Borders in Transplantation

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The theme we have chosen for the second ELPAT meeting is "Borders in Transplantation".

Borders are everywhere: in geography, in time, in anatomy, in thoughts and even in life itself. Borders separate and make distinctions between various entities, e.g. between countries. You can cross them and arrive in a totally different world with unusual landscapes and with people who speak strange languages, and have different cultures, religions and ways of life. Some of the geographical borders are natural borders like the Alps between Italy, Switzerland and France. Hannibal crossed them in 218 BC with 50.000 man, 9.000 horses and 37 elephants. He arrived in a totally strange world and after winning a few battles he found himself isolated from his own people in a hostile environment and within 2 years time he had to give up and sailed back for Carthage. The Channel is another example of a natural border. It separates England from the mainland of Europe and indeed from the rest of the world in splendid isolation.

Geographical borders are not always natural, they may also be truly artificial, e.g. the borders between various States in the USA: just lines drawn in an endless more or less empty space of land. The same holds true for Africa: a whole continent had been divided into separate states just 120 years ago without giving any consideration to the habits, cultures, ethnicity or language of the local people. Borders between counties separate the others from us, strangers from normals, and enemies from friends. Not only do they separate, they also facilitate cultures to evolve further in separate ways thereby increasing existing differences. However, borders may not be permanent; they can change over time, just a snapshot of history. Europe in 1000 AD had a large Holy Roman Empire, Muslims had conquered Spain and the Byzantine Empire still was a vast and powerful political entity. In 1500 AD the Holy Roman Empire had been replaced by a number of small states, the Muslims had left Spain, while the Byzantine Empire, after 1000 years of Christianity, had been replaced by the Ottoman Sultanate. And now, again 500 years later, we are attempting to break down the European borders by building the European Union: from 6 founding member states in 1952 the Union expanded to 27 member states in 2007. Borders change over time and consequently differences in culture also vary over time. So it is not only "Tempora mutantur, nos et mutamur in illis", but also and at the same time "Fines mutantur, nos et mutamur in illis". Borders change and we change within them.

Borders are not always sharply defined. This can be illustrated by the differences between the works of two famous abstract painters: Piet Mondriaan and Mark Rothko. In Mondriaan's compositions black lines sharply separate various rectangles. In his view life, the world, existed of clear distinct entities. This view of the world is hold by many, if not most people. It

gives them a feeling of certainty, a belief in absolute truth. Rothko paintings however, show borders that are not sharply defined. His borders are rather hazy transitions from one color to the other. Nevertheless they separate, but not in an abrupt way. There is an in-between, a no-man's land, a zone of uncertainty. People are not fond of uncertainties.

So borders make distinctions, they separate, but you can cross them and come back if you wish. Some geographical borders are natural barriers, like the Alps or the Channel. Some are the result of long political and cultural processes, while others are artificially imposed at a certain point in time. Borders are not permanent, they change over time, and we change within them. Borders may not be sharply defined; transition zones can also make distinctions.

Borders have a prominent place in transplantation medicine too. In December 1954 the first successful kidney transplantation was performed in Boston. A big medical breakthrough. The kidney was derived from an identical twin brother who was nephrectomized for that purpose. The first border was crossed. Critics were quoting the 2.400 year's old mantra from Hippocrates: "Primum non nocere", "First do no harm". They stated that the integrity of the human body was an absolute border that should not be crossed. Of course the argument against this criticism was that the intention of the donor nephrectomy, not the operation itself, made the procedure morally acceptable. It is remarkable that after a millennium of bloodshed in the name of religion, trade, freedom, and just after the Second World War, a life saving medical procedure was condemned on the basis of the concept of the integrity of the human body. It is even more remarkable that after 55 years of highly successful living kidney donation programs this opinion is still held in many countries with as a consequence that kidney patients die on the waitlists.

The second border that was crossed in transplantation was the HLA system. This system consists of molecular immune structures that make the distinction between self and non-self. Only kidney donations by HLA identical siblings proved to be successful in the fifties. HLA-identity was demonstrated by the acceptance of donor skin by the patient. Transplantation of HLA non-identical donor kidneys inevitably resulted in failure through an immunological reaction: rejection. After medication had been developed that suppressed these immunological reactions it became possible to prevent rejection of organs from non-HLA identical individuals. Not only living, but also deceased individuals became potential organ donors.

Thus now the next border was crossed, the border between life and death: the river Styx between the land of the living and that of the dead. From ancient mythology it is known that this border is not a thin blue line, the river Styx is wide and can only be crossed with help of the ferryman Charon. The Styx is thus not a sharply defined border, but rather a transition process, and this makes that the definition of death is not unambiguous. After the first deceased donations a comparable question was raised as in the case of living donation: are we allowed, and under which conditions, to remove organs from a deceased individual. Indeed the concept of the integrity of the human body does not stop after life. And the same answer as for living donation was given: it is not the action itself, but where the action is needed for, that makes it morally acceptable.

So in transplantation medicine we have crossed several borders: that of the integrity of the human body, the border between self and non-self as defined by the HLA system, and the

border between life and death. Globally there is, however, no consensus on the acceptability of crossing these borders. In some cultures living organ donation is still regarded as a violation of the oath of Hippocrates, while in other societies deceased donation is perceived as morally unjust. Clearly vast differences of opinion exist on these issues, and clearly this stands in the way of optimal recruitment of both deceased and living donor organs. The aim of ELPAT, the movement on Ethical, Legal and Psychosocial Aspects of Transplantation is to address these differences in an attempt to create the necessary transparency for the decisions we have to make in order to save the lives of organ transplant candidates.

Volcanic Ash, Skype and the ELPAT Congress 2010*

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Figure 1 (REUTERS/Lucas Jackson)

How Skype Saved the ELPAT Congress

Before the Congress

'News around the world on Thursday April 15th, 18.00 hours: In Iceland, the Eyjafjallajokull continues to billow smoke and ash. Therefore all flights in Northern Europe are cancelled. ' At this time over 300 doctors, ethicists, legal experts, psychologists, philosophers, and poli-

* This congress was organized by ELPAT, the European platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation and ESOT, the European Society for Organ Transplantation. The congress received funding from the European Commission and the Dutch Ministry of Health, Welfare and Sport.

