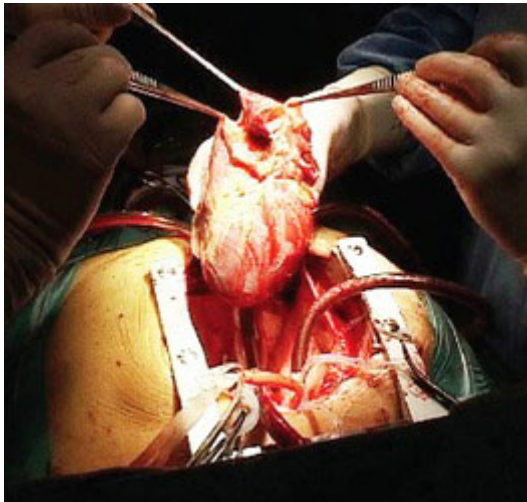


How the heart of Romanian transplants stopped beating

Viața Medicală [Medical Life magazine]Archive | 2013 | December | No 50 (1248)

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http://www.viata-medicala.ro/Cum-s-a-blocat-inima-transplantului-romanesc.html*articleID_7881-dArt.html



In March 2011, the Emergency Institute for Cardiovascular Disease and Transplants in Târgu Mureș lost its legal personality and became a section of the County Emergency Clinical Hospital Târgu Mureș. In October 2012, it recovered the name of 'Institute' and its financial independence, but not also its legal status. In July 2013, the Institute became again a medical facility with legal personality. During all that time, no transplant was performed there and, according to the doctors at the Institute, the activity was affected and some of the specialists working there left after it was dismantled.

In March 2011, when Attila Cseke was the Minister for Health, the Institute, which had been a separate entity since 1995, lost its legal personality and became a section of the Târgu Mureș County Emergency Clinical Hospital, within the premises of which it was located. Horațiu Suci, the head of the Cardiovascular Surgery Clinic for Adults and Children, and Radu Deac, the Institute's former director, who in December 2013 was appointed Director of the National Transplant Agency, claim that the 'Institute was dismantled'. The Ministry uses a different, softer word: the Institute was 'merged' and its activity was not affected.

Why?

The explanatory memorandum attached to the Government Decision on this restructuring operation lists several reasons, without providing details. Those reasons included the fact that some 'medical checks were settled between facilities using checks platforms which were separate but necessary for the operation of each of the two facilities'. The following example was given: The Hospital had a CT scanner necessary for cardiovascular checks, while the Institute had 'capabilities for other checks which the Hospital did not have and were necessary for the Hospital's medical activities'. The expected changes, according to the

explanatory memorandum, included improvement of medical activities and the Hospital's classification as a Level I A regional emergency hospital. The section on social impact contained only a brief remark that it was 'not applicable', and section 4, on financial impact on the consolidated general budget, contained only an empty table.

In a memorandum that the Institute's Medical Board addressed to Minister Cseke when the proposed decision was posted on the Ministry's website, it was pointed out that there had always been 'excellent cooperation' between the Hospital's different sections and that the lack of a cardiovascular surgery unit could not be regarded as grounds for not classifying the Hospital as a Level I A regional hospital, considering that there were also other specialised sections (Urology, Ear/Nose/Throat, Ophthalmology, Maxillo-Facial Surgery) which were not part of the Hospital and were located very far from the Hospital building. Another reason why the Institute's senior management was opposed to the merger was the fact that the Institute did not owe any debts. Furthermore, they argued that the merger would reduce funding by 25%, considering that the Hospital was reporting a lower case-mix indicator and a lower TCP [tariff per weighted case] than the Institute.

Besides the official reasons and documents, there were also certain declarations which inflamed the debate surrounding the Institute's organisation. In an interview of August 2013, in Târgu Mureş, Radu Deac declared that **'the decision to dismantle the Institute had been a political decision and that the Institute's activities had been regarded as inconvenient by many people, in particular the Mayor** (author's note: Dr Dorin Florea, who is still the Mayor). **The Institute was the only medical facility outside the control of the PDL (Democrat-Liberal Party).** Four people met in the office of the Hospital's director and decided this.' Radu Deac did not want to say who those four persons were.

