Organ Donation in the United States and a European Union Perspective

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I. Introduction to Organ Donation in the U.S.

Although researchers began experimenting with organ transplantation on animals and humans in the 19th century, it wasn’t until the mid-20th century that scientists were performing successful organ transplants. Transplants of kidneys, livers, hearts, pancreas, intestine, lungs, and heart-lungs are now considered routine medical treatment. In recent years, many important medical breakthroughs from tissue typing to immunosuppressant drugs have led to a greater volume of transplants and longer survival rate for recipients. Jean Borel’s discovery of an immunosuppressant drug called Cyclosporine in the mid-1970s was a tremendous breakthrough and was approved for commercial use in November 1983.

a. Eligibility for Organ Donation

Organs are matched by blood and tissue type (which can vary by race), organ size, medical urgency, waiting time, and geographic location. Patients are more likely to find matches among donors of their same race or ethnicity. People of all ages may be organ and tissue donors. Physical condition, not age, is important.

a.1. Deceased Organ Donation

The majority of organ donors are people who suffer from a head injury that results in brain death—a condition where the brain has permanently stopped working, as confirmed by a physician. Artificial support systems may temporarily maintain functions such as heartbeat and breathing, but this is not a permanent state. In some cases these people have had a stroke, traumatic head injury due to a car accident or fall, or a brain tumor that has not metastasized.

Death may be pronounced when a person's heart stops beating or when the person's brain stops functioning (brain death). Brain death occurs when blood, and the oxygen it carries, cannot flow to the brain. The person's heart still beats and provides blood and oxygen to the rest of the body, as long as the person remains on a ventilator, or breathing machine. Because these functions remain intact, people who are brain dead can qualify as organ donors.

Uniform Anatomical Gift Act (UAGA)

The UAGA provides individuals who are 18 years of age or older the right to donate organs and tissue for transplantation. A written document of a person’s wish includes a signed donor card or indication on a driver's license. All U.S. states have enacted some form of the UAGA.

On a more complex level, the UAGA also provides information on who can allow donation to occur in the event that the person who died did not make a decision about donation. Most organ procurement organizations approach the patient's family for consent even if there is a signed donor card. The order of priority of “decision makers” is as follows: 1.Spouse 2.Adult son or daughter 3.Either parent 4.Adult brother or sister 5.Grandparent 6.Legal guardian. If consent for donation is given by one of the individuals above, the recovery coordinator or hospital staff will obtain written consent. A recovery coordinator may obtain consent for tissue donation over the phone. This consent form becomes part of the donor's permanent hospital record.
a.2. Living Organ Donation

In addition to deceased-donor transplants, patients may also receive organs from living donors. Living donation offers an alternative for individuals awaiting transplantation while expanding the organ supply. Types of organs that can be given by living donors include:

- **Single kidney**
  This is the most typical living organ donation. For the donor, there is little risk in living with one kidney because the remaining kidney is functional enough to take over the work of both kidneys.

- **Liver**
  Individuals can donate portions of the liver, which has an amazing ability to regenerate the segment that was donated and regain full function.

- **Lung**
  Individuals donate lobes of the lung although lung lobes cannot regenerate. A domino transplant is used in the case when physicians determine that the deceased donor lungs will function best if they are used in conjunction with the deceased donor heart.

- **Pancreas**
  Individuals can also donate a portion of the pancreas. Although the pancreas cannot regenerate, donors usually do not face problems with reduced function.

b. Organ Procurement and Transplantation Network

The Organ Procurement and Transplantation Network (OPTN) policies and bylaws govern the procedures related to policy development, allocation of donated organs and the collection of related data. OPTN committees and the board of directors develop policies while the United Network for Organ Sharing (UNOS) holds the federal contract to operate the OPTN. Policies and bylaws must be submitted for approval by the Secretary of the U.S. Department of Health and Human Services (HHS) to be included in federal regulation. Federal law prohibits buying and selling organs in the U.S. and violators are punishable by prison sentences and fines.

Strict standards govern packaging and transporting of organs and tissue typing materials. Following are several standardized procedures:

1. **Specimen collection and storage**— Written policies established with a laboratory must be approved by the American Society for Histocompatibility and Immunogenetics.