cy makers were registered for the 2nd ELPAT congress on Organ Transplantation entitled 'Crossing Borders in Organ Transplantation'. This would take place in Rotterdam, The Netherlands from April 17-20, 2010. Most delegates came from Europe, but there were also many coming from further away, including USA, Canada, Pakistan, Israel, Argentina, Mexico and New Zealand. In total 297 delegates from 44 countries were listed.
The next day, Friday April 16th 2010, it became clear that it would be very difficult for the participants to reach the Netherlands by airplane, because all flights were cancelled until further notice. Besides this, there happened to be a strike of employees of the trains in France. We received countless emails and telephone calls from delegates all over the world informing us and asking us what to do and whether the congress would go on.
That afternoon the ELPAT/ESOT organisation came together in the World Trade Center (from now on mentioned as WTC) to address the situation. From looking at the number of delegates coming from the Netherlands and surrounding countries (Belgium, Denmark, Germany), we figured that 130 people could reach Rotterdam, assuming they were able to organise alternative means of transportation.
From the rest of Europe, 128 people from 26 countries had registered while from outside Europe we had 40 other registrations from 14 countries. We reckoned that a number of them would be able to come, so we expected approximately 150 participants.
Therefore cancellation was not an option; also this would be a great waste of time considering the intensive preparation during three years, not to mention the financial consequences. This meant that we decided to go on with the conference as planned, and the first thing we did was to announce our decision on the ELPAT website and send an email to the delegates to inform them. In this email we also asked them for an update about their situation at that moment in terms of travelling.
Additional news regarding the flight disruption was posted on the website throughout the conference.
The next thing we did was to discuss with the management and technical staff of the WTC how we could maintain the programme as much as possible, despite the fact that many presenters and chairs would not be able to come. We discussed the possibility of live streaming online, but this was a very costly operation, because we used 4 conference rooms. Moreover there was a lack of time to arrange this in a proper manner.
We decided to make use of Skype, a programme which could easily be downloaded by all presenters and is free of charge. This meant the need of a few more technicians to get everything well organised. The 2 technicians in the plenary room (audio, light/video/powerpoint) were supported with 1 extra person (Skype). Furthermore we decided to have a technician present in each conference room, apart from the one in the upload room. So instead of 4 we had 7 technicians in total; the extra 3 were free lancers.
We then discussed with the management what to do with the reduced number of participants and the costs of ordered consumptions/meals. Because of the unique circumstances and to keep the negative results for all parties as little as possible, we agreed to reduce the number of participants from 250 to 150, without any extra costs.

Planning and Preparation

We looked at the programme day by day, because the situation could potentially change any time and people might still be able to come by plane. The programme for Saturday was fine;

we knew all speakers would be present, except for one from Holland, who could not come home from abroad. He had arranged for replacement. Furthermore, we asked the chairs who were present if they would be willing to replace those who didn't make it.
Friday afternoon we sent out an email to the people who cancelled their presence for Sunday, asking them if they were willing and prepared to do their presentation by Skype. If so, they had to forward their slides of the presentation and their Skype name.
Then, we confirmed the received slides and enclosed instructions for Skype, which we made together with the technical staff of the WTC. In the instructions we mentioned specifically in what room their presentation would take place and the Skype name to use for that room. Delegates (5) who were having more than one presentation in different rooms, were sent instructions per presentation/room/Skype name (see text and instructions in framework on next page).
The next day we collected all the slide presentations and came together to see how many people would actually do their presentation by Skype the day after. Because of the time difference we did not receive all the answers during the day and continued emailing until 2.00 am with other parts of the world.
Because there was no change in the no-flying news, we sent out another email to ask the presenters scheduled for Monday if they were willing to give their presentations by Skype.
We convened twice a day to discuss the programme. At 08.00 hrs am to discuss the morning programme; during lunch to discuss the afternoon sessions. We gave colours to the names in the programme meaning that the presenter: was present, cancelled, did not re-

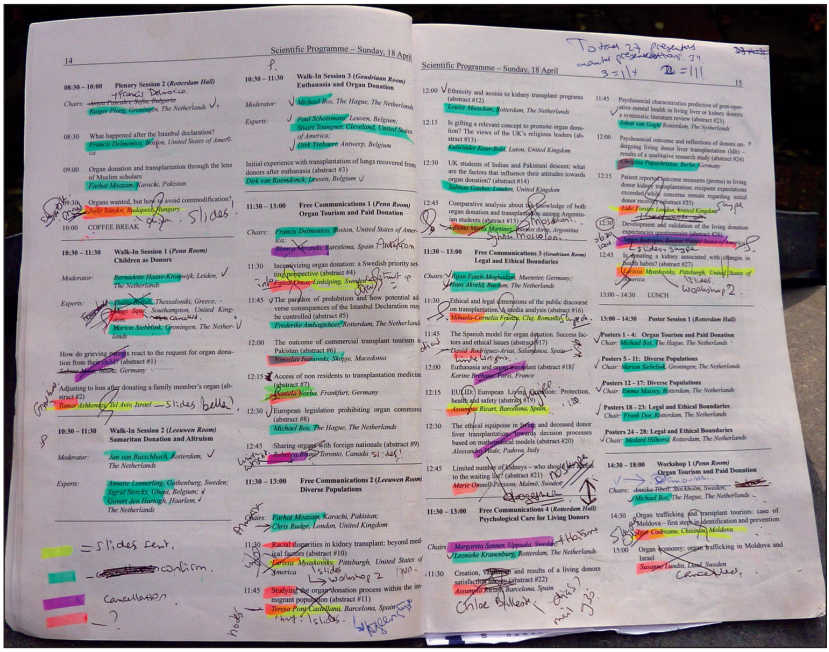

Figure 2
Legends to the figure:
Green = present; Purple = cancelled; Yellow = slides sent; Orange = no reaction (yet)

Thank you that you agreed to give your presentation for the ELPAT congress via Skype. Your presentation during the ... Session on ... is scheduled on ... from ... in the ..... Room (Dutch time).

Please find the adjusted instructions below.

In order to achieve an online connection, we kindly request the following:

1. If you have not yet sent your powerpoint presentation, please do so as soon as possible to ....@gmail.com and office@esot.org.
2. Please print out the handouts of your presentation, as you will not be able to properly see your slides when on Skype.
3. To be able to give your presentation via Skype, you have to download the program from http://www.skype.com. Follow the instructions of the program to install this on your computer.
4. For the ..... Room add the user ..... in your Skype program in order to connect to the technician in the room. Please let him know your full name by sending a Skype message (as written in the programme).
5. Please forward us your skype name.
6. Please ensure that you are online throughout the entire duration of the session.
7. The technician will **call you** via Skype when you are meant to start your presentation. Please refer to the congress program for the approximate time. After accepting the call, you will be connected to the room so that people can hear you. You can only hear the people who talk into the microphone. Unfortunately you will not be able to hear other presentations given in the session.
8. You will be able to see the room and if your webcam is on, the delegates in the room will be able to see you. Again, you will only be able to hear the people who talk into the microphone.
9. While giving your presentation, to go to the next slide, you have to say 'next slide' out loud, so the technician in the plenary room can click to the following slide.
10. A webcam will be directed at our computer, so on your own screen you will be able to see which slide is visible in the plenary room.
11. The guests of the conference will be able to ask you questions via the audio connection between the plenary room and your computer.
12. If you would like to test the connection you can do so in the lunch break 13.00-14.30 Dutch time.

Note: You can give your presentation with only audio or with video and audio.

