ABSTRACT

The choice of transplantation from a living donor offers advantages over a deceased donor. However, it also carries disadvantages related to donor risks in terms of health and safety. Furthermore, there are several controversial ethical aspects to be taken into account. Several national and international institutions and the scientific community have stated standards that have great influence on professional codes and legislations. Living organ donation and transplantation are to some extent regulated by parliamentary acts in most European countries. It is necessary to take a step forward to develop a legal framework to regulate all of these processes to guarantee the quality and to prevent illegal and nonethical practices. It is also necessary to develop and implement living donor protection practices not only in terms of physical health, but also to minimize potential impacts on the psychological, social, and economic spheres. Finally, an additional effort should be made to create a database model with recommendations for registration practices as part of the standardized follow-up care for the living donor. The European Living Donation (EULID) project’s (http://www.eulivingdonor.eu/) main objective was to contribute to a European consensus to set standards and recommendations about legal, ethical, and living donor protection practices to guarantee the health and safety of living donors.

IN THE FIELD of living donor transplantation, attention has focused on the positive aspects of living donation, mostly related to better recipient and graft survivals, greater compatibility, less waiting-list time, more availability, and even economic advantages. However, there is increasing interest in aspects concerning donor health and safety coinciding with the rapid increase in living donation activity. In many countries this activity is higher than that of organ transplantation from deceased donors. Living donation performed in high-quality facilities1–3 is considered a safe practice, especially kidney donation, with low mortality rates as well as few postsurgical complications. Studies of the long-term outcomes4 of living kidney donors have shown that the survival and the risk of end-stage renal disease (ESRD)5 among carefully screened kidney donors appear to be similar to or even better than those among the general population.6 Yet complications appear in 35% of living liver donors, mainly right lobe donors. The fact that
this procedure is performed in a healthy individual, whose benefit must only be moral, forces one to a meticulous evaluation of all aspects of its impact.

The background seems to indicate that the psychosocial impact on living donors is in general minimal. A systematic review considering >5000 living kidney donors from around the world demonstrated that the majority did not show either depression (77%–95%) or anxiety (86%–94%). Donors also reported a high level of satisfaction about their quality of life. The vast majority indicated that it was unchanged after donation, namely, typically >90% would do it again. On a World Health Organization (WHO) quality of life survey, donors showed a lower mean psychological domain score at 6 weeks after donation, although their score was significantly higher than the general population. However, these good results usually come from high-quality facilities with a careful process of donor selection, using donors who were genetically related to their recipients. Those studies also have limitations: not having a control group, being retrospective with the risk of bias from the missed follow-up cases, and not offering results of long-term impact. At the same time, some studies have reported feelings of unattractiveness, depression, anxiety, stress, decreased quality of life and relationships, and psychiatric symptoms.

In the economic sphere, it has been pointed out that there is the potential risk of losing or not having access to services of medical coverage rights, or the right to sick leave, or changes in health insurance conditions, or a decreased possibility to get a loan or mortgage. The protection of the individual will depend on the established national health care system and basic social coverage. The North American Transplant Coordinators Organization surveyed the transplant community regarding current practices: 39% of centers had eligible donors that declined donation due to fear of future insurance problems, and 9% of centers reported that absence of health insurance affected post donation care. It is necessary to move forward in legal frameworks which shelter and protect the living donor, whose altruistic act should not have negative consequences.

The worries about nonethical practices and specifically about organ trafficking and transplant tourism have led health care authorities, international organizations, and the professional community to a categorical positioning against these practices. International agreements have been signed and legislation has been established on this subject, but it is necessary to create a registry for follow-up of living donation activity at the national level.

In 2003, WHO expressed concern about the lack of comprehensive data and oversight, declaring that “Lack of documentation makes it difficult to estimate the extent of ethically unacceptable practices or the relative efficacy and safety of transplantation for the treatment of various conditions and in various settings.” Although several countries have introduced compulsory registration of transplant procedures and some voluntary registries also exist, there is no comprehensive system to collect data on various types of transplantations and their outcomes. The European Commission released a statement stressing the necessity to establish follow-up registries.

LEGAL AND ETHICAL ASPECTS

The general legal framework of most of the European Commission Member States protects the donor with regard to anonymity, confidentiality, and nonremuneration for the donation. The consent for the living donor is regulated by law in most countries. According to a survey performed in 2003 by the European Commission, living donors unable to consent legally (minors or others who are incapacitated) have been excluded from donation by law in 18/25 EU Member States. Three countries gave legal authority for these types of donors if permission was given by parents or guardians. Three other countries gave this authorization only if in addition to such consent, it was an emergency situation. In the remaining countries, it was only authorized under specific circumstances and with the previous authorization of a court. Eighteen countries included a legal provision indicating that the living donor is able to withdraw the consent at any time. A wide variability in the legal procedures related to donor consent for living and deceased donors was observed in this survey. The European Living Donation (EULID) group has analyzed legislations and bylaws in partner countries, and made a survey by creating a detailed questionnaire. The results showed that there was still great heterogeneity in the laws that regulate living donor procedures. For example, although living donation and transplantation activities are submitted to authorization in the majority of countries, procedures are quite different. They vary from countries where it is not necessary for administrative authorization before the surgical procedure, to others such as Spain, where the authorization involves a magistrate. Mandatory national registration of donors is still not a general practice. The concept of commissions or committees is well established, but functions such as informing, evaluating the donor and his/her relationship to the recipient, as well as giving authority to the donation process, change from one country to another and also among the members who take part in it. Even the right to independent advice for the donor is required by most professional recommendations and by the resolution CM/Res(2008)6 of the Council of Europe. A donor advocate is only incorporated in the commissions of 2
partner countries. The majority of the donations in European countries are still from genetically or emotionally related donors. However, in the analysis performed, 4 countries already accept anonymous donation. The WHO alerts that although nonrelated donors may also act altruistically, strong evidence exists of such donors being remunerated directly or indirectly. Some countries limit the possibility of nonresidents to donate only if the recipient is a resident.