2. **Standard Labeling Specifications and Documentation**— When the organ is procured and labeled the Host OPO (Organ Procurement Organization) becomes responsible for ensuring the accuracy of the donor’s ABO and medical data on the container label and on the donor’s documentation. Each OPO establishes and implements its own procedure for verifying the donor OBO data and medical data by a person other than the one who initially performed the labeling and documentation.

3. **Packaging Specifications**— The Host OPO is responsible for packaging, labeling and handling the organ and ensuring arrival without compromise to the organs. Insulation, temperature control, strength of container and container material must comply with standards.
4. Transportation Responsibility— The Host OPO, as defined in Policy 2.1, is responsible for transportation of kidney(s) and tissue typing material to the primary destination designated by the recipient member, (i.e., laboratory, transplant hospital, or OPO). Before the Organ Center will arrange for airline transportation, the Host OPO must agree to use a charter aircraft, and it must be determined who will pay for the charter.

b.1. Policies regarding patient waiting lists

It is mandatory for patients who are potential recipients of deceased organ transplants to be listed on the UNOS Organ Center Waiting List through their local transplant hospital. UNOS Members do not provide organs to non-member transplant centers except to transplant centers in foreign countries as allowed by law. A patient cannot be added to the UNOS Patient Waiting List for a transplant procedure without meeting UNOS criteria and approval. The UNOS Organ Center is staffed 24 hours a day throughout the year. Transplant centers, tissue typing laboratories, and OPOs hold important responsibilities in the organ sharing process.

Selection from the UNOS Waiting List of non-resident alien patients for transplantation is based on the same allocation policies (Section 3.0) that area mandated by the Board of Directors for domestic patients. Favoritism or discrimination based on political influence, national origin, race, sex, religion or financial status is illegal. Transplant centers accommodating aliens on their waiting lists charge non-residents the same fees for service as those charged to domestic patients.

Organ Donation Process

- Patient is registered on UNOS Organ Center Waiting List through transplant hospital.
- Donation is made. Procuring organization accesses UNOS matching system to enter data about donor organs.
- Computer program generates list of potential recipients ranked according to objective criteria.
- Top ranked patient: organ characteristics best match the donor organ and time on waiting list, urgency status, and distance from donor organ comply with policy).
- List of potential recipients is printed. Procurement coordinator contacts transplant surgeon caring for the top-ranked patient.
- Surgeon evaluates factors such as donor’s medical history and current health of the potential recipient.
- Transplant surgeon determines if organ is suitable for patient. If organ is turned down, next listed individual’s transplant center contacted until organ is placed.
- Once organ is accepted transportation arrangements are made for surgical teams to come to donor hospital and surgery is scheduled.
- Recovered organs are stored in cold organ preservation solution and transported from donor to recipient hospital.
- Heart and lung transplants should occur within 6 hours of organ recovery. Livers can be preserved up to 24 hrs.
- Organ is surgically transplanted.
II. Organ Demand Versus Availability

a. Ranking of Organ Demand

The data extracted below (from November 28, 2004) illustrates the excessive demand for organs in the U.S., including the number of candidates currently on the waiting list, by organ type. Despite this incredible shortage, the volume of transplants performed from January through August 2004 of 18,109 is impressive. Kidney and liver transplants rank highest in demand. To complicate matters, from January through August 2004, a much greater supply of organs came from deceased donors. This provides us with some explanation for the variability in supply.

<table>
<thead>
<tr>
<th>Waiting list candidates as of November 28, 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>All *</td>
</tr>
<tr>
<td>Kidney</td>
</tr>
<tr>
<td>Pancreas</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
</tr>
<tr>
<td>Liver</td>
</tr>
<tr>
<td>Intestine</td>
</tr>
<tr>
<td>Heart</td>
</tr>
<tr>
<td>Lung</td>
</tr>
<tr>
<td>Heart/Lung</td>
</tr>
<tr>
<td>*All candidates will be less than the sum due to candidates waiting for multiple organs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transplants performed January - August 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Deceased Donor</td>
</tr>
<tr>
<td>Living Donor</td>
</tr>
<tr>
<td>Based on OPTN data as of 11/19/2004</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Donors recovered January - August 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Deceased Donor</td>
</tr>
<tr>
<td>Living Donor</td>
</tr>
<tr>
<td>Based on OPTN data as of 11/19/2004</td>
</tr>
</tbody>
</table>