For this last option you need a webcam. Also, for video presentation via Skype, a minimum upload speed of 1 Mb/s is necessary. If your upload speed is lower, you can give your presentation with only audio.

spond, forwarded his/her slides, presented using Skype (see photo programme book, fig. 2). We also discussed who we would ask to replace absent chairs. On a total of 52 chairs 13 were replaced.
Hereafter we would inform the technicians in the 4 different rooms and the one in the upload room. The latter is the one who collected all the presentations and made sure they were

presented in the right order and in the right room. Several times a day he would come by to ask if new ones had arrived. Sometimes, if at the last moment, we would bring them.
In addition, we approached the chairs to inform them about the changes in the programme, for instance, who was giving a presentation by Skype, who was giving a normal presentation, who was replacing a presenter and who wasn't presenting at all. This above described scenario was followed on all congress days.
It also sometimes led to confusion, for instance we had not heard from David Terán from Mexico whether or not he was experiencing difficulties in reaching Rotterdam. We assumed therefore that he would not be able to give his presentation and communicated this to technician and chair. To our surprise he came to Holland a few days earlier and was able to do his presentation. So we had to reinform everybody, but were very pleased with this.

During the Congress

The first presentation by Skype was on Sunday by Judit Sándor from Hungary and we were very pleased by the audio-visual quality. The photograph below from Jim Rodrique, USA, shows how this appeared on the screen (Fig. 3). He gave 3 presentations by Skype, 2 of them were, because of the time difference, in the middle of the night local time. The same goes for Larissa Myaskovsky from the USA, also presenting 3 times by Skype.
On a total of 113 presentations we had 34 presentations done by Skype (30 %) from 16 different countries; 10 presentations were taken over by others (9 %). We were very lucky to have with us Linda Wright from Canada, who was already in Europe when the eruption took place. She gave 4 presentations for others, besides her own. There were only 17 presentations cancelled (15 %) from 14 speakers, which means that 85 % of the presentations was given.
Out of these 17 cancellations were 5 presentations from people who were not allowed to use Skype at their working place.

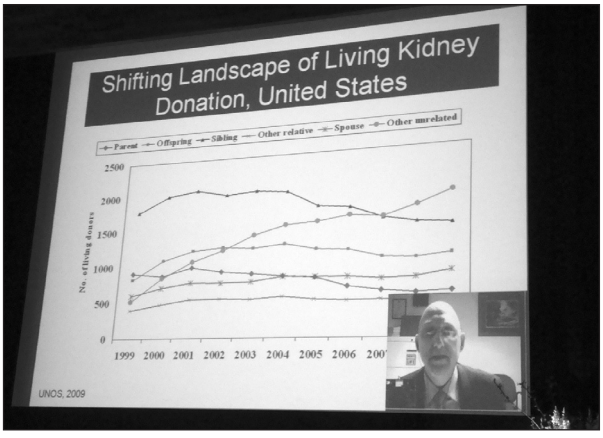

Figure 3

Tab. 1: Planned presentations

Total number:	113	
Presented in person	52	
Skype presentations: – 3 by 2 presenters – 2 by 3 presenters – 1 by 22 presenters	34	by 27 presenters
Countries from where they were given: – 10 from the United States – 7 from the United Kingdom – 2 from Hungary, Spain, Sweden – 1 from Bulgaria, Canada, Israel, Italy, Kuwait, Latvia, Moldova, Portugal, Romania, Slovakia, Slovenia		
Performed by someone else:	10	by 7 presenters
Cancelled: – 1 with 2 presentations – 3 persons no permission to Skype at work, 1 with 3 presentations – 1 with bad experience using Skype – 1 who went to a summer cottage without internet – 8 persons for unknown reasons	17	by 14 persons

Evaluation after the Congress

Eventually, despite of the problems with reaching Rotterdam, 175 people managed to attend the congress. From Europe 162 people attended (12 countries), including 119 people from the Netherlands and surrounding countries.
From outside Europe we had 13 people coming from 7 countries. It helped that prior to our congress a number of these people attended a meeting in Paris so that they could easily reach Rotterdam.
We drafted a questionnaire and sent it one month (May 18th, 2010) after the congress took place by email to all those who registered for the congress (297), including those who did not make it. We got a response of 80 questionnaires. After two weeks (June 4th, 2010) we sent an email to thank and remind people. After this we got back a total of 94 (32%) questionnaires from 27 countries, including 11 Skype presenters.
In the questionnaire we asked if and how people were able to reach Rotterdam; if they managed in the way they were supposed to travel or whether they had to change their schedule/way of transportation. The same questions were asked, if they did come to the congress, for their return schedule.

Also we asked questions about the experiences with Skype; was it the first time they used Skype, did they have to download it, how was the response to the Skype presentations/images by the presenter and by the audience.
We looked at the countries people came from and stratified into the Netherlands and surrounding countries, the rest of Europe, and outside Europe. Finally we asked for suggestions for improvement in case Skype would be used again for presentations during a congress.
From the 94 received questionnaires there were 29 from people who came to the congress solely to attend, 59 from scheduled presenters and 6 left the question unanswered. From the 59 scheduled presentations, 35 people performed their presentation, 11 presented by Skype and 13 were unable to do their presentation/poster.
From the 11 people who gave a Skype presentation, 5 did this at home, 4 at work and 1 left the answer blank.
From the 94 questionnaires there were 45 people who couldn't come as scheduled. From these 45 people 2 people came from Denmark (surrounding countries), 22 from the rest of Europe and 11 from outside Europe. The other 10 from the 45 people who couldn't come as scheduled managed to come by alternative routes; 1 from Pakistan, the others from within Europe (1 x Spain, 3 x Sweden, 2 x Switzerland and 3 x United Kingdom).
The other 49 people responding to the questionnaire came as planned. From these 49, 40 people were coming from the Netherlands and surrounding countries, 6 from the rest of Europe and 3 from outside Europe (Argentina, Canada and Mexico).
Worth mentioning is Nizam Mamode from the United Kingdom, who was scheduled for two presentations. He informed us that he would come for certain from Spain, but on Monday instead of Saturday. So we switched the programme to be able to let him give his presentations. He did arrive on Monday, describing it as follows:

> *'I was in Spain for a planned visit, and had a flight to Holland which was cancelled. I tried to get a train but there was a French train strike. I then tried for a bus but all the buses into France from Barcelona were booked for 3 days. So in the end I took a train at 6 am to the French border high in the Pyrenees. Then I walked across the border and for a few miles down the road. Then I hitch hiked through the mountains and ended up getting to Toulouse. From there I found a train to Bordeaux then one to Paris , arriving midnight. After that it was easy....'*

We were, to say the least, very pleased to see him.
We appreciated very much that Annette Lennerling came driving all the way from Sweden, taking with her a few other participants. The only trouble she had on her way down was getting in a traffic jam just before Rotterdam, which took a long time.

A very nice email we received from Yvonne Fullerton from New Zealand:

> *'Although it was horrible being stuck at Singapore airport for 48 hours before returning home, missing the conference was a bigger disappointment.'*

From Switzerland Francesca Bosiso arrived in Rotterdam, after standing in the train for 16 hours. Similar travel experiences came from people from Argentina and South Korea.

