



ORIGINAL ARTICLE

Financial, policy, and ethical barriers to the expansion of living donor liver transplant: Meeting report from a living donor liver transplant consensus conference

Anjana Pillai¹ | Elizabeth C. Verna² | Neehar D. Parikh³ | Matthew Cooper⁴ |
Carrie Thiessen⁵ | Julie Heimbach⁶ | Elisa J. Gordon⁷ | Gonzalo Sapisochin⁸ |
Nazia Selzner⁹ | Amit Mathur¹⁰  | Emily R. Perito¹¹ | Michelle Jesse¹²  |
AnnMarie Liapakis¹³ | Vineeta Kumar¹⁴ | on behalf of AST LDLT Consensus Conference
Working Group

¹Department of Medicine, University of Chicago Medicine, Chicago, Illinois, USA

²Center for Liver Disease and Transplantation, Columbia University, New York, USA

³Division of Gastroenterology and Hepatology, University of Michigan, Ann Arbor, Michigan, USA

⁴Department of Surgery, Medical College of Wisconsin, Milwaukee, Wisconsin, USA

⁵Department of Surgery, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, USA

⁶Division of Transplant Surgery, Mayo Clinic College of Medicine, Rochester, Minnesota, USA

⁷Department of Surgery, Center for Biomedical Ethics and Society, Vanderbilt University Medical Center, Nashville, Tennessee, USA

⁸Ajmera Transplant Program & HPB Surgical Oncology, Division of General Surgery, Toronto General Hospital, Toronto, Ontario, Canada

⁹Ajmera Transplant Center, Department of Medicine, University of Toronto, Toronto, Ontario, Canada

¹⁰Division of Transplant Surgery, Department of Surgery, Mayo Clinic Arizona, Phoenix, Arizona, USA

¹¹Department of Pediatrics, Department of Epidemiology and Biostatistics, University of California, San Francisco, USA

¹²Transplant Institute, Henry Ford Health System, Detroit, Michigan, USA

¹³Yale Medicine Digestive Diseases, New Haven, Connecticut, USA

¹⁴Division of Nephrology, Department of Medicine, University of Alabama at Birmingham, Birmingham, Alabama, USA

Correspondence

Anjana Pillai, MD, Center for Liver Diseases,
The University of Chicago Medicine, 5841 S.
Maryland Ave, MC 7120, Chicago, IL 60637,
USA.

Email: apillai1@medicine.bsd.uchicago.edu

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Abstract

Introduction: In October 2021, the American Society of Transplantation (AST) hosted a virtual consensus conference aimed at identifying and addressing barriers to the broader, safe expansion of living donor liver transplantation (LDLT) throughout the United States (US).

Methods: A multidisciplinary group of LDLT experts convened to address issues related to financial implications on the donor, transplant center crisis management, regulatory and oversight policies, and ethical considerations by assessing the relative significance of issues in preventing LDLT growth, with proposed strategies to overcome barriers.

Anjana Pillai and Elizabeth C. Verna contributed equally to this study and share co-first authorship.

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Results: Living liver donors endure multiple obstacles including financial instability, loss of job security, and potential morbidity. These concerns, along with other center, state, and federal specific policies can be perceived as significant barriers to expanding LDLT. Donor safety is of paramount importance to the transplant community; however, regulatory and oversight policies aimed at ensuring donor safety can be viewed as ambiguous and complicated leading to time-consuming evaluations that may deter donor motivation and program expansion.

Conclusion: Transplant programs need to establish appropriate crisis management plans to mitigate potential negative donor outcomes and ensure program viability and stability. Finally, ethical aspects, including informed consent for high-risk recipients and use of non-directed donors, can be perceived as additional barriers to expanding LDLT.

KEYWORDS

donors and donation: living, ethics, liver transplantation: living donor

1 | INTRODUCTION

Living liver donors undertake significant risks and life changes to save the lives of their recipients, for no direct medical benefit to themselves. Thus, it is essential to understand and address the effects of living donation on their lives, including loss of financial security. These burdens represent significant barriers to expanding living donor liver transplantation (LDLT) in the United States (US). They are often experienced more profoundly by vulnerable groups and can widen existing socioeconomic and racial disparities observed with living donation.^{1,2}

Additional significant barriers to the expansion of LDLT in the US include transplant program fears of living liver donor morbidity and mortality, as well as transplant providers' uncertainty about how to establish a crisis management plan for cases of living liver donor mortality. This fear of living donor mortality became a reality following a donor death in 2002,³ after which there was a decline in the number of LDLTs performed. Morbidity and mortality (estimated to be 1 in 300) for living liver donors has been heavily publicized.⁴

While donor safety must be prioritized by all LDLT centers, current regulatory and oversight policies intended to help can be contradictory and confusing. Potential donors who initiate evaluation must undergo multiple tests and consultations that can be time-consuming and prolong the waiting time for the potential recipient. Program adherence to work-up, informed consent, and donor follow-up to assure safety and minimize risk can impact program development and donors' motivation.