b. Variables that Determine Supply and Demand

The data extracted below demonstrates how only two criteria for identifying a perfect match, blood type and position on waiting list, complicate the process. Between 1997-1998, candidates with blood type 0 clearly required the greatest median waiting time for a heart and lung transplant of 1,533 days. Kidney transplants for blood type 0 also required an incredibly lengthy median waiting time of 1,592 days. In the case of each organ listed below, the candidates with the more common blood type 0 constituted the greatest volume of people on the organ waiting list. This distribution tells us that candidates with blood type 0 “compete” for organs against a much greater population than do candidates with other blood types. And the waiting time reflects this high demand.
Median Waiting Times for Registrations Listed between 1997-1998 by Blood Type

<table>
<thead>
<tr>
<th>Organ</th>
<th>Year Listed</th>
<th>Blood Type</th>
<th>Registrations Added</th>
<th>Median Waiting Time (Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>0</td>
<td>128</td>
<td>1,533</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>A</td>
<td>104</td>
<td>1,132</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>B</td>
<td>35</td>
<td>644</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>AB</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>0</td>
<td>3,376</td>
<td>350</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>A</td>
<td>3,064</td>
<td>165</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>B</td>
<td>929</td>
<td>170</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>AB</td>
<td>314</td>
<td>72</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>0</td>
<td>138</td>
<td>263</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>A</td>
<td>102</td>
<td>164</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>B</td>
<td>27</td>
<td>-</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>AB</td>
<td>14</td>
<td>111</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>0</td>
<td>18,846</td>
<td>1,592</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>A</td>
<td>13,164</td>
<td>908</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>B</td>
<td>5,567</td>
<td>1,697</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>AB</td>
<td>1,532</td>
<td>485</td>
</tr>
</tbody>
</table>

In addition to blood type, patients are more likely to find matches among donors of their same race or ethnicity. In each of the 4 categories below, white candidates followed by African Americans constituted the greatest volume of registrations. However, these two groups did not always constitute the longest median waiting time. Population densities of ethnicities in the U.S. differ vastly. The chance of an American Indian, for example, receiving a kidney in a timely manner is low. As a result, in 1997-1998, 377 American Indian registrants waited for a median of 1,572 days for a kidney transplant.

Median Waiting Times for Registrations Listed between 1997-1998 by Ethnicity

<table>
<thead>
<tr>
<th>Organ</th>
<th>Year Listed</th>
<th>Ethnicity</th>
<th>Registrations Added</th>
<th>Median Waiting Time (Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>White</td>
<td>128</td>
<td>1,533</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>African American</td>
<td>104</td>
<td>1,132</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>1997-1998</td>
<td>Hispanic</td>
<td>35</td>
<td>644</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>White</td>
<td>6,038</td>
<td>229</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>African American</td>
<td>1,021</td>
<td>223</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>Hispanic</td>
<td>459</td>
<td>175</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>Asian</td>
<td>103</td>
<td>81</td>
</tr>
<tr>
<td>Heart</td>
<td>1997-1998</td>
<td>American Indian</td>
<td>29</td>
<td>256</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>White</td>
<td>201</td>
<td>206</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>African American</td>
<td>41</td>
<td>307</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>Hispanic</td>
<td>31</td>
<td>124</td>
</tr>
<tr>
<td>Intestine</td>
<td>1997-1998</td>
<td>Asian</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>White</td>
<td>21,166</td>
<td>1,043</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>African American</td>
<td>10,869</td>
<td>1,639</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>Hispanic</td>
<td>4,447</td>
<td>1,415</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>Asian</td>
<td>1,668</td>
<td>1,555</td>
</tr>
<tr>
<td>Kidney</td>
<td>1997-1998</td>
<td>American Indian</td>
<td>377</td>
<td>1,572</td>
</tr>
</tbody>
</table>
Apart from the data above, we must consider that decision-making surrounding organ donation is yet another driver of supply and demand. Deceased organ donation is often related to a sudden and tragic death. There are a variety of personal, cultural and religious factors that influence an individual’s decision to consent to organ donation in the event of death as well as the family’s decision on behalf of the deceased. Many donors and their families see the decision to donate as a rewarding choice. The decision to donate can leave a positive legacy through the knowledge that others lived because of that choice.

III. Financial Coverage for Organ Donation

a. Insurance, Medicare and Medicaid

In 2003, the U.S. Senate passed the Organ Donation and Recovery Improvement Act, which authorized expenditure of $25 million in fiscal year 2004 for efforts to increase organ donation. Appropriations will be used to:

- Provide reimbursement for travel and subsistence costs associated with living donations
- Provide more resources to states to enable them to expand their public education and outreach efforts
- Award grants to hospitals and organ procurement organizations for establishment of programs to coordinate organ donation activities.

These appropriations are intended to help to strengthen the efforts of the Gift of Life Initiative launched in 2001.

Insurance

Transplant candidacy also relies on adequate insurance coverage for the surgery, as well as care and medications after discharge. Before final activation for transplant, transplant centers will request verification of coverage from a candidate’s insurance provider. The Health Care Financing Administration (HCFA) changed its policy in 2000 for granting Medicare approval to some transplant centers. Revisions were made in the policy for heart, liver and lung transplant centers, reducing the length of time it takes centers to qualify for coverage. Centers winning Medicare approval may be approved after one year of successful operation. Historically, the process took two years. HCFA concluded the number of transplants performed is a better indicator of outcomes than the number of years in experience. Centers applying for Medicare approval must still meet other requirements prior to approval, including standards for patient selection, patient management, minimum volume and survival rates.

Medicare and Medicaid

Although Medicare coverage differs by state it generally covers transplants of the heart, lung, kidney, pancreas, intestine/multivisceral, and liver under certain conditions and, for some types of transplants, only at Medicare-approved facilities. Medicare only approves facilities for kidney, heart, liver, and intestine/multivisceral transplants. Pancreas transplants are not limited to approved facilities. Transplant coverage includes necessary tests, labs, and exams before surgery, follow-up care for an organ recipient and a live donor, and procurement of organs and tissues.

For an organ transplant to be covered under the Medicaid Program, the surgeon must confirm that the transplant is medically necessary; the failure to perform the organ transplant would create a life-threatening situation; and the prognosis must be that there is a reasonable expectation the transplant will be successful and result in prolonged life
of quality and dignity. In the example of one state, hospital payments for organ transplants will be set at eighty (80) percent of actual usual and customary charges with total payments not to exceed $75,000 per transplant without regard to usual program limits on hospital length-of-stay. Physician payments for organ transplants will be at the usual Medicaid Program rates.

**IV. European Union Perspective**

**a. Overview of current institutions, policies and practices of organ donation among EU member states**

The most important international efforts for transplant related issues in Europe fall under the responsibility of the Council of Europe. The Council of Europe, set up in 1949, is the oldest European intergovernmental organization, which has the general objective to improve the quality of life for European citizens and defend their human rights. Based in Strasbourg and representing approximately 800 million people, it is currently composed of 44 member states. Its decision making body is the Committee of Ministers, which is composed of the Ministers of Foreign Affairs of the member states.

The Committee of Ministers of the Council of Europe set up the European Health Committee (CDSP) in 1954 to encourage closer European co-operation on the promotion of health. Its idealist aim was to create conditions, which would safeguard and improve the health of European citizens. The CDSP bases its strategy on an integrated approach of medical developments on the one hand and values of the individual (legal, ethical, social) on the other. Its activities are aimed at the democratization and humanization of health services.

The European Health Committee is a steering committee of government representatives that guides the health activities across the continent. Through the CDSP, the Council of Europe is the only international organization dealing with the whole range of health related ethical issues. An example of its activity has been the promotion of the non-commercialization of blood, blood products, organs and tissues.

Among other activities of the CDSP, a top priority is given to ethics-oriented health policies (equal access, patients’ rights, citizens’ participation, vulnerable groups such as prisoners, chronically ill and older patients, safety and quality of blood organs and tissues for transplantation and specific selected health policy issues.

The CDSP issues recommendations that provide governments with policy guidelines in any area of health. These recommendations are based on advice given by specialized expert committees (either ad hoc or working for a specific period -usually for two years) or permanent committees. To deal with issues related to international cooperation of organ transplantation, the CDSP has appointed the Committee of Experts on the Organizational Aspects of Cooperation in Organ Transplantation (SP-CTO). This committee is a permanent body that was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organizational and legislative aspects on organ transplantation. The Conference considered that the organizational aspects of organ transplantation were particularly important in meeting the organ shortage and that European cooperation was needed to ensure an efficient management of this field.
a.1. Role of other European/International Bodies in the field of transplantation in Europe: The European Union and the World Health Organization

Although important, the recommendations of the Council of Europe to the member states (through the European Health Committee) are not binding. An exception to these recommendations is the Convention on Human Rights and Biomedicine. The article 21 of the Convention states that "the human body and its parts shall not, as such, give rise to financial gain". The article 152 of the E.U. Treaty has also provided member states with the opportunity to implement measures in the area of organ transplantation. This field of medicine is an important issue for the EU because it is related to the fundamental principles that underlie its constitution: free flow of people (patients), free movement of goods (organs and tissues) and free exchange of services (implantation medicine is a medical service). Therefore, the promotion and control of quality and safety of goods and services is among the most obvious and least contested area of concern to the EU. On this regard, standardized accreditation norms for laboratories and transplantation centers, good laboratory practices (GLPs), good manufacturing practices (GMPs), and the like are essential tools with a view to maintaining high quality standards in this area of medicine.

In undertaking the task of promoting and controlling the free movement of organs and tissues, the EU should draw upon the experience of the Council of Europe. Activities could be undertaken in co-partnership between these two organizations. For instance, after three years of elaboration and discussions, the EU has recently approved the Directive of the European Parliament on “Setting high standards of quality and safety for the procurement, testing, processing, storage, and distribution of human tissues and cells in order to ensure a high level of human health protection in the community”. This document rests on a very important job previously done by the Council of Europe and the same can be expected in the future when organs will be finally managed by the European Union. Another example of this cooperative relationship is the case of a permanent member of the EU who attends the SP-CTO meetings as well as delegates of the Council of Europe who participate in most of the activities of the European Union, thus assuring the coordination between these two institutions.

The European Union also monitors the work of other institutions when attempting to set its policies and practices of organ transplantation. For instance, in 1991 the Health Assembly of the World Health Organization (WHO) endorsed a set of Guiding Principles on Human Organ Transplantation. These Guiding Principles, whose emphases include voluntary donation, non-commercialization, genetic relation of recipients to donors and a preference for cadavers over living donors as sources, have influenced professional codes, national, state and provincial legislation as well as the policies of intergovernmental organizations. Despite these positive influences, the WHO Health Assembly has recently indicated that its Guiding Principles and commentaries may benefit from re-examination in light of the medical/legal developments of the last decade, (which does not imply any changes in their ethical premises) and from various ethical and practical perspectives identified among different regions. In sum, the goal of protecting people, whether recipient or donor should remain a priority and is a task that needs constant reinforcement. Moreover, additional matters such as confidentiality and anonymity of both parties need to be tackled. Since the Council of Europe and the WHO share the same principles and objectives, it is critical that they continue working together.
a.2. Contributions of the Committee of Experts on the Organizational Aspects of Cooperation in Organ Transplantation

The established leading principles guiding the work of this Committee in the area of organ transplantation are:

- Ensuring the dignity of the human being
- Maintenance and further realization of human rights and fundamental freedom
- Non-commercialization of substances of human origin
- Protection of donors and recipients

Some of the more important recent initiatives of this Committee are the following:

- The preparation of a comprehensive document on how to meet the organ shortage
- The yearly publication of a newsletter, which collects the annual data on organ transplantation activities
- General list of recommendations and publications in the organ transplantation field

b. International Cooperation Program Among EU Countries

According to the recommendations of the Council of Europe, international cooperation on the promotion of organ donation is desirable to maximize organ donation and equalize access to transplantation between countries. In assisting the needs of patients and institutions involved with organ donation and transplants, governments should actively promote such cooperation. Some fields that are more benefited from a joint effort are those related to improving standards of training and exchange of experience, which helps guarantee the safety of organs and the ethical standards by which they are retrieved and transplanted.

In promoting wider international cooperation, the Council of Europe has developed a full document in 1999 that aims to set the guidelines for all country members to meet the organ shortage across the continent. It also intends to discuss the strategies for improvement of organ donation, which leads to a specific recommendation in each of the subjects developed.

The document is structured around two critical areas of content: Organ Procurement and International Cooperation. The chapter on organ procurement discusses the following issues:

- Transplantation process in six steps
- Detection and identification of potential donors – i.e. specific programs for hospitals to improve the availability and acceptability of organs
- Donors management – i.e. maintaining the potential donor in a medical condition which will maximize the viability of the organs
- Brain death legal requirements, diagnosis and legal certification
- Authorization or consent to organ donation: legal requirements, factors that affect this issue, the role of media and communications, information tools and the approaching of the relatives of the deceased to improve consent
• Guidelines for organ retrieval in terms of age, condition and management of the
donor and organ damage during the process of removing the tissues
• Organ allocation and its organizational issues: organ sharing offices (OSOs) and
organ exchange organizations (OEOs) such as Euro Transplant and France
Transplant
• Organizational support for transplantation: hospital organizations, organ
procurement organizations (OPOs), transplant support organizations and the role
of national health administrations in the system

In the chapter specifically related to International Cooperation, the document includes
guidelines and recommendations to deal with exchange of organs among different
country member to ensure confidence in the screening and retrieval systems of the
donor countries. Following is the link to the Council of Europe web page that contains
the full document: “Meeting the organ shortage: current status and strategies for
improvement of organ donation”

c. The Role of the Transplant Support Organizations Across the EU

There is general agreement about the need for some sort of organization to support
transplant activity in a specific area, country or group of countries. Many such
organizations already exist and are primarily organ sharing offices (OSOs) or Organ
Exchange Organizations (OEOs), which were originally closely related to the tissue
typing laboratories. The first and largest European organizations (Eurotransplant and
France Transplant) had their origin and philosophy on kidney sharing during the sixties.
They were created and developed as a result of professional agreements, which evolved
further during the eighties to cover non-renal organs. However, existing transplant
organizations vary significantly from country to country in terms of:
• Scope – i.e. regional, national, supranational;
• Size of population served – i.e. small <10 million; medium 10-60 million; large
>60 million;
• Management – i.e. professional; health administration; mixed;
• Structure – i.e. non-for-profit foundation; state agency; private agency;
• Organization – i.e. centralized/decentralized;
• Objectives and responsibilities – i.e. organ sharing/ exchange/ procurement;
• Activities – i.e. organs +/- tissues +/- bone marrow

Such differences result from the origin and development of the organization, the
national health system of the country, the resources available and even the personal
profiles of the founders and directors. Most organizations worldwide are, however,
dedicated at least to maintaining common patient waiting lists, agreeing and effecting
organ sharing and allocation methods, registering donors and/or transplants, producing
statistics and, in some cases, organizing organ retrieval team arrangements. Following is
a brief view at some of the most important transplant support organizations across
Europe:

The Eurotransplant International Foundation is responsible for the mediation and
allocation of organ donation procedures in Austria, Belgium, Germany, Luxemburg, the
Netherlands and Slovenia. In this international collaborative framework, the participants
include all transplant hospitals, tissue-typing laboratories and hospitals where organ donations take place. The Eurotransplant region numbers well over 118 million inhabitants.

Prof. Dr. Jon J. van Rood founded Eurotransplant in 1967 to allow for a central registration of all patients who were waiting for a donor organ; the aim was and is to increase the chance of finding a good match between the donors and the recipients tissue groups. According to Van Rood, doing so would improve considerably the transplant results. Therefore, one of the most important tasks of Eurotransplant is the registration of patients who qualify for a transplant operation. At the moment the more than 75 transplant hospitals participating in the Eurotransplant network have a joint waiting list of approximately 15,000 patients. Originally, Eurotransplants activities only concerned kidney transplants, but in the late seventies it also came to mediate for liver transplants. A few years later, heart, lung and pancreas transplants followed. Recently, patients qualifying for an intestine transplant operation have also joined the international waiting list.

The goals of the organization are:

- To achieve an optimal use of available donor organs
- To secure a transparent and objective selection system, based upon medical criteria
- To assess the importance of factors which have the greatest influence on transplant results
- To support donor procurement to increase the supply of donor organs
- To further improve the results of transplantation through scientific research
- Promotion, support and coordination of organ transplantation in the broadest sense of terms

Founded in 1969 by Nobel Prize winner Professor Jean Dausset, France Transplant has developed a transplantation program over the past 25 years, thanks to coordination among 7 regions around the country.

Later in 1994, the Établissement Français des Greffes (EFG) was founded, an organization responsible for all sanitary, standards and functionality of transplant offices in France. EFG reports to the French Ministry of Health.

Maintaining the Association France-Transplant was the topic of a review then a favorable majority vote by referendum. The statutes of the Association were centered on two priorities that met EFG’s approval as well as the other Associations for organ donation: to promote organ transplant and to maintain and develop regional community services for transplant recipients.
Scandiatransplant is a Nordic organ exchange organization that covers a population of 24 million people in five countries; Denmark (5.3 million), Finland (5.2 million), Iceland (280,000), Norway (4.4 million), and Sweden (8.9 million). Scandiatransplant includes a cooperation of all 11 Nordic transplant centers in addition to eight immunology laboratories.

The purpose of the Scandiatransplant association is fourfold:

- To effect the exchange of organs and tissue between the participating transplant centers
- To operate a database and communicate information from it
- To contribute to promoting the provision of human organs and tissue for transplantation
- To support scientific activities

The office of Scandiatransplant is located at the University Hospital Skejby in Aarhus, Denmark. Scandiatransplant was founded in 1969 on the initiative of Nordic pioneers within the organ transplantation field such as professor Flemming Kissmeyer Nielsen.

Transplant centers in the Nordic countries have had a close collaboration during more than 30 years within the frame of Scandiatransplant. The economy is solely based on transplant center fees. All Nordic patients waiting for an organ transplant are registered on one common waiting list for each organ. More than 19,000 kidneys from deceased donors have been transplanted within the frame of Scandiatransplant since it was founded in 1969.

The organ that has been exchanged the most between centers within Scandiatransplant is liver followed by heart. The overall exchange rate of kidneys has stabilized around 15% during the last years. The number of performed kidney transplantations per year has stabilized around a little more than 800 per year for the whole Scandiatransplant network, including one fourth of total kidneys obtained from living donors.

Scandiatransplant has a decentralized organization with a rather small central office that keeps the database running, but receiving data input and extending its service at each transplant center within Scandiatransplant.

Probably the most successful transplant organization across Europe in terms of donors rate per million population is Organización Nacional de Trasplantes (ONT) or National Transplant Organization in Spain. The ONT is a technical entity under the authority of
the Spanish Ministry of Health. Its mission is to coordinate all the activities related to organ transplants and tissues within the national territory of Spain.

The ONT was created on February 22nd, 1980 by decree 426/1980. Nevertheless, its physical infrastructure and personnel was not assigned until late 1989. Nowadays, the ONT is an administrative unit that reports to the sub-secretary office of the Ministry of Health.

Since the ONT is a national organization, there are internal structures that aim to ensure the coordination of efforts at a national level with the needs of the regional Autonomous Communities. For instance, there is a permanent unit of transplants that depends on the Inter-regional Council of the National Health System, where Autonomous Communities are represented by the ‘Autonomous Transplant Coordinator’. This commission discusses all the issues that are beyond the decision of a single Autonomous Community and that require the opinion and consensus of all of them. Nevertheless, each Autonomous Community is a sovereign territory to issue the legal permission to retrieve and implant organs and tissues, which is nonetheless coordinated among all of them to promote organ donation and transplants.

In terms of services the ONT personnel is in charge of:

- Keeping updated the waiting lists of patients that need to receive a solid organ
- Coordinates the transplant procedures
- Builds the official statistics of organ and tissue retrieval
- Promotes training and investigation in the field of transplant and donation
- Informs all parties and authorities involved in donation and transplants activities
- Offers a 24-hour/7 days-a-week ‘hot line’ to provide information to the public
- Cooperates with any entity that requires its assistance
- Prepares technical reports for health authorities and other entities
- Develops an extensive cooperation effort with national and international organizations and foundations with the goal of promoting donation and transplant activities

**UK Transplant**

The United Kingdom Transplant organization is the only Special Health Authority entity within the National Health System with a UK-wide authority. Its key role is to ensure that donated organs are matched and allocated in a fair and unbiased way. Matching, particularly in the case of kidneys, is so important that donation and allocation needs to be organized nationally and the larger the pool the better the likelihood of a good match.

UK Transplant is also in a unique position because it does not have a direct relationship with patients and does not provide "hands on" care. However, in providing support to transplantation services across the UK, everything that the organization does has an impact on the quality of service delivered to individual patients.

UK Transplant is directly accountable to health ministers in Scotland, Wales and Northern Ireland and to Parliament through the Department of Health in England. The Authority was originally established in 1991 as the UK Transplant Support Service.
Authority (UKTSSA). In July 2000, UK Transplant was formed with a new, extended authority to increase organ donation rates.

The origins of the organization go back to the year 1968, in which the National Tissue Typing and Reference Laboratory (NTTRL) was established at Southmead Hospital, Bristol. Later, in 1972, it was followed by the foundation of the National Organ Matching and Distribution Service (NOMDS) in 1972. In the year 1979, NTTRL and NOMDS merge to become UK Transplant Service, which emerges as the Special Health Authority and is renamed United Kingdom Transplant Support Service Authority (UKTSSA) in 1991. Recently, in the year 2000, UK Transplant takes over from UKTSSA with new and extended activities.

UK Transplant's specific responsibilities include:

- Managing the National Transplant Database which includes details of all donors and patients who are waiting for, or who have received a transplant
- Providing a 24hr service for the matching and allocation of donor organs and making the transport arrangements to get the organs to patients
- Maintaining the National Organ Donor Register
- Improving organ donation rates by funding initiatives in the wider NHS
- Contributing to the development of performance indicators, standards and protocols which guide the work of organ donation and transplantation
- Acting as a central point for information on transplant matters
- Providing central support to all transplant units in the UK and Ireland
- Auditing and analyzing the results of all organ transplants in the UK and Ireland to improve patient care
- Raising public awareness of the importance of organ donation

V. Conclusion

A common objective in the US and in Europe is the implementation of technology for the coordination and management of donors and recipients. Working independently, the US has developed a sophisticated information platform to match organs with patients in need of a transplant. Nevertheless, demand of organs continues to outpace supply in the US and further promotion and changes in regulations to make a default donation may be necessary to improve the situation.

In the case of Europe, we observe that despite the recommendations of the Council of Europe and the efforts of national transplant organizations, there is still not an official European organization that has established a shared network across the continent. Given that the European Union was created on the basic principle of free movement of people, goods and services across borders, the same notion should be applied to the organ transplant field. The lack of physical barriers in combination with the European policies of free movement might eventually enable each country to expand its outreach in the pursuit of a more efficient organ match. An extension of the local networks should help improve the likelihood and speed of matching organs with recipients. The future holds interesting prospects and challenges with the EU serving as an emerging example of healthcare and policy integration.
VI. Sources

U.S. Sources of information:

- Organ Procurement and Transplantation Network (OPTN): [www.optn.org](http://www.optn.org)
- United Network for Organ Sharing (UNOS)
- The National Organ Transplant Act ([Public Law 98-507](http://www.optn.org/unos/))
- National Institutes for Health: [www.nih.gov](http://www.nih.gov)
- Health Care Financing Administration's End Stage Renal Disease Program Management and Medicaid Information System-downloadable information on approved providers of kidney dialysis and transplantation.

E.U. Sources of information:

- Council of Europe [www.coe.int/T/E/Social_Cohesion/Health/Activities/Organ_transplantation](http://www.coe.int/T/E/Social_Cohesion/Health/Activities/Organ_transplantation)
- International Foundation Responsible for the Mediation and Allocation of Organs Among Several Countries [www.eurotransplant.org](http://www.eurotransplant.org)
- World Health Organization [www.who.int/ethics/topics/human_transplant](http://www.who.int/ethics/topics/human_transplant)
- Organización Nacional de Trasplantes [http://donacionrganos.ua.es/ont/](http://donacionrganos.ua.es/ont/)
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- France Transplant [http://www.france-transplant.com](http://www.france-transplant.com)