From the questionnaires it became clear that most participants were able to return home as planned or as rescheduled. We were very pleased on the last day to be able to inform participants that the air traffic in Europe had started again.
We also sent the questionnaire to the 7 technicians at the WTC who did the technical assistance during the congress in 3 small conference rooms (cap. 80 people) and one large conference room (max cap. 980 people). One regular and two freelance technicians responded. For one of them it was the first time he helped with Skype presentations. All were pleased with the alternative of Skype presentations and considered the quality of Skype images reasonable. Contact with the presenters was considered good, but sometimes a little confusing. They all had disconnections during the presentations and were able to continue later on. If the Skype connections failed, it was because of a bad or slow connection. In those cases they continued the presentation without video, but only with sound. One technician experienced problems in finding the Skype names of the presenters; they would use nicknames instead of real names.
With regard to the view of the presenter they would recommend a good webcam, because some webcams didn't have a good picture. Also good light conditions are important and there should not be an open window behind the presenter.
Generally they all thought it was fun to do the congress in this way; they had very good, sometimes amusing, contacts with the presenters and saw all kind of rooms/wallpaper/husbands/children passing by while waiting for the presenter to start his/her presentation. It was also amazing to see people when they did the try-out and then later on when they were all dressed up and did their hair and sometimes make-up, for the live presentation. During one presentation from the USA we saw the sunrise in the background.

Discussion

The instructions sent by us how to use/download Skype were overall considered as very helpful. It is essential to have the right Skype names from the presenters, especially when they use a nickname. Also it is preferable to use a very good webcam and a headset. This improves the audio quality.
The quality of Skype is determined by the speed and quality of the internet used by the presenter. Unfortunately the technicians are unable to improve this.
It is better to use an extra camera in the rooms; one on the screen but also one on the room, so the presenter can see who is asking questions. During our congress most of the time they only saw the back of the people standing at the microphone. Also most of them expressed the need to be able to watch/Skype during the entire session.
The technician should have 2 home accounts, so he can connect more than one person at the same time. If this is the case he does not have to connect the next speaker in such a short time and this next speaker can listen to the presentation before his/hers.
Another alternative would be to broadcast live the whole congress, which is a very expensive solution, especially if you need to broadcast more than one room.
Also it would be advisable to have a direct way of communication between the secretariat and the technicians, for instance an extra laptop. If one laptop is occupied by the waiting and listening of a presenter before his own presentation, then the other laptop can be used to mail each other for urgent matters. This is to avoid having to go to the room and disturbing the presentations. Especially the chairs became very nervous every time we walked in because they were afraid of last-moment changes in the programme.

Before the morning programme began and in the lunch break we communicated with all technicians regarding the programme. Did they already have contact with the presenters of the next session, were there changes in the programme, were the slides present, did they have all Skype names, etc. This proved to be very successful and made the sessions go very smoothly.
We learned that the best thing to do is to leave the programme as it is as much as possible. Time differences were hardly a problem for presenters.
Chairs must be informed in time about the programme; they should also be informed if people are rescheduled for instance for a day later. They also must be instructed to keep to the time limits, even if it is a Skype presentation. This to avoid, like it happened this year, that the session goes on for too long. The result was that people didn't have a chance to attend a parallel session. The time for the poster sessions was also far too short because of the long sessions.

Conclusion

The Skype presentations were generally considered as good. People consider Skype as a fantastic solution in an emergency case like we had with our congress. It is not the answer to everything. From the participants and from the questionnaires it became clear that it does not replace the presence of people.
In normal conditions it is highly appreciated that experts and other professionals communicate on the subjects as mentioned in our congress programme and have a chance to meet each other in a nice surrounding. Also mentioned a lot of times in the questionnaires is the fact that this also improves the discussion at the end of the presentations.
The people who did attend the congress saw 85% of the presentations as scheduled and this was highly appreciated. Also from the questionnaires and by email we received a lot of appreciation for the manner in which we handled the situation on such short notice.
The situation also led to a feeling of solidarity between the participants, caused by the fact that they did not know until the last day whether they were able to return home as planned.

Acknowledgements

Annalisa Ponchia and Chiara Parisotto from the ESOT Executive Office, who helped us organizing the congress and without whom we could not have managed the situation. Chiara did most of the logistics and Annalisa was present everywhere. In particular she managed the contacts with the speakers/technicians regarding the Plenary Sessions.
Martijn Stoutjesdijk, Audiovisual Manager, from the World Trade Center and his team of technicians, who did an outstanding job in making the whole Skype event happening. They made the presenters feel at ease and guided them to the successful presentations.
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Expanding Living Organ Donation in Europe and the New EU Member States

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The paper explores some ethical and legal challenges of expanding living organ donation in Europe by addressing three aspects of the issue: the overall promise of living organ donation, the concrete trends in organ donation in the new member states of the European Union, and the specific realities of organ donation in Bulgaria. The paper examines in detail the legal environment, practical realities and ethical challenges of living donation in Bulgaria. It identifies a loophole in the donation policy that unjustifiably deprives a particular category of patients from the opportunity to receive an organ from a living donor due to legal restrictions limiting living donation to related individuals and because of the very low rates of cadaveric donations. The result is poor quality of life for the patient, life-long dependency on dialysis, high morbidity and mortality, and high costs to the health care system. The paper presents a recent controversial Bulgarian case, which illustrates the tragic consequences of limiting living donation to related donors and reveals the peculiarities of the political and cultural context of organ donation in Bulgaria. The paper identifies the major challenges to expanding organ donation in Bulgaria: lack of public trust, lack of institutional transparency, and lack of public awareness and broad consensus. It offers a possible explanation for the low rates of cadaveric vis-a-vis living donation, and identifies a potential for expanding living donation in the country.

Key words: transplantation, living related donation, living unrelated donation, new EU member states, Bulgarian transplantation law, organ donation, bioethics

Introduction: The Promise of Living Organ Donation

As Europe faces the reality of a growing demand for transplantable organs, shortage of organs and long waiting lists (1), health professionals, scholars and policy makers increasingly focus their efforts on finding new ways to expand the pool of available organs and to increase the rates of organ donation in Europe (2). In order to achieve this goal, it is necessary to detect and remove the existing barriers to organ procurement and donation, and to identify additional sources of transplantable organs. In the context of this analysis, it is important to explore the promise of living donation in its various forms (related and unrelated donation, directed and non-directed donation) as a means of increasing the number of available organs and improving the success rates of transplantation. In the same time, we need to identify the obstacles to donation at the national and European level in order to overcome them. An important step in this process is to identify and address the ethical, legal and psy-

chosocial barriers to transplantation. In this regard, the new member states of the European Union become a particularly important object of investigation.

Trends in Organ Donation in the New EU Member States

The new member states are characterized by lower than average rates of organ donation (3), yet many of them exhibit relatively high rates of living donation as compared to deceased donation (4) and a high level of acceptance and support for living organ donation. For example, Poland has been considering legalizing unrelated living donation (5), Romanian law in principle does not prohibit it (6) and the public opinion in Bulgaria has been quite supportive of it. The data on the rates of living donation versus cadaveric donation in these countries is quite revealing. The most impressive statistics come from Cyprus: in 2006, there were 54.3 living kidney transplantations per million population (pmp) vs. 5.7 deceased organ donors pmp (7). Even in countries with lower rates of living transplantations, the proportion of living versus deceased transplantations is high. For 2006, in Romania, there was only 1 diseased donation versus 8.0 living donations. For the same period in the Slovak Republic, there were 12.1 deceased donations and 5.2 living transplantations, and in Bulgaria, there were 2.7 diseased donations and 0.7 living donations.

