LIVE DONOR COMMUNITY OF PRACTICE

Live Donor Informed Consent Process: Regulatory Guidelines, Challenges, and Considerations in Protecting Donor Voluntariness

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ISSUE

Potential and actual live donors are a unique patient population, who gains no medical benefit from undergoing this voluntary surgery. As such, informed consent for live donation is an ethical prerequisite and is required by US regulations. Live donors must undergo the procedure voluntarily, prepared with adequate information about risks, benefits, process, and outcomes, and without undue inducement and monetary incentive. Protecting potential donors' voluntariness is especially important given the known pressures around live donation decision-making—pressures that can come from within families and from the urgent need to find an organ transplant.

The concept of undue influence spans along a continuum, and the point where voluntariness transforms into undue influence or coercion may be unclear. Thus, maintaining clear definitions of undue influence and coercion is important for determining whether such influences are occurring. Coercion pertains to when an explicit threat of harm is presented by one person to obtain compliance by another. Undue influence pertains to an offer of "an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance." (Belmont Report).

Potential LDs may feel different forms of undue influence to donate given the urgent situation of saving the life of the transplant candidate. For example, potential LDs may feel driven to save the life of their loved one facing liver failure, given that the alternative to donation is certain death, despite the high risks of complications to the LD. Additionally, potential LDs may feel pressure to donate to help their loved one with kidney failure to increase their survival and quality of life.

DATA

- LDs' reported experience of undue pressure ranges from <4% to <40%.
- Pressure can be internally driven, or derive from external social, emotional pressures from family, religious, financial, and cultural factors.
- Many LDs report feeling like they have "no choice" but to donate. This perception is commonly experienced among parents donating to their child. However, perceptions of "no choice" do not necessarily equate to feelings of undue pressure.
- LDs commonly report experiencing hesitancy, reluctance, fear, anxiety and insecurity regarding whether to donate, which may be indicative of experiences of undue pressure.

- Some LDs withdraw or opt out of the donor evaluation process.

Mandated elements of live donor care at U.S. transplant centers that protect elements of informed consent (notably voluntary status):

1. **Confidentiality.** The potential and actual live donor's medical record is confidential from the intended recipient. This means that neither the recipient – nor the recipient's home nephrologist nor primary care physician-- is informed of the status of live donor testing. This preserves the right of the potential donor to withdraw from testing at any time.
2. **2-step consent process.** Potential live donors consent to the risks associated with donor evaluation separately from the donor surgery. Risks of evaluation include new, previously unknown diagnoses and the associated need for treatment at the donor's expense. Transplant centers may (or may not) have policies to address misattributed relationship discovered during donor evaluation (most frequently, misattributed paternity). In addition, donors must provide a third consent to participate in paired exchange.
3. **Right of the potential donor to withdraw from donation at any time.** In many centers, this includes the provision of a medical excuse or alibi, which is employed a variety of ways, but most often entails a general statement describing unsuitability for donation and followed by rehearsal/role-play with the donor about how to discuss this in the family support system. Although ways to employ a medical alibi are controversial, the right of the donor to withdraw at any time is not, and is mandated in regulation.
4. **Right of the live donor to know basics about expected outcomes for the kidney transplant recipient.** Regulatory guidelines mandate that potential live donors understand ESRD treatment options. Since live donor outcomes and satisfaction have been shown to be linked to recipient outcomes, if an intended recipient is considered high risk, there is debate about whether the recipient should be approached for permission to discuss expected outcomes with the potential live donor.
5. **Disclosure of increased-risk USPHS status.** All potential live donors are asked questions (similar to those asked prior to blood donation) about any factors that might place them at higher risk of HIV or hepatitis. If the potential live donor answers affirmatively, a basic description about them being in a higher-risk category is disclosed to their intended recipient prior to transplantation. Donors have the right to withdraw from donation rather than have this information disclosed.
6. **Agreement to abide by National Organ Transplant Act restrictions.** In the US, it is illegal for a live donor to receive "secondary gain" such as a financial reward associated with donation; transplant centers are required to exclude potential live donors for whom there is identified secondary gain motive.
7. **Provision of an Independent Living Donor Advocate (ILDA),** who provides no care to the person with ESRD, but rather, serves to assess the LD's voluntariness and advocate on their behalf.
8. **Other methods to promote meaningful donation decision-making.** Some kidney transplant programs (11%) require LDs to take a cooling off period before surgery to reflect on their decision. Others utilize a test of donor comprehension about risks and expected outcomes. Some have employed motivation interviewing techniques (Dew et al. 2013).

RECOMMENDATIONS

Transplant providers involved in the live donor evaluation process should engage in clear dialogue with potential living donors about the live donor evaluation process,

including confidentiality and ways that potential donors can withdraw from the evaluation process without having their reasons for withdrawal known to the transplant candidate.

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Note: The recommendations in these chapters are the opinions of the Living Donor Community of Practice of AST. They are not meant to be prescriptive and opinions by other groups or institutions may be equally valid.