Report from the Scandiatransplant Work Group on Evaluation of Membership for organ transplant hospitals in Riga (Latvia) and Kaunas and Vilnius (Lithuania)

Submitted to the Scandiatransplant administration on 18.th July 2022

Work group participants

Are Holm (chair)	(Thoracic transplant)	Oslo University Hospital, Oslo
Mats Bengtson	(Tissue typing/immunology)	Uppsala University Hospital
Carola Schaumann	(Transplant Coordinator)	Helsinki University Hospital
Søren Schwartz Sørensen	(Kidney transplant)	Rigshospitalet, Copenhagen
Virge Pall	(Director of Transplant)	Tarttu University Hospital
Runolfur Pàlsson	(Kidney transplant)	Landsspitali, - The National University Hospital, Reykjavik
Heikki Makisalo	(Liver transplant)	Helsinki University Hospital
Bo Göran Ericzon	(Chairman Scandiatransplant)	Karolinska University Hospital
Kaj Anker Jørgensen	(Medical Director)	Scandiatransplant

Abbreviations

Work Group	Scandiatransplant Work Group on Evaluation of Membership for organ transplant hospitals in Riga (Latvia) and Kaunas and Vilnius (Lithuania)
Sctp	Scandiatransplant

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Introduction

Solid organ transplantation (SOT) emerged as a treatment for a variety of terminal conditions after the development of feasible vascular surgery techniques at the beginning of the 20th century, and the development of effective and tolerable immunosuppression in the early 1980's.[1] SOT is uniquely different from other kinds of health care in three ways. First, while all health care requires some specific resources, the primary resource for SOT is the organ of another human being, a donor. If the organ can safely be removed from a donor without significant harm for the donor, living donation is an option. Thus, about 30% of kidney transplant performed in the Nordic countries are done using organs from living donors. If the organ is vital, however, the donor must be declared dead before the organ can be removed. This requires a consensus about the *definition of death*. Second, for such donation to occur, usually some sort of consent is required in each case, either as a pre-mortem expression by the donor or by surrogates (next-of-kin). Such consent is highly dependent on *public trust* in the health care system providing the transplants. Third, although all health care should ideally be individually adapted, in SOT the *individual matching of donor and recipient* is an absolute necessity. Together, these factors contribute to the prevailing scarcity of organs suitable for transplantation. Other characteristics of the SOT practice, although not unique, are the vast needs for resources, the wide cross-disciplinary range of skills and collaboration required, and the importance of time-sensitive coordination across administrative and often geographical barriers. These factors make SOT a treatment option that is conceivable only in highly developed health care systems.

Such health care systems are usually defined by national borders. To avoid unethical organ trade and transplant tourism, there is international agreement that organ procurement is a national responsibility and that nations should strive to be self-sufficient with organs for transplantation.[2] However, to increase the availability and selection of suitable organs and to develop and maintain the professional expertise required, many cross-border collaborations have been established, such as Eurotransplant[3] and Scandiatransplant.[4]

Scandiatransplant was established in 1969 following an initiative by the Nordic Council. It was established as a collaboration between the transplant hospitals in Norway, Denmark, Sweden, Finland, and later Iceland. In 2021 the transplant clinic in Tartu, Estonia, was accepted as a full member. In the bylaws of Scandiatransplant, three specific aims are outlined for the organization. First, there should be *organ exchange* between the countries to maximize

the availability of suitable organs. Consequently all candidate recipients for organ transplant and all organ donors must be listed in a common Scandiatransplant database. The membership contract of the Scandiatransplant collaboration acknowledges that each available organ should be allocated according to certain rules that are binding for all member centers. These rules vary according to type of organ and are decided in specific committees, or organ groups. Such allocation rules may be based on immunological suitability (*i.e.* HLA matching) or medical urgency, sometimes granting supranational priority over national priority. In some cases, the receiving center is obliged to return an organ to the donating center at a later time ("pay back"). Whatever the case, the balance in organ exchange between the centers is continuously monitored and discussed (see for instance Auråen et al.2018),[5] and about 20% of all organs in Scandiatransplant are transplanted following such exchange. If an organ offer is not accepted by any member center, the organ should be offered to transplant centers outside Scandiatransplant (usually to centers in Eurotransplant, in Swisstransplant or in the UK, administered through the respective organ procurement organizations). Transplantation of patients who are not residents of any of the member countries is not accepted,[4] a rule that may be said to be in agreement with the previously mentioned obligation each nation has to ensure its own supply of organs for transplantation. For comparison, the Eurotransplant Manual states that although transplantation of non-nationals or non-residents may not be prohibited by Eurotransplant, the numbers of transplants given to non-residents should be closely monitored (by Eurotransplant) to ensure that it does "not undermine the country's ability to provide transplants for it's own population" (Eurotransplant Manual pt. 2.1.5.1; https://www.eurotransplant.org/wp-content/uploads/2021/09/H2-The-Recipient-2021.2-September-24-2021.pdf). Stricter rules may apply in some of the member countries of Eurotransplant.

The second objective for Scandiatransplant is to *maintain and operate registries* of organ donors and recipients, both to maintain common waiting lists of the transplant candidates and to ensure traceability between donor and recipient.

The third objective for Scandiatransplant after organ exchange is to encourage the *scientific collaboration* between the transplant centers. Such collaboration and research activities are also managed in the organ-specific groups.

In 2021, representatives from the Pauls Stradiņš Clinical University Hospital in Riga, Latvia, submitted a request to the Scandiatransplant office in Aarhus, Denmark, for membership. A work group was established consisting of transplant professionals from all current member countries, representing the major groups of Scandiatransplant. The Work Group was tasked to evaluate the consequences of a future membership for the transplant center in Riga.

Work group mandate and method

The Scandiatransplant Work Group on Evaluation of Membership for organ transplant hospitals in Riga (Latvia) and Kaunas and Vilnius (Lithuania) (hereafter referred as the Work Group) was established according to the decision at the Sctp Board meeting No. 91 on the 21.st of January, 2021 (http://www.scandiatransplant.org/about-scandiatransplant/scandiatransplant-board/Minutes_Board_No_91_21.Jan.2021_virtualZoommeeting.pdf).

Group participants

To ensure a complete representation from all groups of Scandiatransplant (Sctp) and a cross-disciplinary representation, the following individuals were asked and agreed to participate in the Work Group:

1. Mats Bengtson (Sctp Tissue Typers Group, Uppsala University Hospital)
2. Carola Schaumann (Nordic Transplantation Coordinators Group, Helsinki University Hospital)
3. Søren Schwartz Sørensen (Nordic Kidney Group, Rigshospitalet Copenhagen)
4. Virge Pall (Director of Transplant, Tartu University Hospital)
5. Runólfur Pálsson (Nordic Kidney Group, Landspitali–The National University Hospital, Reykjavik)
6. Heikki Makisalo (Nordic Liver Transplantation Group, Helsinki University Hospital)
7. Are Holm (Sctp Heart and Lung Group, Oslo University Hospital)
8. Bo-Göran Ericzon (Chair of Sctp, Karolinska University Hospital, Stockholm)
9. Kaj Anker Jørgensen (Sctp Medical Director)

Mandate

The mandate for the group was to:

- Describe how organ donation and transplantation is organized (in Latvia and Lithuania)
- Identify any problems with medical/technical standards
- Identify how transplantation/donation is financed
- Identify any legal and/or ethical problems
- Write a report to the Council evaluating criteria and possibilities for membership

Time line

The Work Group was charged to submit its report to the Sctp Council by the 8th of August 2022 (three weeks prior to the meeting of the Sctp Council in Reykjavik on 31 of August 2022). The Work Group first convened (digitally) on the 21st of October 2021, with consecutive digital meetings on the 18th Nov.-21, 18th Jan.-22, and 30th March-22. From the 1st to the 2nd of June 2022 the Work Group visited Pauls Stradiņš Clinical University Hospital in Riga.

