

DEVELOPING MULTI-ORGAN TRANSPLANT CENTER IN ROMANIA: MANAGERIAL PREMISES

Narcis COPCĂ¹,
Constanța MIHĂESCU-PINȚIA²

¹ Bucharest University of Economic Studies

² National School of Public Health, Management and Professional Development, Bucharest

OBJECTIVE of this paper is to present a realistic opportunity to develop first Multi-organ Transplant Center in Romania, of South-Eastern European importance, in order to better respond to increasing needs of patients, with sustainable costs.

METHODOLOGY. For this paper we used the following tools: descriptive analysis of situation, literature review regarding transplant center management, secondary data compilation and analysis regarding human organ transplant at international level - Global Observatory on Donation and Transplantation, and at national level - National Transplant Agency, legislative diagram applicable, case study of St. Maria Clinical Hospital in Bucharest as recipient of future multi-organ transplant Center (in terms of structure, activity, indicators, performance, SWOT analysis, advantages, undertakings, barriers).

Limitations: scarcity of studies and evidences regarding organization, management, effectiveness and efficiency of transplant centers; uncertainty and significant deficit of organ donation for transplant in Romania, making almost impossible to anticipate evolution of transplantology; given the ethical considerations, human transplant cannot be associated with a business approach.

INTRODUCTION

Replacing damaged body parts of body was a concern for humans since the ancient times, according to evidences discovered in a few regions of the world. But from here to the transplantation of cells, tissues and organs, millennia passed, and the medical success came only during the second half of the 20th century after many trials and experiments performed by pioneers of human transplant in several countries. Consolidation and maturity of this laborious process came between 1964-1980 [1].

Transplantation has become a current medical practice, achieved through a double-stage surgical procedure, recommended to an increasing number of patients being usually in a critical condition and depending on donation and transplant.

Various countries of the world have developed their own models and networks of transplantation, according to their specific needs, resources, professional experi-

Shortage of organ donation is the main challenge in transplantation all around the world. In Romania, transplantology has progressed despite many obstacles: lack of information and education for organ donation; scarcity of funds to support and develop transplant centers, within an underfinanced health system; scandals around transplants, affecting people trust and thus reducing the number of donors; waiting time for patients registered on transplant lists; hardships in transplant management and communication at national level; some legislative deficiencies; lack of strategic approach and concern to support and promote results of this activity de excellence. In 2018, Romania has registered a rate of just 13.42 solid organ transplants per million of inhabitants, compared to European average of 57.23 and international average of 54.82. Transplantation activity is going through a difficult period, over 3640 patients Romanians are currently waiting for a solid organ transplant (kidney 2999, liver 615, heart 30, lung 5), while other 596 patients already died waiting... But the potential is considerable in terms of medical teams very well trained and experienced in transplant, and Romanian patients deserve more. "St. Maria" Clinical Hospital from Bucharest has been modernized and continuously developed in the last 10 years, proving its capacity and medical performance, recently achieving first six successful lung transplants in Romania and strives for the new stage: to develop a multi-organ transplantation center.

Keywords: *transplantation center, multi-organ transplant, hospital management*

ence, health policies and with their own value systems. For example, the Organ Procurement and Transplantation Network, a collaborative organization of the United States Department for Health and Human Services, covering the 11 national regions with the mission to increase the patient access to a successful transplant, based on evidences and safely performed [2].

In order to better respond to an increasing number of patients, given the shortage of organs donated towards the needs, several states have built regional collaboration networks aimed to facilitate prompt exchange of expertise and organs donated. Such an example is the Eurotransplant, a nonprofit organization of eight European countries - Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, Netherlands and Slovenia, aiming to represent a mediator between the donor and the recipient in order to ensure an optimal use of the available organs, in compliance with medical and ethical criteria. History of the first successful transplants in the world indicates two countries: United States and Germany. (Table 1)

Transplant is a very complex surgical procedure for replacing a damaged, dysfunctional part of the human body (organ, tissue, or cells), with a compatible healthy and functional one. Transplanted part could come from: the same organism; living donor, other than recipient (a relative or not); deceased donor; sometimes from an animal or artificial replacement. Transplant is clinically defined as "transfer (grafting) of human cells, tissues or organs from donor to recipient, accomplished in order to restore body function(s); when transplant is done between different species, as from an animal to a human, it is called xenotransplant" (heterologous) [4].

Table 1. First successful transplants

Year	First TR* achieved outside the Eurotransplant region	First TR achieved within the Eurotransplant region
1954	kidney TR, living donor (USA)	
1963		kidney TR, deceased donor (Leuven, Belgium)
1966	pancreas/kidney TR (USA)	
1967	heart TR (South Africa)	
1967	liver TR (USA)	
1972		liver TR (Hannover, Germany)
1979		pancreas TR (Munich, Germany)
		pancreas/kidney TR (Munich, Germany)
1981	heart and lung TR (USA)	heart TR (Munich, Germany)
1983	single lung TR (Canada)	heart-lung TR (Munich, Germany)
1986	double lung TR (USA)	
1987	intestine TR (USA)	lung TR (Innsbruck, Austria)
		domino heart donor (Vienna, Austria)
1988	split liver TR (USA)	split liver TR (Hannover, Germany)
1989	liver TR, living donor (USA)	intestine TR (Innsbruck, Austria)
		double lung TR (Hannover, Germany)
1990	lung TR, living donor (USA)	
1991		liver TR, living donor (Hamburg, Germany)
1992		pancreatic isles TR (Gießen, Germany)
1996		domino liver donor (Ghent, Belgium)

Source: Eurotransplant, 2019 [3]

*TR=transplant

European Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation, introduced in definition the concept of “process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient”. Kidney and liver are the most frequent solid organ transplants performed in the world.

This two-stages procedure (procurement of the healthy compatible organ/tissue from donor and transplant it to beneficiary) is complex, risky and costly, but vital for an increasing number of patients. Only well trained, skilled and experienced physicians are able to achieve this intervention, within an interdisciplinary clinical team. Support, administration and financing team members augment this team in order to cover the procurements, supply, registration, reporting, billing and documents for reimbursement of services provided by the hospital to transplanted patient. The Organ Procurement and Transplantation Network, within the U.S. State Department for Health and Human Services, envisage that transplantation team should be build upon the following experts:

- The clinical team: 1) clinical transplant coordinators – in charge with patient evaluation, treatment and follow-up medical care, 2) transplant physicians – managing the case in terms of medical tests, investigations, medical care and medication, with or without post-transplantation care, 3) surgeons specialized in transplantation – performing the surgical procedure and follow-up care of the patient;
- The support team: 4) financial coordinator (connection between hospital doctors and administrative staff, in-

surer and authorities in terms of costs of the services provided to the patient before, during and after the transplant), 5) social worker – providing the patient and their family with support in order to cope with the status of transplanted person (issues, side-effects) [2].

European Directive 2010/45/EU, applicable in Romania, defined the transplant center as “the health care establishment (institution), a team or a unit of a hospital, or any other body which undertakes the transplantation of organs and it is authorized to do so by the competent authority under the regulatory in the Member State concerned”.

Transplantology is fundamentally different from all the other health services especially by: time pressure between organ harvesting and transplant procedure urge a perfect coordination between the teams and factors involved in this entire process; donation implies a significant variability of con-

text and activity to which professionals must constantly adapt; achievement and success of each transplant depend on both donor and recipient characteristics; transplant process cannot be fully standardized, and clinical decision making requires a high level of expertise and autonomy of transplantologists; therefore, interdependence and adaptability are core features of a transplantation system [5].

From an ethical point of view, human transplantation was always a vivid source of controversy, criticism and disproof. Main ethical dilemmas appear to be related to the following aspects: ensuring an equitable and fair access to transplant for all the patients in need, irrespective of their social or financial status; if people should be encouraged or not to donate and what would be the most proper way to express this option for donation; principles and criteria for transplant waiting lists; acceptability of a financial reward for living donors, as an appropriate or a perverse incentive; if survival rate should be or not the first criterion for a transplant.

As transplant is an exceptional medical performance, we believe that leadership of transplant centers and networks should be of the highest quality. Exceptional leadership means to prove core competences: being a visionary, communicate and share your vision; always the team concern - building, motivating, coordinating, developing and energizing the medical, surgical and nonmedical team; consensus in transplant organization and network; proving emotional intelligence (with your team, patients, authorities, public, journalists), generating informal power; giving feedback; cultivating adaptability

and motivating participation and creativity; earning people trust and loyalty; directing efforts and result without bearing on personnel engagement [6]; in other words, inspiring others.

Authors of a study on 11 Spanish hospitals performing transplantation, applying quality criteria and indicators from the Baldrige model, have observed the following: high quality levels achieved by these hospitals are mainly due to the leadership and strategic planning performed; link between high scores obtained for Baldrige quality indicators, and technical efficiency of these hospitals has been proved, also suggesting the importance of applying Baldrige model; excellence of harvesting and transplant services requires excellence in process management, as well as in the coordination mechanisms [5].

On the other hand, a recent study on public hospital governance in Romania has indicated several recommendations, some of them relevant for accredited transplant centers from public hospitals: implementing an effective consensual mechanism needed for reconfiguring and increasing autonomy of these hospitals, thus allowing a better planning, standardization, classification of the hospital and incentives for performance; update and improve the DRG reimbursement system; reform of the public procurement system in hospitals; “reconsidering the managerial model” both clinical and administrative, oriented to the current healthcare needs of the population considering the financial limitations; investing in hospital management competencies and continuous organizational development [7]

Performance in human transplant mainly depends on two essential components:

- The transplantation center – interdisciplinary medical team composed by highly trained, experienced and motivated specialists; dedicated spaces complying with standards and norms for the entire pathway of the patient transplanted; appropriate medical equipment and technology, including for labs, operating theater and ICU; supportive organization and coordination of the transplant within the hospital and network; prompt supply of necessary medicines and health materials; appropriate funding;
- Organ donation (solid organs, tissues or cells), a very sensitive action influenced by the information, education, values and beliefs of people, implicitly by the trust that the transplant system manage to build among their citizens.

While clinical research results in human transplant traces clear, consistent, robust and relevant evidences, with continuity, literature about organization, accreditation, funding, coordination and networking of the transplant centers within and between different healthcare systems, is scarce. Hospital leadership and management are also relatively scarce in terms of academic research and scientific evidences. Organizational culture, variability and considerable differences between the hospitals (even of the same type) and between healthcare systems of nations, inconveniences in their comparative evaluation – are just a few reasons. Nevertheless, certain conclusions of some studies are relevant to this paper regarding the transplant center management.

Some experts au advert to fact that traditional leadership model of public hospitals, usually defined by lack of flexibility, control and autocracy rather than collaboration, cannot properly answer anymore to the multiple, complex challenges faced in hospital administration and coordination [8], especially in a globalized world in process of digitalization. On the other hand, information generated by a literature review unfold that authentic and transformational leadership – visionary, honest, responsible, dedicated, available, motivational, continuously learning, supporting and encouraging people – is correlated with high performance and quality of health services, especially in hospitals [9].

Hodgetts considers that leadership in healthcare organizations should be situational, non-hierarchic and relational, in order to better respond to current challenges, while effective leadership is considered as common ground of all management evaluation criteria used in the UK Top Hospital Award: quality and change, safety, leadership, organizational culture, and external influence. Author also underlined that hospital leadership is not a one-way process of the leader orienting and influencing the organization, but also works the other way: organizational structure and culture influence the leader, change them on long term, and sometimes even destroy them [10].

Literature and practice suggest that public hospital management, especially for clinical / university ones, should be flexible, responsible, documented, modern and even innovative, in order to be able to respond properly to the needs of their teams and patients, within an even more complex and demanding environment. Such a managerial direction is all the more relevant for the hospitals performing very specialized services, as transplantation.

Managing transplant in Romania

Although organ transplant is the only chance to survive for an increasing number of patients and we have excellent specialists, transplant has declined in Romania during the latest years. Perceived as a very complicated, costly, non-transparent and controversial procedure, without educating population for donation, and within the context of a scarce and criticized health system, transplantation remains currently far from the patients’ needs, from EU standards, and also from its own potential for development.

Romanian journey in the field of transplantology is interesting and might be regarded as a management lesson. Since the beginning of the 20th century, doctor Florescu experimented first kidney transplants, unsuccessful, in a laboratory of the Bucharest University of Medicine. In the second half of the last century, in medical university centers the following have been done: first skin graft, achieved by professor Agrippa Ionescu (1958), first cornea transplant (1962), experimental liver transplants, while first successful solid organ transplant was a living donor liver accomplished by professor Eugeniu Proca (1980) in Fundeni Institute, followed by a deceased donor kidney transplant, successful, accomplished by professor Petru Dragan in Timisoara. Then only few kidney transplants have been accomplished, while development of modern transplantology in Romania begun in 1995 by

organizing transplant centers within a network (including “Fundeni” Clinical Institute - Bucharest, Clinical Institute of Urology and Kidney Transplant - Cluj-Napoca, Clinical Emergency Hospital “Floreasca” – Bucharest, and Clinical County Hospital Targu-Mures), organizing and financing the National Program for Transplant, and encouraging people to donate [11].

Year 1997 marked the creation of Romtransplant, the professional association of transplantologists in our country. Law 2 on human tissues and organs harvesting and transplant was developed and adopted in 1998, then reviewed and introduced within the Health Reform Law 95/2006 (Title VI – Harvest and transplant of human organs, tissues and cells for therapeutic purposes). Specific training of the transplant coordinators began at the end of '90s. During the Romtransplant congress held in 2000, the Patriarch has officially announced the agreement and support of the Romanian Orthodox Church for organ donation and organ harvesting from people in cerebral death, an important step and signal for an Orthodox country. Romania is also represented in the European Committee on organ Transplantation - Council of Europe, by professor Irinel Popescu since 1999.

The National Transplant Agency (NTA) was set up as the state authority for transplant coordination, under the Ministry of Health, through the Law 588/2004 completed by the Regulation 228/2005 regarding its organization and operation.

Standards for selection and evaluation of human tissues and cells donors, warning systems and emergency procedures, qualification of the personnel din de tissue and cells banks, quality system, import and export of human tissues and cells, relationships between cell and tissue banking and third parties, adopted through the Order 1242/2007, periodically updated.

The National Transplant Registry (NTR) has been introduced in 2009, through the MoH Order 477/2009 (regarding the foundation of the National Transplant Registry, designate persons in charge with administration of the NTR data within the health facilities accredited to perform organ transplant and the data set necessary to register a person for assigning unique registration code at the NTA). NTR includes currently the following 10 National Registries for: transplant of heart, liver, kidney, lung, pancreas, skin graft, bone-tissue, cornea, in-vitro fertilization, stem hematopoietic cells. The National Register of donors of human organs, tissues and cells has been founded in 2012, through the Order 1158 signed by the Minister of Health and the Minister of Justice.

In 2005, Romania started to celebrate the National Transplantation Day, following the European model, a good opportunity to gather representatives of all transplantology stakeholders in order to discuss about results of their activity, problems and alternative solutions, medical news and premieres in this field; therefore transplantologists meet their colleagues and also public authorities, researchers, transplanted patients, patient associations etc.

MoH Order 860/2013, with further changes and edits, provided specific accreditation criteria for: organ harvesting centers, organ transplant centers, HLA laboratories for

transplantation, packing, labeling and specialized transportation for organs transplant centers, transplant centers for central peripheral blood hematopoietic stem cells.

Current legislative framework is concordant with the following European Directives and strategic documents regarding the human transplant: Directive 2010/53/EU - Quality and safety organs intended for transplantation; Directive 2012/25/EU - Information procedures for the exchange, between Member States, of human organs intended for transplantation; Action Plan on Organ Donation and Transplant: Strengthening the Cooperation between the Member States [12].

RESULTS AND DISCUSSIONS

The number of donors was always very scarce, and consequently the deficit of organs for transplantation was chronic, as no systematic education in organ donation existed. After media scandals related to transplants since the end of year 2016 and 2017, Romanian people became even more reluctant to donate, therefore transplants dropped dramatically, directly affecting the patients registered on waiting lists (from 138 deceased donors and 448 solid organ transplants achieved or rate 20.74 TR/mil., compared to European average rate of 44.23 TR/mil. in 2014, to only 65 donors deceased and 215 transplants or 10.91 TR/mil., compared to European average rate of 60.49 and international average rate of 26.12, in 2017) [11,13].

In 2018, Romania had in total 17 centers accredited for solid organs transplants (kidney - 5, liver - 4, cardiac - 3, pancreatic - 3, lung - 1, heart and lung - 1) in 11 hospitals, and 63 public and private centers for cells/tissues transplant, most of them located in Bucharest and university cities Iasi, Cluj-Napoca, Timisoara, Targu-Mures. Only few of all the accredited centers actually perform transplantation.

An overview of the current situation, regarding the accredited centers, number of transplants performed up to date, waiting list and number of patients deceased on the waiting list, on each type of transplant, are presented in table 2.

A comparative image on donation and transplantation in Romania and other countries in the European region and in the world, in absolute numbers and rates (per million of inhabitants), per each type of solid organ transplant, is presented below. (Table 3, Figures 1 and 2))

Spain and United States are among the most prolific countries in terms of organ donation and transplantation. Romania, with 3.32 deceased donors/mil. and 13.42 TR/mil. loc. in 2018, is behind former socialist countries in the region (Hungary 17.32 D/mil. and 52.06 TR/mil.; Czech Republic 26.6 and 83.4; Slovakia 14.44 and 37.22; Poland 13.07 and 38.64; Slovenia 21.9 and 51.9;) except for Bulgaria (2.3 and 6), while the European averages are 17.1 deceased donors/mil. and 57.23 TR /mil., and global averages are 15.1 and 54.82 TR [13].

Developing transplantation at the „St. Maria” Clinical Hospital Bucharest

„St. Maria” Clinical Hospital, a 303-beds public facility in Bucharest, became the second Liver

Table 2. Current transplant capacity in Romania: centers and activity

Transplant type	No. of accredited centers	No. of TR achieved	No. of patients on waiting list	No. of patients deceased
Cardiac (1 Center heart-lung)	4	87	30	77
Reproductive - embryo transfer cells	25	12.222	1515	0
Stem hematopoietic cells	5	1058	455	89
Cornea	6	374	302	0
Liver	4	644	615	286
Bone-tissue	17	95	29	1
Lung	1	6	5	2
Kidney	5	1990	2999	141

Source data: National Transplant Agency, July 2019 [13]

Transplant Center in Romania in 2014 (after the reference Center from the Clinical Institute Fundeni, Bucharest), and the first Lung Transplant Center since 2018. Hospital team have been working hard and made great efforts for several years in order to reach the necessary conditions, medical equipment, competences and accreditations for high surgical activity and transplantation, so that Romanian patients to be treated in the country at high quality standards with lower costs.

Average cost of liver transplant achieved in our hospital is up to 50,000 Euro, unlike the amount of 80,000-90,000 Euro charged in other EU member states. Total cost of successful lung transplant is up to 90,000 Euro in our hospital, including pre-transplant evaluation and tests, preparation, transplant procedure, post-transplant treatment, monitoring and care, unlike the amount of 120,000 Euro paid abroad only for the procedure, without transport or other pre- and post-transplant medical services, not to mention the costs of family member who accompanies the patient. There was the idea that "Marius Nasta" Pneumophthiology Institute Bucharest would be the most appropriate hospital to organize and perform lung transplant in Romania, and it could have been true if not considering poor conditions in their 100-years-old buildings with deficiencies in medical equipment, confirmed last year by deceases of several patients caused by hospital-acquired infections, confirmed by complaints of their physicians.

Bases of the Transplantation Center in our hospital were laid years ago, by gradually transforming a modest surgery department, in a modern Center of hepato-pancreato-biliary (HPB) surgery, fully equipped, including a Surgery Research Center, with an excellent team trained in Hannover - Germany. Our purpose was and is to be able to increase the life expectancy and quality of life for our HPB patients, at reasonable costs, after analyzing incidence, characteristics and hospitalized morbidity of these cases in Romania. Concomitantly other services for the new Center have been developed, modernized or newly introduced: extended /complex / high performance medical investigations, blood transfusions, gastroenterology, pneumonology, thoracic surgery, pathology. Close collaboration between the Romanians team of surgeons, including experts from other hospitals in Bucharest, and the German team of Hannover Transplantation Center, has continued after the

training program și supraspecializare, resulting in studies and successful transplants performed together in this new Center and communicated to reuniunile de specialitate [14,15].

Exterior and interior rehabilitation and modernization of the hospital building were performed first, with support from the local authorities, then the hospital was medically equipped, in several stages. Meanwhile, efforts were undertaken to complete, motivate, train and retain the medical teams, despite the migration that still affects staffing in the public hospitals in Romania. Currently, physicians represent 20% of total employees, and nurses - 45%. Hereby, the hospital

offers high quality medical services in ambulatory, day care and hospitalization in following specialties: general surgery, liver surgery, thoracic surgery, plastic and reconstructive surgery, oral and maxillofacial surgery, ENT, ICU, gastroenterology, internal medicine, rheumatology, medical rehabilitation, oncology, cardiology, pneumonology, neurology, medical laboratory and imaging of high performance. Among the most complex and special procedures achieved, are to be mentioned the following: major and minor liver and pancreatic resections, pancreatectomies (>200), successful liver transplant (44), successful lung transplant (6), breast tumor resection and reconstruction (>600), other oncologic procedures (>100), complex procedures on digestive system (>200), gastrectomies, esophagectomies, esogastric procedures, many sophisticated ENT interventions, minim invasive thoracic procedures, multiple pleural drainages using Seldinger technique, pericardial drainage using Seldinger technique under ultrasound guidance.

The pathology solved in this hospital is classified in major diagnostic categories (MDC) as following: MDC08 (Diseases and disorders of) Musculoskeletal System and Connective tissue - 37%; MDC06 Digestive System - 17.5%; MDC03 ENT - 15%; MDC07 Hepatobiliary System and Pancreas - 8.7%; MDC09 Skin, Subcutaneous Tissue & Breast - 4.4%; MDC05 Circulatory System - 2.8%; MDC12/13 Male/Female Reproductive System - 2.7%; MDC11 Kidney and Urinary tract - 2.2%; MDC01 Nervous System - 2.1%; MDC04 Respiratory System - 1.3%; MDC17 neoplasms - 0.7%; the others - 1.8%.

Values attained by the hospital at the main performance indicators in recent six years, are presented in table 4.

Values registered indicate a good dynamic and development in recent years, in comparison with national averages, under constant diversification and growing complexity and severity of cases treated, at short length of stay - except for transplants and very severe cases, at low hospital-acquired infection rate, correctly reported, due to prevention and control measures. Degree of patient satisfaction with the quality of medical services and care received in the hospital is high, while the level of job satisfaction of the medical personnel of our hospital is very high, as periodical surveys indicate.



Table 3. Comparative view on transplantation in 8 countries versus European and global averages, 2018

Indicator	Country/region	USA	Canada	Germany	France	Spain	Poland	Hungary	Romania	Europe	Global
Deceased donors	no.	10722	...	955	1881	2241	498	168	65	13158	30493
	rate	32,81	...	11,6	28,85	48,3	13,07	17,32	3,32	17,1	15,1
renal	no.	22003	1706	2291	3567	3313	946	335	183	27738	70931
	rate	67,33	46,11	27,84	54,71	71,4	24,83	34,54	9,34	36,04	35,13
hepatic	no.	8250	536	877	1325	1230	316	80	69	10481	24320
	rate	25,24	14,49	10,66	20,32	26,51	8,29	8,25	3,52	13,62	12,05
cardiac	no.	3440	193	318	459	321	147	62	7	2801	7326
	rate	10,53	5,22	3,86	7,04	6,92	3,86	6,39	0,36	3,64	3,63
lung	no.	2562	361	375	382	369	43	23	4	2183	5707
	rate	7,84	9,76	4,56	5,86	7,95	1,13	2,37	0,2	2,84	2,83
pancreas	no.	1027	57	95	78	82	20	5	...	801	2234
	rate	3,14	1,54	1,15	1,2	1,77	0,52	0,52	...	1,04	1,11
intestine	no.	104	...	3	3	6	43	173
	rate	0,32	...	0,04	0,05	0,13	0,06	0,09
Total	no.	37386	2853	3959	5814	5321	1472	505	263	44047	110691
	rate	114,4	77,11	48,1	89,17	114,68	38,64	52,06	13,42	57,23	54,82

Data source: GODT, July 2019

Figure 1. Deceased donors and transplant rates by type (number./mil. inh.) in some countries, 2018

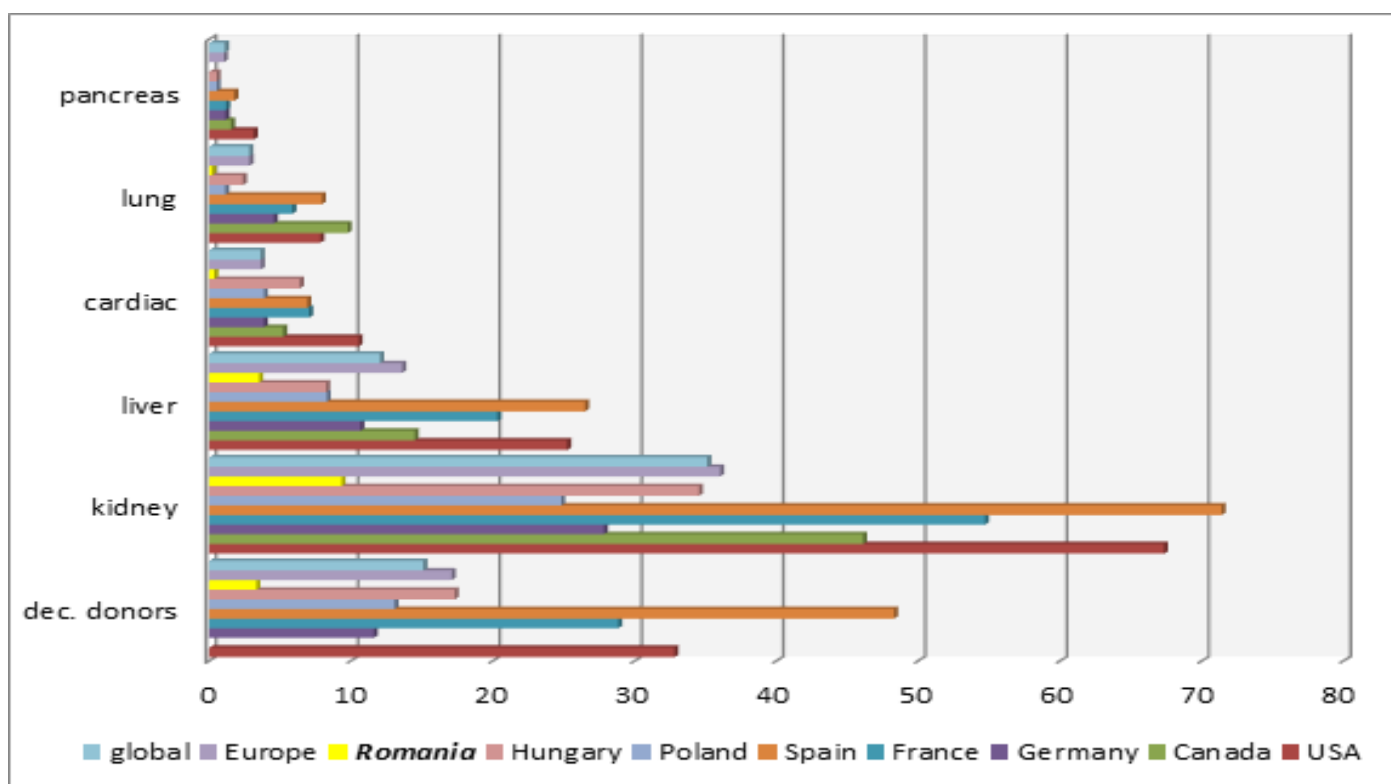
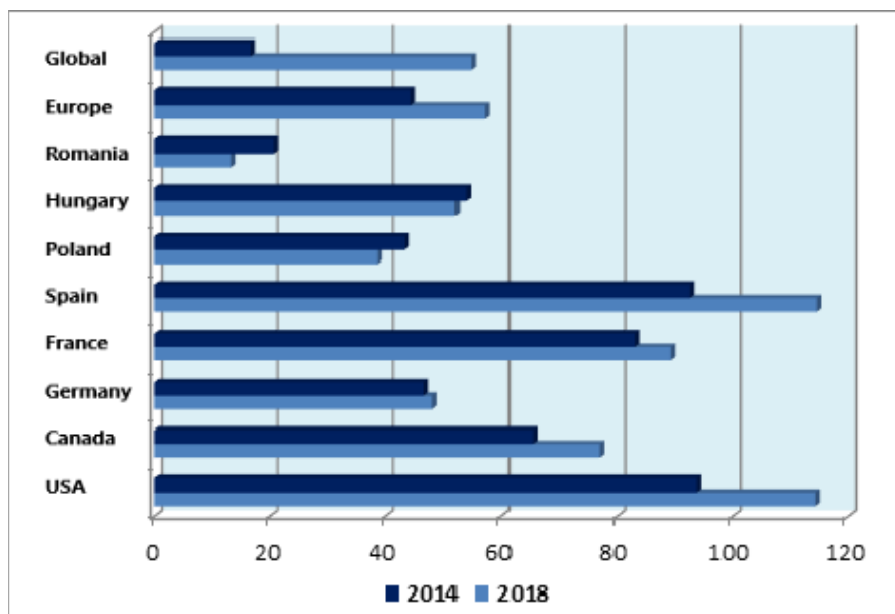


Figure 2. Total transplants rate in Romania compared to other countries/ regions, in 2014 and 2018



Data source: <http://www.transplant-observatory.org/summary/>

Table 4. Dynamic of main hospital indicators, 2013-2018

Indicator	2013	2014	2015	2016	2017	2018
Number of outpatient visits	26,316	23,519	25,292	23,316	22,656	28,203
Number of day care cases	4321	4070	4833	4105	11,885	6227
Number of hospital admissions	11,921	11,740	12,173	11,746	10,857	11,172
Number of hospitalization days	57,822	58,583	65,247	64,251	56,457	47,146
Average length of stay (ALOS) - days	4.84	4.99	5.36	5.47	5.20	4.22
Case-mix index (CMI)	1.0708	1.1505	1.1511	1.5196	1.58	1.63
% emergencies in total hospital admissions	34.7	35.3	27.8	23.5	23.6	24
Mortality rate (%)	0.37	0.60	0.79	0.99	0.82	0.80
Hospital-acquired infection rate %	0.18	0.17	0.07	0.3	0.72	0.28
Concordance between admission-discharge diagnostics (%)	57.1	54.40	50.00	53.04	53.73	58.15
Hospital tariff per weighted case (TCP)* - lei	1442	1442	1783	1783	1783	1783

Source data: statistical reports St. Maria Clinical Hospital, 2013-2018 [16]
* Values published in annual Framework Contract norms.

For SWOT analysis, see Table 5.

Beyond all that, our hospital team mission is to measurable improve patient health status by providing services of high quality adapted to each patient needs, practicing evidence-based medicine supported by modern health technology, within a safe environment, by specialists recommended by their results and continuously. Hospital Values: accessibility, "patient first", safety, effectiveness, professionalism, collaboration, respect for patient rights, sustainability, efficiency.

The next stage in hospital development would be a modern Multi-organ Transplant Center, of national and regional importance in South-Eastern Europe, according to established models, given that potential of the Romanian specialists overcomes the current practice. Vision, continuous effort and a persuasive leadership are essential to achieve this. Experience indicates that multi-organ transplant centers are more effective and efficient than the separated ones (located in distinct hospitals at considerable distances), because: concentrates the best and most experienced specialists, adequate medical equipment and health technology, best expertise and resources for organ harvesting, patient evaluation, transplant procedure, treatment, care and monitor the recipient, thus improving the clinical results (donors, solid organs harvested on time, successful transplants, survival, saved lives, patient quality of life), at lower costs compared to developed countries, retention of excellent medical professionals, prestige, as well as increasing trust in Romanian healthcare system.

This initiative is a managerial challenge, especially within a poor health system ranked on 34 out of 35 countries in the European Region, getting only 549 points according to the European Health Consumer Index in 2018 [17].

Hospital advantages:

- Hospital transit to local administration since 2010 was benefic: hospital team managed to convince local authorities – Bucharest General City Hall and Sector 1 City Hall – to support the hospital with enough funds for modernization and medical equipping; in addition, they also cover the hospital utility expenses;
- Excellent environment and working conditions offered by the hospital determined very good physicians to join and complete the team, thus performing new services and procedures, diversifying the cases treated and approaching complex pathologies, while competing with other public and private hospitals in Bucharest and across the country;
- Advantage of salary raises paid to medical personnel working in public hospitals (25% in 2016 and up to 100% in 2018); additionally, transplant team also benefit from a raise of 70%; all this income growth represents a strong financial motivation for physicians and nurses, consolidating our hospital efforts to eliminate "under-the-table" payments from the patients;

Table 5. SWOT analysis, “St. Maria” Clinical Hospital

Internal analysis	
Strengths	Weaknesses
<ul style="list-style-type: none"> – Hospital of grade II without compliance plan – Hospital building is rehabilitated and modernized – Very good medical equipment and health technologies – All hospital wards are clinical, providing highly specialized services, addressed by patients from all the counties – Medical personnel - well trained, enough, reputed physicians with great results, experienced teams, CME – Accredited Center for liver, pancreatic and lung transplantation, all procedures were successful – Extensive range of medical tests and imaging available – Working in national health programs (oncology, ICU-anesthesia, transplant, rare diseases) – Concomitant training and research activities, projects - national and European funds – Frequent medical events organized by/or within the hospital – Good communication between hospital personnel and the patients – Good quality of nonmedical services provided – Patients declare satisfied with the quality of services received in the hospital – Continuous organizational development. 	<ul style="list-style-type: none"> – Existing spaces are not enough for certain medical and administrative activities, as hospital developed a lot – Underuse of some services – Variations in ambulatory and day care provided – High hospital costs due to modern medical technologies used, complexity of cases treated, increased salaries of personnel medical, many training and research activities achieved, severe / complex cases treated – Some clinical protocols and operational procedures need revision/update – Retention of nonmedical personnel is difficult – Post-accreditation monitoring and reporting are laborious – Poor presentation and promotion of the hospital services, equipment, doctors, teams and results / accomplishments – Hospital website needs updates – Lack of parking lots in the hospital yard and nearby hospital.
External analysis	
Opportunities	Threats
<ul style="list-style-type: none"> – Substantial financial support from City Hall (ASSMB) – Significant salary raise for medical personnel since 2018, plus weighting for TR team – Accessing new national health programs – Collaborations with reputed, reference medical centers in Europe (ex. Hannover) – Accessing national and European funds for new research-development projects in the hospital – Very good collaboration with (central and local) public authorities – ASSMB, Sectorial City Hall, Bucharest Health insurance Fund, Public health Authority, MoH, NTA, National Agency for Quality Management in Health – Opportunities for collaboration with other public and private clinics from Bucharest and abroad – National Health Strategy 2014-2020 included specific actions to improve hospital sector. 	<ul style="list-style-type: none"> – Frequent political and legislative changes – Media campaigns against public hospitals, deteriorating their image and reorient several patients to private sector and other countries – Scandals related to transplantation, dramatically affecting population trust and organ donation – Current de contracting and reimbursement mechanism with insurance fund does not encourage hospital performance, nor efficiency – Administrative staff is demotivated after recent salary raise for medical personnel – Certain indicators and criteria for hospital reaccreditation are difficult to comply with – Migration of good doctors and nurses – Increasing poverty negatively influences behavior and health status of a significant proportion of population, with tardive or no access to adequate, timely medical services.

- Catering, laundry, cleaning and security services have been externalized, freeing spaces and reallocating them to medical activities, decreasing hospital costs with nonmedical personnel, and reducing associated risks;
- As public nonprofit institution, the hospital uses annual financial surplus for organizational development and improvement of the quality of services offered (implicitly no taxes, no dividends);

- According to public accounting law, public hospitals do not register nor include depreciation in their costs, therefore there is no such a pressure for investment recovery in a time limit, as practiced in the private clinics;
- Despite the difficult situation caused by the hospital-acquired infections in many public Romanian hospitals, our facility is known for the low rate of these infection, honestly reported;

- Internal efficiency conducted our hospital to save up to 20-50% from the total amounts reimbursed for each transplant achieved, depending on each case, besides the 30,000-40,000 Euro saved by the state for each successful transplant performed in Romania versus abroad;
- Besides transplantation, surgical teams of the hospital also accomplish new/and uncommon procedures, effectively approaching difficult cases and avoiding / preventing complications, in an increasing pathology range; the Ministry of Health has granted our Transplant Center and Surgery Clinic with the "Health Excellence Award" in 2015;
- Hospital medical teams periodically access additional funds for clinical research, results dissemination and continuous professional development;
- Financial management of the hospital including our projects is conducted in full respect for generally accepted accounting principles (GAAP), Romanian legislative framework, accountability and efficiency, despite so many frauds and arrears registered in the public system.

Premises: documentation, getting official approvals and support for this project from local administrative and health authorities; transfer the ownership of hospital land from the General City hall of Bucharest to the sector City Hall; pre-feasibility study and first draft of the new building projection; selection between offers for feasibility study by city hall; most of the medical equipment, health technology and instruments necessary for the new Center already exist in the hospital, as well as an excellent medical team specialized in Hannover Multi-organ Transplantation Center, with important clinical accomplishments; significant experience cumulated by hospital in HPB surgery and transplant; hospital portfolio of studies, research projects, publications and participations in valuable scientific events, basis for the new Research Center associated with the multi-organ transplantation activity; continuous development of the hospital in recent years.

Center is projected in a new modern building of 3S+P+7 (seven floors over-ground floors plus three underground floors), totaling approx. 7.000 m² as developed area, at a maximum cost of 2.500 Euro/m², to be located in the hospital yard and connected to the old building. Structure of the new Center will comply with operational circuits, modern endowments, equipment and hospital standards, and will include: laboratories for complete medical tests and imaging; medical departments of cardiology, oncology, pneumonology, neurology, nephrology; surgical departments: thoracic surgery, cardiovascular surgery, interventional cardiology, urology; extended transplantation clinic; operation theater; intensive care unit; patient rooms with high accommodation amenities (comfort); ambulatory covering all the specialties; training and conference center; technical and administrative rooms; underground car park. The hospital number of beds will remain the same (around 300) by redistribution of the current beds according to the new structure, after obtaining the public health authorization.

Financing sources for the new Center are identified in the budget of the Bucharest Municipal City Hall and of the Sector 1 City Hall, in partnership, while the hospital will participate with all the medical equipment already available and the almost all the medical and nonmedical personnel as necessary.

CONCLUSIONS

Romanian citizens who need a transplant have the right to receive these services on time and at the highest quality as possible, provided in accredited transplant centers in the country, at reasonable costs covered by the state (saving 30,000-40,000 Euro in average per case), instead of being postponed, delayed, some of them sent abroad and suffering discomfort, sometimes covering catastrophic payments for all required services (medical tests and evaluation, transplant procedure, post-surgical treatment and care, transport, post-discharge medical surveillance). Current transplant activity in Romania dropped in comparison with previous years and does not respond to the population needs, nor to capacity of medical system: only 3.32 deceased donors/mil. inhabitants (compared to 48,3 in Spain or European average of 17.1) and consequently just 13.42 transplants/mil. inhabitants in 2018 (compared to Spain 114.68 and European average of 57.23).

Romanian potential in terms of high performance surgical procedures overcomes the current practice. Experience indicated that multi-organ transplant centers are more effective and efficient than the separated, isolated ones, by gathering the best specialists, health technologies, expertise, experience and resources available for organ harvesting and preservation, evaluating and preparing the patients, transplantation procedure, and post-transplant care and monitoring, thus improving: specific health results (donors, successful transplants, lives saved, post-transplant survival, quality of life of transplanted patients), prestige and retention of valuable professionals, as well as population trust in transplant system, all at lower costs compared to transfer abroad. Additionally, Multi-organ Transplant Center will also provide excellent conditions for clinical research medical and the opportunity to become a local and regional training hub for specialists, thus strengthening the Romanian capacity in organ transplantation.

Given the pathway, achievements, premises and advantages of our hospital, while the current needs for transplant are increasing, shortly presented in this paper, we consider pertinent the proposal to create the first Multi-organ Transplantation Center in Romania and South-Eastern Europe, within the Hospital Clinic Sf. Maria in Bucharest, in order to better respond to specific needs of so many patients who wait for a life-saving transplant. The initiative involves substantial organizational, financial and managerial efforts, but on long term perspective, the Center is necessary, sustainable, effective and efficient despite all adversities encountered. However, without right information, transparent communication and proper education in organ donation, by authorities, transplant cannot be performed.

On the other hand, at the Romanian centenary, actions done to reduce exodus of physicians by involving them in modern medical centers with resources comparable with

those in the most developed countries, as well as treating the Romanian patients in the country at high quality standards, would be a duty of honor for the health leaders.

References:

1. Barker C.F., Markmann J.F. (2013). *Historical overview of transplant*. Cold Spring Harbor perspectives in medicine, 3 (4), a014977. doi:10.1101/cshperspect.a014977
2. Organ Procurement and Transplant Network, U.S. Department of Health and Human Services. (2019). *The Transplant*, <https://optn.transplant.hrsa.gov>
3. Eurotransplant. (2019). www.eurotransplant.org
4. Global Observatory on Donation and Transplant, the World Health Organization. (2009). *Global Glossary of Terms and Definitions on Donation and Transplant*, Geneva, November 2009, <https://www.who.int/transplant/activities/GlobalGlossaryonDonationTransplant.pdf?ua=>
5. Pablos-Herederó C., Fernández-Renedo C., Medina-Merodio J.A. (2015). *Technical Efficiency and Organ Transplant Performance: A Mixed-Method Approach*. Int J Environ Res Public Health. 2015 May; 12(5): 4869–4888, 10.3390/ijerph120504869
6. Dye C. F., Garman A.N. (2006). *Exceptional Leadership. 16 Critical Competencies for Healthcare Executives*, Health Administration Press, Chicago, IL
7. Duran A., Chanturidze T., Gheorghe A., Moreno A. (2018). *Assessment of Public Hospital Governance in România: Lessons from 10 Case Studies*, International Journal of Health Policy and Management, pp.1-12, https://www.ijhpm.com/article_3581.html
8. Saltman R.B., Duran A., Dubois H.F.W. (2011). *Governing Public Hospitals. Reform strategies and the movement towards institutional autonomy*. European Observatory on Health Systems and Policies, WHO Regional Office for Europe (pp.18-22)
9. West M., Armit K., Loeventhal L., Eckert R., West T., Lee A. (2015). *Leadership and Leadership Development in Health Care: The Evidence Base*. Faculty of Medical Leadership and Management, Center for Creative Leadership, The Kings Fund, UK, (2-11), https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/leadership-leadership-development-health-care-feb-2015.pdf
10. Hodgetts S. (2011). *Effective Leadership: The Key To Successful Spital Management*, Health Management, Volume 13, Issue 5/2011, <https://healthmanagement.org/c/spital/issuearticle/effective-leadership-the-key-to-successful-hospital-management>
11. Agenția Națională de Transplant. (2019). *Istoric, legislație specifică, Registrul Național de Transplant*
12. European Parliament and European Council. (2010). *Directive 2010/45/EU on standards of calitate and safety of human organs intended for transplant*, Official Journal of the European Union, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32010L0053>
13. Global Observatory on Donation and Transplant. (2019). *Summary transplant data per country, region and global, 2016-2018*, <http://www.transplant-observatory.org/summary/>
14. Copca N., Hanna A., Pivniceru C., Campeanu I. (2013). *Experimental Liver Transplant on Pigs – Technical Considerations*, Chirurgia, 108(4):542-6 Aug.2013
15. Copca N., Chirita D., Stroescu C., Hrehoret D., Popa L. (2018). *Centrul de Chirurgie HBP și Transplant al Spitalului Clinic Sf. Maria București: constituire, experiență, viitor*, Congresul Național de Chirurgie HBP și Transplant Hepatic, Cluj-Napoca, 20-22 Sept. 2018
16. Spitalul Clinic „Sf. Maria”. (2019). *Rapoarte statistice, clinice, financiare, rapoarte anuale de activitate, proiecte strategice și manageriale, perioada 2013-2018*; website <https://spitalsfmaria.ro>
17. Bjornberg A., Phang A.Y. (2019). *European Health Consumer Index 2018 Report*, Health Consumer Powerhouse, 2018-01-29 (pp. 19, 25-26)