Why are the overall rates of organ donation in the new member states so low and how can they be improved? Why is living donation favored in these countries and how can both living and deceased donation be optimized there? Is there a correlation between the rates of donation and other factors such as the cultural, religious, historic, economic or political background? Are there common characteristics, which could account for the donation profile of the new member states? Except Malta and Cyprus, these countries share a common socialist past. Yet, the countries of Eastern Europe, which we tend to group together because of their shared political past, in fact, have very different cultural, religious and legal traditions, and their current socio-economic profiles are quite diverse. For example, The Czech Republic and Poland are Catholic countries, whereas the major religion in Bulgaria and Romania is Eastern Orthodox Christianity. In most of these countries, bioethics is relatively young and so is the civil society. Are donation rates influenced by factors such as religion, political past and civic traditions, and to what degree?

Answering these questions does not only have academic value but also practical importance. The answers would allow us to understand better the reasons behind the rates of donation and the extent to which they are affected by local, national characteristics versus broader, more global or even universal factors, processes and values. Such knowledge would allow us to develop concrete measures for stimulating organ donation in the new member states and Europe-wide, and will help to direct the efforts to harmonize and coordinate joint actions at the European level.

At present, however, we don't have the answer to these important questions. Comparative comprehensive research on living donation in Europe is still to be conducted and it goes well beyond the resources of a single researcher or institution. Hopefully, the newly started multi-country project on living donation in Europe (EULOD) that was initiated by ELPAT and funded by the European Commission under the leadership of ESOT will begin to answer such questions. My goal here is to take a step in advancing the discussions by taking a closer look at some of the legal and ethical challenges of living donation through the experience of Bulgaria.

Falling through the Cracks: A Loophole in the System of Living Organ Donation in Bulgaria and its Ethical Ramifications

The system of organ donation and transplantation in Bulgaria has been plagued with problems: from low donation rates and long waiting lists to admissions of illegal transplants from living donors (8). The shortage of organs and the violations of the law, however, are not the only sources of trouble. The law itself may generate ethically repugnant outcomes. Among the less known problems of living organ donation in Bulgaria is a loophole in the transplantation system, which unjustifiably deprives a particular category of patients from the opportunity to receive an organ from a living donor. The loophole emerges at the interface of the restrictions of the law, which limits living donation to genetically or emotionally related individuals only, and the limitations of the practical realities of organ donation in Bulgaria characterized by consistently low rates of cadaveric donations. These circumstances result in the unjustified discrimination of patients who, for a variety of reasons that are often tragic and out of the patient's control, have no known genetic relatives and who are not emotionally related to others in the required legal sense and, thus, do not qualify to receive organs from living donors. Yet, due to the lack of diseased donors, such patients could not be transplanted with cadaveric organs either. The result is poor quality of life for the patient, life-long dependency on dialysis, a high morbidity and mortality and high costs to the health care system.

To understand the real dimensions of the loophole and the mechanisms behind it, it is important to examine the practical realities and the legal environment of organ donation in Bulgaria. The country has one of the lowest rates of diseased donation in Europe: the statistics of the Bulgarian Executive Agency for Transplantation shows that, since 2001, in Bulgaria, the rate of diseased donations is under 2 pmp with the exception of year 2006 when the rate of donations increased to 2.6 pmp (9). In Bulgaria, transplantation is regulated by the *Law for transplantation of organs, tissues and cells* (10). The law permits living donation subject to the following restrictions: a donation may take place only between persons who are legal relatives or emotionally related, the donation should not endanger the donor's life, the donor must provide informed consent in writing and the document must be notarised, the donor must be a competent adult (18 yrs. or older), and the donated organ must be either self-generating e.g., a liver, or one of two paired organs, e.g., a kidney. The law also prohibits offering a material award ***to*** the donor or accepting a material award ***from*** the recipient. The law adopts the view that the sole owner of organs separated from the body for the purposes of transplantation is the state's Executive Agency for Transplantation (11). This is also consistent with the adopted model of presumed consent for post mortem donation in the country, which implicitly endorses the state as the owner of the deceased body. The Executive Agency for Transplantation controls and allocates the organs, yet these organs have a special, peculiar status of "quasi-property" in that they are the subject of a limited kind of transactions only, namely those related to transplantation. This peculiar, limited property status of the organs seems to preclude conceptually certain uses of donated organs, i.e., transactions that require full ownership of the organ such as the selling or buying of organs and establishing a legal market for organs. Bulgarian law thus recognizes the individual's right to donate an organ but it is not grounded in moral values or bioethical argumentation. Rather, Bulgarian legal scholars operate in a discourse, in which bioethical values are largely absent, or external. They interpret the legal right to organ donation as an extension of the individual autonomy in general and, specifically, the liberty to take health risks (as expressed in the free-

dom to participate in clinical trails) and a limited liberty to self-mutilation (as in the right to early abortion) (12).

It is on this backdrop that living donation takes place in Bulgaria. The features of the law and the designation of ownership in the state-run Transplantation Agency would be logically consistent with a system that limits or precludes directed donation and permits unrelated donation but this is not the case. The only living donation permitted by the law is donation to a legal relative ("legal" is used to account for individuals related through adoption) or an emotionally related person (e.g., a spouse or a partner in a civil union).

These legal arrangements seem rather accommodating of living donation. However, they have limitations that may lead to ethically problematic results. A vivid illustration of this is a recent Bulgarian case from the summer of 2009, which generated a heated public debate in the media. The case shows the unfortunate consequences of limiting living donation to related donors and tested the morality of the legal provisions on living donation. In the same time, the case stimulated a debate which revealed important aspects of the political climate and cultural context of organ donation in Bulgaria.

The case was widely publicized in the press, presumably, with the consent of the affected parties whose photographs were shown on the central pages of some of the leading newspapers such as the daily "Trud" ("Labor" in Bulgarian) (13). It involved a 31-year old woman, Petrana Romanova and a 36-year old man, Slavey Boyanov (14). Petrana was an orphan and spent much of her life in state orphanages. She had suffered complete renal failure ten years ago and reportedly "had no kidneys". For ten years, she has been completely dependent on dialysis. She spends 12 hours of her life each week (three times a week for 4 hours) hooked to a machine. According to her physician, Dr. Alexander Osichenko, the life expectancy in such cases is between 5 and 10 years, in rare cases up to a maximum of 18 years. Petrana was already in her 10th year of dialysis. She was on the waiting list for a kidney but her only chance was a kidney from a diseased donor because she was not married and had no known blood relatives. Because of the low donation rates in Bulgaria, Petrana has little chance of receiving a cadaveric kidney transplant. Hers is the case of a patient in grave need, who is destined to fall through the cracks of the system of organ donation in Bulgaria because of the unfortunate combination of being in dire need of a kidney and having no relatives in a country with one of the lowest organ donation rates in Europe.

