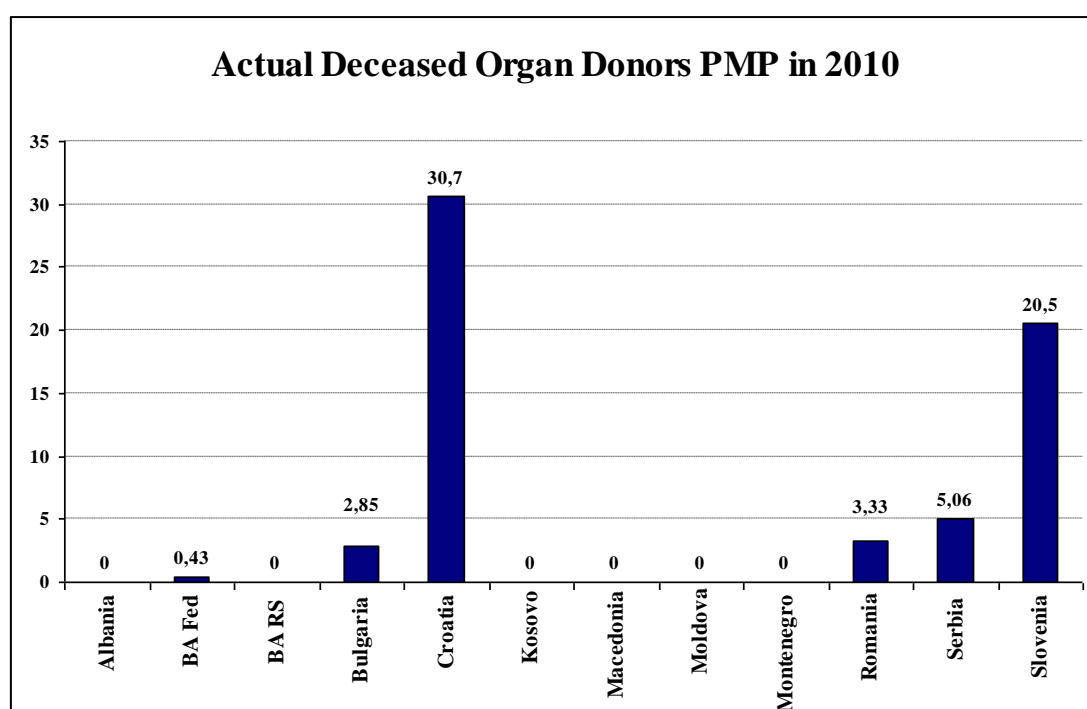


Fig. 2. Actual number of donors per SEE country and pmp.

