Living Liver Donor Informed Consent Process

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ISSUE

Living liver donors (LLD), as with living kidney donors, are a patient population who gain no medical benefit from undergoing voluntary surgery; therefore informed decision-making is crucial for positive outcomes.

DATA

Informed consent for LLD is an ethical prerequisite. The live organ donor consensus group recommended practice guidelines for the care team of living organ donors and stated that *"the person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient."* (1) As such, all living organ donors must undergo the procedure **voluntarily**, prepared with adequate information about the procedure, risks, benefits, and alternatives of donation to themselves, and to the recipients.(1, 2)

Transplant center policies must incorporate this recommendation into the informed consent process for any potential LLD, although the actual process varies across transplant programs. Moreover, living donation becomes ethically justified when the "benefits to both the donor and the recipient outweigh the risks associated with the donation and transplantation of the living donor organ."(1-4) Transplant centers must use this rubric to evaluate potential living donors' candidacy.

The International Liver Transplant Society Guidelines on living liver donation further recommend:(5)

1. Informed consent must include full information on the surgical, medical, financial, and psychological risks (including death) of a hepatectomy.
2. The responsibility of the Independent living donor advocate/Team (ILDA/ILDAT) is to assist the potential donor throughout the pre-donation and post-donation phases.
3. Potential outcomes for the recipient must be disclosed to the donor.

Components of the informed consent process, including aspects of care and content elements to disclose, are outlined in CMS conditions of participation for transplant center and in OPTN guidelines.(6, 7)

We highlight 3 aspects of informed consent specific to the LLD context: risk of decision-making pressures; effect of timing pressures on donor evaluation; and disclosure elements. We also offer point-by-point responses to OPTN informed consent process requirements from the context of LLD care.

Decision Making

Assuring potential LLD's voluntariness is especially important given the known pressures or (undue) influences around LLD decision-making—pressures that can come from within families and from the urgent need to find a suitable liver for transplant.(3,4,8) Living liver donor candidates may experience undue (or even coercive) influence to donate given the risk of recipient mortality while waiting for a deceased donor and given the high rate of living donor candidate rule-out. (8, 9,10) These pressures may be magnified for recipients whose health status is particularly vulnerable.

Coercion and concepts of undue influence span along a continuum; the breaking point when voluntariness transforms into undue influence or coercion may be unclear, thus, maintaining a clear distinction between undue influence and coercion is important for determining whether such influences are occurring. Potential LLDs may feel internal pressures (e.g., religious obligations, personal duty) to save the life of their loved one, despite risks of complications to the LLD.(8)

If possible, donor teams should reduce donor candidates' feelings of being solely responsible for their loved ones' survival. In addition, internal pressures should be distinguished from any pressure imposed by the recipient, extended family, community, or transplant team members.

Timing

When a recipient is critically ill or in acute liver failure, LLD evaluations are expedited.(9) Even in this context, it is essential for live donor candidates to receive adequate teaching, meet with donor team members, and to make an affirmative decision about donation prior to proceeding.(9,10)

Disclosure

Liver donors assume risk when undergoing partial hepatectomy, therefore we highlight essential disclosure elements. Surgical risks should be carefully described for LLD and expected recovery time reviewed. In addition, given that donor depression and regret have been linked to recipient mortality, expected recipient outcomes should also be reviewed, as well as resources to provide support/counseling in the event of a poor recipient outcome.(11)

Mandated elements of living donor care at U.S. transplant centers that protect elements of informed consent, and comments specific to the LLD:

- **Confidentiality**. The potential and actual living donor's medical record is kept confidential from the intended recipient. This means that neither the recipient – nor the recipient's care team-- is informed of the status of living donor testing. This preserves the right of the potential donor to withdraw from testing at any time.(12)

  With LDLT, it is essential - even in the context of acute liver failure - for the living donor evaluation to occur by a different team from the recipient. However, sharing donor anatomical findings and size with the recipient team will eventually be required to ensure successful outcomes for the transplant recipient.

- **2-step consent process**. Potential living donors consent to the risks associated with donor evaluation separately from and prior to consenting to the donor surgery. Risks of evaluation include new, previously unknown diagnoses and the associated need for treatment at the donor's expense.(6)

- **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 in a variety of ways. Most often, the alibi entails a general statement describing unsuitability for donation. Transplant teams may engage in rehearsal/role-play with the donor about how to discuss this outcome with 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. 6, 7)

  Team/LLD discussions surrounding the decision to withdraw in the context of LDLT must be carefully implemented. The donor candidate must understand the implications of the withdrawal, especially how they may feel if the transplant candidate dies without a transplant. Additionally it is more difficult to claim a medical alibi further along in the evaluation process or if they have reported normal test results to the intended recipient. They must also understand that the withdrawal may not be reversed.

- **Right of the live donor to know basics about expected outcomes for the liver transplant recipient**. Regulatory guidelines mandate that potential living donors understand end-stage liver disease treatment options. Organ Procurement and Transplant Network requires that the center disclose that any transplant candidate may have an increased likelihood of adverse outcomes (including, but not limited to, graft failure, complications, and mortality) that exceed local or national averages, but do not necessarily prohibit transplantation, and are not disclosed to the living donor.(6)

  Since living donor outcomes and satisfaction have been shown to be linked to recipient outcomes, if an intended recipient is considered at high risk for graft failure, recurrence of disease or death, there is debate about whether the recipient should be asked by the transplant team to give permission to discuss

expected outcomes with the potential LLD. This can be done in the context of a meeting with the intended recipient's team.