Finally, the ethical issues that arise with LDLT, particularly related to informed consent in a high acuity setting and the use of anonymous non-directed donors, may comprise additional barriers to the increased use of LDLT.⁵ Current literature suggests that the process of informed consent for LDLT is sub-optimal despite Organ Procurement and Transplantation Network (OPTN)/Centers for Medicare & Medicaid Services (CMS) regulations.⁶

Therefore, a multidisciplinary group of experts addressed barriers to LDLT relating to financial implications of LDLT on the donor, LDLT transplant center crisis management, regulatory and oversight policies, and ethical considerations by assessing the relative importance of these issues as barriers to LDLT expansion, with proposed strategies to overcome these barriers.

2 | METHODS

In early 2021, the Living Donor (LDCOP), Liver and Intestinal Community of Practice (LICOP), and the Psychosocial and Ethics Communities of Practice (PSECOP) of the American Society of Transplantation (AST) identified the need to foster the safe expansion of LDLT across the US to accomplish this important objective, the Community of Practices (COPs) outlined goals to (a) collaboratively bring together US and International leaders in LDLT to exchange experience and knowledge, (b) to identify barriers and data gaps to broaden expansion of LDLT in the US, and (c) to develop consensus recommendations to address barriers and data gaps to promote the safe expansion of LDLT. Workgroups focused on selected domains encompassing the entire process of LDLT were created. Consensus conference participants were selected, invited, and distributed among the workgroups. The consensus conference was held virtually October 18–19, 2021. A modified Delphi approach was utilized as the consensus methodology. Complete information including the list of consensus conference workgroup domains (and subtopics noted below), and process regarding consensus conference participant selection, development and refinement of consensus statements, and modified Delphi methodology including consensus polling, are reported in Liapakis et al.⁷

A literature search was developed and performed by two librarians with expertise in systematic reviews. Medline and Embase were searched for studies with no first date limitations through June 28, 2021. Specific search terms and strategies provided in Supplemental

Table S1. Search terms, excluding grey literature and following deduplication, resulted in 535 potential articles for title, abstract, and article selection. All references were sent to the workgroup for review and appropriate article selection. Due to the breadth of topics included, a full systematic review process for article review was not performed at this time. If titles/abstracts appeared relevant to domains/subdomains, corresponding full texts were acquired and reviewed for possible inclusion in the data driven, interactive lectures and to support the development of empirically supported barrier and mitigation strategy consensus statements.

To determine consensus, a modified Delphi approach was implemented including both the virtual consensus meeting, where consensus statements were discussed and refined for content and clarity, and two separate polling sessions (approximately two months apart). Polling responses were based upon a nine-point scale, barrier statements response options ranged from 1 = unimportant to 9 = very important. Mitigation strategies were rated for both impact and feasibility, with response options ranging from 1 = not impactful or not feasible to 9 = very impactful or very feasible. Consistent with Delphi polling approaches, the center point across all response options (or a rating of 5) permitted for a response of "Uncertain." For the definition of consensus, minimum consensus participant response rate to each poll was set at 70% and minimum consensus across statements was again conservatively set at no greater than 30% of respondents' rankings outside of the central interquartile range (IQR). In other words, across respondents, if more than 30% of respondents rated an item outside of the 25th to 75th percentiles, then consensus was not met. For example, if IQR was 7–9 but 31% or more of respondents rated the item as 6 or lower, then consensus was not met for that item. Analyses of polling responses were simple descriptives using IBM SPSS V.27 software.

3 | CONSENSUS FINDINGS

Participation across polling sessions related to our workgroup exceeded minimum participation thresholds,⁸ with 42 of 51 participants completing the first round of polling (82.4% response rate) and 46 of 51 participants completing the second round of polling (90.2% response rate). Complete consensus statements with impact and feasibility scores are shown in Table 1. All barriers are listed in order of rated importance as viewed by the conference participants, based upon mean scores.

3.1 | Donor financial implications

Living liver donor candidates in the US can incur substantial financial costs associated with the evaluation process, donation surgery, and post-operative recovery. Despite calls for financial neutrality for living donors, there are few policies in place or resources available to financially support potential living donors.⁹ In a survey of 271 living liver donors from the Adult-to-Adult LDLT (A2ALL) Cohort

Study, 37% incurred out-of-pocket medical expenses not covered by insurance, while 75% reported nonmedical costs including travel, lost wages, or food expenses. Some of these medical costs may be a particular barrier in the US given the lack of universal health care and a complex insurance system. In total, 44% of living liver donors reported these as burdensome expenses.¹ Donation costs were deemed a burden in 39.6% at 3 months post-living donation, and persisted up to 2 years post-living donation in 19.4%. In total, 24% of living liver donors reported that costs were greater than expected. No data are as yet available on costs or other burden incurred by living donors of pediatric liver recipients, but these costs may be more burdensome as living liver donors are often parents who are both supporting the family and caregiving for the transplant candidate and other children concurrently.

A major unmet need is standardizing state or national programs to financially support living donors. The National Living Donor Assistance Center (NLDAC: <http://livingdonorassistance.org>) can provide financial support for potential living donors at all US transplant centers, although this is not widely utilized. NLDAC is means-tested based on the recipient income (currently set at 350% of federal poverty guidelines for household size) for directed donors, and without recipient income-means testing for non-directed donors.¹⁰ The National Kidney Registry, a privately-run kidney paired exchange program, has developed the Donor Shield program to comprehensively address financial barriers to living kidney donors by covering lost wages, travel/lodging, dependent care costs, and disability and life insurance.¹¹ This model has recently expanded to include living liver donors.

Consensus conference participants achieved a high level of agreement that financial losses represent a significant barrier to living liver donation, especially among socioeconomically underserved populations (Table 1, Barrier #1). Financial burden may also be a key barrier for donors to pediatric recipients, as the living donor is most often a parent – who is also a primary caregiver to and financial supporter of the recipient (Table 1, Barrier #3).

While the existence of barriers was well recognized, further study of the implications of living liver donation for donors in both short- and long-term were deemed moderately impactful and feasible. Further data on mediators of financial burden before and after living liver donation, in addition to financial deterrents to living donation were considered as moderately impactful and feasible. An important point of agreement was the need for standardized discussion points during the potential living liver donor evaluation process with donor candidates on the financial implications of donation to facilitate financial planning and timely pursuit of supporting resources. In addition, Consensus Committee participants rated addressing living liver donor caregiver burden as highly impactful to facilitate living donation, with moderate feasibility.

Consensus conference participants rated several policy-based solutions as important strategies to address these barriers to LDLT. Priority was assigned to making the act of living liver donation financially neutral as possible, increasing awareness of programs such as NLDAC or connecting uninsured living donors to resources to obtain health insurance. However, developing standardized programs to achieve financial

TABLE 1 Ethics, policy, and expanding LDLT (*n* = 46, 90.2% response rate).

# Priority importance of barrier Strategy(ies)		Consensus responses Mean (SD); median (IQR)
#1 Financial losses, including lost wages, job insecurity, dependent care costs, and medical/insurance costs represent a significant barrier to living donation, especially among socioeconomically underserved populations	Importance:	8.38 (1.01); 9 (8, 9)
	Impact:	7.4 (1.86); 8 (7, 9)
	Feasibility:	7.41 (1.57); 8 (7, 9)
	Impact:	8.51 (.93); 9 (8, 9)
	Feasibility:	7.19 (1.74); 8 (6, 9)
• More research is needed to study the short- and long-term financial implications of living <i>liver</i> donation and its impact upon rates of LDLT as well as disparities in access to LDLT		
• The transplant community should prioritize making the act of living donation (any living donor) being financially neutral or at least as close to financially neutral as possible through advocacy at the state and especially at the federal level		
• All LDLT centers in the US should make potential donors aware that there is a national financial assistance program (NLDAC)	Impact:	8.43 (.97); 9 (8, 9)
	Feasibility:	8.28 (1.20); 9 (8, 9)
• For uninsured potential donors, the transplant center should guide the donor to any available resources to obtain health insurance	Impact:	8.20 (1.09); 9 (8, 9)
	Feasibility:	7.4 (1.42); 8 (7, 9)
#2 Fears of significant living donor morbidity and mortality prevent programs from developing Living Donor Liver Transplant programs	Importance:	7.83 (1.20); 8 (7, 9)
• Encourage granularity of national data reporting of LDLT outcomes, including long-term components, through the OPTN and dissemination of data using established national reporting avenues to demonstrate the relative infrequency of such events	Impact:	8.00 (1.01); 8 (7, 9)
	Feasibility:	7.17 (1.72); 7 (6, 8.25) ^a
#3 The financial security of the living donor is a major impediment to increasing the number of patients eligible for living donor transplantation and contributes to increased pediatric wait list mortality	Importance:	7.83 (1.31); 8 (7, 9)
• Standardized programs at the state or national level to financially support living donors will increase the pool of living donors	Impact:	8.12 (1.13); 8 (8, 9)
	Feasibility:	6.80 (1.59); 7 (6, 8) ^a
• Medicaid and all insurance programs should preferentially refer to programs that offer all donor options	Impact:	7.96 (1.32); 8 (8, 9)
	Feasibility:	6.34 (1.81); 7 (5, 8)
• Caregivers as living liver donors have additional special needs that need to be addressed and supported (e.g., childcare needs) to make LDLT a feasible option for more families	Impact:	7.91 (1.19); 8 (8, 9)
	Feasibility:	6.74 (1.61); 7 (5, 8)
• NKR as a model for donor shield for living liver donors. www.donor-shield.org	Impact:	7.67 (1.45); 8 (7, 9)
	Feasibility:	6.70 (1.56); 7 (5.75, 8)
#4 Overly prescriptive transplant program policies aimed at limiting risk may lead to a lack of interest in living donor liver expansion	Importance:	7.57 (1.49); 8 (6.75, 9)
• Internal policies should be balanced to ensure donor safety and safe expansion of programs. Increasing the program volume (minimum program volume averaged over 3 years) can mitigate some of this impact	Impact:	7.26 (1.51); 8 (6, 8.25)
	Feasibility:	6.89 (1.74); 7 (6, 8) ^a

(Continues)

TABLE 1 (Continued)

# Priority importance of barrier Strategy(ies)		Consensus responses Mean (SD); median (IQR)
#5 Conflicting policies from oversight agencies to regulate donor evaluation process impact the expansion and development of living donor programs	Importance:	7.33 (1.69); 8 (6, 9)
	Impact:	7.74 (1.60); 8 (7, 9)
• CMS and OPTN policies must align to support the safety of living donor liver transplantation and empower transplant programs to request appropriate resources (personnel, ICU support, consultants, etc.) to expand liver transplant services	Feasibility:	7.02 (1.77); 7 (6, 8.25) ^a
#6 Little is known about minimum information living donors require for informed consent, perceptions of expedited consent processes, strategies to mitigate perceptions of undue influence to donate	Importance:	7.22 (1.88); 8 (6, 9)
	Impact:	6.63 (1.89); 7 (5, 8)
• Diverse research methods are needed (e.g., mixed-methods)	Feasibility:	6.57 (1.86); 7 (5, 8) ^a
	Impact:	6.76 (2.25); 8 (5.75, 8) ^a
• Future research should assess perceptions of expedited consent processes in the acute setting, information that donors would require for informed consent, and strategies to mitigate perceptions of undue influence to donate in this and other circumstances	Feasibility:	6.76 (1.59); 7 (5.75, 8)
	Impact:	7.39 (1.74); 8 (6, 9)
• There may be a benefit to focusing on the risks/benefits of LDLT early in the course of the patient's evaluation when possible	Feasibility:	7.24 (1.45); 8 (6, 8) ^a
#7 Uncertainty of the process necessary to establish a crisis management plan for donor adverse events prevents further development of Living Donor Liver Transplant programs	Importance:	7.11 (2.28); 8 (6, 9)
	Impact:	7.72 (1.59); 8 (6.75, 9)
• Share complete guidelines and best practices from established programs regarding Living Donor crisis management plans within the AST website	Feasibility:	8.07 (1.08); 8 (7, 9)
	Impact:	7.73 (1.42); 8 (7, 9)
• Develop a "mentorship" program for longstanding, developed, and successful programs to work collaboratively with new programs looking to develop/grow a LDLT program	Feasibility:	7.57 (1.29); 8 (7, 9)
#8 The use and selection of the anonymous living donor is not well defined among transplant centers	Importance:	6.85 (2.12); 7 (5.75, 9)
	Impact:	7.20 (1.83); 8 (6, 9)
• Dissemination of published outcomes of anonymous living donors should be encouraged	Feasibility:	7.20 (1.63); 8 (6.75, 8) ^a
	Impact:	7.09 (1.89); 8 (6, 9)
• Research and education are needed in this area for best practices to minimize donor adverse outcomes (both short and long term)	Feasibility:	6.87 (1.47); 7 (6, 8)
#9 Selection of recipients for non-directed organs are arbitrary and not uniform. Defined set of criteria are missing	Importance:	6.67 (1.96); 7 (5.75, 8) ^a
	Impact:	7.09 (1.50); 7 (6, 8) ^a
• Transplant centers should draft defined set transparent, equitable, and fair criteria for allocation of these donors based upon specific center-related considerations.	Feasibility:	7.04 (1.37); 7 (6, 8)
#10 Multiorgan sequential living donation is a complex process that is infrequently utilized and with little data regarding the cumulative attributable risks and benefits to the donor	Importance:	6.61 (1.95); 7 (5, 8) ^a

(Continues)

TABLE 1 (Continued)

# Priority importance of barrier Strategy(ies)	Consensus responses Mean (SD); median (IQR)	
<ul style="list-style-type: none"> Systematic and prospective data gathering and follow up of multiorgan sequential living donors is necessary. Sharing safety and outcomes data gathered with the LDLT community will help enhance optimal use of this scarce resource and in the informed consent of these donors 	Impact:	6.80 (1.89); 7 (6, 8) ^a
	Feasibility:	6.93 (1.44); 7 (6, 8) ^a
#11 Terminology associated with living donors is outdated and can further exacerbate existing biases	Importance:	6.09 (2.32); 6.5 (5, 8) ^a
<ul style="list-style-type: none"> All living donors should be considered "altruistic" and that terminology should not be used. Terminology for living liver donors should be focused on the presence or absence of anonymity and whether the donation is directed or non-directed 	Impact:	6.48 (2.31); 7.5 (5, 8) ^a
	Feasibility:	7.56 (1.85); 8 (6.5, 9)

Note: Barriers ordered from highest to lowest rated priority. Response options rated from 9 = very important, very impactful, or very feasible to 1 = unimportant, not impactful, or not feasible. AST, American Society of Transplantation; CMS, Centers for Medicare & Medicaid Services; LDLT, living donor liver transplantation; NLDAC, National Living Donor Assistant Center; OPTN, Organ Procurement and Transplantation Network.

^aIndicates consensus was not met across responses, based upon above outlined consensus methods.

neutrality through advocacy at the state and federal level was rated as moderately feasible.

Overall, conference participants agreed on the importance of addressing the significant burden placed on living liver donors due to the financial implications of donation. Potential strategies, as mentioned above, to minimize these burdens were considered to be likely impactful, though with variable feasibility. While all transplant programs should increase potential living donors' awareness of existing financial support programs immediately, policy-level strategies, including engagement of government and payers to alter policies, will require a more substantial long-term effort.

3.2 | Center crisis management

Liver donor deaths in the US have been very rare and few data are available on mortality rates around the world. Following a publicly heralded living donor death at a prominent transplant program in 2002 and concerns regarding the safety and oversight for institutions performing these high-risk procedures, Miller et al. encouraged living liver transplant programs to build contingency plans for potential catastrophe.⁴ Consequently, a significant decrease in the number of living liver donor cases was observed and the Independent Living Donor Advocate (ILDA) was formed to protect the rights of the living donor and to obtain comprehensive informed consent. Despite survey data demonstrating that over 50% of transplant programs are either extremely or moderately concerned about a future living liver donor death, few transplant programs responded to Miller et al.'s recommendation.¹² Potential causes for this inactivity included the overall low likelihood of these events, the effort appearing burdensome by transplant program personnel and the concept of a programmatic living liver donor death causing discomfort and undue fear for program staff. Consequently, programs may be ill prepared or inadequately resourced in the

event of a death of a living donor. They may not be ready to complete a thorough corrective action plan for "near-miss events" which includes both internal communications and sharing lessons learned with the broader transplant community.¹³⁻¹⁵ This is precisely why participants of the consensus conference ranked highly the need to address the barrier that fears of living donor morbidity and mortality are currently preventing development of LDLT in many programs (Table 1, Barrier #2).

The question therefore remains as to whether the lack of a true crisis management plan has resulted in stagnation of living liver donor programs. Effective crisis management is known to be essential even in the rare instance of a living donor catastrophe, including a system of communication with families and the public, a process for program accountability and, importantly, care for the transplant team members (Figure 1).¹³ Fears of significant living donor morbidity and mortality were identified as the second most significant barrier to expanding LDLT by the consensus conference participants. Conference participants found that the most impactful and feasible approach to mitigate such fears was to encourage granularity of national data regarding LDLT outcomes, including long-term outcomes, to demonstrate the relative infrequency of such events. Efforts to collect robust current protocols and process maps from programs who have already completed this process could support individual program assessment and development and act as a resource document to share with health systems or hospital administration.

Concerns about the implications of adverse outcomes among living liver donors remain a crucial barrier to LDLT expansion; however, data on long-term outcomes are lacking. Conference participants reported that universal establishment of a crisis management plan at existing transplant programs is paramount. Strategies to improve national reporting of LDLT outcomes including complications, and robust dissemination of the overall safety of these procedures in US programs, would be both highly impactful and feasible to overcome this barrier.

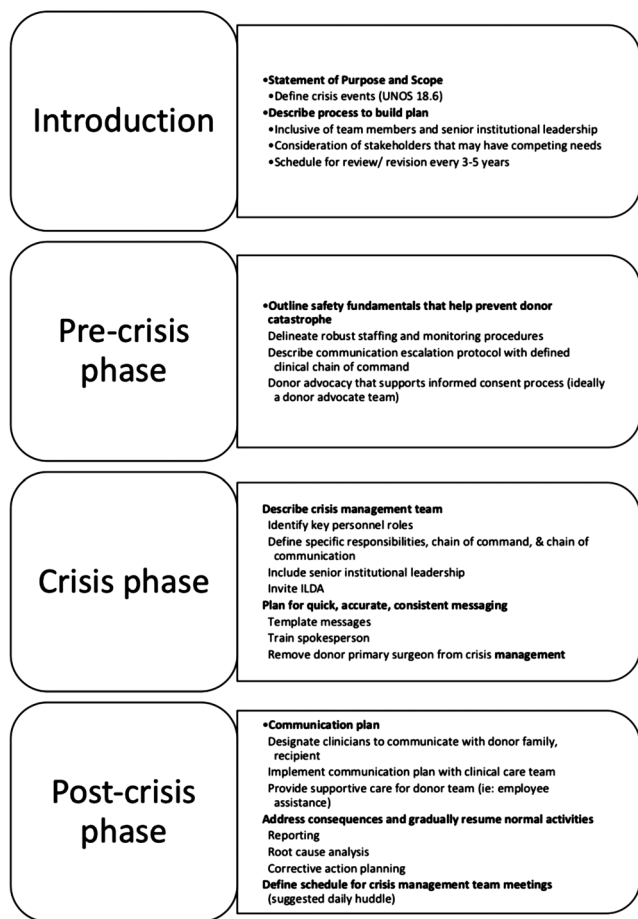


FIGURE 1 Living donor crisis management plan – pre-crisis, crisis, and post-crisis contingency plan for transplant programs to prepare for potential living donor catastrophe. Used with permission from Am J Transplant. 20(2):546-552, DOI: 10.1111/ajt.15618.

3.3 | Regulatory oversight barriers/policy

Current external oversight of LDLT in the US is provided at the Federal level by the OPTN and CMS (Figure 2). A few individual states also have an oversight role of living donation. Both CMS and OPTN require that transplant programs maintain specific protocols and policies for the evaluation and care of living donors, although in some cases, they do not specify what should be in the policy. For example, OPTN policy 14.4C¹⁶ requires that hospitals must develop and follow a written protocol for hypercoagulable state evaluation, but the policy does not specify the components of this evaluation, nor what should be done about particular conditions which may increase the risk of thrombosis such as factor V heterozygosity. In other cases, the OPTN and/or CMS provide very precise recommendations. For instance, the OPTN requirement for the residual volume following living donor hepatectomy (policy 14.4) has broad conformity for the necessity of such a requirement. In other cases, such as the requirement in CMS Guideline §482.98,¹⁷ which contends that “every potential living donor must be assigned to and have an interview with an ILDA or an Independent Living Donor Advocate Team (ILDAT) prior to the initiation of the

evaluation,” can be further interpreted to be prior to any blood tests such as ABO verification or basic screening such as body mass index (BMI). There is no broad agreement for such a requirement and this can be viewed as an unnecessary burden for transplant programs and potential living donors.

Consensus conference participants agreed that revision of internal transplant center policies and federal oversight policies was important to facilitate expansion of LDLT in the US (Table 1, Barriers # 4, 5). The impact of such revisions was also strongly ranked for center policies and federal policies. However, there was a lack of consensus on the feasibility of such an undertaking. This is likely due to perceived challenges in how the LDLT community may be able to influence individual program policies. There may also be skepticism on whether CMS or the OPTN would be willing to converge policies to reduce discordance, or to revise oversight policies in response to community feedback, outside of the public comment process. Optimization of federal policies that may inadvertently limit LDLT expansion is another important goal for the community.

3.4 | Ethical controversies in LDLT

Informed consent for donor evaluation and donor hepatectomy is critical to respecting donors’ autonomy and protecting their safety. Systematic reviews found that 88%–95% of potential living liver donors reported understanding the risks and benefits of surgery. However, many living liver donors describe gaps in knowledge about risks, procedure details, and potential complications.^{6,18} Ensuring the adequacy of informed consent is complicated when recipients rapidly develop high acuity diseases (e.g., acute liver failure)⁵ or are at increased risk of post-operative complications.

Additionally, the terminology regarding living donors can be confusing, particularly for individuals who donate without specifying an intended recipient. Such living donors have variously been described as “non-directed,” “altruistic,” and “Good Samaritan.”^{19,8} Since all living donors can be considered altruistic, consensus conference participants recommended that living donor terminology be standardized to focus on the donor’s preferences for anonymity and the relationship between the living donor and the intended recipient. Living liver donors would therefore be categorized as directed, non-directed donors, anonymous directed, or anonymous non-directed living donors.

Anonymous directed and anonymous non-directed living donors currently comprise 5% of the living liver donor population²⁰ and have the potential to expand the donor pool. The rationales for remaining anonymous include avoiding recipient indebtedness, seeking internal satisfaction, limiting emotional attachment to the recipient, forestalling negative perceptions among family and friends, and ambivalence to meeting the recipient. A growing body of evidence suggests that anonymous non-directed living liver donors have physical and psychosocial outcomes on par with directed donors.²¹ The use of anonymous living donors raises ethical considerations, including conditions under which anonymity may be problematic (e.g., estranged family members seeking to donate), difficulties in maintaining anonymity

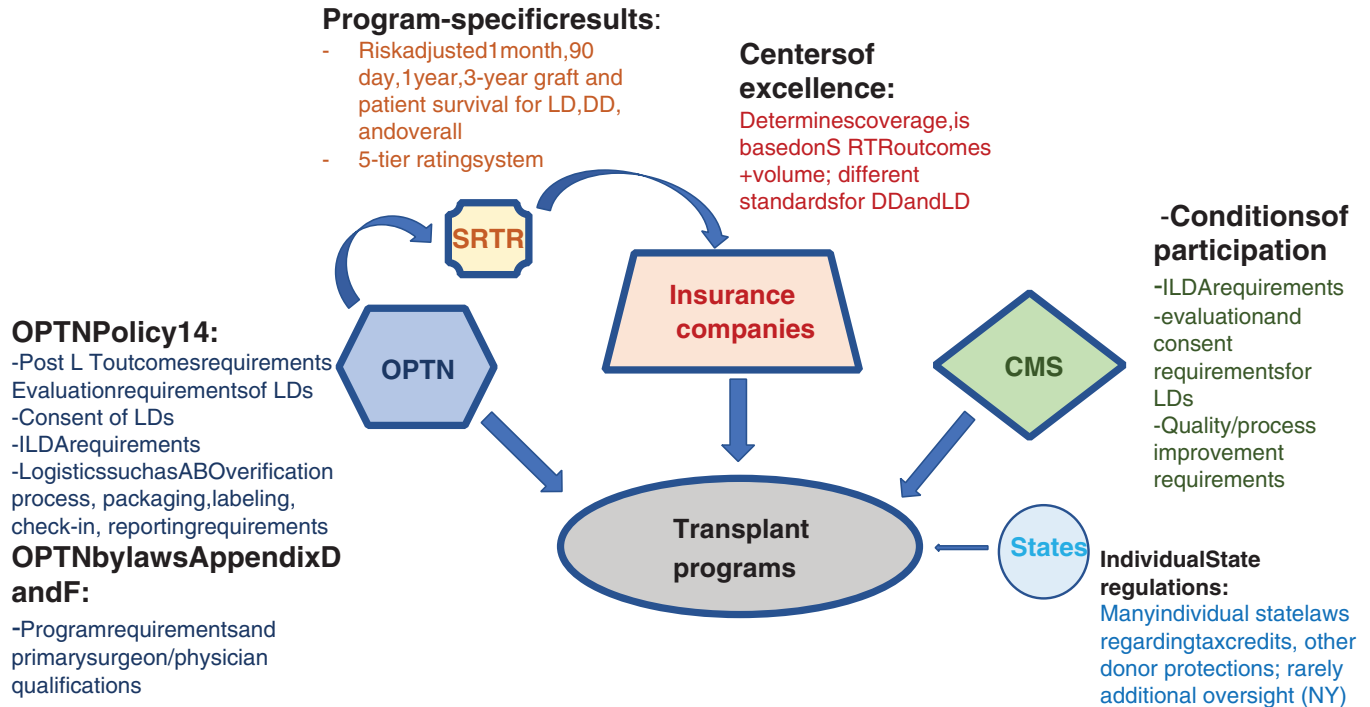


FIGURE 2 Interaction between federal, state, and center regulatory policies.

in the context of social media, and the appropriate level of benefit relative to risk to the living donor (e.g., should anonymous non-directed donors be allowed to accept as much risk as individuals who seek to donate to a family member?). Not all programs have established criteria for selecting a recipient candidate for non-directed donors. The process of recipient selection may therefore be perceived as arbitrary and may unintentionally perpetuate racial disparities.²²

Issues related to living donor informed consent and strategies to mitigate the perception of undue influence were identified as the working group's sixth most significant and highest-ranking ethical barrier to expanding LDLT. Conference participants found that the most impactful and feasible approach to improving LDLT consent would entail integrating discussion about the risks and benefits of LDLT early in the potential living liver donor evaluation process. Participants agreed that further research employing a range of methodologies and better assessment of the informed consent process during expedited living liver donor evaluation would be valuable, but these strategies were deemed less impactful and feasible than the other issues identified in the ethics and policy section.

Conference participants believed that the other ethical concerns ranked lower as barriers to LDLT: the use of anonymous living donors ranked 8th, recipient selection for non-directed living donors ranked 9th, and the need to establish consistent terminology ranked 11th. The most impactful and feasible strategy for addressing ethical concerns about anonymous living donation was dissemination of extant research on the outcomes for anonymous LDLT donors. The strategy of developing transparent, equitable allocation criteria for non-directed living donors was regarded as moderately impactful.

4 | SUMMARY AND NEXT STEPS

This consensus conference identified and prioritized several barriers to LDLT pertaining to donor financial status, center crisis management, regulatory oversight, and ethical issues. Strategies to overcome each of these barriers were identified to facilitate LDLT expansion, and to engage the liver transplant community with proposed interventions.

Financial neutrality for the living liver donor achieved broad consensus as an essential barrier that must be addressed in a multipronged approach, including (1) increased utilization of NLDAC for all currently eligible donors, (2) increasing the benefits of this program to a broader group of living donors, (3) advocacy at the state and federal levels for long-term health insurance for all living donors, and (4) engagement of patient organizations and private groups in creating a system to achieve living liver donor financial neutrality.

Living donor safety is of paramount importance to our community, and concerns about adverse medical outcomes in living liver donors remain a significant barrier to expansion of LDLT. Strategies to mitigate the impact of this concern include (1) improvement in the granularity and dissemination of national data reporting on LDLT outcomes, (2) creation of specific crisis management plans at existing LDLT programs, and (3) streamlining federal regulatory requirements for LDLT programs such that living donor safety remains central to these policies, including clarification of the CMS Guideline §482.98 regarding use of the ILDA.

Finally, several ethical considerations must be addressed, including (1) initiation of the potential living donor informed consent process early in the recipient's evaluation, (2) research to identify the optimal

informed consent process for potential living liver donors, particularly in the context of acute or severe recipient illness, (3) research regarding long-term physical and mental outcomes of non-directed living liver donors to assure protection while respecting donor autonomy and benevolence, and (4) coordinated effort within the transplant community to embrace transparency around center-based policies for living donor evaluation criteria and recipient selection for non-directed living liver donor organs.

Implementation of these aforementioned specific steps will help advance the field of LDLT.

AUTHOR CONTRIBUTIONS

All authors drafted portions of the manuscript. Anjana Pillai and Elizabeth C. Verna revised and provided critical revision of the manuscript. All authors approved the final manuscript submitted.

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CONFLICT OF INTEREST STATEMENT

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AST LDLT Consensus Conference Working Group

Marwan Abouljoud, MD, FACS, CPE, MMM, Henry Ford Transplant Institute, Detroit, MI, USA; Oya Andacoglu, MD, Transplant Surgery, University of Oklahoma, OK, USA; Medhat Askar, MD, PhD, Baylor University Medical Center, Dallas TX, USA, and Hamad Medical Corporation, Doha, Qatar; Therese Bittermann, MD, MSCE, University of Pennsylvania, Philadelphia, PA, USA; Dieter Broering MD, PhD, FEBS, FACS, King Faisal Specialist Hospital & Research Centre, Riyadh, Saudi Arabia; Matthew Cooper, MD, Medstar Georgetown Transplant Institute, Washington, DC, USA; Mary Amanda Dew, PhD, Department of Psychiatry, University of Pittsburgh School of Medicine and Medical Center, Pittsburgh, PA, USA; Juliet Emamaullee, MD, PhD, FRCSC, FACS, University of Southern California, Los Angeles, CA, USA; Jean

C. Emond, MD, Transplant Surgery, Columbia University, New York, NY, USA; Sukru H. Emre, MD, FACS, Visiting Professor of Surgery Ege University School of Medicine, Izmir, Turkey; Swaytha Ganesh, MD, Transplant Hepatology, Starzl Transplant Institute, University of Pittsburgh, Pittsburgh, PA, USA; Nicolas Goldaracena, MD, Transplant Surgery, University of Virginia Health, Charlottesville, VA, USA; Elisa J. Gordon, PhD, MPH, FAST, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; Adam D. Griesemer, MD, NYU Langone Transplant Institute, NYU Langone Health, New York, NY, USA; Hyosun (Helen) Han, MD, Keck Medicine of University of Southern California, Los Angeles, CA, USA; Christine E. Haugen, MD, PhD, Johns Hopkins Hospital Department of Surgery, Baltimore, MD, USA; Julie K. Heimbach, MD Professor of Surgery and Director, Transplant Center Mayo Clinic Rochester, MN USA; Abhi Humar, MD, Starzl Transplant Institute, University of Pittsburgh, Pittsburgh, PA, USA; Heather F. Hunt, JD, Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Living Donor Committee, Richmond, VA, USA; Whitney E. Jackson, MD, Division of Gastroenterology and Hepatology, University of Colorado, Aurora, CO, USA; Michelle T. Jesse, PhD, FACT, Henry Ford Transplant Institute, Detroit, MI, USA; Mureo Kasahara, MD, PhD, Organ Transplantation Center, National Center for Child Health and Development, Tokyo, Japan; Rohit Kohli MBBS, MS, Children's Hospital Los Angeles, Los Angeles, CA, USA; Vineeta Kumar, MD, FAST, Comprehensive Transplant Institute, University of Alabama at Birmingham, AL, USA; Daniela Ladner, MD, MPH, Northwestern University Transplant Outcomes Research Collaborative (NUTORC), Comprehensive Transplant Center, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA; Dianne Rudow LaPointe, ANP-BC, DNP, FAAN, Recanati Miller Transplantation Institute, Mount Sinai Hospital, New York, New York, USA; Krista L. Lentine, MD, PhD, FAST, Saint Louis University Transplant Center, St. Louis, MO, USA; Josh Levitsky, MD, FAST, Comprehensive Transplant Center, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; AnnMarie Liapakis, MD, Yale School of Medicine and Yale New Haven Transplant Center, New Haven, CT, USA; Jayme Locke, MD, MPH, Comprehensive Transplant Institute, University of Alabama at Birmingham, AL, USA; Didier A. Mandelbrot, MD, University of Wisconsin Hospitals, Madison, WI, USA; Amit K. Mathur, MD, Transplant Surgery, Mayo Clinic, Phoenix, AZ, USA; Alisha Mavis, MD, Duke University Health, Durham, NC, USA; Saeed Mohammad, MD, MS, Vanderbilt University Medical Center, Nashville, TN, USA; David Mulligan, MD, FACS, FAASLD, FAST, Yale New Haven Transplant Center, New Haven, CT, USA; Kim M. Olthoff, MD, Transplant Surgery, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA, USA; Neehar D. Parikh, MD, MS, Division of Gastroenterology and Hepatology, University of Michigan, Ann Arbor, MI, USA; Emily R. Perito, MD, University of California San Francisco, San Francisco, CA, USA; Anjana A. Pillai, MD, FAASLD, FAST, University of Chicago Medicine, Chicago, IL, USA; Elizabeth Pomfret, MD, PhD, Transplant Surgery, University of Colorado, Aurora, CO, USA; John P. Roberts, MD, UCSF Department of Surgery, San Francisco, CA, USA; Manuel Rodriguez-Davalos, MD, Transplant Surgery, Intermountain Healthcare, Salt Lake City, UT, USA; Garret Roll, MD, FACS, University of California San Francisco, CA, USA;

Benjamin Samstein, MD, Weill Cornell Medicine, New York, NY, USA; Gonzalo Sapisochin, MD, PhD, MSc, Toronto General Hospital, Toronto, Canada; Nazia Selzner, MD, PhD, University of Toronto, Toronto, CA; Mark Sturdevant, MD, Department of Surgery, Division of Transplant, University of Washington Medical Center, Seattle, WA, USA; Carrie Thiessen, MD, PhD, University of Wisconsin School of medicine and Public Health, Madison, WI, USA; James Trotter, MD, Transplant Hepatology, Baylor University Medical Center, Dallas, TX, USA; Elizabeth C. Verna, MD, Transplant Hepatology, Columbia University, New York, NY, USA; Gerald Scott Winder, MD, MSc, Department of Psychiatry, University of Michigan, Ann Arbor, MI, USA.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Amit Mathur  <https://orcid.org/0000-0002-9215-2014>

Michelle Jesse  <https://orcid.org/0000-0003-0847-0368>

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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