[I would mention here that Radu Deac was taken into consideration for the USL \[Social-Liberal Union\] lists at the last parliamentary elections. Dr Horațiu Suci](#)[u was a USL candidate for a Mureş County Council seat.](#)

Two weeks ago, after two years of silence on this topic, former Minister Cseke told us that 'given the way this campaign about Târgu Mureş started, it was clear that the intention was to cause a scandal.' He said that the financial aspect of the merger was not taken into consideration when the decision was taken, despite all the discussions on this issue'. However, he also mentioned double reimbursements as one of the reasons why it made no sense for the Institute to keep its legal personality, and admitted that, had it not been located within the Hospital's premises, 'the Institute would probably have not been dismantled'.

Consequences

Both Radu Deac and Horațiu Suci admitted that the dismantlement of the Institute was the reason why no other transplants were performed in Târgu Mureş. Radu Deac mentioned as an example the reactives which were no longer purchased for the immunological test laboratory. 'The entire system fell apart. Before, we could have any medicine we needed within 24 hours. In November 2011, we asked for transplant medicine, but we have never received it', he added. Dr Horațiu Suci said that, in order to develop its transplant activities, the Institute needed to be independent, so as to develop a strategy. Some specialists, including three anaesthesiologists involved in transplant operations, left precisely because of this lack of perspective.

Horațiu Suci confirmed that, during all this period, he received notifications of hearts available for harvesting, but he was forced to refuse due to the shortages which could have endangered the operation.

In an interview in September 2013, Dr. Victor Zota stated that 'in Târgu Mureş it was no longer possible to perform transplants for technical reasons, because they no longer had anybody or anything to work with'. 'Besides the lack of personnel, they were also lacking the medicine required to treat patients after the transplant'.

Dr. Şerban Brădişteanu was of a different opinion: **'I would not link the dismantling of the Institute to the end of transplants. I cannot accept that ... because I do not need a company in order to do a certain thing. Could we link it to Mr Deac's departure? That is something that I could agree with. (...)** I do not have a company and what I do does not depend on what is written on my door'. Radu Deac retired only a few months before the dismantling/merger of the Institute.



Former Minister Cseke is convinced that 'the activity was not affected between 2010 and 2012' and that transplants were not performed only because of compatibility factors. He also presented separate figures for the number of procedures performed by the Institute and the Hospital in 2010, and the number of procedures performed jointly after the merger, in 2012. Those figures show some increases following the merger: 69% more extracranial vascular procedures with disastrous or severe complications, 2 000% (!) more major thoracic procedures without disastrous complications, and 92% more coronary bypasses.

When asked to explain these figures, Vlad Iliescu, head of Heart Surgery Clinic II at the 'C. C. Iliescu' Institute in Bucharest, said that a larger number of operations could be due to more funding. Secretary of State Adrian Pană, who endorsed the reopening of the Institute in 2013, explained that a larger number of procedures is only part of the picture and that we should also take into account other outcomes: 'survival, the fact that you can work with the optimum number of doctors ... ultimately results also imply costs'.

The 55 wasted hearts

In May 2013, a few months before the reopening was decided, a statement by Dr. Radu Deac was widely quoted in the media: 55 hearts (20 in 2011 and 35 in 2012) had allegedly been wasted as a result of the Institute not being able to perform transplants. Some TV channels turned this into '55 hearts thrown out in the rubbish'. That wording was factually incorrect. The hearts in question were never harvested, and the heart of a donor is not always usable, even if the kidneys and other organs are harvested. Moreover, the age of the donors has increased constantly over the last few years, and the age limit for harvesting a heart is 45 for men and 40 for women.

Victor Zota, the national transplant coordinator, confirmed that there were probably 20-25 hearts which 'would have been eligible for a transplant' in 2012-2013. 'There are also other conditions which have to be met', he added. 'The medical facility involved has to be able to perform the transplant, which did not seem to be the case in Târgu Mureş any more. Even in Bucharest there were difficulties

... Second, even if it had been possible to perform the transplant in Bucharest, it would have been necessary to get the heart there in time - and most of the donors were in Transylvania'.

The coordinator of the second centre in the country where a

transplant could have been performed, Dr Şerban Brădişteanu, referred to incompatibility between donors and recipients, and organisational problems: 'If you tell me that you have a heart in Oradea, and I have a recipient, I cannot go to Oradea for that heart. The return journey is too long (author's note: in the case of a heart, cold ischemic time is only 3-4 hours). It is mere coincidence that no transplant was performed at Floreasca either, in those two years. This year there was only one, in July.'

Transplanturi de cord efectuate în România comparativ cu alte țări europene

| | România | Spania | Belgia | Croația |
|------|---------|-------------------------|--------|---------|
| 2007 | 7 | 241 | 74 | 6 |
| 2008 | 6 | 292 | 75 | 20 |
| 2009 | 10 | 274 | 68 | 20 |
| 2010 | 7 | 243 | 68 | 36 |
| 2011 | 7 | 237 | 76 | 38 |
| 2012 | 2 | 247 | 77 | 44 |
| 2013 | 1 | date încă nedisponibile | | |

sursa: Agenția Națională de Transplant / International Figures on Donation and Transplantation (Consiliul Europei)

[Key to the table above:

Title: Heart transplants performed in Romania, compared to other European countries
2013: data not yet available for Spain, Belgium and Croatia

Source: National Transplant Agency/International Figures on Donation and Transplantation (Council of Europe)

Reopening

After signing in October 2012 (as interim Minister for Health) the order giving the Institute financial independence (the contract between the Insurance Office and the Hospital was to mention separately the amounts intended for the Institute, and the Institute's senior management was to take part in negotiating that contract), Victor Ponta addressed the following request to Minister Eugen Nicolaescu (Liberal) at a Government meeting in May 2013: 'I am asking you personally, because it is an old problem, to come up with a decision regarding the Heart Institute in Târgu Mureş. I know that there are also problems related to personal ambitions and different approaches among doctors.'

The solution came one month later: reopening the Institute as a medical facility with legal personality. **It is interesting that the explanatory memorandum attached to the decision on reopening the Institute includes an argument which was also in the decision on dismantling the same Institute:** 'increasing the quality of medical activities; operating within the same building as the Hospital would not affect such activities'. Not even one word about a major change that was about to occur: possible declassification of the Hospital below Level I A, in the absence of a cardiovascular surgery unit.

The methodology for classifying emergency hospitals contains a provision which states that 'in order to provide the full range of emergency medical services and to receive the classification in question, Level I A regional hospitals shall also cooperate with other medical facilities in the Level I B category in the same locality'.

Secretary of State Adrian Pană could not confirm whether such a cooperation protocol exists between the Hospital and the Institute in Târgu Mureş, but he is convinced that the protocol 'certainly exists', if the Hospital has not been declassified.

I asked former Minister Cseke what was the reason for reopening the Institute: '**Certain persons' ambition to have an institute with legal personality, to have a separate manager and separate directors. (...) I believe that we are the only ones in the EU who have a hospital with legal personality within another hospital. We do not simply transfer patients from one section to another; instead, we discharge them and then we readmit them on the second floor**'.

Secretary of State Adrian Pană said, however, that the decision was not based on any personal ambitions.

When the Institute was dismantled, Dr. Raed Arafat was Under Secretary of State in the Ministry of Health, and he was in favour of that action. When it was reopened, he was a Secretary of State and he opposed that decision. In his negative opinion, he argued that such a solution 'would serve the interests of persons who wish to control the Institute and its activities, thus transforming the Institute into a feudal system and strengthening the position of certain persons within the Institute'.

He added that the organisational and administrative problems mentioned by those working at the Institute could be resolved regardless of its having legal personality, and were due largely to failure to apply the provisions of the Order of October 2012 on separate budget appropriations. According to him, some of the consequences of the separation from the Hospital would be declassification from level I A to level II A, an increase in certain costs under the Single Health Insurance Fund, and the creation of a precedent based on which other hospital units might also request to become institutes.

No heart transplants at Floreasca

The accreditation criteria for transplants were published in July 2013. From that moment on, any hospital which wished to harvest organs and perform transplants had to apply for re-accreditation, and some of the results have already been published.

Victor Zota, the national transplant coordinator, declared that 'hospitals would have EU-level accreditation. There is none left with one of the old accreditations, which were based on other criteria, mostly on experience and historical background'. The new accreditation process was ushered in by Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation, which was to be implemented before August 2012.

According to H el ene Le Borgne, expert in organ donation and transplantation policies at the European Commission, 'the rules clearly state that we need common standards on quality of organs, tissues and cells. There are, however, many aspects which are within the competence of national government: managing waiting lists, criteria for declaring brain death, criteria for allocating organs'.

Victor Zota said that he had expected more accreditation applications: 'I thought there would be ten centres wishing to perform liver transplants. I received only one application. I expected 15 centres to apply for kidney transplants. I received only three applications.' The expectations were met only in the case of heart transplants, where four requests were received, from the Heart Institutes in Iaşi, Timi oara, T rgu Mure  and Bucharest. The Iaşi-based institute was not accredited, the one in T rgu Mure  was, and the other two, in Bucharest and Timi oara, are still waiting for a decision. The accreditation decisions might be announced, by Order of the Minister, before the end of the year.

The surprise was that the Floreasca Hospital, where the only transplant of this year took place, did not request accreditation.



Dr Șerban Brădișteanu, head of the cardiovascular surgery unit there and the person who performed the first heart transplant in Romania, did not show any interest in that process, during an interview in October 2013. After first telling us that he would perform a transplant 'whenever the occasion arises', when we mentioned that his hospital had not submitted an accreditation request, he replied: 'I will not perform any

transplants. It would be as if you told me what I should do in the operating room. I would give you a piece of paper saying that I know how to perform the operation, and you would tell me that you believed that I could not do it.' Asked whether he would be contacted again by the National Transplant Agency to perform a transplant, he answered: 'That is the Agency's problem. I am not going to ask the Agency to contact me. Usually, it is the Agency asking me to respond'.

123 persons on the heart waiting list in Romania

At the end of last year, there were 64 000 people on waiting lists for an organ in the European Union. 2 000 of them were waiting for a heart. 123 of those 2 000 were in Romania. 40 were added to the list in that year, and 11 died waiting. There are no data available for 2013, because the list is updated at the end of the year.

The statistics show that 10 people die every day in Europe waiting for an organ. That figure might be even larger, because not all of them are added to the waiting list. The list is extremely dynamic, and it is not possible to speak of a 'position' on the list. You can be first today, based on your medical condition, but fall to the fifth position tomorrow. The decision to allocate an organ is very difficult and involves medical, social, ethical and organisational considerations. It is not just the emergency that matters, but also the length and quality of post-transplant life.

In the European Union, 1 960 heart transplants took place in 2012. In Romania there were only two, and in 2013 only one.

Before the reaccreditation was introduced, Romania had two centres which could perform heart transplants: the reopened Emergency Institute for Cardiovascular Diseases and Transplants in Târgu Mureș and the Surgery Unit for Heart and Large Vessels at the Floreasca Emergency Clinical Hospital. Spain, with a population of 46 million, had last year 16 such centres, and 433 persons on the waiting list. Only 14 persons were removed from that list.

However, according to Rafael Matesanz, Director of the National Transplant Organisation in Spain, the number of heart transplant centres is too high, because the demand has declined as a result of other methods of treatment. Moreover, the age of donors has also increased together with the number of donors, and this makes it impossible to harvest hearts. In Spain, average waiting time for a heart transplant is three months, but there are also cases where

the wait is longer, such as children or overweight persons. Most centres in Europe have waiting lists two or three times longer than the number of available organs.

The budget allocated under the National Health Programme for 2013 was RON 41.8 million, and an amendment adopted in the summer added more money. The number of heart transplants budgeted for was 18, but by the beginning of December only one had taken place. The budget also covered a heart and lung transplant, but no such transplant has yet taken place in our country. The average cost of a heart transplant has been estimated at RON 107 000. Minister Eugen Nicolăescu declared in November 2013 that he wanted a larger budget for 2014, and that he also wanted three national programmes to become exemplary: the cancer programme, the transplants programme and the diabetes programme. Given the accreditation of a large number of hospitals for declaring brain death, the number of donors is expected to increase.

The coordinators have not yet been paid

The European experience, particularly in Spain, has shown that successfully increasing the number of donors depends on the presence of an effective network of 'key donation persons' and transplant coordinators. The first category includes doctors specialised in anaesthesia and intensive care, who identify brain-dead donors, declare their brain death and preserve them. The transplant coordinators can be either doctors or nurses. They talk to the families of potential donors in order to obtain their agreement to harvest the organs, and ensure coordination with the harvesting teams. In Spain, after the appointment of transplant coordinators, the donation rate increased in only a few years from 14 to 35 per million inhabitants. The same happened in Greece, in only four years between 2001 and 2005.

The legislation governing the activities of these two professional categories was introduced in December 2012, during Raed Arafat's short term as the Minister for Health. Five regional coordinators were appointed at that time: in Bucharest, Iași, Târgu Mureș, Cluj and Timișoara, covering the 35 hospitals authorised to harvest organs. Subsequently, transplant coordinators and 'key donation persons' were identified and confirmed at each hospital.

Rafael Matesanz insisted that organ transplants should not be regarded as a luxury, because in some cases it is actually a source of savings. According to him, the savings could go to the transplant coordinators, especially considering that they are paid as part-time staff for this activity. 'People do not want to hear that this field is affected by financial problems. You ask them to donate organs to save lives. You cannot say then that the transplant cannot take place because of financial problems', he added.

He stressed that expensive media campaigns and changes in mentality will not solve the problem of how to increase the donation rate. In Spain, favourable attitudes towards donation are at the same level, i.e. 58%, as in 1989, the year when the National Transplant Organisation was set up. In Romania, the National Transplant Agency was created only in 2004. Nevertheless, the number of donors grew exponentially, not by changing mentalities, but by creating networks of transplant coordinators.

Spain has around 400 transplant coordinators for a population of 47 million. According to Matesanz, this implies that Romania should have around 200.

Under the same Order of 2012, which laid down the duties of transplant coordinators, they were to be paid with money from the national transplants programme. This did not happen, because they could not be paid if the hospitals were not accredited for harvesting. **'We also have hospitals which were accredited but still did not pay the coordinators. There are various impediments in this respect, but I would want not to talk about that.** Next year we will include payments for coordinators and anaesthesiologists involved in declaring brain death', Victor Zota declared in October 2013.

Payment means RON 500-700 per month per coordinator. Victor Zota confirmed that even if these almost derisory amounts were not included in the budget for previous years, they could have been paid from the money for a single transplant. 'There was no will', he said. Whose will? 'The Ministry's', added Victor Zota.

The surgeon Horațiu Suciu confirmed that, at present, there are materials and medicine available in Târgu Mureș for 2-3 transplants before the end of the year, provided that there are donors.

Since the reopening of the Heart Institute in Târgu Mureș, six months ago, only one heart transplant was performed in Romania ... in Bucharest.