Work Group disclosure

None of the work group members have any conflicts of interest relevant to the evaluation of a membership for the Pauls Stradiņš Clinical University Hospital. Sctp paid the travel and accommodation for the visit to Riga. Representatives from the Pauls Stradiņš Clinical University Hospital paid the dinner on the evening 1.st of June.

Work Group approach

The mandate was operationalized into the following tasks:

1. Gathering all relevant information about organ donation and transplant activity in Latvia and Lithuania.

This was done by a) submitting questions to the corresponding transplant centers, with follow up questions, and b) by a physical visit to the corresponding transplant center. Regarding tissue typing and transplant coordination, there was direct contact between Work Group members and peers in the corresponding countries. Also, general information about any societal, political, or public health factors that might be relevant was sought through openly available sources.

2. Analyzing possible impact that an inclusion of the transplant centers in Latvia and Lithuania might have on the Sctp organization.
This was done by asking for a separate assessment from each of the Sctp groups and an assessment from the Sctp office, following a defined list of questions.
3. All information gathered was discussed in the group.
Information the Work Group considered might be of importance for the Council to make a decision about future membership is summarized and discussed in the present final report.
4. *The Work Group defined possible scenarios and made a brief risk and benefit analysis for each scenario, based on the available information*.

All Work Group members contributed to writing all parts of the report. The final report was submitted to the Sctp Administration (att. Medical Director Dr. Kaj Anker Jørgensen) on the 18.th of July 2022.

Organ donation and transplantation in Lithuania

On the 5th of January 2022 Scandiatransplant Director Kaj Anker Jørgensen received an email from Kęstutis Runkelė at the National Transplant Bureau in Lithuania (Transplantacijų kordinavimo skyriaus vedėjas) stating that the Lithuanian transplant centers were not yet ready to participate in the Scandiatransplant organization. In an answer from the Work Group chair, Mr. Runkele was notified that the further evaluation of membership for the Lithuanian centers was put on hold until further notice. A further evaluation of a possible membership for the Lithuanian transplant centers in Vilnius and Kaunas is therefore not included in this report.

The health care system in Latvia

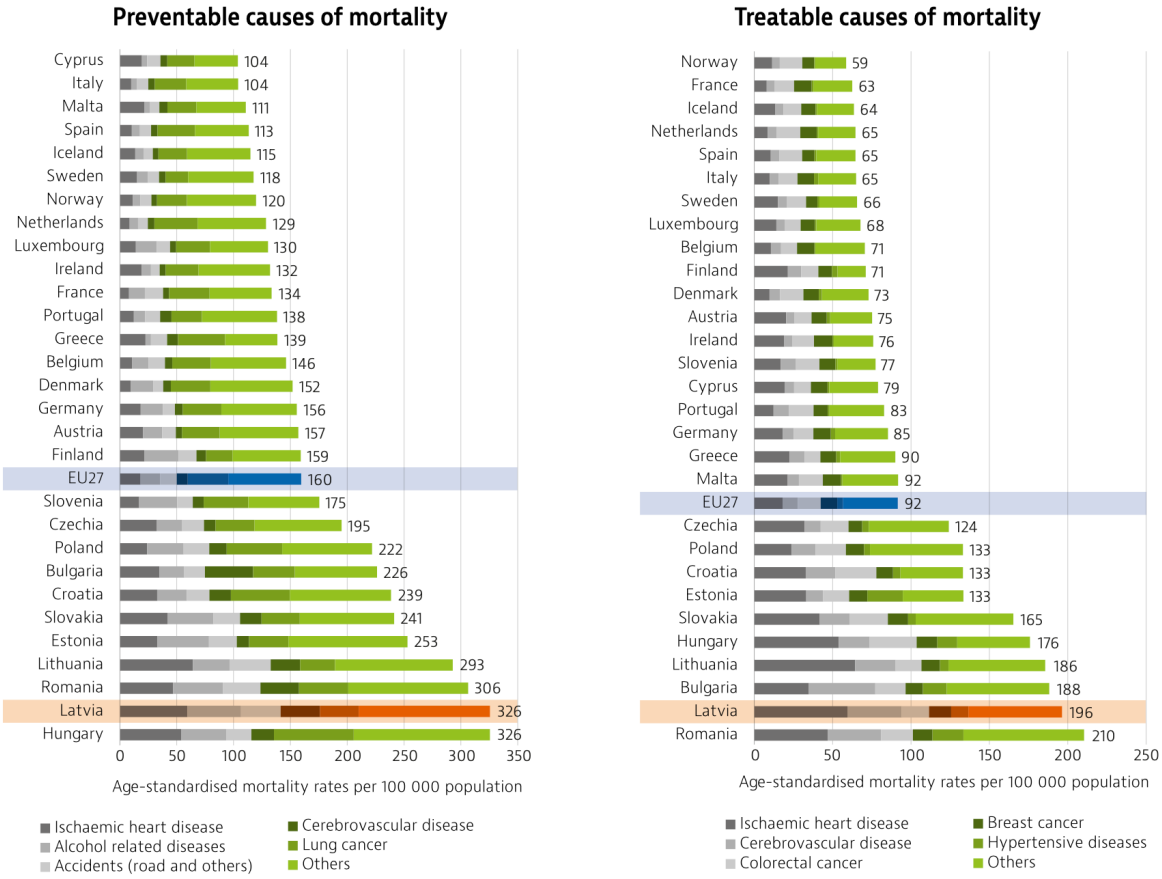
All Scandiatransplant countries and Latvia are constitutional democracies, either republics or monarchies, with parliamentarism. Sweden, Finland, Estonia, Denmark, and Latvia are all members of the European Union. Iceland and Norway are members of the closely associated European Economic Area (EEA). Free movement of people, goods and services across the member countries of the EU and the EEA are guaranteed by the member charters.[6]

There are certain limitations for the health care services,[7] but in principle all citizens have full access to health care in all members countries, while the costs must be covered by each patients' local health authority or health care provider. Alternatively, the patients may cover the costs themselves. Additionally, it is acknowledged that the treatment of non-residents in each EU/EEA country must not reduce the access for the residents. Moreover, in §15 of the the directive (2011/24 of the European Parlament and of the Council of 9 March 2011 on application of patients' rights in cross-border healthcare) it is stated that "Given their specificity, access to and allocation of organs for the purpose of transplants should fall outside the scope of this Directive".[6,7] Thus, although the Eurotransplant Manual does not preclude the transplant of non-nationals, the cross-border health-care directive of the European Union does not seem to include organ transplants.

All Scandiatransplant countries and Latvia have a comprehensive national health care system of the Beveridge model, with health care services funded by the government by taxation.[8] The European Health Observatory acknowledges that while the National Health Service (NHS) in Latvia was established in 2011 to provide universal population coverage, there are challenges to equitable access with issues around the geographical distribution of health professionals, user charges, and long waiting lists. The publicly funded health benefits package is limited in scope and only covers a pre-determined number of services each year that are provided by NHS-contracted providers and institutions.[8] In Latvia there is a mix of public and private providers, while in the other Scandiatransplant countries, the provider is mostly public. When comparing the systems, two additional factors should be considered. The first is similar to what Okma and Marmor called the divergence between "two worlds of welfare".[9] In our comparison, this divergence is relevant for the comparison because it may be expected that the social welfare system in Latvia is considerably less developed than the one found in the original Scandiatransplant countries. This may lead to a misattribution of effects to either the health care or the social care. The other caveat is the self-payment. While all countries have some point-of-care self-payment, the proportion is far higher in Latvia as considered in purchase parity compared to the original Scandiatransplant countries. Only 61% of the health

expenditure in Latvia is publicly funded, and the share of out-of-pocket expenditure is second highest in the EU.[10]

Latvia also has a significantly higher mortality rate than all other Scandiatransplant countries, both for preventable and for treatable diseases (see Figure 1).