Petrana was a warm, brave young woman with a big smile on her face, she shared her dreams to have a family and children. Her case attracted the attention of the media and, in the summer of 2009, it was published on the web page of "Trud", one of the most popular newspapers, in connection with a campaign to promote organ donation in Bulgaria. The case made a strong impression on the public. Among those moved by Petrana's fate was Slavey Boyanov, a convicted criminal who was serving a life sentence for his role in a botched burglary that ended with double murder (15). Slavey wanted to help Petrana and to do something good to compensate for his criminal deeds. He contacted the media and offered to donate a kidney to Petrana. The newspaper published the information and it started a wave of debates in the media.

The main reaction was an outrage at the law which offers little hope for Petrana. Many citizens expressed the view that the prisoner should be allowed to donate his kidney. There was little appreciation for the fact that he was not free, that his autonomy was severely limited institutionally, and that this puts him in a vulnerable position. Many were angry at the law and the politicians for creating such an imperfect law. During debates in the media, I had to stress repeatedly that prisoners cannot be donors and that this is not a matter of a defect in the national law but a well established principle in bioethics and a matter of international con-

ventions that our country has ratified. The Oviedo Convention requires the free and informed consent of the donor (16). Many physicians asked for a change in the Transplantation law to allow unrelated living donation. Members of the Bulgarian parliament saw this as an opportunity to engage in populism during the on-going election campaign in the summer of 2009. Others argued that the National Ethics Commission ought to take an exception to the law and allow for the donation to take place if it establishes that there are no ulterior motives behind Boyanov's wish to donate. Yet others became creative and looked for ways to circumvent the restrictions of the law. They suggested that Pertana and Slavey should marry *pro forma* in order to meet the legal requirements. However, they were soon disappointed to learn that Bulgarian law requires a husband and wife to have lived together for at least two year before they can make a live donation to each other (17).

What can we learn from the juxtaposition of the law and this emotionally charged case? It reveals significant aspects of the issues surrounding organ donation in Bulgaria. The case shows that the topic of organ donation is highly emotionally charged, and the country lacks a systematic ongoing debate, continuing public education and empowerment. Rather, the public opinion is formed through sporadic sensational cases. It further shows that laws and public policies are often shaped by external political goals and pressures. The law often changes to reflect the political agenda of a given party or *ad hoc* compliance with some international requirement rather than a considered public consensus. The case also exposes the high level of mistrust in two leading groups in Bulgarian society, which groups have an important role for transplantation, namely physicians and politicians. According to recent polls, Bulgarians consistently rank politicians and physicians among the top most corrupt occupations (18). This perception has direct impact on public trust and on transactions that require trust because a given stakeholder lacks the capacity to control the transaction, such as organ donation. This may partly explain why Bulgarians are reluctant to leave posthumously their organs to the doctors and do not wish to donate their organs post mortem, when the donor is no longer there to control the transaction. This might also explain the demonstrated acceptance and support for living donation by the public and the proportionally high rates of living donations. Perhaps Bulgarians are more willing to make a living donation because this is a transaction they can control to ensure that their wishes will be respected.

The case of Petrana and Slavey also reveals the relative lack of bioethics awareness among the public. Autonomy is understood only superficially and the values of informed consent and protection of the vulnerable are still to be fully understood and appreciated by the average Bulgarian. The principles of bioethics are seen as external norms that should be observed for compliance purposes rather than from moral motivation and commitment. Last but not least, this case illustrated a low trust in the public institutions that are instrumental to organ donation. As numerous polls show, Bulgarians are rather suspicious (and often rightly so) of policy makers, legislators, physicians and the health care system as a whole (19), which has a negative effect on organ donation.

Conclusion: Advancing Organ Donation in Bulgaria

If organ donation in Bulgaria is to improve and expand, it is imperative to analyse and address each and everyone of the issues and challenges identified above: the lack of public trust, lack of institutional transparency, and lack of public awareness and broad consensus on organ donation. These challenges need to be addressed at the level of theory and at the practical level of public policies and civic engagement. At the theoretical level, it is neces-

sary to examine the existing normative arguments for and against organ donation in general and living donation in particular in order to determine their applicability and adequacy to the concerns of a less trusting Bulgarian public who does not buy easily into the discourse of altruism. At the practical level, a successful organ donation system requires continuous public education, institutional transparency and public trust that take years to establish and which are lacking in Bulgaria today. In the same time, the case reviewed here reveals significant potential for expanding living organ donation in this new member state as witnessed by the open-mindedness of the Bulgarian public and the willingness of the medical establishment to advocate for expanding unrelated living donation in the country.

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The Role of the Council of Europe and the European Union with Respect to Cross-border Aspects of Organ Transplantation

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Throughout Europe the supply of donated organs and tissues of human origin (henceforth: 'organs') falls far behind the demand. As a result, many Europeans suffering from the failure of essential organs are deprived of the possibility to live a longer and better life. This situation raises serious health and human rights concerns, requiring States to undertake action.
At present, the length of waiting lists and the duration of waiting times for access to donated organs differ from State to State. The same holds true for the consent requirement for donation and the criteria for attribution of organs from living and deceased persons.
Against this background, it should not come as a surprise that individuals in need of a new organ sometimes try to acquire a donor organ in States with faster and/or easier access to organs than in the State where they reside. Making use of these cross-border organ transplant possibilities may entail (health and human rights) risks, particularly in case of differences with respect to the national standards concerning the safety and quality of organs and the rights of (potential) donors and recipients.
These developments raise the question to what extent, if at all, the Council of Europe and the European Union can assist in reducing the scarcity of donor organs and helping to solve the inconsistencies between national standards and practices. This article describes, examines and compares the various norms and criteria developed by these organisations, in an effort to identify areas where future action with respect to the regulation of cross-border organ transplantation is needed to ensure equal access to safe and high quality donor organs throughout Europe.

Key words: organ scarcity, European Union legislation, human rights law, organ trade and tourism, free movement of persons, cross-border health care, Council of Europe/European Union health promotion policies

Introduction

For many persons, receiving an organ from another (living or deceased) human being is the only way to restore their health and prolong their life expectation. In Europe, the supply of human organs for transplantation ends has not kept pace with the increased demand for them. According to recent (2007) estimates, there are 58.200 European citizens on the waiting list for a kidney, heart or liver transplant. Despite the 25.900 transplant operations taking

place annually in our region, every day around 10-12 European citizens die while waiting to be transplanted.[1]

There is worldwide consensus that 'donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other consideration.'[2] Compliance with these criteria, embedded in the principles of distributive justice and equity and in full accordance with European human rights law, is difficult to ensure in times of dramatic shortages of donated organs that become available through the regular health care sector. The lack of organs we are facing today has caused heated discussions on the introduction of less strict consent systems for cadaver organ donation[3] and new incentives for acquiring more donors (e.g. by various ways of compensating donors or their relatives for organ donations[4]), of alternative distribution and allocation policies (e.g. by introducing reciprocity-based systems[5] and Living Donor List Exchange[6]), proposals to exclude or give lower priority to potential recipients due to their risk behaviour[7] or on the basis of their age[8] or nationality.[9] The shortage of available donor organs has also resulted in patients endeavouring to acquire an organ in other States,[10] sometimes after paying large sums of money.[11] It should not surprise that all this has also been an incentive for – the meanwhile widely condemned practices of – organ trafficking and transplant tourism.[12]

Increasing the number of donor organs through the health care system is a primordial requirement to save lives and human health,[13] and to combat organ trafficking at the expense of the health and life of vulnerable groups. At the same time, it is important to improve the preparation, preservation, storage and other (organisational) aspects of organ transplantations as well as to bring the various standards with respect to the quality of donor organs and the rights of (potential) donors and recipients in line with each other. The need to do

[1] 'Un riñón a 50.000 euros para el "turista de transplante"', El País 26 October 2009 and information from ES-OT.