- **Disclosure of United States Public Health Service "Increased Risk" status**. All potential living donors are asked questions (similar to those asked prior to blood donation) about any factors that might place them at higher risk of transmitting HIV or hepatitis. (13) If the potential LLD answers affirmatively, a basic description about them being in a higher-risk category is disclosed to their intended recipient prior to transplantation. Living donors have the right to withdraw from donation rather than have this information disclosed.(13)
- **Agreement to abide by National Organ Transplant Act restrictions**. In the US, it is illegal for a living donor to receive "secondary gain" such as a financial reward associated with donation. Transplant centers are required to exclude potential living donors for whom there is an identified secondary gain motive.(6, 7)
- **Provision of an Independent Living Donor Advocate (ILDA) or team.** The ILDA provides no care to the person in need of transplant, but rather, serves to assess the LLD's voluntariness, advocate on their behalf, and ensure they have been informed about the informed consent process including: informed consent requirements, evaluation process, psychosocial and medical evaluation requirements, the surgical procedure, and the need and benefit of LLD follow-up requirements.(6, 7)

  Who the center chooses to be the ILDA for the LLD varies from center to center but they must have a clinical skill set to manage the complexities of living donor decision-making in the context of critically ill liver transplant candidates.(14)
- **Other methods to promote meaningful donation decision-making**. Some transplant programs require LLDs to take a cooling off period before surgery to reflect on their decision.(12) Others utilize a test of donor comprehension about risks and expected outcomes.(4,5)

RECOMMENDATIONS

1. Careful assessment of a potential living donor's motivation is warranted as part of the informed consent process. Donors are often motivated by the quality of the relationship with the transplant candidate.
2. The team providing education and evaluation must be aware that the decision to be a LLD is commonly made upon learning of the need for LDLT and before learning about the process/risks. Therefore the team's assessment of the potential living donor's understanding of the LLD process is a key part of the informed consent process.
3. LLDs generally report high levels of comprehension of risks but report that the amount of information can be overwhelming. They admit to gaps in knowledge about recovery and complications. The living donor team needs to individualize

the informed consent process and ensure that education occurs at multiple points in the evaluation process with an emphasis on the risks and benefits.
4. The living donor team must assess potential living donors for indications of internal and external undue influence as part of the evaluation process. Living donors' reported experience of undue pressure ranges from <4% to <40%. This pressure can be internally driven or derived from external social or emotional pressures from family, religious, financial, and cultural factors.
5. Some LLDs withdraw or opt out of the donor evaluation process. Such donors may need to receive follow-up from the psychosocial team to process their decision.

REFERENCES

1. Abecassis M, Adams M, Adams P, Arnold RM, Atkins CR, Barr ML, Bennett WM, et al. Consensus Statement of the Live Organ Donor. JAMA. 2000 Dec 13;284(22):2919-26.
2. Henderson ML, Gross JA. Living organ donation and informed consent in the United States: Strategies to improve the process. Journal of Law Medicine and Ethics 2017 45 66-76.
3. Gordon EJ. Informed Consent for Living Donation: A Review of Key Empirical Studies, Ethical Challenges, and Future Research. American Journal of Transplantation 2012; 12 2273-2280.
4. Gordon, EJ, Daud A, Caicedo JC, Cameron KA, Jay C, Fryer J, Beauvais N, Skaro A, Baker T. Informed consent and decision making about adult to adult living donor liver transplantation: A systematic review of empirical research. Transplantation 2011 92(12) 1285-1296.
5. Miller CM, Durand F, Heimbach JK, Kim-Schluger L, Lee SG, Lerut J, Lo, CM, Quintini C, Pomfret EA. The International Liver Transplant Society Guideline on living liver donation. Transplantation. 2016. 100(6) 1238-1243.
6. Organ Procurement and Transplantation network Policies: Policy 14 Living donor transplantation, accessed at https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf on April 23, 2020.
7. Centers for Medicaire and Medicaid Services Conditions of Particpation: Transplant Centers. Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Transplant on April 23,2020.
8. Gordon EJ, Mullee J, Skaro A, Baker T. Live liver donors' information needs: A qualitative study of practical implications for informed consent. Surgery 2016;160 (3) 671-682.
9. Spital A. More on parental living liver donation for children with fulminant hepatic failure: addressing concerns about competing interests, coercion, consent and balancing acts. Am J Transplant. 2005;5(11):2619-2622.
10. Knibbe M, Maeckelberghe E, Verkerk M. Confounders in voluntary consent about living parental liver donation: no choice and emotions. Med Health Care Philos.2007;10(4):433-440.

11. Ladner DP, Dew MA, Forney S, et al. Long-term quality of life after liver donation in the adult to adult living donor livers transplantation cohort study (A2ALL). *Journal of Hepatology*. 2015; 62: 346-353.
12. Thiessen C, Kim YA, Formica R, Bia M, Kulkarni S. Opting out: confidentiality and availability of an 'alibi' for potential living kidney donors in the USA. J Med Ethics 2015;41(7):506-10
13. Organ Procurement and Transplantation network Policies: Policy 15 Identification of Transmissible Diseases accessed at https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf on April 23, 2020.
14. Hays RE, LaPointe Rudow D, Dew MA, Taler SJ, Spicer H, Mandelbrot DA. The independent living donor advocate: a guidance document from the American Society of Transplantation's Living Donor Community of Practice (AST LDCOP). Am J Transplant 2015;15(2):518-25.

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