Note: Preventable mortality is defined as death that can be mainly avoided through public health and primary prevention interventions. Treatable mortality is defined as death that can be mainly avoided through health care interventions, including screening and treatment. Half of all deaths for some diseases (e.g. ischaemic heart disease and cerebrovascular disease) are attributed to preventable mortality; the other half are attributed to treatable causes. Both indicators refer to premature mortality (under age 75). The data are based on the revised OECD/Eurostat lists.
Source: Eurostat Database (data refer to 2018, except for France 2016).

Figure 1. Mortality rates for preventable and treatable diseases in Latvia compared to other European countries.[10]

Specific features describing the demographics of the current Scandiatransplant members and Latvia are shown in Table 1.

	Sweden	Finland	Denmark	Norway	Iceland	Estonia	Latvia
Population (mill.)	10.1	5.5	5.8	5.4	0.3	1.3	1.9
GDP/inhab.	51,9	49,0	60,9	67,3	59,3	23,3	17,6
Life expectancy at birth (years)	83	82	81	83	83	78	75
Gini index	29.3	27.7	27.7	27.7	26.1	30.8	34.5

Table 1. Demographic and health care indicators for the Scandiatransplant countries and Latvia (data for 2020)[8,11,12]
GDP: Gross domestic product

While average life expectancy is 81-83 years in the original Scandiatransplant member countries, it is 78 in Estonia and 75 in Latvia.[10] The gross domestic product (GDP) is less than half the figure for any other of the original Scandiatransplant members,[11] and the Gini index is higher than in any other country, indicating higher socio-economic differences.[12]

Minorities and disadvantaged groups

The current Scandiatransplant countries may be said to have populations that are linguistically and culturally fairly homogenous. The Swedish-speaking minority in Finland is well integrated with the Finnish-speaking majority, at least there has been no reported inequity in access to health care services or specifically to organ transplant between the two groups. It is conceivable that some groups of non-western immigrants who have come to the Nordic countries in the last decades may be in a generally disadvantaged social position and that there may be some disparities in the access to health care for these groups. Whether this inequity also affects access to organ transplant has not been studied.

In Latvia 25.4% of the population are of Russian ethnicity, speaking Russian.[13] After the dissolution of the Soviet Union in 1989 and the establishment of the independent state of Latvia, certain restrictions were introduced for the ethnically Russian population. Whether this group is at some socio-economic disadvantage today is not clear to the Work Group.

A strong association between poverty and health has been demonstrated.[14] Of the current Scandiatransplant countries, most have among the world's highest ratios for GDP per inhabitant, and most show very high levels of social equality, as expressed by low Gini indices (Table 1). Estonia is an exception, with a GDP of only 40% of the average of the original member countries, and a higher Gini index of 30.8, indicating greater social differences. Latvia has an even lower GDP/inhabitant, at 30% of the average of the original

Scandiatransplant countries, and an even higher Gini index, at 34.5 (Table 1). There have been no studies examining whether access to organ transplantation is lower in individuals with lower income in Estonia or Latvia.

Organ donation and transplantation in Latvia

Contact persons and legal authoritative individuals

All organ transplantation in Latvia is performed at Pauls Stradiņš Clinical University Hospital in Riga, which is therefore considered to be the formal applicant for membership in Sctp. The hospital is owned by the Ministry of Health in Latvia.

In the case of an agreement, the Chairman of the Board of the Hospital would be the formally commissioned underwriter, with delegated authority from the Ministry of Health. Chairman of the Board is Dr. Ilze Kreicberga. Dr. Kreicberga is also authorized to sign a Data Processor Agreement with Sctp.

Other relevant contact persons are Professor Eva Strike (chief physician), Professor Valdis Pirags (Head of the Medical Council), and Dr. Jurijs Bormotovs (Head of the National Transplant Coordination Unit).

Additionally, the following professionals are involved each in their respective professional field: Dr. Janis Vilmanis (Deputy Chief Physician, Head of Department of General Surgery), Prof.P .Stradins (Head of the Centre of Heart Surgery), Prof. Uldis Strazdins (Head of the Heart Transplantation Unit), Dr. G.Vēvere (cardiologist), Dr. Janis Jušinskis (Head of Latvian Transplantation Centre), Prof. A.Petersons (Head of Center of Nephrology), Prof. I.Ziedina (nephrologist), Dr. A.Stāka (Head of Department of Gastroenterology), Prof. A.Puķītis (Head of Centre of Gastroenterology), Dr. Z. Dobele (Head of HLA Laboratory).

Financial considerations for donation and transplantation in Latvia

Pauls Stradiņš Clinical University Hospital is funded by the National Health Service, and additional funding is provided by out-of-pocket payments for health services and paid services (as stated by the Hospital representatives). The funding is considered to be stable. For the transplant recipient, there is no self-payment for health care costs or medications related to organ transplant.

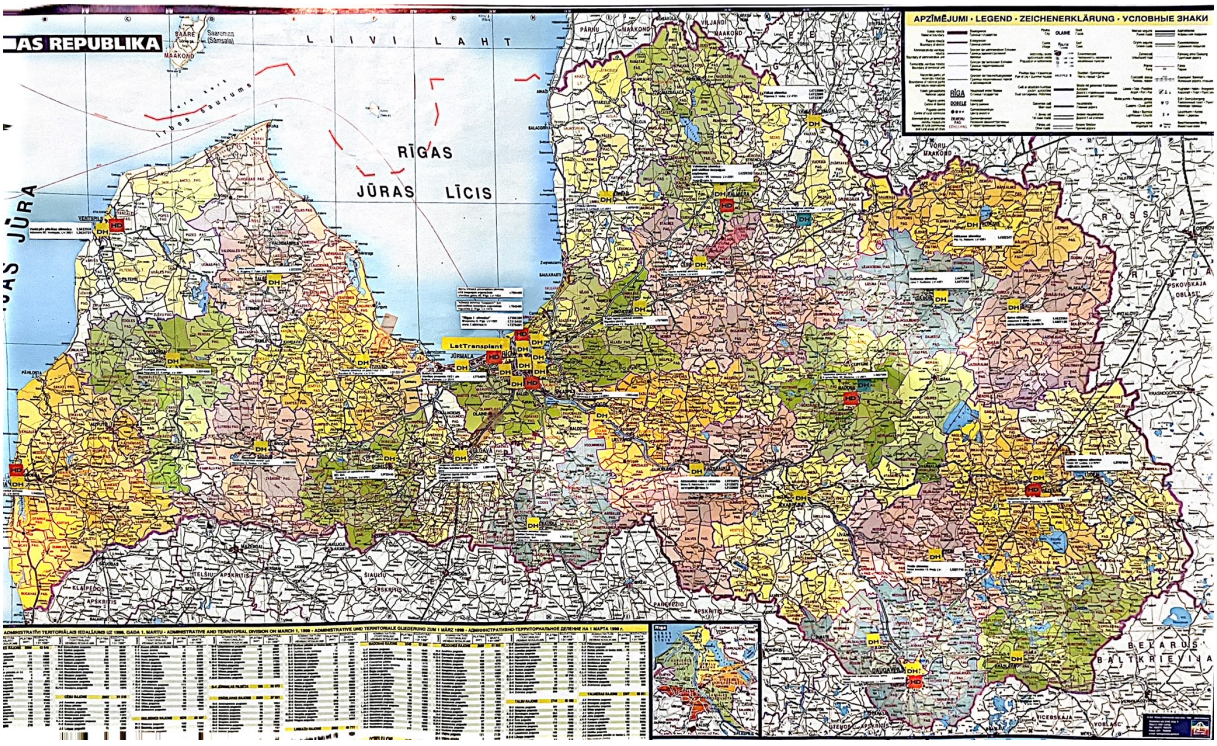


Figure 2. A map of Latvia, showing the donor hospitals (red marks). (Map kindly provided by Jurijs Bormotovs, Head of National Transplant Coordination Department, Pauls Stradiņš Clinical University Hospital, Riga).

