The use of organs from live donors is an important component of transplantation today. The Ethics Committee of the Transplantation Society (TTS) has previously published a statement on ethical considerations pertaining to the live kidney donor (1). Evolving technologies have now allowed for the successful transplantation of organs from the live lung, liver, pancreas and intestine (extrarenal) donors. The Ethics Committee of TTS was convened at the Vancouver Forum to deliberate upon the use of live donors for extrarenal transplantation. The following is a summary of the committee’s deliberations. We believe that live extrarenal donation should proceed within the context of the ethical principles established for live kidney donation. The physical and psychosocial welfare of a healthy donor must be put in context of the needs of the recipient and impact of the recipient’s illness upon the donor. In principle, the Ethics Committee of TTS recommends that live lung, liver, pancreas and intestine donation should only be performed when the aggregate benefits to the donor-recipient pair (survival, quality of life, psychological, and social well being) outweigh the risks to the donor-recipient pair (death, medical, psychological, and social morbidities).

At the Vancouver Forum, emerging data pertaining to the aggregate risks and benefits of live lung, liver, pancreas and intestine transplantation provided more information regarding the factors that enter into the ethical decision to place a healthy person in harms way. It is now evident that live donors are the sole source of organs for transplantation in many societies; however the limited availability of information about outcomes for the donors and recipients mandates that live lung, liver, pancreas and intestine organ donation and transplantation must proceed with thoughtful independent oversight and transparency. As organs recovered from deceased donors offer substantial (and sometimes superior) benefits to potential recipients, with no risk to a healthy, live donor, efforts to maximize the use of organs from deceased donors must not be impeded by the development of live organ donation.

This consensus statement comes from the deliberations of the Ethics Group of the Vancouver Forum which was charged with defining the essential ethical elements of the process for the transplant center performing live lung, liver, pancreas and intestine donor. Special emphasis upon elements and issues of informed consent, assurance of donor autonomy and the patient selection process is included for clarity.

Responsibility of the Transplant Team Performing Live Donation

- Information about organ donation and transplantation should be provided repetitively to the prospective donor in order to facilitate the decision to proceed with live organ donation.
- Medical, psychological and social suitability should be determined after complete and thorough evaluation by a team that has the expertise to assess the suitability of an individual for organ donation.
- If medical conditions are identified in a prospective donor that need treatment (some may preclude donation), then the transplant team should counsel and encourage acquisition of medical care to treat such conditions.
- Recognizing that the donation process is stressful whether or not it proceeds, psychological support should be available throughout the evaluation and donation process.
- Live organ donation should be voluntary and the transplant team should make efforts to assure that the decision to donate is voluntary and has not been manipulated.
- Medical care for the donor should be provided until there is recovery from the donation procedure.
- Quality assurance/improvement procedures should be utilized to decrease risk during the donation process.
- The transplant center should facilitate the long-term follow-up and treatment of the donor with donation related acquired conditions.
- The transplant center should contribute to the general knowledge base by reporting complications and outcomes to registries and the medical community.
- The transplant center should work with appropriate authorities, agencies and insurance companies (as applicable) to minimize disincentives and penalties towards live organ donation.

A transplant center that performs live organ transplantation must implement procedural safeguards to enhance do-
nor understanding, safety and autonomous decision-making. These are considered to be essential to the process of live organ donation, particularly for the live lung, liver, pancreas and intestine donor.

The essential procedural components include:
- Inclusion of health care professionals in the donation process, who are exclusively responsible to the donor’s evaluation and welfare. Such an individual should not have direct contact with the recipient or be overtly influenced by concerns for the recipient.
- Repetition of the information pertaining to live donation, in recognition that informed consent is a process not an event.
- Psychosocial evaluation, to include the capacity of the donor to process information and give informed consent. Additional safeguards may include:
  - Reflection period after medical acceptance and decision to donate.
  - Assessment of donor retention of information and understanding.
  - External review committees.

Informed Consent

Informed consent from an individual is essential in the performance of live organ donation. The prerequisites for an individual to give informed consent are that:
- The potential donor must have a cognitive capacity sufficient to make the decision to donate.
- The decision must be voluntary.
- The donor must receive and understand relevant and sufficient information about the procedure.

Informed consent is predicated upon the individual’s receipt of adequate information about the evaluation process to become an organ donor and the donation procedure and possible consequences. The disclosure should include information about the associated risks, including but not limited to:
- The risk of death, reported worldwide and at the center where the procedure is proposed.
- Medical morbidities.
- Changes in health and organ function.
- Impact upon insurability/employability.
- Potential effects on family and social life.
- Psychological impact of donation and non-donation.

In addition, the potential donor should be given information about:
- The responsibility of the individual and health and social systems in the management of discovered conditions (such as the discovery during the evaluation process of HIV, tuberculosis or other transmissible diseases);
- Any specific recipient conditions which may impact upon the decision to donate; however, no information can be given to the potential donor until permission is obtained from the recipient;
- Expected transplant outcomes (favorable and un-favorable) for the recipient.
- Information on alternative types of treatments for the recipient, including deceased organ transplantation;
- The limited information available on extrarenal live donation results in uncertainty about donor and recipient outcomes;
- The request that the potential donor participate in long-term information gathering (registries) to increase the knowledge base.

Donor Autonomy

The decision to donate must be voluntary and the individual must be reassured that:
- The freedom to withdraw from the donation process at any time exists, without consequence and within a supportive environment;
- Medical and other reasons for not proceeding with donation will be kept confidential.

However,
- Donor consent and autonomy is necessary, but not sufficient to proceed to donation; medical evaluation and concurrence are essential;
- Donor autonomy does not overrule medical judgment and decision making.

Donor Selection

- Individuals who are legally incompetent or who lack the capacity for autonomous decision-making should not be donors. In the rare instance that these individuals might be considered as live organ donors, an independent advocate for the donor must be appointed using the mechanisms available within a particular society.
- In the event that non-directed or distant acquaintance live organ donation is entertained, special considerations to prevent donor exploitation should be made.
- Because many of the long-term consequences of extrarenal organ donation are not known, centers should consider long-term access to health care after the procedure as a prerequisite for donation.
- The donation process and follow-up should be cost neutral for the donor.

The use of healthy individuals to provide extrarenal organs for transplantation is predicated upon donor voluntariness and the aggregate benefit to the individuals outweighing the aggregate risk of adverse outcomes. Additional Ethics Committee recommendations are hampered by insufficient information pertaining to donor and recipient outcomes after live lung, liver, pancreas and intestine donation. As a consequence, procedural elements become paramount in the process in order to safeguard personal and system integrity, while minimizing the risk for exploitation of the donor. Voluntariness is predicated upon willingness to donate, with an understanding of the associated risks and benefits of the process. Without additional information relating to likely outcomes from extrarenal live donation, the informed consent process will be incomplete. There is a clear need for more information on short and long term consequences and risks associated with live donation of lung, liver, pancreas and intestinal organs. The transplantation community and the individual transplant team have a responsibility to collect and share data on donor outcomes in a consistent and comparable fashion. National, international and/or organizational donor registries should be established and maintained.

REFERENCE