Ethical issues have been discussed among EULID partners. Each of the pillars of bioethics and each of the categories—directed donation to a loved one or a friend, nondirected donation to the general pool, and directed donation to a stranger—yield different ethical concerns. The Amsterdam Forum experts already considered that donor consent and autonomy are necessary, but not sufficient. Donor autonomy does not override medical judgment and decision-making. The EULID participants considered that specific actions may be taken to ensure donor autonomy in the field of formal collection of the consent. They require extensive specific information, a reflection period, and the involvement of a donor advocate, and exclude minors and noncompetent donors. In observance of the nonmaleficence principle and distributive justice, the group reasserts with previous positioning that living donation must be considered only in the context when there is no alternative with similar efficacy and thus transplantation from cadaveric donors is not possible.

On this subject, it is the responsibility of health care authorities and transplant professionals to promote cadaveric donation to the limit of their capability. All legislations of the countries from the EULID group include prohibition and penalization of organ trafficking, and severely reject any kind of financial gain. Discussion is focused in the debate about so-called incentives, whose limit on reimbursement of expenses must be well established, since EULID partners also reject any kind of incentives or rewards.

DONOR PROTECTION

Donor protection should be a minor worry if proper donor selection is achieved, and the national health care system covers by default the health problems as happens in most European countries. However, living donation, especially liver donation, implies risks such as lost wages, family suffering, job loss or diminished capacity to perform the same tasks afterward, loss of insurance, and medical disability.

The EULID partners have analyzed these risks. The psychological impact can be prevented through proper evaluation prior to donation. Motivations other than an altruistic desire to help somebody increase the risk of psychological side effects, as does granting an informed consent that goes further than a legal procedure. Information to the donor which minimizes these risks includes not only data about aspects concerning the surgical process, but also information about the foreseen recipient outcome. The information provided should include the potential risks for normal development of donor labor activity as well as information about corresponding rights such as sick leave, laws about insurance penalties, medical insurance, medical follow-up, reimbursement of costs, and the possibility to withdraw at any moment. The importance of these aspects, which if not protected imply a clear dissuasive effect for living donation, should urge the institutions and states to establish and legislate protection practices.

Analyzing the systems of protection in different countries, we observed great heterogeneity. For instance, not only in the establishment of public medical insurance, but also in essential aspects such as sick leave limitation, the possibility of being fired after sick leave, and systems of reimbursement. The concept of special insurance to cover the consequences of a catastrophic outcome also has not been settled.

REGISTRATION PRACTICES

The development of living donation activity registry systems is the essential core upon which should be developed quality policies to monitor the ethical use of this therapeutic option. In our analysis, registration practices are widespread, although in one third of countries there is not yet a legal requirement for data collection about living donation. Even the experts themselves do not feel that a full reporting takes place; are audit system at a national level does not exist in all countries.

There is consensus among EULID participants that systems to monitor the living donor should be developed at a national level. These systems should allow one to obtain enough information to detect areas of improvement through a benchmark program. They should contribute to the proper transparency of the transplantation programs, which means that there should be a certain level of access for the general population.

Any registry proposal must be realistic and, therefore simple; its implementation must be feasible. For this reason, 3 accomplishment levels are proposed. The most essential or basic is based on general data activity, type of organ, survival, donor-recipient relationship, and donor and recipient nationalities. This level allows watching the living donation activity and the percentage of each category of donor-recipient relationship. Survival data provide a gross indicator about the quality of the process. The advanced level collects clinical data both prior to donation and afterward, which permits going deeper into the evaluation of the quality of the donation program to determine the complications and to establish correlations. Finally, an excellence level evaluates the quality of the entire living donation program, donor quality of life and satisfaction, as well as aspects about management, policies, and legislation.

DISCUSSION

The EULID project approaches the transplantation of organs from living donors with a focus on the donor and
those aspects that could put the donor at risk. It is not only interested in the physical aspects related to the surgical process, but also the possible impacts on the emotional, social, and economic levels. The project analyzes living donor legislation in various partner countries, the protection practices already developed, and the current registration practices. It also studies the ethical dilemmas that this therapeutic option raises. Even though all partner countries have laws that regulate this procedure, there is great heterogeneity among them. Similarly, most analyzed countries have a public system that covers their citizens’ basic health care needs, but there are few cases in which the specific risks for living donation are covered.

Few examples of protection practices have been found to cover the potential impact on the development, for example, of usual labor activity, or loss of social rights and privileges as those related to insurance and credits. The project also detected little establishment of registration systems regulated at the national level to allow monitoring of the donor, as well as evaluation and comparison of the quality of living donor transplant programs.

In conclusion, the EULID project seeks to contribute to a European consensus that could lead to best practices and to elaborate recommendations that will help to establish a protection framework for living organ donors’ health and safety through laws and regulations in the labor, social, medical, and psychological fields. In the same way, the consensus and elaboration of common registries and the recommendations of their application are important improvements to be implemented in the living organ donor field.

REFERENCES