Transplant activity

The first kidney transplant in the Nordic countries was done in Oslo in 1959 and the first thoracic transplant in 1983 (heart) and 1989 (lung), both in Oslo. The first solid organ transplant in Latvia was a living donor kidney transplant done in 1973, and the first successful liver transplant was done in 2011. By January 2020, 2062 kidney, 27 heart, nine liver, and four pancreas transplantations have been performed in Latvia. During last five years Latvia has exported 14 livers, eight hearts and eight kidneys to Lithuania, France, Germany, the Netherlands, and Switzerland.

Organ donation

There are nine donor hospitals in Latvia (Fig. 2), and Pauls Stradiņš Clinical University Hospital is the only organ transplant center. All donor hospitals are reachable within 3 – 3 ½ hours by car from Riga. Currently, no teams are available to be sent out for organ harvest if air transport is required.

Family consent rate for donation is currently 71%, and the country has an "opt-out" system (presumed consent with the option to reservation), however, the consent of next-of-kin must be sought.

The current annual donation and transplant volume in the Scandiatransplant countries and in Latvia is shown in Table 2. Table 2 also gives an estimate of the availability of organs for transplant.

	Sweden	**Finland**	**Denmark**	**Norway**	**Iceland***	**Estonia**	**Latvia**
Tx centers	4	1	3	1	1	1	1
Utilized donors (n)	174	121	121	101	4	33	20
Utilized donors pmp	17,2	22,0	20,9	18,7	13,3	25,4	10,5
Living kidney donors (n)	116	31	78	59	7	4	3
Living kidney donors pmp	11,5	5,6	13,4	10,9	23,3	3,1	1,1
Kidney tx (n)	429	263	278	240	10	47	41
Kidney tx pmp	42,5	47,8	47,9	44,4	33,3	36,2	21,6
Liver tx (n)	172	75	66	88	0	12	2
Liver tx pmp	17,0	13,6	11,4	16,3	0,0	9,2	1,1
Heart tx (n)	54	22	33	30	0	0	2
Heart tx pmp	5,3	4,0	5,7	5,6	0,0	0,0	1,1
Lung tx (n)	51	21	29	28	0	0	0
Lung tx pmp	5,0	3,8	5,0	5,2	0,0	0,0	0,0

Table 2. Transplant activity for the Scandiatransplant countries and Latvia (data for 2020).[4]
* Until 2020, only living donor kidney transplants were performed in Iceland. In 2020, deceased donor kidney transplants were done using one of the donated kidney pair, while the other was done in Gothenburg along with all other suitable organs.
Tx: transplant; n: number; pmp: per million inhabitants

Notably, while kidneys may be realized from virtually all organ donors, the procurement of other organs (i.e. the utilization rate) depends on the condition of the donor, the skills of the procurement teams, and on the actual need for the particular organ. While the donor utilization rates (organs retrieved per donor) for heart and for lungs is about 30% in the original Scandiatransplant countries, which is similar to many other Western countries, the utilization rate for the thoracic organs is less than 10% in Estonia and Latvia (Table 2). Upon direct question from the Work Group, the quality of the organ was stated to be a main reason for not using a potential organ. The ambition of the Pauls Stradiņš Clinical University

Hospital is to provide 40-50 kidney transplants, 10-15 liver transplants and 5-10 heart transplants per year and to initiate a lung transplant program. These numbers would correspond to the numbers transplanted per million inhabitants in the other Sctp countries. During the Work Group's visit, it remained unclear how the donor team and the transplant teams collaborated, and it was unclear who had the complete picture and overall responsibility of the whole pathway.

Organ allocation

The respective departments at Pauls Stradiņš Clinical University Hospital consider referrals for organ transplant and are responsible for nominating suitable candidates for the transplant waiting lists. The annual volumes of candidates on the waiting list shown in Table 3.

	2017		2018			2019			2020			2021		
Month	Kidney	Heart	Liver	Kidney	Heart	Liver	Kidney	Heart	Liver	Kidney	Heart	Liver	Kidney	Heart
January	27	7		51	8	5	37	6	6	36	8	7	25	11
February	28	4		53	3	7	29	6	6	36	8	7	25	11
March	28	4		51	8	7	37	7	6	36	8	7	30	11
April	18	2		51	8	7	40	7	6	36	8	9	23	11
May	41	5		49	3	7	40	7	6	36	8	9	29	11
June	41	5	6	41	5	4	39	7	6	36	8	9	29	11
July	41	5	3	38	5	8	38	7	6	36	8	9	29	11
August	37	7	3	34	2	7	35	8	7	26	9	9	29	11
September	37	7	4	38	4	7	39	8	7	26	9	11	29	11
October	41	5	4	38	4	6	35	8	6	30	11	11	29	11
November	53	8	4	38	4	6	29	8	6	30	11	11	29	13
December	51	8	5	35	5	6	29	8	6	30	11	11	29	13

Table 3. Waiting list figures for Latvia 2017-2021 (ref. National Transplantation Coordination Unit, Latvia)

To the Work Group the waiting lists appeared surprisingly short. This was explained by lack of referrals from the various hospitals in Latvia, and by the fact that the low number of transplants influence the number of patients that would be reasonable to list for transplant.

Allocation to non-Latvian nationals

In the written answer to the Work Group, it is clearly stated that access to organ transplants is restricted to residents only (see attachment). This was also confirmed by hospital authorities in response to direct questions at the visit in June. Knowing that non-nationals have historically had access to organ transplant in Latvia, the Work Group specifically asked when this practice was stopped, which appears to have been in 2017.

Transplant organization at Pauls Stradiņš Clinical University Hospital

The Pauls Stradiņš Clinical University Hospital has three established donation and transplantation programs: kidney, liver, and heart. The National State Agency of Medicine performs audits of the transplantation process once every third year. The last audit was in 2020. The Work Group has not asked to see this report. The following information about the organization of the organ procurement process was provided by representatives from the Pauls Stradiņš Clinical University Hospital (presumably written by the Dr. Jurijs Bormotovs, Head of the National Transplant Coordination Unit):

Quality control of organ donation and procurement based on EDQM guidelines, Latvian Law on the Protection of the Body of Decreased Humans and Regulations of the Cabinet of Ministers regarding determination the fact of brain and biological death, and medical use of human organs.

The Hospital has developed and established standards of procedures (SOPs, based on EDQM guidelines) for:

1.Initial report for suspected serious adverse events or reactions.
2.Final report for serious adverse events or reactions.
3.Act of human organ transfer for transplantation.
4.Donor organ evaluation and description (for each organ).
5.Deceased and living donor selection, screening and allocation.
6.Organ exchange between foreign countries.
7.Waiting list maintenance.
8.Organ procurement from deceased and living donor.
9.Work organization of specialized transplant team.
10.Preservation of each donor organ.
11.Organ traceability (incl.in case of international organ exchange).
12.Acceptance and rejection of donor organs.
12.Utilisation of rejected donor organs.
13.Safety of donor organ packing, labeling and transporting.

Each step of organ donation, starting from the referral to procurement, is fully documented and protocolled according to hospital's guidelines. Each event is documented in the Registry of the Organ Procurement Organization (hereafter – OPO). Each donor is being encoded with unique number assigned by OPO. The data from the potential donor's medical record is registered (paper and e-registry). Each donor is screened for infectious diseases (incl. toxoplasma, syphilis, HIV, HCV (Ag, anti-HCV), HBsAg, anti-HBs, anti-HBc, CMV IgM and IgG, EBV VCA IgM and IgG, EBV EBNA IgG).

After having collected necessary data, the OPO transfers all information to the transplant team involved, who performs allocation for each organ and refers back to OPO. If any of available organs will not be used in Latvia, OPO together with transplant team complete and sign the act of making an offer of donor's organ to other countries or OPOs. In the case of an international organ exchange, the same procedures are performed and followed: donor organ description is given to the transplant coordinator of the foreign OPO, an act of organ transfer is signed, the organ package is labelled, and a feedback form about the results of transplant and condition of the recipient is received from the host OPO.

All data is documented, archived and protected according to EU regulations and national legislation.

The transplant coordinator performs the monitoring, documentation and tracking of any events during procurement surgery on-site until each organ is packed, labelled and given away to transplant surgeons, according SOPs mentioned above. To maintain the safety and quality of the donor organ, transportation to the recipient hospital is monitored and protocolled.

To maintain the qualification of the transplant coordinators, annual courses are held locally. Debriefings of OPO office are organized every three months.

ICU physicians and anesthesiologists who are involved in transplantation participate in conferences together with Latvian Transplantation Centre and Latvian Association of Anesthesiologists and reanimatologists on regular basis. For coordinators and ICU staff in all donor hospitals of Latvia, annual training course are held at least once in a year.

To measure and to evaluate the results, The Hospital adopted and introduced the following quality indicators on: organ donor detection, evaluation, referral, precise brain death diagnosis, proper donor management, family consent rate, ratio of median waiting time for organ to size of waiting list, and education in organ donation and transplantation.

At the Work Group's visit in June 2022, most of this information was orally confirmed, but no written documentation was reviewed by the group.

Kidney

Dialysis services plants in Latvia provided by private dialysis centers and hospital-based public health system driven facilities

The renal transplant program in Riga comprises deceased and living donor transplants, including ABO incompatible transplantations and paired kidney exchange. Average waiting time for kidney transplant candidates is 222 days. We do not know the number of highly-immunized patients, i.e. patients that would be eligible for the STAMP program. Presently in Latvia about 500 individuals are alive with a functioning kidney graft. Retrieval teams use LifePort-perfusion machines for deceased donor kidneys.

HLA matching and advice from immunologists seems to be given lower weight for allocation than what is usual at the Scandiatransplant centers.

Quality of the renal transplant program is ensured through yearly reports from a national renal registry comprising patients on renal replacement therapy, thus both patients on dialysis as well patients with a functioning kidney graft. Status for patient and kidney graft are retrieved and reported to the registry on a annual basis. However, there is no crosschecking with the national death registry and the yearly report is not published.

Pediatric renal transplantation for small children is not performed in Latvia but are done in Hamburg, Germany.

General impression: The renal transplant program in Latvia has a rather small volume but seems overall to be up to technical standards.

The tissue typing laboratory is not yet EFI accredited. This will be a prerequisite for exchanging kidneys with the transplant Latvia (Riga)

Thoracic organs

The Cardiac Surgery Centre of the Hospital performs more than 1000 open heart surgeries each year, and the low number of heart transplants is explained to be due to lack of identification of suitable candidates. The number is expected to increase following better education and through the construction of separate postoperative intensive care rooms that are planned for 2022.

Pediatric transplants

Pediatric transplants are currently performed in Hamburg, Germany. The nature of this agreement is not clear to the Work Group. The Work Group has recently sent a request to Eurotransplant acquiring data about Latvian nationals transplanted in Eurotransplant.

Tissue typing

Transplantation laboratory services are provided by the Laboratory of Histocompatibility and Immunogenetics (hereafter – H&I) which is integrated in the Hospital's general laboratory that also performs clinical chemistry and microbiology. The Laboratory is ISO 15189 accredited since 2016 and this also includes the tests for H&I. This indicates that there is a well-established quality system at the laboratory. Currently the only medical doctor at the HLA lab does not have a background in immunology but in human genetics. She has only two years' experience in her current position. There is currently no deputy. The core technology that the laboratory uses for HLA typing is reverse SSO that takes longer time than the Q-PCR which most Sctp laboratories use. Currently they type for HLA ABC DRB1 DQA1 DQB1 and DPA1 DPB1 and thus the only missing loci that are mandatory within Sctp are DRB3/4 and 5 genes. The plan is however to start to also type for those genes during 2022 and also to switch to the Q-PCR platform in 2023.

Scandiatransplant has a requirement that the affiliated HLA laboratories must be EFI accredited and the current plan is to submit the application in 2023 to gain accreditation in 2024.

The platforms used for crossmatching and HLA antibody screening are the same as used in most Sctp laboratories and the lab has also successfully participated in Instand and ET organized external proficiency testing for HLA typing, crossmatching and screening.

The lab has 24/7 service but most work is performed during regular hours since samples are received well in advance of organ procurement in most instances

One weakness of the laboratory is the lack of experience of the "director" and this will probably be the major problem for EFI accreditation. The Work Group also thinks that there may currently be a lack of expertise to participate in HLA-driven programs such as STAMP and STEP with own (Latvian) patients. Once the laboratory has included typing for loci currently not done, The Work Group feels assured that the HLA results with the current techniques can be trusted, and hopefully the lab will switch to Q-PCR that also gives faster results.

Transplant coordination

In the last three years, the donor activity has been low, with only 51, 46, and 42 potential donors, and 19, 21, and 18 actual donors. Many of the potential donors do not become actual ones due to lack of consent from family members.

The head of NTCU has handled all organ exchange during this period (mainly to Lithuania). The coordinators (nurses) take the calls and collect data on potential donors from donor hospitals. We asked if they can manage to answer organ offers in 30 minutes in English and Dr.Jurijs Bormotovs said that he will and can (he is the one who would do it).

This means that he needs to be on call 24/7 because only one of four coordinators speaks and understands English. It seems likely that the NTCU has not realized the amount of organ offers from Scandiatransplant they need to answer every week, and it is necessary to clarify whether the NTCU is able to handle the number of contacts should the Hospital become a member of Scandiatransplant. Another concern is the logistics of organ exchange (or mostly import of organs), because at present the Hospital does not have much experience with import of organs and currently there are no funds to cover private jets.

A collaboration between Latvia and Scandiatransplant will give the coordinators more organ offers to handle, and it will increase the workload. The NTCU is vulnerable because the Head of National Transplantation Coordination Unit Dr. Jurijs Bormotovs, who is enthusiastic and really committed to his work, is the only person who can handle NTCUs workload when it comes to organ donation and exchange.

Current international collaboration

The Pauls Stradiņš Clinical University Hospital has previously collaborated with several international transplant centers to ensure organ transplant for Latvian citizens, and currently there is some collaboration with the transplant center in Vilnius, Lithuania. Pediatric (liver?) candidates from Latvia are transplanted in Hamburg, Germany. The Work Group has no information about the volume or conditions of this collaboration, but a request has been sent to Eurotransplant where transplantation of foreign nationals must be registered according the Eurotransplant Manual.

Motivation to join Scandiatransplant

The decision to join the Scandiatransplant was taken by the Ministry of Health together with heart, kidney, and liver transplant specialists, pulmonologists and NTCU at the Pauls Stradiņš Clinical University Hospital.

The main reasons to join Scandiatransplant are:

- Geographic location.
- The nearest network for organ sharing
- Previous collaboration with member states in transplantation and other fields of medicine.
- Latvian national airline (Air Baltic) has convenient and fast connections to Scandiatransplant member cities.

At the visit to the Hospital and after personal interviews with transplant professionals, hospital leaders and with the Chair of the Hospital Board, Dr. Kreicberga, the Work Group was in no doubt that all were highly motivated to further develop transplant medicine in Latvia and to seek further collaboration with Scandiatransplant

The Work Group made no complete analysis of the current workload at the transplant units in Riga, precisely how the workload might increase following a future membership, or of what changes would be required. Such changes could include changes in human resources or the staff's English language skills; transport logistics; costs, including membership fee; demands on organ quality, including EFI accreditation for histocompatibility lab; organ exchange timeline etc.

Numerical impact of organ exchange and allocation

Should a membership be granted to the Pauls Stradiņš Clinical University Hospital in Riga, the number of member centers in Sctp would increase from 11 to 12, the number of member countries from six to seven and the total population from 28.4 to 30.3 million (7%). Given the current donation rate and waiting list numbers in Latvia, a membership would increase the total Sctp donor pool by about 3.6% and the total number of wait-listed patients by about 2.9% (pancreas excluded, data for 2021 and 2022).

Impact on the Scandiatransplant organization

As of July.2022, Sctp has 11 member hospitals in six countries covering a total population of 28.4 million inhabitants. All organ donations and transplantations in these countries is organized through Sctp, and Sctp keeps an updated registry for the mandatory matching of donors and recipients (*i.e.* tracing) and a record to regulate organ allocation and exchange within and between the member centers. The Sctp registry also contains the option to report

adverse events. Furthermore, through six professional groups, the rules for organ exchange and research projects are organized.

Impact on the central Scandiatransplant administration

Membership: Any hospital performing organ transplantation can apply for "associate membership" (http://www.scandiatransplant.org/about-scandiatransplant/organisation/ARTICLESsigned_amended2021May19_repr_Helsinki.pdf - article 4) since 2016. Hospitals from the Nordic countries have always been able to apply for membership, but after 2021 hospitals from Estonia can also apply for full membership. It is the Council that in each case decides if a hospital can become a member or associate member.

Increased workload for the Office: The consequences for the Scandiatransplant Office if Riga University Hospital joins Scandiatransplant are difficult to predict exactly, but Sctp did gain some experience in the recent process of accepting Tartu as a member. (http://www.scandiatransplant.org/Documentation/estonia). Implementing Riga and all donor hospitals into YASWA would take some preparation and programming. This will be done with the available staff at the Office prioritized with other tasks at time. There will therefore be a time gap between when the decision to accept the Pauls Stradiņš Clinical University Hospital is taken by the council until the Hospital can actually functionally be a member of Sctp. The Office estimates that the programming could be done in one or two weeks, but that depends upon the priority this task is given.

There will be a need to train people in Riga in the use of YASWA. It could be necessary for people from the Office to go to Riga and maybe people from Riga will have to come to Aarhus. In the case of Tartu, two people from Tartu came to Aarhus and after that introduced YASWA to the relevant people in Tartu. Much can be done on-line and by telephone. This will also have to be prioritized with other tasks at that time.

After joining and training there will be a need for support, similar to the current need at any other center in Sctp. This will also be done by the present staff.

At this time the Office is fully staffed. It would be very difficult to expand the room facilities at the Office and we have no plans for that. According to the judgment of the Sctp Director, an integration of Riga in Scandiatransplant can be done using the existing staff.

Finance, income: This would increase a little. With 40 transplantations per year it would lead to an increase of 120,000.00 DDK per year. If as expected the number of transplantations in Latvia increases, then this would also increase. The price per transplantation is fixed every

year by the Council of Representatives, but an increase would not be because of Riga joining. It would likely happen independently of a membership for Riga, mainly due to increased costs at the Office, primarily through increases in wages.

Finance, cost: As explained above an increase in the office staff is not expected as a consequence of a future membership for Riga. Initially there may be some extra expenditure for travel and meetings. Sctp would pay travel for one coordinator to the coordinators group meeting (maximum two times per year). It is our judgment that any extra costs could be kept within their payment for the transplantations.

In this evaluation we have not considered whether Sctp should to support Riga in any special way due to their lack of resources.

Conclusion: The Office thinks that inclusion of Riga into Scandiatransplant can be done without a need to expand the Office and the accounts would remain balanced.

In the following chapter, we show the specific answers provided from each of the Sctp Groups in response to questions sent to all by the Work Group.

Impact on the Scandiatransplant Groups: Transplant Coordinators

1. How might including the new members affect organ exchange rules as governed by your group?

Pro:

- Increased risk for recipients to receive an organ on HU/highly-immunized cases for all member states.
- Increased donor pool might be positive in general, *i.e.* increased recipient pool for surplus organs

Con:

- Increased workload with additional centers (coordinators, surgeons, other professionals).
- Risk of complicated and/or expensive logistic (few/no flight between all countries)
- Accumulation of pay-back organs might be greater
- Increased number of centers will prolong the process when surplus organs are offered
- It is of the utmost importance for new members to be able to communicate in English so that there is no risk of serious misunderstandings in the process.

2. How might the governance of the group be affected (meetings, communication, voting, discussions etc.)?

Pro

- In general, no negative consequences with voting, meetings etc.

Con

- Language might be an obstacle.
- Risk that it may be more difficult to find meeting times that suit everyone.

3. What changes to group bylaws/guidelines would be necessary?

Pro

- None, or absolute minor changes

Con:

- Ensuring a minimum of standard is a prerequisite

4. Would membership have practical consequences for meeting routines?

Pro

- For the existing group today, there will probably be less or no major consequences
- Access to on-line meeting (for all members) maximizes the opportunity for participation in the meetings

Con

- Again, challenges related to language
- Biggest challenge for Lithuania/Latvia (logistic, costs)

Impact on the Scandiatransplant Groups: Tissue Typers

1. How might including the new members affect organ exchange rules as governed by your group?

Depending on the ratio of donation in both countries, we could increase the pool for our patients. We think we have a stable system and cooperation, which could handle including more centers not so far away. If the HLA allele frequency is very different, then there might be more rare haplotypes as a payback. Otherwise, there is no need to change any rules.

2. How might the governance of the group be affected (meetings, communication, voting, discussions etc.)?

Since there will be maximum three new centers (*i.e*. considering Latvia and Lithuania), there would be only three more representatives and we do not think that this will affect the group negatively. The meetings will probably be longer, but that is not a problem. However, we might need to discuss balances in STAMP and STEP Committees as currently, only one tissue typer represents each country in these groups. Perhaps it should be changed to one tissue typer from each transplantation center to keep the balance of these committees?

3. What changes to group bylaws/guidelines would be necessary?

The Lab should naturally be accredited by EFI, so same rules for HLA typing etc. We think we have to adjust the guidelines, which will be a part of the project and the process.

4. Would membership have practical consequences for meeting routines?

We think that we can keep the routines regarding the meetings with minor adjustments and we do not see major practical consequences.

Impact on the Scandiatransplant Groups: Kidney

1. How might including the new members affect organ exchange rules as governed by your group?

No effect is expected as we assume that new members will accept the rules and that new members will have to meet the same standards as we presently have in Sctp, *e.g*. EFI accredited tissue typing facilities, 24/7 coordinator function etc.

2. How might the governance of the group be affected (meetings, communication, voting, discussions etc.)?

Presently the group consists of one member from each of the ten member centers. The members elect a chairman, and each of the six countries appoint a country representative that together with the chairman serves as sort of an executive committee. In countries with only one enter, the NKG representative is also the country representative, in countries with more than one center (Sweden and Denmark), one of the representatives serves as country representative.

The group meets in person once a year

Nearly all decisions are taken during the annual meeting. Decisions are taken after a consensus has been reached. We have never voted. In some cases, the executive committee has spoken on behalf of the group in between the annual meetings. The present answer is an example of this. No descriptions regarding which rules must be followed when decisions are made exist in the bylaws. This reflects the fact that the group members have worked together

for many years and all know each other personally and that the group primarily has served as a reference group for the Sctp board. Most decisions were formerly taken by the Council. This has changed over the years and our bylaws probably need revision anyhow.
More members could potentially make discussions and communications more complex. If both applications are met this will mean an increase from 10 to 13 centers and from 6 to 8 countries in NKG, constituting a substantial increase.
3. What changes to group bylaws/guidelines would be necessary?
As already mentioned, the group bylaws probably need revision. Presently our bylaws do not reflect the latest changes in Sctp bylaws especially §12. We need a clear description on how decisions are taken, and a description of voting when necessary. This is not a simple matter as we have small and large centers. How this is weighted in relation to voting needs careful consideration. We may also need to reconsider how the whole group is organized. Should large centers have more members than small centers? This is going to be a complex process that will take time, but probably need to be finalized before new members join.
Revision of the bylaws should also include a description of sub-groups, where we presently only have one, NPRTSG. However, NPRTSG has changed over the years. After being a stand-alone work group with own registry it has now been fully incorporated in the SCTP structure and registry. Our bylaws need to reflect this
4. Would membership have practical consequences for meeting routines?
Probably not at present as we will expect that new members will accept how this is done now. However, revision of the bylaws, may reveal that also meeting routines need to be changed

Impact on the Scandiatransplant Groups: Liver
No answers received from the liver group.

Impact on the Scandiatransplant Groups: Thoracic
1. How might including the new members affect organ exchange rules as governed by your group?
The organ exchange rules would not need to be changed. It would need to be discussed how the small centers should be handled on the Rota list.
2. How might the governance of the group be affected (meetings, communication, voting, discussions etc.)?

No major changes foreseeable. The guidelines have recently been revised and somewhat formalized and further revisions might be necessary independent of a membership for Riga.

3. What changes to group bylaws/guidelines would be necessary?

See above.

4. Would membership have practical consequences for meeting routines?

None.

Ethical considerations

Organs for transplantation are a scarce resource and are usually allocated according to the ethical principles of beneficence, utility, and justice. In this context, beneficence means that the chance of a successful outcome after transplant should exceed the risk of poor outcome, *i.e.* there should be an expected survival benefit. The strict adherence to the rule that the donor must be dead before vital organs are removed could also be regarded as dictated by the principle of beneficence (or synonymously by its inverse, non-maleficence). Because of the organ scarcity and the ensuing rationing, the transplant candidates with the highest expected utility should be prioritized. Justice, in this context, is mainly understood to mean that there should be equal access to organ transplantation for all.

Reiterating these principles is relevant when considering a membership for the transplant hospitals in Latvia or Lithuania. Although not explicitly stated, it is usually expected that countries that exchange organs for transplantation have similar understanding of these principles. Nevertheless, some differences occur, and are apparently accepted, such as in definitions of death, which is what guides the varying acceptance of donation after circulatory death.[15] Organ trade and transplant tourism, however, are generally agreed to be unacceptable. Nevertheless, in countries where the flow of payment for health services is not entirely transparent, accusations and even convictions of transplant-related crimes have been described. This is particularly problematic if the organ retrieval is not entirely transparent.[16] Transplantation of foreign nationals in itself cannot be regarded unethical, but allowing foreign nationals access to organ transplant creates vulnerability for transplant commercialism (sale of human organs). This would particularly be the case when the organ procurement is not entirely transparent. Moreover, if there is direct payment-for-performance to the transplant professionals, even if this is accepted within the country (as it is in for instance Germany or Austria), the presence of such a system for payment to transplant professionals creates a vulnerability for transplant commercialism. This Work Group has not examined any

evidence concerning transplant of foreign nationals, but was assured that since 2017, no non-national had been transplanted in Latvia.
The interpretation of equality regarding access to transplantation in Latvia vs. the current Scandiatransplant member countries could also be of particular relevance for this report, but no written documents proving such differences have been available for this report.

Another ethical consideration that might be of relevance could be the notion that the current, mostly wealthy and highly developed Scandiatransplant members have a responsibility to help an economically less well-developed country like Latvia to build a functional organ transplant service for its citizens. Such an ethical obligation could rest both on the notion of a remedial responsibility (we should do it because we can do it) and a relational responsibility (we should do it because we are related). The latter would depend on the assumption that the Nordic countries have a particular historical or geographical relation to Latvia.[17] This ethical responsibility could also mean that it might hurt the reputation and the internal coherence of Scandiatransplant if a contribution to the development of transplant medicine in a neighboring country was declined or met with indifference. Finally, including Latvia might increase the total Scandiatransplant donor pool, since the total population would increase by about 7% should Latvia be included among the Scandiatransplant countries. The actual quantity of this benefit would depend on the number of organ donations in Latvia, and this utilitarian consideration should be weighed against the other ethical considerations (equity, responsibility) as mentioned above.

Legal considerations

Latvia abides to all relevant EU regulations and has relevant legislation to regulate organ donation and transplantation. The Regulation of the Cabinet of Ministers on the organization of the transplantation process are available by following the links on the Internet (in English):

1. Republic of Latvia, Cabinet Regulation No. 70, adopted 29 January 2013 “Regulations Regarding Use of Human Organs in Medicine, as well as Use of Human Organs and Body of Deceased Human Being for Medical Studies” https://likumi.lv/ta/en/en/id/254753
2. The Supreme Council of the Republic of Latvia, 15 December 1992 “Law on the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine, https://likumi.lv/ta/en/en/id/62843

Additionally, the hospital has a set of procedures that regulate the organ transplant process, stakeholders and related activities (shown in Annex 2 of the attachment "Answers from the to the questions sent by the Work Group"). Documents in English regulating the process of international organ exchange are shown in Annex 4 of the same attachment.
The Scandiatransplant regulations for international collaboration and organ exchange are outlined in the Sctp guidelines: http://www.scandiatransplant.org/organ-allocation/GuidelinesforDeceasedorgantransplantationNonScandiatransplant_March2017.pdf.

Possible scenarios for a future membership

The Work Group outlines four conceivable scenarios:

I. **Stop now.** A letter of decline is sent and no further steps are taken to evaluate the membership of the Pauls Stradiņš Clinical University Hospital in Scandiatransplant.

II. **Become an associate member now.** The Pauls Stradiņš Clinical University Hospital is granted full membership rights now and the process of integrating the hospital in the Scandiatransplant procedures is started. Also, specific conditions for a full membership status and a specific date for evaluation of full membership status are defined.

III. **Start a cooperation with certain current member hospitals.** This means that steps are taken to specify the conditions for starting a collaboration with one or several current Scandiatransplant centers according to the guidelines (see Figure 3). A prerequisite for Scenario III is the willingness of one or several centers to engage in a binding collaboration. Benefits for such centers must be ensured by specific agreements, and could for instance include prioritized access to organs that are not used in Latvia. The Board could make new guidelines to accommodate to the specific situation if the current guidelines preclude a reasonable cooperation. The conditions for proceeding to full membership should be specified and a date for evaluation decided.

IV. Continue the evaluation

If the Scandiatransplant Council or Board does not consider the evaluation thus far to be sufficient for making a decision, the following further evaluation could be considered:

A. Scandiatransplant continues to further investigate matters that are not completely clarified (*e.g.* precise number of highly-sensitized renal patients,

precise criteria for candidate selection and organ allocation, work flow from donor to recipient, resource availability, data registration and documentation quality etc.)

B. Scandiatransplant continues to observe and monitor the development of organ transplantation in Riga.

C. Specific requirements for becoming associate members in Scandiatransplant are presented to the representatives at the Pauls Stradiņš Clinical University Hospital

3. Scandiatransplant members can arrange cooperation agreements that include transplantation of individuals from a non-Scandiatransplant member country and agreements allowing the use of organs from non-Scandiatransplant countries. Such agreements are subject to the following provisions: they shall only be made with transplant units within formally established organ exchange organisations,

1. they shall include training and education to promote good quality organ transplantation programmes,
2. they shall attempt to establish a balance between the number of organs made available to Scandiatransplant, and organs applied for transplantation of patients from the organisation in question,
3. they shall ensure that patients from non-Scandiatransplant membership countries subject to such agreements shall be selected for transplantation in accordance with the same criteria that apply to Scandiatransplant patients,
4. they shall not involve payment for organs,
5. they shall be presented to and approved by the board of Scandiatransplant.

Figure 3. Guidelines for Deceased organ transplantation of individuals from a non-Scandiatransplant member country performed within Scandiatransplant and the use of organs from such countries for Scandiatransplant recipients (http://www.scandiatransplant.org/organ-allocation/GuidelinesforDeceasedorgantransplantationNonScandiatransplant_March2017.pdf)

Analysis of risks and benefit for each scenario

The Work Group has listed a number of conceivable risks and benefits associated with each of the possible scenarios (for simplicity, here, the Pauls Stradiņš Clinical University Hospital is termed "Riga").

Scenario I: Stop now

Benefits: No further efforts are spent evaluating membership, and Riga may concentrate on collaborations elsewhere. Scandiatransplant may continue current practices without the risk associated with having to adapt to a new member. Riga may continue to develop collaborations with Lithuania, Eurotransplant end elsewhere.

Risks: Riga may continue to face the problem of a low number of organ donations and transplants, there may be a slow development of many aspects of organ donation and transplant medicine leading to unnecessary suffering of patients in need for transplant, and opportunities for scientific collaboration would be lost. Scandiatransplant may lose the opportunity to increase its organ exchange and scientific collaboration with Latvia and later possibly also Lithuania, and Scandiatransplant may loose authority and credibility if hesitating to contribute to the development of transplant medicine in a neighboring country.

Scenario II: Become an associate member now

Benefits: Increased access to organs for Riga, including a real opportunity for their highly sensitized renal patients in the STAMP (and STEP) program. Similarly, albeit quantitatively of less importance, there would be increased access to organs for the Scandiatransplant members.

Increased scientific collaboration, which for Riga would be likely to entail a general increase in the quality of care for Latvian patients, an increase in donor rate and improved transparency in recipient selection. This could be of particular benefit for lung, heart and liver patients in Latvia. A membership would also facilitate an increased collaboration with Tartu. The scientific collaboration would also undoubtedly be an advantage for Scandiatransplant.

For Riga a membership would give access to an IT-system which may ensure transparency, documentation and adherence to regulations.

The revision of guidelines that would be required if Riga were to become a member may be healthy for the governance of Scandiatransplant and its groups.

For Scandiatransplant, contributing to develop transplant medicine in Latvia would be in agreement with the ultimate purpose of the organization and may increase the awareness of the common motivation (the "why" of Scandiatransplant).

Risks: For Riga, a membership would entail increased cost (organ procurement, membership fees, travel etc.). Riga must also terminate existing exchange agreements with other countries. For the Scandiatransplant Office there might be an increased workload. Language barriers due to suboptimal proficiency of the English language may be problematic. Travel distances and poor flight connections may impede the collaboration. The informal dialogue currently common in Scandiatransplant may be jeopardized when a new member is introduced. Several organ exchange rules may be complicated by the introduction by a member with an asymmetrical size such as Latvia. The cultural, historical and economic differences between Latvia and the original Scandiatransplant countries may lead to misunderstandings and distrust (unless a high level of transparency and communication is actively pursued). Finally,

the tissue typing laboratory in Riga is not EFI accredited, but an application is planned to be sent in 2023 or 2024.

Scenario III: Start a cooperation with certain current member hospitals

The disadvantages of scenario I would not need to be considered, and many of the benefits in scenario II could gradually be enjoyed. For the collaborating Scandiatransplant center, an increased access to organs could be of benefit, also the increased scientific and cultural collaboration, with a mutual education and learning opportunity. A risk could be that the workload for the collaborating center could be large. For Riga, the access to an existing Scandiatransplant center could be a step on the way towards full membership, helping to develop the transplant program. A risk could be that the collaboration might not work as expected, which could delay the development in Riga.

Scenario IV: Continue the evaluation

A further evaluation might provide additional information ensuring an optimal decision. A potential risk is that continuing the evaluation might bring no new significant information, and that it would be a waste of time, effort and trust.

Further evaluation of membership for Lithuanian hospitals

Since the evaluation of the Lithuanian centers has been put on hold, risks and benefits associated with the Lithuanian membership are not further considered. However, it seems reasonable to assume that should a Lithuanian membership be considered at a later time, the additional scenarios would be similar to those of including Riga for each of the two Lithuanian transplant centers, adding the foreseeable complexities arising from the fact that there are two transplant centers in Lithuania.

Conclusion

Following an initiative from transplant professionals in Latvia and Lithuania, a work group representing all organ groups within Scandiatransplant was assembled to evaluate a possible membership for the transplant hospitals in these countries. Later, Lithuania asked for a pause in the process, and therefore is not considered further in this report. This report is therefore focused on evaluating the possible membership of the Pauls Stradiņš Clinical University Hospital in Riga, Latvia in Scandiatransplant.

While the traditional Scandiatransplant countries enjoy a high economic development, relatively small social differences and well-developed health care systems with a high degree

of governmental funding, Latvia is among the EU countries with the lowest score on all of these parameters. Nevertheless, a solid organ transplant system has been developed, and it is integrated in the publicly funded health care system. Organ donation and transplantation is entirely financed by governmental funding, with no point-of-care expenses for the organ recipients, despite the otherwise relatively high degree of out-of-pocket payments in the Latvian health care system. The donation rate is about half the rate in the Scandiatransplant countries, but it is organized through an accountable national organ procurement system and in accordance with EU regulations and ethical standards. The transplant coordinator function may seem underfunded and may have difficulties meeting the requirements of a Scandiatransplant membership. The tissue typing quality and capacity are satisfactory and could fairly easily meet Scandiatransplant standards, but certain vulnerability due to staffing shortages may be present.

The options for Scandiatransplant are

I. To stop any further evaluation of a collaboration with Latvia
II. To approve associate membership
III. To develop a collaboration between one or several existing member hospitals, and
IV. To continue the evaluation process.

The council must decide which of these avenues to pursue. For scenario III it is necessary that one or several existing centers volunteer to enter such collaboration. For scenario IV the Council or Board must specify what should be further evaluated, and by whom.

The Work Group sees no legal or ethical obstacles to granting a membership to the Pauls Stradiņš Clinical University Hospital in Riga. There is no access to organ transplants for non-Latvian residents. For Scandiatransplant, it might be considered an ethical challenge not to engage in further collaboration to develop solid organ transplant medicine in Latvia.

Attachments

1. Answers from Riga to the questions sent by the Work Group
2. Program for Work Group visit to Riga 1.-2. June 2022

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