[2] Principle 9 WHO Guiding Principles on human organ transplantation (1991, currently being revised).

[3] L. Cherkassky, 'Presumed Consent in Organ Donation: Is the Duty Finally upon Us?', European Journal of Health Law 2010, p. 149-164

[4] A.J. Matas, 'In Defense of a Regulated System of Compensation for Kidney Donation', in: W. Weimar, M.A. Bos & J.J. Busschbach (Eds.), Organ Transplantation: Ethical, Legal and Psychosocial Aspects. Towards a Common European Policy, Lengerich: Pabst Science 2008, p. 55-63.

[5] M.S. Nadel & C.A. Nadel, 'Using Reciprocity to Motivate Organ Donations', Yale Journal of Health Policy, Law and Ethics 2005, p. 293-325.

[6] W. Dondorp, 'Does Justice Allow Living Donor Exchange? A Recent Report from the Health Council of the Netherlands', in: W. Weimar, M.A. Bos & J.J. Busschbach (Eds.), Organ Transplantation: Ethical, Legal and Psychosocial Aspects. Towards a Common European Policy, Lengerich: Pabst Science 2008, p. 111-116.

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[8] Ch. Hackler & D. Micah Hester, 'Age and the Allocation of Organs for Transplantation: A Case Study', Health Care Analysis 2005, p. 129-136.

[9] J.M. Prottas, O. Jonasson, J.I. Kneing, 'In organ transplants, American first?', Hastings Center Reports 1986 (5), p. 23-25.

[10] E. Buggins, Allocation of organs to non-UK EU residents, London: Department of Health 2009.

[11] 'Un hígado por 130.000 euros', El País 13 March 2010.

[12] Recommendation Rec(2004)7 of the Committee of Ministers of the Council of Europe to the member states on organ trafficking and The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (Istanbul, 2008).

[13] This is not to suggest that the lack of organs can simply be solved by increasing their supply; a greater availability of donor organs is likely to affect the formulation of attribution criteria.

so, preferably on a transnational level, is particularly urgent in Europe, given its relative open borders and large number of patients engaged in cross-border health care.[14]
Against this background it should not come as a surprise that Europe's main regional organisations with a mandate in the field of health and human rights, the Council of Europe and the European Union (EU), both have deployed various initiatives to increase the availability of organs, to improve their safety and quality, to enhance the fair and just distribution and allocation of organs, as well as to guarantee respect for the fundamental rights and freedoms of (potential) donors and recipients. These standards build, although with some variation,[15] on the guidelines and principles defined by the World Health Organization (WHO)[16], even though some European standards go well beyond the scope of those set by WHO.[17]
The aim of this article is to describe, examine and compare the standard setting activities of the Council of Europe and the EU in the field of organ transplantation, with a view to identify areas where future action with respect to the regulation of cross-border organ transplantation is needed to ensure equal access to safe and high quality organs throughout Europe.

Council of Europe

The Council of Europe, founded in the aftermath of the Second World War, is an intergovernmental organisation seeking to create a common democratic and legal area throughout the whole of the European region, ensuring respect for human rights, democracy and the rule of law. Or, according to Article 1 (a) of the Statute of the Council of Europe (1949): 'The aim of the Council of Europe is to achieve a greater unity between its members for the purpose of safeguarding and realising the ideals and principles which are their common heritage and facilitating their economic and social progress.' The membership of the organisation gradually grew from 10 (1949) to 47 (since 2007) States. In addition, there are five States formally affiliated to the Council with the status of observer (Canada, Holy See, Japan, Mexico and United States) while two applications for full membership are still pending (Belarus and Montenegro). It can therefore be said that the organisation covers the entire European continent, even though some States currently are not yet full members.
The organisation is particularly well known for its standard-setting activities in the field of human rights. The most famous achievement in this respect is the adoption, in 1950, of the Convention for the Protection of Human Rights and Fundamental Freedoms (henceforth: 'European Convention on Human Rights' or ECHR) and its additional protocols.[18] The ECHR obliges States Parties, amongst others, to respect the right to life, to ensure that no person

[14] H. Vollaard, Political Territoriality in the European Union: The Changing Boundaries of Security and Healthcare, Diss. Leiden University 2009.
[15] E.g. with respect to living donors WHO is above all concerned about the risk of exploitation of vulnerable individuals, in Europe the (health) advantages of a living donor above a deceased donor are emphasised.
[16] The WHO, established in 1948, is a specialized agency of the United Nations with a large mandate in the field of global health. The organisation has its own Constitution, according to which it strives towards 'the attainment by all people of the highest possible level of health.' WHO has it headquarters in Geneva, Switzerland, and has at present 193 members states.
[17] J.K.M. Gevers, 'A Fair Distribution of Organs for Transplantation Purposes: Looking to the Past and the Future', European Journal of Health Law 2007, p. 215-219.
[18] At present that Convention has been supplemented/amended by 14 Protocols (with a Protocol no. 14 and a Protocol no. 14b).

on their territory is subjected to inhuman and degrading treatment and to respect the right of everyone's physical integrity. All these rights are highly relevant with respect to organ transplantation, and oblige States to increase the supply of organs, while guaranteeing their safety and quality and protecting the rights and freedoms of (potential) donors. In this respect, the case-law of the European Court of Human Right (henceforth: Court of ECtHR) with respect to the State's obligation to save lives[19], to guarantee the safety and quality of blood and other products for human use[20] and to ensure respect for the principle of informed consent[21] is crucially important. This is not to deny that there are some inherent tensions between the aims enshrined in these rights, now that the rights and interests of potential recipients and donors are not necessarily akin.

The Council of Europe's work is not confined to the field of human rights. The Council has undertaken various important activities to promote health and prevent diseases in an effort to achieve greater unity between the member states of the organisation. Already in 1954 the Committee of Ministers – the Council's decision making body – set up the European Health Committee (CDSP), a body with officials appointed by national governments. This body strives towards the creation of conditions to safeguard and improve the health of European citizens. The work of the CDSP as well as other health promotion activities undertaken by the Council generally take place under the umbrella of 'social cohesion', even though their impact sometimes reaches much further. In this respect it is important to recall that the protection of health is also a human right, laid down in the Council's European Social Charter, adopted in 1961 and revised in 1996.