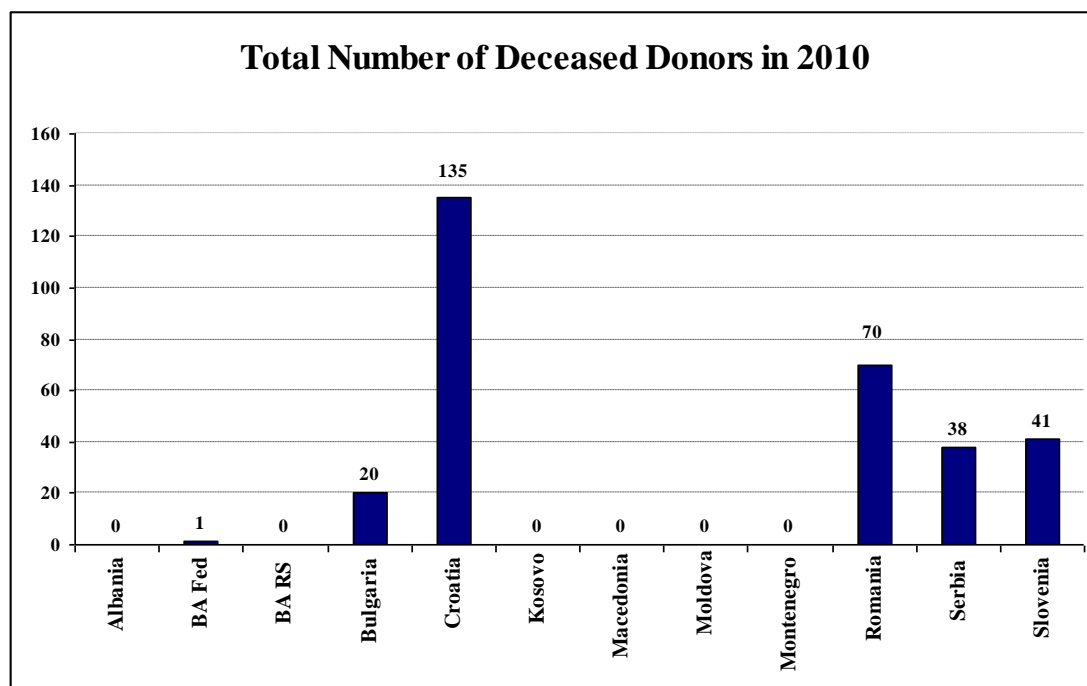


Fig. 3. Actual total number of deceased donors per SEE country.

Table 1. Current status in SEE countries on organ transplantation in 2010 (official data presented by National Focal Point person from each invited country except Kosovo).

Country	AL	BA Fed.	BA RS	BG	HR	MK	MD	MN	RO	RS	SI
Population (Million Inh.)	3.2	2.3	1.4	7.0	4.4	2.1	3.5	0.7	21	7.5	2
Kidney DD	0	2	0	37	227	0	0	3	137	67	61
Kidney LD	20	11	3	13	20	12	0	8	88	32	0
N-Kidney-pmp	NA	5.7	2.1	7.1	56.1	5.7	0	NA	10.7	13.2	30.5
DD/pmp	0	0.43	0	2.87	28.86	0	0	0	3.33	5.06	20.5
N – DD	0	1	0	20	127	0	0	5	70	38	41
Liver LD/DD	0/0	1/0	0	2/13	2/103	0/0	0/0	0/2	7/51	1/21	0/23
Heart	0	0	0	5	36	0	0	0	7	0	19
Pancreas	0	0	0	0	6	0	0	0	0	0	1
N-K/LTx cent.	1/0	2/1	1/0	4/2	4/3	2/0	1/0	0/0	5/1	5/3	1/1
N-WL-Kidney	0	170	103	850	225	0	0	0	2661	739	53
N-DD centers	X	1	9	21	31	8	X	X	12	7	10
Legislation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Consent	Expl.	Expl.	Both	Pres.	Both	Expl.	Both	Expl.	Expl.	Expl.	Both
Publ. educ.	N	Y	N	Y	Y	Part.	Y	N	N	Y	Y
Tx registry	N	N	Y	Y	Y	N	Y	N	N	Y	Y
LD. Registry	N	N	Y	N	Y	N	N	N	N	Y	N
NTC	N	N	N	Y	Y	N	Y	Y	Y	Y	Y
Allocat. rule	NA	N	Y	Y	Y	NA	Y	N	Y	Y	Y
Train.Proc.Tx	N	N	Part.	Y	Y	N	Y	N	Y	Part.	Y
Fund/DD-Euros	0	Gen.	Gen.	Gen.	7000	Gen.	0	Gen.	Gen.	4000	9000
Hosp.Tx Cor.	N	N	Y	Y	Y	N	Y	Y	Y	N	Y
Train.Tx.Med.	N	N	Y	N	Y	N	Y	N	Y	N	Y

Abbreviations - country's codes: AL – Albania; BA Fed – Bosnia Federation and BA RS – Bosnia Republic of Srpska; BG – Bulgaria; HR – Croatia; MK – Macedonia; MD – Moldova; MN – Montenegro; RO – Romania; RS – Serbia; SI - Slovenia

Abbreviations – responses from the predefined country report questionnaire: Population (Million Inh.) – Inhabitants; DD – Deceased donors; LD - Living Donors; N-Kidney-pmp – Number of Kidney transplantation pmp; N-K/LTx cent. – Number of Kidney/Liver Transplant centers; N-WL – Number on Waiting List; N-DD centers – Number of potential Deceased Donors procuring centers; DD-centr.-\$ - Is there a centralized budget allocation (Y – Yes, N – No); Legislation – Is there legislation on transplantation; Consent (Expl. – explicit, Pres. – presumed, Both); Publ. educ. – Is there public education on transplantation; NTC – Is there National Transplant Coordinator; Allocat. rule – Is there allocation rules (NA – not applicable); Train. Proc. – Is there training in organ procurement (Part. – Partially); Fund/DD-Euros – Fund given per DD in Euros (Gen. – General); Hosp.Tx Cor. – Is there

Hospital Transplant Coordinator; Tx registry – Transplant follow up registry; Train.Tx.Med - Is there adequate and continuous education in Tx surgery and medicine?