Throughout the years, the Council of Europe has been very active in the field of organ transplantation. Besides the establishment, under the CDSP, of the Select Committee of Experts on the Organisational Aspects of Cooperation in Organ Transplantation and the adoption of recommendations – e.g. on the management of organ transplant waiting lists and waiting times,[22] on organ trafficking[23] and on the background, functions and responsibilities of a National Transplant Organisation[24] – the Council of Europe has defined the ethical principles governing organ transplants and published guidelines on the safety and quality of organs.[25]

So far the Council has adopted two legally binding instruments regulating aspects of organ transplantation. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (henceforth: 'Biomedicine Convention') which was adopted in 1997 contains various provisions on organ and tissue removal from living donors. As a rule, organs may only be removed for the therapeutic benefit of a recipient and provided that no cadaver organ or other forms of treatment is available (Article 19(1)). In addition, such removal can only take place after the 'necessary consent' was given 'expressly and explicitly' (Article 19(2)).This means that living organ donation may only take place in the absence of other alternatives and on the basis of informed con-

[19] ECtHR 30 November 2004, Öneryildiz v. Turkey (GC), no. 48939/99 and ECtHR 20 March 2008, Budayeva et all v. Russia, no. 15339/02, 21166/02, 20058/02, 11673/02 & 15343/02.

[20] ECtHR 23 March 2010, Oyal. t. Turkey, no. 4865/05.

[21] ECtHR 9 March 2004, Glass v. the UK, no. 61827/00 and ECtHR 23 March 2010, M.A.K. & R.K. v. the UK, nr. 45901/05 & 40146/06.

[22] Recommendation Rec(2001)5.

[23] Recommendation Rec(2004)7.

[24] Recommendation Rec(2006)13.

[25] Guide to safety and quality assurance for organs, tissues and cells (3th edition), Strasbourg: Council of Europe Publishing 2006.

sent. The Convention allows for the possibility of living organ donation by a person unable to consent, however only in very exceptional situations and provided that strict criteria are met (Article 20).
The Additional Protocol to the Biomedicine Convention concerning transplantation of organs and tissues of human origin, adopted in 2002, seeks to protect the human dignity and human rights of individuals involved in organ and tissue transplantation, including deceased persons. According to this protocol, each State Party is obliged to guarantee patients equitable access to transplantation services (Article 3). This provision moreover stipulates that organs shall only be allocated among patients on an official waiting list according to medical criteria and that, in case of international organ exchange programmes, 'the procedures must also ensure justified, effective distribution ... in a manner that takes into account the solidarity principle within each country.' This Protocol emphasises the importance of informed consent from a living donor (Article 13). In addition, the Protocol provides that organ donation from the body of a deceased persons can only taken place after 'consent or authorisation as required by law' (Article 17). This provision seems to be incompatible with presumed consent systems for deceased persons, thus restricting the possibilities of introducing systems on the basis of which all persons are donors after their death unless they have expressed their opposition.[26]
By the beginning of 2010 the Biomedicine had been ratified by 25 European States; the Additional Protocol concerning transplantation of organs and tissues of human origin received 11 ratifications.

European Union

Like the Council of Europe, the European Union (EU) is a regional organisation committed to strengthen the bonds and collaboration between European States, initially in a limited number of fields. Different from the Council of Europe, the EU is not a mere intergovernmental organisation but bestowed with – although limited – supranational powers.[27] The predecessors of the EU are the European Coal and Steel Community, formed in 1951, the European Economic Community, established in 1957, and the European Atomic Energy Community. All three organisations consisted of the same six States. In 1967, the three organisations merged to become the European Communities, later – following a complicated transition period with a three pillar structure (1992-2009) – European Union.
Initially, the European Union strove towards a new form of economic integration, by removing trade barriers and eradicating the distortion of competition between member states. To achieve this EU law guarantees the free movement of persons, goods, services and capital and upholds the principle of free competition.
Since the establishment of the European Communities, the organisation not only expanded its membership (now: 27) but it also acquired more and wider competences no longer confined to the promotion of economic integration. In fact, since the 1970s the EU gained a much greater role when it came to supranational decision making or coordination in such

[26] For a more in-depth analysis see H. Nys, 'Organ Transplantation', in: J.K.M. Gevers, E.H. Hondius & J.H. Hubben (Eds.), Health Law, Human Rights and the Biomedicine Convention, Leiden: Martinus Nijhoff Publishers 2005, p. 219-230.
[27] Case 26/62 Van Gend en Loos v. Nederlandse Administratie der Belastingen [1963] ECR 1.

fields as asylum policy, border control, consumer protection, environmental law, security and social policy.

Through the so-called Treaty of Maastricht of 1992, the member states gave the EU also some, though rather reluctantly, powers in the field of health care. Since then the Treaty establishing the European Community contains a separate provision on public health. According to this provision (Article 129 EC), the EU 'shall encourage cooperation between the member states' in specific fields of public health. Moreover, this provision stipulates that the Council of Ministers can, under certain conditions, adopt 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any member state from maintaining or introducing more stringent protective measures.' Even though the Treaty establishing the European Community has undergone various changes since 1992, the wording of this provision has remained unchanged and forms, since 2009, part of the Treaty on the Functioning of the European Union (Lisbon Treaty), now Article 168.

The reference to organs in a special provision on public health prevented a thorny and not sheer academic debate on the legal status of donor organs under EU law. Without such a provision, it could be argued that donated organs of human origins are mere 'goods', subject to ownership and property rights, and that all related rules and practices should comply with the principles of free movement of goods and the non-distortion of competition. Or, it could even be maintained that a (potential) organ donor could be classified as a 'service' provider, who is entitled to the free movement of services under EU law.[28] National distribution and attribution criteria for donor organs and restrictions with respect to the exchange of organs could then easily have been challenged as being contrary to EU law and principles. But by mentioning organs in a separate provision on public health, it becomes clear that member states did not want organ transplantation to fall under the rules governing the internal market. In fact, they acknowledged that organ transplantation should be regulated by *sui generis* rules that have the promotion of public health as their primary objective. This is not to suggest that member states enjoy under EU law the exclusive competence to regulate organ transplantation. The EU has, according to Article 168 TFEU, a mandate to legislate on quality and safety standards for human organs, a competence that the EU has effectively made use of.

In 2004, the EU adopted a directive[29] on the quality and safety of human tissues and cells[30], followed by two Commission directives to implement this standard.[31] The EU thus introduced common and legally binding safety and quality standards on a European level. The purpose of these standards was to facilitate a safer and easier exchange of tissues and cells between the member states and to improve safety standards for European citizens. Organs, however, were deliberately excluded from coverage due to 'serious differences' between them and tissues and cells.[32] In the absence of similar safety and quality standards for organs, it remained the exclusive competence of member states to set such standards for their own territory.[33]

[28] See also Directive 2006/123/EC on services in the internal market (also called 'Services Directive' or 'Bolkestein Directive'), even though it should be noted that health care has been excluded from coverage.

[29] A piece of EU legislation elaborating one or more treaty provisions and requiring member states to achieve a particular result, within a certain period of time, and without dictating the means of achieving that result.

[30] Directive 2004/23/EC.

[31] Commission Directive 2006/17/EC and Commission Directive 2006/86/EC.

[32] Directive 2004/23/EC, § 9 (Preamble).

[33] For a comparison, see e.g. European Commission, Human Organ Transplantation in Europe: An Overview, Luxemburg: European Commission 2003, http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf