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May 2023

## Splitting Deceased Donor Livers to Double the Transplant Benefits: Addressing the Legal, Ethical, and Practical Challenges

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Available at: <https://scholarlycommons.law.case.edu/healthmatrix/vol33/iss1/5>

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# SPLITTING DECEASED DONOR LIVERS TO DOUBLE THE TRANSPLANT BENEFITS: ADDRESSING THE LEGAL, ETHICAL, AND PRACTICAL CHALLENGES

*Evelyn M. Tenenbaum<sup>†</sup> & Jed Adam Gross<sup>††</sup>*

## ABSTRACT

Liver transplantation is different from transplanting other solid organs because some recipients can achieve good long-term outcomes with only *half* of a donor's liver (or less). This means that some deceased donor livers can be split, saving two lives instead of one. However, although more than 10 percent of cadaveric livers meet the criteria for splitting, only about 1.5 percent are actually split in the United States. This article identifies a set of ethical, legal, and logistical challenges to a more extensive use of split liver transplantation (SLT) within existing legal frameworks. We then discuss how each of these challenges can be overcome with a set of realistic clarifications and changes to the current liver transplant architecture.

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† Professor of Law, Albany Law School, Professor of Bioethics, Albany Medical College. I am very grateful to my research assistant Rachel Meyer for her dedication to ensuring this article was completed, enormous help in researching the issues, and consistently insightful suggestions. This article is considerably better due to her assistance and recommendations. Thank you to Jed Gross for his making this collaboration so beneficial and enjoyable; to my colleagues at Albany Medical Center for giving us a forum to discuss our ideas and for their helpful comments; and to Albany Law School for consistently supporting my scholarship.

†† Department of Clinical and Organizational Ethics, University Health Network, Toronto, ON. This article benefited from conversations with colleagues at the Cleveland Clinic and University Hospitals in Cleveland, University Health Network and the Hospital for Sick Children in Toronto, and the Canadian Society of Transplantation. I am deeply grateful to Evelyn Tenenbaum and Rachel Meyer for the opportunity to pursue this project together in a spirit of collegiality.

Three guiding values shape liver allocation policy in the United States: maximizing expected outcomes, ensuring broad access, and prioritizing the sickest patients. While the last value is in tension with SLT (because the sickest patients often need a whole liver), we maintain that greater adoption of SLT is consistent with this normative balance. In addition, the distribution infrastructure is not designed to facilitate splitting. When a surgical team is offered a liver for a specific patient, they feel duty-bound to give that specific patient the whole organ. Further discouraging SLT, performance metrics, including those used to determine a transplant program's eligibility for Medicare and Medicaid funding, focus on surgical outcomes rather than waitlist mortality.

Our preferred remedies entail clarifying the informed consent requirements for SLT, using a national clearinghouse to identify livers that are prime candidates for splitting, offering these livers to qualifying programs for SLT only, and establishing a separate regulatory reporting and outcomes evaluation pathway for SLT. Together, these reforms, many of which have precedents in the transplant field, will support the expansion of SLT in carefully controlled conditions and save more lives.

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## I. INTRODUCTION

The supply of human livers donated for transplant is not meeting the needs of patients experiencing liver failure under existing allocation policies, and there is a better way to utilize available livers. In a single year in the United States, approximately 1200 individuals found medically eligible for a liver transplant die while waiting on the list of candidates managed by the national Organ Procurement and Transplant Network (OPTN).<sup>1</sup> Another approximately 1200 patients are removed

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1. *National Data, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK*, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#> [<https://perma.cc/8DX7-8ERP>] (last visited July 23, 2021); Elizabeth Miller, *Split Liver Variance*, OPTN BRIEFING PAPER, 2019, at 1 (“Because there are not enough livers donated to meet the demand for liver transplantation, 1,157 candidates died while awaiting a liver transplant in 2018”).

from the waitlist because they become too sick to transplant.<sup>2</sup> These numbers do not include patients deemed unsuitable for listing due to contraindications (e.g. risk of cancer recurrence or history of problematic substance use) who might have been reasonable candidates if transplants were more readily available.<sup>3</sup>

The gap between supply and demand is not unique to liver replacement; there are also substantial waitlists for donated hearts, kidneys, and lungs.<sup>4</sup> Further, this imbalance is not isolated to the U.S. healthcare system; waitlists are also readily documented in Canada,<sup>5</sup> European Union countries,<sup>6</sup> Japan,<sup>7</sup> and South Korea,<sup>8</sup> to cite a few examples. However, there is a distinct opportunity for the U.S. to optimize the use of available livers because many patients can recover from liver disease with

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2. Pamela L. Valentino et al., *Frequency of Whole-Organ in Lieu of Split-Liver Transplantation Over the Last Decade: Children Experienced Increased Wait Time and Death*, 19 AM. J. OF TRANSPLANTATION 3114, 3114 (2019) (“The majority of waitlist candidates who are delisted have been ‘too sick’ for transplant and are typically counted as a death on the waitlist in transplant literature.”).
  3. Greg A. Knoll & Steven J. Chadban, *Preexisting Cancer in Transplant Candidates: Time for a Change in Practice?*, 102 TRANSPLANTATION 1037, 1037 (2018); Claudio A. Marroni et al., *Liver Transplantation and Alcoholic Liver Disease: History, Controversies, and Considerations*, 24 WORLD J. GASTROENTEROLOGY 2785, 2793 (2018).
  4. *OPTN Metrics*, OPTN, <https://insights.unos.org/OPTN-metrics/> [<https://perma.cc/Y9T2-RPNA>] (last visited Feb. 28, 2022) (Organ-specific data can be disaggregated using the “Organ” pull-down menu).
  5. *Annual Statistics on Organ Replacement in Canada, 2011 to 2022*, CANADIAN INST. FOR HEALTH INFO., <https://www.cihi.ca/en/annual-statistics-on-organ-replacement-in-canada-2011-to> [<https://perma.cc/KP2Y-HZQB>] (last visited Feb 28, 2022).
  6. Silvio Nadalin, *Living Donor Liver Transplantation in Europe*, 5 HEPATOBIILIARY SURGERY & NUTRITION 159, 160 (2015).
  7. Akihiko Soyama et al., *Liver Transplantation in Japan*, 22 LIVER TRANSPLANTATION 1401, 1402 (2016).
  8. Juhan Lee et al., *Development of a Korean Liver Allocation System Using Model for End State Liver Disease Scores: A Nationwide, Multicenter Study*, 9 SCI. REPS. 1, 4 (2019).

substantially less than a whole liver.<sup>9</sup> This possibility stems not only from size differences between donors and recipients<sup>10</sup> but also from the liver's unique capacity to regenerate.<sup>11</sup> Beginning in the 1980s, surgical innovators introduced split liver transplantation (SLT), a technique that enables two recipients to benefit from a single donated liver.<sup>12</sup> Today, outcomes of SLT approach those of whole liver transplantation (WLT) if the surgical team is properly equipped and appropriate recipients are selected.<sup>13</sup> Yet, available data suggests that far fewer livers are being split than would maximize lives saved.<sup>14</sup>

In short, the existing U.S. organ sharing system, which evolved in response to organizational needs in the field of transplant medicine,<sup>15</sup> is not designed in a way that optimizes the

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9. Christina Hackl et al., *Split Liver Transplant: Current Developments*, 24 *WORLD J. GASTROENTEROLOGY* 5312, 5313 (2018).
  10. Robert Merion, *Predicted Lifetimes for Adult and Pediatric Split Liver Versus Adult Whole Liver Transplant Recipients*, 4 *AM. J. TRANSPLANTATION* 1792, 1792 (2004).
  11. Abhinav Humar et al., *Liver Regeneration After Adult Living Donor and Deceased Donor Split-Liver Transplants*, 10 *LIVER TRANSPLANTATION* 374, 374 (2004) (“Liver growth after such transplants occurs at a rapid pace. Most recipients and [living donors] have near-complete regeneration of their liver volumes within a matter of a few weeks.”).
  12. Andrea Lauterio et al., *Current Status and Perspectives in Split Liver Transplantation*, 21 *WORLD J. GASTROENTEROLOGY* 11003, 11004 (2015). Throughout this article, “SLT” will be used as an abbreviation for both “split liver transplantation” and “split liver transplant.” “WLT” will be used for “whole liver transplantation” and “whole liver transplant.”
  13. Kazunari Sasaki et al., *Elevated Risk of Split-Liver Grafts in Adult Transplantation: Statistical Artifact or the Nature of the Beast?*, 25 *LIVER TRANSPLANTATION* 741, 749–50 (2019) (discussing the surgical “learning curve” and noting that SLT with two adult recipients “demands the perfect combination of recipient/donor/center factors,” in the right circumstances, it may be possible to “achieve similar outcomes as [WLT]”).
  14. See *infra* notes 265, 394 and accompanying text.
  15. Jed A. Gross, *E Pluribus UNOS: The National Organ Transplant Act and its Postoperative Complications*, 8 *YALE J. HEALTH POL. L. & ETHICS* 145 (2008) (noting the historical origins of the U.S. OPTN and emphasizing the broad policy objectives of improving

use of splittable livers. Rather, we posit that many aspects of the existing legal framework inhibit the practice of SLT, even when leveraging opportunities for SLT would advance the OPTN's stated objectives. After elucidating how specific policies and policy gaps all but ensure missed opportunities, we outline a set of proposed arrangements to remedy these deficiencies. Our recommendations include a clear, robust pathway for obtaining informed consent for SLT; a national clearinghouse for identifying prime livers to be offered for SLT and matching them with appropriate patients at qualified transplant centers; and a distinct registry for evaluating SLT outcomes. With these reforms in place, SLT will be a more attractive option for certain patients and transplant programs, allowing more lives to be saved with the available pool of donated livers.

Our article proceeds as follows. Immediately following this introduction, Part II provides the necessary background for understanding SLT's potential and limitations, including how livers are currently offered to surgical teams for patients through the OPTN and how this approach results in the underutilization of SLT. Attention is given to the incremental refinement of surgical techniques and candidate selection criteria.

Part III addresses the unique challenges of ensuring informed, voluntary consent for a complex procedure that is risky, but may nonetheless represent the best treatment option for patients with fluctuating or declining health status. This Part highlights the importance of disclosing the surgical team's relative experience with splitting livers and providing ongoing patient information while on the wait list, including a three-stage pathway for obtaining informed consent.

Part IV considers the potential for coercion or manipulation inherent when offering SLT and identifies ways of mitigating these risks.

Part V shifts focus from the individual doctor-patient interaction to the organizational structure of transplant programs. This Part identifies ways in which surgeons' fiduciary duties to individual patients who receive liver offers and compliance standards that emphasize individual case outcomes over net waitlist mortality can work against the interests of other patients awaiting an offer. Part V goes on to show how these

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funding, information technology, and coordination in a nascent, resource-intensive biomedical field).

misaligned incentives can be remedied in a manner consistent with principles of biomedical ethics.

Finally, Part VI catalogues our recommendations for facilitating wider adoption of SLT and saving more lives through modest policy changes and greater legal clarity.

## II. BACKGROUND

The extreme shortage of organs is the most significant factor limiting organ transplantation worldwide.<sup>16</sup> This is particularly true for liver transplantation.<sup>17</sup> The high demand for donor livers compared with the low supply has resulted in thousands of patients dying while on the transplant waiting list and others enduring long illnesses prior to receiving a suitable liver.<sup>18</sup> These negative outcomes are likely to increase because the indications for recommending a liver transplant are expanding, aggravating the already severe shortage.<sup>19</sup> The increase in patients needing a

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16. Kun-Ming Chan et al., *Encouraging Split Liver Transplantation for Two Adult Recipients to Mitigate the High Incidence of Wait-List Mortality in the Setting of Extreme Shortage of Deceased Donors*, 8 CLINICAL MED. (SPECIAL ISSUE) 1, 10 (2019); Valentino, note 2, at 3114 (“Organ shortage is an important barrier in liver transplantation”).
  17. Pierluigi Toniutto et al., *Current Challenges and Future Directions for Liver Transplantation*, 37 LIVER INT’L 317, 317 (2017) (“The discrepancy between the number of patients on the waiting list and available donors remains the key issue and is responsible for the high rate of waiting list mortality.”).
  18. Greg Moorlock et al., *An Empirically Informed Analysis of the Ethical Issues Surrounding Split Liver Transplantation in the United Kingdom*, 25 Cambridge Q. Healthcare Ethics 435, 435 (2016); Amit Nair & Koji Hashimoto, *Extended Criteria Donors in Liver Transplantation—From Marginality to Mainstream*, 7 HEPATOBIILIARY SURGERY& NUTRITION 386, 386 (2018) (“[T]here exists a constant divide between organ supply and demand, with the numbers of new entrants to liver transplant waiting lists consistently and significantly outstripping that of transplants performed annually[.]”).
  19. Uta Herden et al., *Long-Term Follow-Up After Full-Split Liver Transplantation and its Applicability in the Recent Transplant Era*, 32 CLINICAL TRANSPLANTATION 1, 1 (2018); Daniele Pezzati et al., *Strategies to Optimize the Use of Marginal Donors in Liver Transplantation*, 7 WORLD J. HEPATOLOGY 2636, 2637 (2015) (“Due to improvement in surgical techniques, immunosuppressive strategies, and patient management, the number of candidates [for

liver transplant and the number of people dying while waiting underscore the importance of having an organ allocation system that makes optimum use of existing donor livers.

The critical need for a deceased donor organ allocation system was first addressed by Congress in 1984 when it passed the National Organ Transplant Act (NOTA).<sup>20</sup> Under NOTA, the Department of Health and Human Services (HHS) was given the responsibility for choosing a nonprofit entity to maintain the OPTN.<sup>21</sup> HHS would delegate to this nonprofit organization the task of managing “a national list of people who need organs . . . and [devising] medical criteria for allocating the organs.”<sup>22</sup>

In 1986, HHS selected the United Network for Organ Sharing (UNOS) to maintain the OPTN,<sup>23</sup> and UNOS has continuously

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liver transplants] has dramatically grown in the last decades while the number of donors has remained stable.”).

20. 42 U.S.C. § 274; Evelyn M. Tenenbaum, *Bartering for a Compatible Kidney Using Your Incompatible Live Kidney Donor: Legal and Ethical Issues Related to Kidney Chains*, 42 AM. J. L. & MED. 129, 142 (2016); J. M. Smith et al., *Kidney, Pancreas and Liver Allocation and Distribution in the United States*, 12 AM. J. TRANSPLANTATION 3191, 3191 (2012) (noting that Congress passed NOTA to “address the nation’s critical organ donation shortage and improve the organ matching and placement process.”).
21. 42 U.S.C. § 274(a)–(b)(2)(A) (2013) (instructing the Secretary of HHS to contract with a “private nonprofit entity that has an expertise in organ procurement and transplantation . . . for the establishment and operation of an [OPTN]”); see Dan Davis & Rebecca Wolitz, *Staff Working and Discussion Paper: The Ethics of Organ Allocation*, PCBE (Sept. 2006), <https://bioethicsarchive.georgetown.edu/pcbe/background/davispaper.html> [<https://perma.cc/8JV7-KLWM>] (noting that both the OPTN and UNOS are private, not-for-profit entities).
22. 42 U.S.C. § 274(b)(2)(A)–(B) (2013); see Alexandra K. Glazier & Scott Sasjack, *Should It Be Illicit to Solicit? A Legal Analysis of Policy Options to Regulate Solicitation of Organs for Transplant*, 17 Health Matrix 87, 88–89 (2007) (“In 1984, Congress authorized the [OPTN] to set national organ allocation policies through NOTA”).
23. Ian Ayers et al., *Unequal Racial Access to Kidney Transplantation*, 46 VAND. L. REV. 805, 813–14 (1993).

operated that entity ever since.<sup>24</sup> In fulfilling its mission of determining the medical criteria for allocating organs, UNOS was bound by federal law and regulations, which mandate that UNOS allocate organs “equitably.”<sup>25</sup> UNOS interpreted “equitable” to require balancing utility (achieving the best possible benefit from donated organs)<sup>26</sup> and justice (a fair allocation of scarce donor organs).<sup>27</sup> Justice also included considering urgency – the immediacy of a patient’s need.<sup>28</sup>

Establishing an equitable balance between utility and justice created some “ethical quandar[ies].” For example, offering donated livers to younger individuals first would result in better post-transplant outcomes but arguably deprive older individuals

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24. Michael T. Morley, *Increasing the Supply of Organs for Transplantation Through Paired Organ Exchanges*, 21 YALE L. & POL’Y REV. 221, 233–34 (2003).
  25. 42 U.S.C. § 273(b)(2)–(3) (2013) (“An [OPO] shall . . . have a system to allocate donated organs equitably among transplant patients according to established medical criteria[.]”); 42 C.F.R. § 121.8(b) (2016) (“Allocation policies shall be designed to achieve equitable allocation of organs among patients.”); see Evelyn M. Tenenbaum, *Swaps and Chains and Vouchers, Oh My!: Evaluating How Saving More Lives Impacts the Equitable Allocation of Live Donor Kidneys*, 44 AM. J. L. & MED. 67, 79 (2018).
  26. Anji E. Wall et al., *Advanced Donation Programs and Deceased Donor-Initiated Chains – 2 Innovations in Kidney Paired Donation*, 101 TRANSPLANTATION 2818, 2819–20 (2017) (noting that “[t]he principle of utility states that an action is right if it promotes as much or more good than an alternative action” and further explaining that “aggregate good can be measured in graft survival, patient survival, or quality adjusted life years, among other criteria”).
  27. C. Bradley Wallis et al., *Kidney Paired Donation*, 26 NEPHROLOGY DIALYSIS TRANSPLANTATION 2091, 2094 (2011) (noting that UNOS “defines ‘equitable’ as a balance between utility and justice”); see Davis & Wolitz, *supra* note 21 (“[T]reat[ing] everyone fairly as individuals . . . sometimes may trump . . . the maximization of the benefits”); Tenenbaum, *supra* note 25, at 72.
  28. Monika Bobbert, Nadia Primc, & Rebecca Schafer, *Is There an Ethical Obligation to Split Every Donor Liver? Scarce Resources, Medical Factors, and Ethical Reasoning*, 23 PEDIATRIC TRANSPLANTATION 1, 3 (2019) (“[I]mportant aspects [of organ allocation criteria] include . . . urgency (i.e. need) of transplantation”).

of equitable access.<sup>29</sup> In theory, “[a] truly equitable transplant allocation system should allow for equal access to transplants for all who are qualified without prejudice, discrimination, or biases,”<sup>30</sup> and that would include giving those who are older a fair chance at receiving a liver transplant. Many other ethical concerns arise in distributing organs for transplant, and UNOS’s goal is generally to achieve an equitable balance between competing needs. However, despite efforts by UNOS and the transplant community to achieve just access, significant disparities continue to exist in deceased donor liver allocation.<sup>31</sup>

#### A. *The MELD System of Donor Liver Allocation*

During the 1990s, deceased donor livers were allocated based on the candidate’s time on the waiting list and “hospital level of care.”<sup>32</sup> This method of allocation had the disadvantage of giving clinicians leeway to exaggerate the severity of some patients’ liver disease, unfairly moving those patients ahead of others on the transplant waiting list.<sup>33</sup> “To make transplant prioritization more objective”<sup>34</sup> and deal with the high mortality of patients on the transplant waiting list,<sup>35</sup> UNOS adopted the Child Turcotte-Pugh score in 1998.<sup>36</sup> In 2002, UNOS replaced this score with the Model

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29. See, e.g., Nabeel A. Wahid et al., *A Review of the Current State of Liver Transplantation Disparities*, 27 LIVER TRANSPLANTATION 434, 440 (2021).

30. *Id.*

31. *Id.* (“[D]espite attempts made by the liver transplant community and substantial improvements over time, significant disparities based on demographic profile persist at each stage of the liver transplant process”).

32. *Id.* at 434.

33. Aaron Ahearn, *Ethical Dilemmas in Liver Transplant Organ Allocation: Is It Time for a New Mathematical Model?*, 18 AM. MED. ASS’N J. ETHICS 126, 127 (2016) (noting that MELD scoring “mostly eliminated the transplant clinician’s abilities to exaggerate a patient’s disease severity”).

34. Wahid et al., *supra* note 29, at 434; see Ahearn, *supra* note 33, at 127.

35. Ahearn, *supra* note 33, at 128 (“A major driver of adopting an urgency-based system was the extremely high mortality of high-MELD end-stage liver disease (ESLD) patients”).

36. Wahid et al., *supra* note 29, at 434.

for End-Stage Liver Disease (MELD)<sup>37</sup> and Pediatric End-Stage Liver Disease (PELD) scores<sup>38</sup> because they were more precise in predicting severity of disease.<sup>39</sup>

The MELD score is based on a mathematical algorithm that, with some exceptions, has been found to accurately predict a candidate's risk of death within three months without a liver transplant.<sup>40</sup> The MELD score “rang[es] from 6 (less ill) to 40 (gravely ill).”<sup>41</sup> The chances of a patient with a score of 40 dying within three months is greater than 90% unless the patient receives a liver transplant.<sup>42</sup>

To reduce mortality on the waiting list, the current UNOS allocation system “directs deceased donor livers to candidates with the highest (most medically urgent) MELD scores.”<sup>43</sup> In this way, livers are successfully allocated to those candidates whose need is most medically urgent or, in other words, those candidates

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37. *Id.*

38. LEE BOLTON, UNOS POL’Y DEP’T, *SPLIT VERSUS WHOLE LIVER TRANSPLANTATION* 4 (2016), [https://optn.transplant.hrsa.gov/media/1919/ethics\\_splitvwhole\\_livertx\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1919/ethics_splitvwhole_livertx_20160815.pdf) [<https://perma.cc/3QXX-K22F>].

39. See Andrea Tsois & Clinton A. Marlar, *Use of the Child Pugh Score in Liver Disease*, STATPEARLS, <https://www.ncbi.nlm.nih.gov/books/NBK542308/> [<https://perma.cc/2Z7U-YL6G>] (last updated Mar. 22, 2021).

40. Jayme E. Locke et al., *Quantifying Sex-Based Disparities in Liver Allocation*, 155 J. AM. MED. ASS’N SURGERY 1, 2 (2020) (“The MELD score is a mathematical algorithm that uses objective laboratory data, including sodium level, serum total bilirubin level, serum creatinine (sCr) level, and the international normalized ratio (INR) for prothrombin time, to estimate wait list mortality within 90 days”); N.Y. STATE DEP’T OF HEALTH WORKGROUP, *Workgroup on Expanded Criteria Organs for Liver Transplantation*, 11 LIVER TRANSPLANTATION 1184, 1190 (2005) (“[T]he [MELD] score is predictive of the risk of death in the absence of a liver transplant within the next three months.”); Beat Müllhaupt et al., *Hot Topics in Liver Transplantation: Organ Allocation – Extended Criteria Donor – Living Donor Liver Transplantation*, 48 J. HEPATOLOGY S58, S59 (2008) (“[The MELD score] can accurately predict 3-month mortality [with exceptions].”).

41. N.Y. STATE DEP’T OF HEALTH WORKGROUP, *supra* note 40, at 1190.

42. Ahearn, *supra* note 33, at 128.

43. N.Y. STATE DEP’T OF HEALTH WORKGROUP, *supra* note 40, at 1190; see BOLTON, *supra* note 38, at 4.

with the highest risk of dying within the next three months.<sup>44</sup> Indeed, “most patients are critically ill before receiving priority for a liver transplant.”<sup>45</sup> The MELD system also has the advantage of limiting opportunities for bias and exaggeration by clinicians because it uses actual lab values to calculate the candidate’s score.<sup>46</sup> This makes the score “objective, quantifiable and verifiable.”<sup>47</sup>

Although the MELD score is generally quite reliable, for some liver diseases it is not an accurate predictor of mortality.<sup>48</sup> Patients with these diseases are assigned a “MELD score equivalent” to ensure they are not unduly disadvantaged by the MELD allocation system.<sup>49</sup>

The introduction of the MELD system in the U.S. has been widely viewed as a success.<sup>50</sup> Using MELD scores has “reduced wait list mortality without significant[ly] chang[ing] posttransplant survival.”<sup>51</sup> However, in general, patients with high MELD scores tend to have worse post-transplant outcomes

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44. Ahearn, *supra* note 33, at 127.

45. BOLTON, *supra* note 38, at 4.

46. Ahearn, *supra* note 33, at 127 (“[T]he MELD score is a mathematically accurate predictor of waitlist mortality and therefore can successfully allocate organs based on medical urgency.”).

47. *Id.* (noting that MELD scoring “has mostly eliminated the transplant clinician’s abilities to exaggerate a patient’s disease severity in order to move ‘up’ the patient’s place on the transplant list”).

48. Müllhaupt et al., *supra* note 40, at S59 (“[T]he MELD score does not accurately predict mortality for all diseases . . . which are currently treated by liver transplantation”).

49. *Id.*; Lauren D. Nephew et al., *Exception Points and Body Size Contribute to Gender Disparity in Liver Transplantation*, 15 CLINICAL GASTROENTEROLOGY & HEPATOLOGY 1286, 1286–87 (2017) (“In select patients, in whom the MELD score is thought to underestimate disease severity, additional exception points can be allocated increasing the MELD score. The most common indication for receipt of exception points is [liver cancer].”).

50. Müllhaupt et al., *supra* note 40, at S59 (“The introduction of the MELD score in the US was a success story.”).

51. Ahearn, *supra* note 33, at 127.

than those with lower MELD scores because they are so ill when receiving the transplant.<sup>52</sup>

B. *The Introduction of SLT*

To further reduce mortality on the waiting list and improve outcomes, clinicians were innovative in expanding opportunities for liver transplants.<sup>53</sup> One important innovation was using SLT.<sup>54</sup> With this technique, a deceased donor liver “is separated into [two] viable sections that can be transplanted into [two] recipients.”<sup>55</sup> This innovation was originally designed to reduce the high death rates for pediatric patients.<sup>56</sup> Pediatric patients were much less likely than adults to receive donated livers because deceased donor organs from children are rare and children are generally too small to receive the available donated livers from adults.<sup>57</sup> As we will discuss, physicians were able to use SLT to

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52. *Id.* at 128; Pezzati et al., *supra* note 19, at 2637 (noting that the gap between the demand for livers and the supply “has stimulated innovative strategies to increase the donor pool”).
  53. Dave Collett, John O’Neill, & James Neuberger, *Splitting Livers – Balancing the Gain and the Pain*, 21 *TRANSPLANT INT’L* 218, 218 (2008) (“To meet the increasing demand for organs in the face of dwindling supply, surgeons have been innovative in making the best use of those organs that are available[.]”).
  54. *See* Valentino et al., *supra* note 2, at 3114 (“One method used to increase [liver transplants], optimize organ utilization, and reduce waitlist mortality is to perform [SLT]”).
  55. Valentino et al., *supra* note 2, at 3114–15; Koji Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era: A Single Center Experience in the United States*, 14 *AM. J. TRANSPLANTATION*, 2072, 2072 (2014).
  56. Collett, O’Neill, & Neuberger, *supra* note 53, at 218 (“Splitting of selected livers was introduced primarily to reduce the mortality of children on the waiting list.”); *see* Moorlock et al., *supra* note 18, at 435–36; Chan et al., *supra* note 16, at 2 (“[SLT] was initially proposed as a method in which an adult liver graft is divided into a smaller graft for a pediatric recipient and a bigger graft for an adult recipient.”).
  57. Moorlock et al., *supra* note 18, at 435 (“Before livers were split, average waiting times and waiting list mortality for pediatric patients were particularly high.”); Wahid et al., *supra* note 29, at 439 (“Pediatric liver candidates are at a unique disadvantage in the transplant allocation process because of the difficulty finding appropriately sized grafts.”).

provide more opportunities for children to receive life-saving transplants.

1. SLT for One Pediatric and One Adult Patient

To deal with the high death rate of pediatric patients on the transplant waiting list, in 1984, Henri Bismuth successfully reduced the size of an adult liver to create a smaller graft for a pediatric patient.<sup>58</sup> This approach became popular because of its overwhelming success in improving survival for pediatric patients.<sup>59</sup> The shortcoming of Bismuth's technique was that the remaining sections of the liver had to be discarded.<sup>60</sup> From this shortcoming came the idea of splitting the liver into two functioning grafts.<sup>61</sup>

In 1988, Rudolph Pichlmayr's team in Hannover, Germany, performed the first split liver transplant.<sup>62</sup> A donor liver was divided into a smaller left part containing segments II and III and a larger right part containing segments I and IV-VIII.<sup>63</sup>

The smaller graft is generally directed to a pediatric patient and the larger right graft is usually given to smaller adults,<sup>64</sup> a majority of whom are women.<sup>65</sup> This splitting technique not only further benefitted pediatric patients but also substantially benefitted adult patients of short stature who were also

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58. Koji Hashimoto et al., *Split Liver Transplantation in Adults*, 22 WORLD J. GASTROENTEROLOGY 7500, 7501 (2016).
59. See KOJI HASHIMOTO & BIJAN EGHTEHAD, SPLIT LIVER TRANSPLANTATION, CONTEMPORARY LIVER TRANSPLANTATION 82 (Cataldo Doria ed., 2017).
60. *See id.* at 82.
61. *See id.*
62. Lauterio et al., *supra* note 12, at 11004; Neal R. Barshes et al., *Adult Liver Transplant Candidate Attitudes Toward Graft Sharing Are Not Obstacles to Split Liver Transplantation*, 5 AM. J. TRANSPLANTATION 2047, 2049 (2005).
63. Lauterio et al., *supra* note 12, at 11004.
64. Moorlock et al., *supra* note 18, at 436 (“The two recipients of a split liver are usually an adult and a child, although sometimes the recipients are an adult and a smaller-sized adult.”).
65. See Jin Ge et al., *Split Liver Transplantation Is Utilized Infrequently and Concentrated at a Few Transplant Centers in the United States*, 20 AM. J. TRANSPLANTATION 1116, 1121 (2020).

disadvantaged by their inability to accept average and larger-size liver grafts.<sup>66</sup>

Before split liver transplantation, “mortality rates for children on the transplant waitlist approached 40% in some locations.”<sup>67</sup> But because pediatric patients were initially disadvantaged due to their smaller size,<sup>68</sup> the expansion of split liver transplants has resulted in a substantial decline in waiting time for pediatric patients and a precipitous reduction in pediatric waitlist mortality.<sup>69</sup> Children also experience lower mortality than adults after a transplant is performed, in part because of the strong correlation between longer survival and younger age.<sup>70</sup> Moreover, for pediatric patients, the risk of graft failure or death

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66. HASHIMOTO & EGHTEHAD, *supra* note 59, at 84–85 (noting that while it is important that children receive split liver grafts, “[i]t is equally important . . . that small adults who are often bypassed on the waiting list due to size mismatch can have more opportunities by SLT.”); Ge et al., *supra* note 65, at 1121 (“Women and men with short stature are . . . currently disadvantaged . . . by the allocation system due to inappropriate size matching.”); Aydinca Akdur et al., *Large-For-Size Liver Transplant: A Single-Center Experience*, EXPERIMENTAL & CLINICAL TRANSPLANTATION, (Supp. 1), 108, 108 (2015) (noting that large-for-size transplant “is caused by discrepancy between the small abdominal cavity and large graft and is characterized by decreased blood supply to the liver graft and graft dysfunction.”).
67. Anntim Vulchev et al., *Ethical Issues in Split Versus Whole Liver Transplantation*, 4 AM. J. TRANSPLANTATION 1737, 1737 (2004).
68. Lee Bolton, *Split Versus Whole Liver Transplantation*, UNOS POL’Y DEP’T (2016) (“Since pediatric donors are less common than adult donors, [SLT] has significantly reduced time and mortality for patients on the pediatric waitlist.”).
69. Vulchev et al., *supra* note 67, at 1737 (noting that after SLT, “mortality rates for pediatric patients have declined precipitously”); HASHIMOTO & EGHTEHAD, *supra* note 59, at 82; Moorlock et al., *supra* note 18, at 446 (noting that since the UK began splitting livers, “children now tend to have relatively short waiting times for liver transplants[.]”).
70. *Ethical Principles of Pediatric Organ Allocation*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethical-principles-of-pediatric-organ-allocation/> [<https://perma.cc/S7SZ-KYUX>] (last updated Nov. 2014); Herden et al., *supra* note 19, at 4 (noting that there is “a significantly better survival in children following [SLT] compared to adult recipients[.]”).

from a split liver transplant is not significantly different than for children receiving a WLT.<sup>71</sup>

## 2. Hemiliver SLT for Two Adult Patients

Although split liver transplants were successful in reducing pediatric mortality, adults on the liver transplant waiting list still suffered from the critical organ shortage.<sup>72</sup> Splitting an adult donor liver for a child and an adult did not increase the number of donor livers available for adults; it just ensured that assigning adult livers to children would not result in a net loss for adults on the waiting list.<sup>73</sup> However, if deceased donor livers could be split into two separate parts, each part suitable for an adult patient, this technique would expand the adult donor pool and help overcome the chronic donor liver shortage without having to resort to living donors.<sup>74</sup>

In 1988, Bismuth and his colleagues at Paul Brousse Hospital in France tried just that, splitting a donor liver for two adult recipients.<sup>75</sup> In May of that year, there were two women at the hospital suffering from liver failure, both of whom were in a coma and near death.<sup>76</sup> The liver of a 40-year-old man who was brain dead became available for transplant and was a suitable match for both patients.<sup>77</sup> Bismuth could not choose which of the two patients should receive the life-saving transplant so he decided to

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71. BOLTON, *supra* note 38, at 5; Collett, O'Neill, & Neuberger, *supra* note 53, at 220.
  72. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2072.
  73. Ge et al., *supra* note 65, at 1121 (noting that pediatric/adult SLT “does not ‘remove’ a liver for the adult waitlist pool, unless the secondary segment is discarded.”); Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2072 (explaining that pediatric/adult SLT “has successfully reduced mortality on the pediatric waiting list without compromising outcomes in adults”).
  74. Lauterio et al., *supra* note 12, at 11011.
  75. AP, *Health; Paris Surgeons Transplant Same Liver Into 2 Patients*, N.Y. TIMES, at 7 (May 12, 1988), <https://www.nytimes.com/1988/05/12/us/health-paris-surgeons-transplant-same-liver-into-2-patients.html> [<https://perma.cc/2CEL-Z9AZ>]; Lauterio et al., *supra* note 12, at 11004.
  76. Lauterio et al., *supra* note 12, at 11004.
  77. AP, *supra* note 75.

split the donor liver into two segments and transplant one segment into each of them.<sup>78</sup> “Because the liver is the only organ in the human body that can regenerate itself,” the hope was that each half would grow into a fully functioning liver within each patient.<sup>79</sup> After receiving the SLT, both of the women regained consciousness and normal liver function but unfortunately died within the following two months.<sup>80</sup> Both died from causes that were “not specifically related” to the SLT.<sup>81</sup>

Since this initial adult/adult SLT (now also known as hemiliver SLT), the methods for splitting a deceased donor liver to benefit two adult recipients have improved significantly.<sup>82</sup> The SLT procedure for adult patients (**Figure 1**) now entails creating two hemiliver grafts, the left lobe (which consists of segments I to IV, making up 30-40% of the liver) and the right lobe (which consists of segments V-VIII, making up 60-70% of the liver).<sup>83</sup> This technique “remains one of the few surgical options to expand the [adult] donor pool in view of the ongoing shortage of organs and the increasing waitlist mortality rates.”<sup>84</sup>

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78. *Id.*

79. *Id.*; Aparna R. Dalal, *Split Liver Transplantation: What’s Unique?*, 5 *WORLD J. TRANSPLANTATION* 89, 92 (2015) (“[SLT] is based on this unique ability of the liver to regenerate.”); Amelia J. Hessheimer et al., *Somatostatin and the “Small-for-Size Liver,”* 20 *INT’L J. MOLECULAR SCI.* 2512, 2512 (2019) (“When partially removed or damaged, the liver also has incredible potential for regrowth.”).

80. Lauterio et al., *supra* note 12, at 11004.

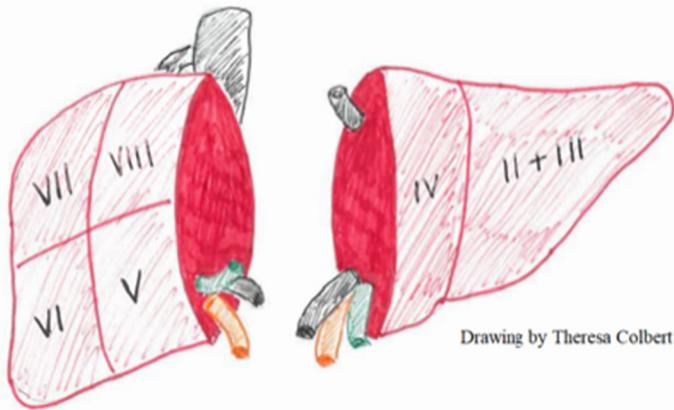
81. *Id.*

82. Hashimoto et al., *Split Liver Transplantation in Adults, supra* note 58, at 7501 (noting that “gains in knowledge have introduced the use of 2 hemiliver grafts . . .”).

83. HASHIMOTO & EGHTEHAD, *supra* note 59, at 82.

84. Lauterio et al., *supra* note 12, at 11004.

*Figure 1: Splitting a Liver for Hemiliver Transplantation*



Note: Segment I (posterior) is included in the left hemiliver for transplant purposes.

Unfortunately, although SLT is widely used for the combination of a pediatric and adult patient, SLT for two adult patients is rarely performed and is still considered controversial.<sup>85</sup> The main reasons for transplant centers' reluctance to use this technique include "technical, logistical, and ethical challenges."<sup>86</sup> For example, the technical complexity of hemiliver SLT can result in additional complications for recipients during and following surgery.<sup>87</sup> The logistical challenges result, in part, from the fact

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85. Herden et al., *supra* note 19, at 1; Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501 ("Although hemiliver SLT theoretically doubles the number of liver grafts for adults, this technique has been underutilized . . ."); Ge et al., *supra* note 65, at 1120 ("[In the U.S.] SLT is almost always initiated by allocation to a pediatric recipient (92%) . . .").

86. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501.

87. *E.g.*, James D. Perkins et al., *New Evidence Supporting Increased Use of Split Liver Transplantation*, 104 *TRANSPLANTATION* 299, 299 (2020) ("A meta-analysis revealed no difference in patient or graft survival, but more complications in using [split liver] grafts than whole liver grafts."); Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2072; *see* Chan et al., *supra* note 16, at 2 ("[S]plitting the liver during graft procurement is technically more challenging than transplanting the whole liver . . . [and] the many complications after [SLT] remain a matter of concern."); Herden et al., *supra* note

that SLT “requires maximum team effort in what is always an urgent situation.”<sup>88</sup> Once a donated liver is allocated to a particular patient, there is limited time to make the multiple assessments necessary to determine whether the organ is suitable for SLT.<sup>89</sup> Additionally, the MELD system requires that the sickest patients receive deceased donor livers first and these patients are generally not “the most suitable” for SLT.<sup>90</sup>

Despite these and other hurdles, the growing experience of transplant surgeons with performing SLT has resulted in improved surgical outcomes which, in turn, has resulted in a somewhat increased use of hemiliver transplants worldwide.<sup>91</sup> But more needs to be done.<sup>92</sup> While there are still challenges,<sup>93</sup> the rewards of making optimum use of hemiliver SLT are worth the

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19, at 6 (“[T]here are high overall complication rates described in patients undergoing full-split [liver transplants], with up to 64% grade III or IV postoperative complications.”).

88. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2072.
89. *Id.* (“During a short time period from organ allocation to transplant, a comprehensive assessment of graft-recipient selection is required in terms of graft quality, graft size, cold ischemia time, medical urgency and the severity of portal hypertension.”).
90. *Id.*
91. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501 (“Over time, [ ] technical advancements and better donor-recipient selection have led to more frequent use of SLT and better outcomes.”); Lauterio et al., *supra* note 12, at 11004 (noting the “promising results” of hemiliver SLT).
92. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2072 (noting that SLT is an “important technique” to “provide more opportunities to our adult-sized patients”); Anita Zimmerman et al., *Outcomes of Full-Right-Full-Left Split Liver Transplantation in Adults in USA: A Propensity-Score Matched Analysis*, 7 INT. J. ORGAN TRANSPLANT MED. 69, 74 (2016) (suggesting that “every effort should be made to improve the utilization and outcomes of SLT in adults”).
93. *See, e.g.*, Dong-Hwan Jung et al., *In Situ Split Liver Transplantation for Two Adult Recipients: A Single-Center Experience*, 22 ANNALS TRANSPLANTATION 230, 235 (2017) (noting that hemiliver SLT “remains challenging because it is associated with relatively poor outcomes, suboptimal graft condition, and technical difficulty”).

effort.<sup>94</sup> Greater use of SLT would result in a significant reduction in loss of life on the transplant waiting list.<sup>95</sup> Achieving this goal will require not just using current improved surgical techniques, but also better donor, recipient, and transplant center selection.<sup>96</sup>

*C. Selecting Donors, Recipients, and Transplant Centers*

Because SLT for two adults is associated with a greater risk of complications, the procedure is only recommended in limited situations.<sup>97</sup> Favorable results for this type of SLT depend on careful selection of donors and recipients, and surgeons who are experienced in adult/adult SLT.<sup>98</sup> Given appropriate selection, the outcomes for adult/adult SLT can be comparable to WLT.<sup>99</sup>

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94. Lauterio et al., *supra* note 12, at 11004 (explaining that SLT would “expand the donor pool in view of the ongoing shortage of organs and the increasing wait list mortality rates”); Sandy Feng et al., *Organ Donors with Positive Viral Serology or Malignancy: Risk of Disease Transmission by Transplantation*, 74 *TRANSPLANTATION* 1657 (2002) (“The risks of death and significant loss of quality of life while awaiting transplantation are increasingly recognized.”).
95. Ge et al., *supra* note 65, at 1121 (“[P]olicies to incentivize SLT in the United States could increase the number of pediatric and adult candidates transplanted and decrease deaths on the waiting list.”); Sasaki et al., *supra* note 13, at 750 (suggesting that “SLT can be the ideal procedure to improve the organ shortage in the United States”); HASHIMOTO & EGHTEHAD, *supra* note 59, at 82 (noting that hemiliver SLT “has shown a great success worldwide and could theoretically double the number of available organs . . .”).
96. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501 (noting that donor-recipient selection has played a role in “better outcomes” for SLT); Sasaki et al., *supra* note 13, at 750 (pointing out that SLT “is a hazardous procedure that demands the perfect combination of recipient/donor/transplant center factors”).
97. Jung et al., *supra* note 93, at 235 (“Splitting of the donor liver is only recommended in highly selected situations.”).
98. *Id.* at 239; Lauterio et al., *supra* note 12, at 11011 (“Favorable results with SLT depend . . . on scrupulous recipient and donor selection, and dedicated resources.”).
99. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7500 (“With favorable circumstances, outcomes of adult SLT can be comparable to [WLT].”); Bobbert, Primc, & Schafer, *supra* note 28, at 1 (“The question is no longer whether, but under what conditions SLT is able to achieve results similar to those of [a WLT].”).

The first step in successful hemiliver SLT is selection of an appropriate donor.<sup>100</sup> Because the current data indicates that recipients of adult/adult SLT are more likely to suffer post-transplant complications,<sup>101</sup> only the “best-quality” deceased donor livers are split for two adult recipients.<sup>102</sup> The livers are from younger donors, in part because the liver loses its ability to regenerate with aging.<sup>103</sup> The upper donor age limit for SLT is generally “considered to be between 40 and 50 years of age.”<sup>104</sup> Other important characteristics of the donor besides age include normal liver function, death by neurological as opposed to cardiocirculatory criteria, and short time in the intensive care unit (ICU) before death.<sup>105</sup> A study at the Cleveland Clinic found that

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100. Jung et al., *supra* note 93, at 231; Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7500 (“Careful donor selection through consideration of split graft quality are essential in adult SLT.”).
101. *See* Valentino et al., *supra* note 2, at 3121 (“SLT has been reported to be associated with increased risk of complications.”).
102. Collett, O’Neill, & Neuberger, *supra* note 53, at 218 (“Only optimal livers can safely be split and must be used for those recipients who are relatively fitter.”); *see also* Moorlock et al., *supra* note 18, at 436 (“[S]ome data suggest that the adult recipient in particular is at higher risk of post-transplant complications than if he or she received a whole liver” and that “[t]o mitigate these risks, only the best-quality livers are split.”).
103. Dalal, *supra* note 79, at 90 (“[A]cceptable donor age [for SLT] is usually less than 50 years [old]” because “[t]he liver’s regeneration capacity is compromised by aging.”).
104. Bobbert, Primc, & Schafer, *supra* note 28, at 2; Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501.
105. Moorlock et al., *supra* note 18, at 436 (2016) (noting that the “best-quality livers” are “from donors under 40 years who have died following brainstem death and who have had short ICU stays”); *see also* Bobbert, Primc, & Schafer, *supra* note 28, at 2–3 (noting that other donor factors mentioned as important for SLT include liver enzymes normal or mildly elevated, stable hemodynamics, normal gross appearance of the liver, short cold ischemia time, degree of portal hypertension, and low BMI.); Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2073; HASHIMOTO & EGHTEAD, *supra* note 59, at 82.

out of 1,089 deceased donor livers, only 137 were suitable for SLT or approximately 12.6%.<sup>106</sup>

Once a liver is determined to be suitable for splitting, it is vitally important to find recipients who are appropriate to receive the hemiliver grafts.<sup>107</sup> Patients who are critically ill are not ideal recipients for a partial liver graft because “they are less able to tolerate the more-frequent complications.”<sup>108</sup> Indeed, there is a general consensus that critically ill patients should not be selected for SLT because they do better with whole livers as opposed to hemiliver grafts.<sup>109</sup>

The fact that critically ill patients are generally not appropriate choices for hemiliver SLT makes routine use of this procedure controversial.<sup>110</sup> Under UNOS policy, the sickest patients – those with the highest MELD scores – should receive deceased donor livers first.<sup>111</sup> Thus, to make greater use of hemiliver SLT, this UNOS policy would have to be modified.<sup>112</sup>

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106. See HASHIMOTO & EGHTEAD, *supra* note 59, at 85; see also BOLTON, *supra* note 38, at 6 (noting that a “limited number of donated livers (more than 10% of all donated livers) . . . meet OPTN-specified criteria for splitting”); Roberta Angelico et al., *A National Mandatory-Split Liver Policy: A Report from the Italian Experience*, 19 AM J. TRANSPLANTATION 2029, 2030 (2019) (“[I]t is estimated that 20% of deceased donors meet [UNOS] guidelines for split livers.”).
107. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501; HASHIMOTO & EGHTEAD, *supra* note 59, at 85.
108. BOLTON, *supra* note 38, at 6; see also Shutang Feng et al., *Characteristics Associated with Liver Graft Failure: The Concept of a Donor Risk Index*, 6 AM. J. TRANSPLANTATION 783, 788 (2006) (“[C]andidates who are most ill may have disproportionately poorer outcomes with higher risk grafts.”).
109. Herden et al., *supra* note 19, at 7.
110. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7500.
111. *Id.* at 7504.
112. HASHIMOTO & EGHTEAD, *supra* note 59, at 84 (“Under the philosophy of the ‘sickest first’ MELD allocation, [livers suitable for splitting] are allocated to those recipients with a high MELD score who are generally unsuitable for SLT.”).

However, modifying UNOS policy might disadvantage those who are sickest<sup>113</sup> and would benefit most from a transplant.<sup>114</sup>

Not only must the recipient be healthy enough to receive an SLT, but the recipient must also be appropriately matched with the donor due to the potential for graft failure if the split graft is too small.<sup>115</sup> Adult recipients must have grafts that are sufficiently large to meet their metabolic demand.<sup>116</sup> A graft that is too small “can result in increased incidence of primary non-function or small-for-size graft syndrome.”<sup>117</sup> For this reason, smaller adults are generally more suitable to receive hemiliver grafts.<sup>118</sup>

In addition to having a donor liver and recipients that are suitable for SLT, the transplant center and surgeons must also be experienced in performing adult/adult SLT to achieve optimum results.<sup>119</sup> In general, “[t]he outcome of complex surgical

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113. BOLTON, *supra* note 38, at 8 (“[C]ritically ill patients . . . could . . . be disadvantaged if all donor livers meeting split criteria were primarily offered only as a split.”).
114. Feng et al., *supra* note 108, at 788 (“Candidates who are most ill face the greatest risk of death without transplantation and have the greatest survival benefit from transplantation.”).
115. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7500 (“[H]emiliver SLT requires stricter donor and recipient selection to prevent graft dysfunction associated with size-mismatch.”).
116. Jung et al., *supra* note 93, at 231.
117. *Id.*; Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7501 (“Hemiliver SLT for adult recipients carries the potential risk of graft failure due to size mismatch . . .”).
118. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2077 (noting that “hemiliver grafts were, in general, taken from larger donors and transplanted into smaller recipients” and that this pairing “appeared to be very helpful to avoid small-for-size syndrome”); Herden et al., *supra* note 19, at 6 (“ . . . only slight patients with less impaired liver function are suitable recipients for a [hemiliver] graft.”); Hessheimer et al., *supra* note 79, at 2512 (“Small-for-Size’ syndrome (SFSS) . . . is one of the most feared consequences of partial liver transplantation . . . [and] is associated with high morbidity and short-term mortality rates of up to 80%.”).
119. Bobbert, Primc, & Schafer, *supra* note 28, at 3 (“A lack of sufficiently trained surgical teams or logistical deficiencies can have negative impacts on the outcome of SLT . . .”); Lauterio et al., *supra* note 12, at 11007 (mentioning that SLT is “technically

interventions largely depends on surgical precision and the training of the attending surgeons,” and hemiliver SLT is no exception.<sup>120</sup> Both the recovery of the liver from the donor and the transplants into the recipients are more complex with SLT than with WLT and “requir[e] detailed knowledge of liver anatomy” and experience with SLT surgery.<sup>121</sup> The expertise of the donor surgical team is perhaps the most important not only because recovery and splitting of the organ involves technically-demanding and complex surgical skills,<sup>122</sup> but also because the team recovering the liver must understand the recipient’s situation “including body size, medical urgency, portal hypertension and surgical anatomy.”<sup>123</sup> The techniques for removing and splitting a donor liver vary<sup>124</sup> and knowledge about the recipient is essential to selecting the best splitting technique.<sup>125</sup> The recovery team should also minimize operating time to avoid reducing the quality of the graft by unnecessary delays and to allow other organs to be successfully retrieved from the deceased donor.

For successful hemiliver SLT, the surgeons also need the institutional resources of a transplant center that can support

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demanding” and “requires . . . significant infrastructure, logistical, and organizational changes . . .”).

120. Bobbert, Primc, & Schafer, *supra* note 28, at 3.
121. MILLER, *supra* note 1, at 2; Herden et al., *supra* note 19, at 8 (explaining that hemiliver SLT “remains a challenging technique taking a high complication risk.”).
122. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7503 (“SLT organ recovery requires highly complex surgical techniques.”).
123. *Id.*
124. MILLER, *supra* note 1, at 2 (“ . . . clinical decisions that must be coordinated between two transplant teams [include] deciding the splitting technique and how the blood supply and bile duct will be shared . . . ”); Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2072 (“[T]here is no consensus [in SLT] regarding the sharing pattern of critical vessels or the common bile duct.”); Vulchev et al., *supra* note 67, at 1739 (explaining that excellent communication is necessary between transplant centers “with regards to the planned technical aspects of the split”).
125. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7503.

them and help overcome the logistical and surgical hurdles inherent in SLT. For example, the transplant center must have the appropriate technical equipment to support the SLT team.<sup>126</sup> This includes having preoperative imaging equipment to estimate liver mass and anatomy so that the center can facilitate the best donor/recipient match.<sup>127</sup> In addition, if only one of the two SLT recipients is at the transplant center where the surgical team is based, the center must coordinate with another recipient hospital.<sup>128</sup> The two hospitals must also coordinate on the techniques to be used for removing and splitting the donor liver<sup>129</sup> because the ideal technique for the initial recipient may not be ideal for ensuring the best overall outcomes for both patients.<sup>130</sup> Coordination may take additional precious time if teams from both hospitals want to participate in the recovery of the liver from the donor.<sup>131</sup> If adequate coordination is lacking, not only may transplant outcomes be compromised, but the second liver segment may have to be discarded.<sup>132</sup> In addition, the transplant center must ensure that there is a viable back-up plan in place for both recipients in case the SLT has to be abandoned late in the process.<sup>133</sup> Unfortunately, despite its importance, the amount of cooperation between transplant centers varies considerably in the U.S.<sup>134</sup>

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126. Lauterio et al., *supra* note 12, at 11011–12 (“SLT often lacks the preoperative imaging essential for liver mass estimation and anatomical evaluation . . . in order to advance the best graft-to-recipient match.”).

127. *Id.* at 11008.

128. MILLER, *supra* note 1, at 2.

129. *Id.* (explaining that transplant teams must coordinate “who has priority in deciding the splitting technique”).

130. *Id.*

131. *Id.* (“It is likely that the transplant teams from both hospitals will want to participate in the recovery . . .”).

132. Bobbert, Primc, & Schafer, *supra* note 28, at 3 (“[L]ogistical deficiencies can have negative impacts on the outcome of SLT or provoke the loss of the second split.”).

133. MILLER, *supra* note 1, at 2.

134. James D. Perkins et al., *New Evidence Supporting Increased Use of Split Liver Transplantation*, 104 *TRANSPLANTATION* 299–307 (2019) (highlighting the need for greater cooperation between transplant centers to manage cold ischemic time when sharing

Not only do transplant centers need to support their surgeons by addressing the technical and logistical concerns necessary for optimal SLT success, but they should also ensure that the surgeons have adequate expertise and training.<sup>135</sup> Research studies suggest that significant improvements in outcomes can be achieved once the surgical teams have performed 20 to 50 split liver surgeries.<sup>136</sup> On the other hand, inadequate training can lead to negative patient outcomes or loss of the second graft.<sup>137</sup> Indeed, lack of surgeon experience may be an important reason why only 54 out of 147 active liver transplant programs performed any SLT in 2017,<sup>138</sup> and why only approximately one percent of deceased donor livers in the U.S. are used for SLT.<sup>139</sup>

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livers). For an illustration of how the degree of collaboration between centers has historically varied, *see, e.g.*, Timothy C. Lee et al., Split-Liver Transplantation Using the Left Lateral Segment: A Collaborative Sharing Experience Between Two Distant Centers, 5 AM. J. TRANSPLANTATION 1646–51 (2005). For a more recent picture, *see* ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, *OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary* (Jan. 7, 2022), [https://optn.transplant.hrsa.gov/media/pzgd3d1s/20220107\\_liver\\_summary.pdf](https://optn.transplant.hrsa.gov/media/pzgd3d1s/20220107_liver_summary.pdf) [<https://perma.cc/3QSF-ULC3>] (describing two separate organized split-liver programs within the U.S. OPTN, one limited to geographic Region 8 and one that is characterized as “open”). These “variances” are also discussed at *infra* note 177.

135. Goldaracena et al., *Expanding the Donor Pool for Liver Transplantation with Marginal Donors*, 82 INT’L J. SURGERY 30, 33 (2020) (“Only experienced liver surgeons should perform SLT.”); Lauterio et al., *supra* note 12, at 11012 (“Dedicated resources and incentives must be made available to implement programs and facilitate surgeon recruitment and training . . .”).
136. Bobbert, Primc, & Schafer, *supra* note 28, at 3 (“A cross-center study suggests that a significant improvement in outcome is achieved as soon as the surgical team has carried out 30-50 SLTs.”); Perkins et al., *supra* note 87, at 306 (“Our data suggest that a guideline for programs is to obtain experience with approximately 20 split grafts over a few years to achieve better graft survival.”).
137. Bobbert, Primc, & Schafer, *supra* note 28, at 3.
138. MILLER, *supra* note 1, at 2; BOLTON, *supra* note 38, at 6 (“[V]ery few centers have consistently performed [SLT] over the past decade.”); Herden et al., *supra* note 19, at 8 (emphasizing that adult/adult SLT “remains a rare procedure restricted to experienced liver transplant centers”).
139. A.J. Kwong et al., *OPTN/SRTR 2019 Annual Data Report: Liver*, 21 AM. J. TRANSPLANTATION (SPECIAL ISSUE 2) 1, 6 (“In

D. *The UNOS Allocation Process for SLT*

Although careful donor, recipient, surgeon, and transplant center selections produce optimal hemiliver SLT results, UNOS policy undermines ideal donor/recipient selection. Under UNOS policy, organ allocation begins when a deceased donor liver becomes available.<sup>140</sup> At that time, the OPTN generates a list of candidates who are eligible to receive the organ. “[T]his list is referred to as a match run.”<sup>141</sup> With limited exceptions, the top candidates on the list are located within the same geographical area as the donor and are selected based on MELD score and blood type.<sup>142</sup> Approximately 70% of the time, the donated liver is allocated to one of the top three individuals on the match run.<sup>143</sup> These three candidates will usually have a high MELD score and be critically ill.<sup>144</sup>

UNOS policies generally limit SLT because critically ill patients are not the best choices for SLT.<sup>145</sup> In addition, the OPTN uses UNOS criteria to identify donor livers that are suitable for splitting.<sup>146</sup> However, the actual decision about whether to split is made by the organ recipient’s physician.<sup>147</sup>

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2019, . . . [o]f all liver transplants . . . [t]here were 96 split livers (1.2%), unchanged from previous years.”); Ge et al., *supra* note 65, at 1123 (noting that between 2015 and 2018, only 4.3% of the deceased donor livers that met the “optimal split criteria” were actually split”).

140. See Nephew et al., *supra* note 49, at 1286.

141. *Id.*

142. *Id.*

143. *Id.*

144. Lauterio et al., *supra* note 12, at 11010 (“In a MELD-based allocation policy, one of the [SLT] grafts was allocated to the first priority patient in the waiting list with the highest MELD score”). For a more detailed account of how livers are offered and accepted for patients in ranked order, see notes 359–361 and accompanying text.

145. See Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2079 (questioning “how to safely expand the utilization of [hemiliver SLT], especially where the ‘sickest first’ MELD system regulates organ allocation”).

146. See MILLER, *supra* note 1, at 1.

147. Emily R. Perito et al., *Split Liver Transplantation and Pediatric Waitlist Mortality in the United States: Potential for Improvement*,

Physicians owe a fiduciary duty to their patients and, thus, focus on the best outcome for each individual patient rather than on the optimal outcome for liver transplant patients as a whole.<sup>148</sup> Because patients risk additional complications if they receive a split liver graft,<sup>149</sup> physicians rarely choose hemiliver transplantation for their patients except when the whole donor liver is too large for the transplant recipient.<sup>150</sup> In those rare cases where the physician agrees to split, the secondary graft will be allocated to a size-matched recipient,<sup>151</sup> commonly a smaller individual.<sup>152</sup>

### *E. The Future of SLT*

The question remains whether it is better to use SLT to provide a larger number of transplants or to limit adult/adult SLT so that those transplants that are performed yield the best results.<sup>153</sup> In reaching an answer to this question, it is important to consider the increased risk of death, deterioration of the

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103(3) TRANSPLANTATION 552, 556 (2019) (“Currently, the decision to split a liver is made at organ allocation by an individual provider for an individual patient.”); Nephew et al., *supra* note 49, at 1287 (“An organ offer can be declined by the patient and/or the transplant team.”).

148. Ahearn, *supra* note 33, at 128–29 (noting that selecting SLT creates a conflict of interest for the recipient’s physician because “what’s optimal for society . . . might not be what’s best for the [individual] patient”).
149. Valentino et al., *supra* note 2, at 3121 (explaining that because SLT “has been reported to be associated with increased risk of complications . . . when faced with an offer of a whole organ for an adult patient, the transplant team may rightfully choose to advocate for their patient and accept the entire graft”).
150. Perito et al., *supra* note 147, at 556 (“Almost all [SLT] in the US occur[s] when the primary recipient is too small for the entire allocated liver.”).
151. Lauterio et al., *supra* note 12, at 11010.
152. Ge et al., *supra* note 65, at 1121 (noting that “secondary splits largely benefit smaller adults”); Jung et al., *supra* note 93, at 231 (noting that “most of the secondary recipient candidates . . . had small body size”).
153. Moorlock et al., *supra* note 18, at 436; see Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7504.

patient's condition,<sup>154</sup> and “considerable mortality from advanced liver disease”<sup>155</sup> as patients wait for a liver transplant. Moreover, with growing experience and improved surgical techniques, survival rates for those receiving partial grafts have been similar to survival for those receiving WLTs.<sup>156</sup> While SLT patients do have a greater risk of serious complications that “require hospitalization and invasive procedures,” those complications “are largely treatable.”<sup>157</sup> Current studies indicate that SLT is worth the additional risk of complications because splitting livers provides greater net survival for those on the liver transplant waiting list by providing more opportunities for life-saving transplants.<sup>158</sup>

While the procedural and logistical challenges inherent in SLT persist – it is technically complex, adds ischemic time, and carries an increased risk of complications<sup>159</sup> – as surgical experience with hemiliver transplants grows, outcomes should improve even further.<sup>160</sup> But to realize the full benefits of adult/adult SLT, the “culture of using SLT needs to be fostered along with trust and collaboration between transplant centers and support from organ procurement organizations and UNOS.”<sup>161</sup> To

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154. Collet et al., *supra* note 53, at 218 (noting that waiting time increases “the risk of death on or removal from the transplant list”).

155. Wahid et al., *supra* note 29, at 434.

156. Valentino et al., *supra* note 2, at 3121 (“Transplant outcomes . . . have repeatedly demonstrated similar survival rates between SLT and [WLTs] in recent eras.”).

157. Perito et al., *supra* note 147, at 557.

158. Moorlock et al., *supra* note 18, at 436 (“Current data suggest that [SLT] provides overall benefit to the liver-recipient population.”); Valentino et al., *supra* note 2, at 3121 (“[A]dult mortality on the waitlist can . . . be reduced with increased SLT use . . . .”); see Chan et al., *supra* note 16, at 7–8 (“The comparison of survival curves showed that [SLT] remarkably provided a survival benefit . . . .” over those who waited for a [WLT]).

159. Perito et al., *supra* note 147, at 554–55.

160. See Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7504 (“As experience has grown worldwide, resulting in technical advancements and better donor-recipient matching, [SLT] has become more feasible and has achieved excellent outcomes”).

161. Valentino et al., *supra* note 2, at 3122.

foster this trust, the ethical and legal concerns with SLT also need to be addressed,<sup>162</sup> which are the focus of this article.

### III. INFORMED CONSENT

While informed consent is both ethically and legally required before any surgical procedure can be performed on a patient, SLT presents unique challenges. Splitting a liver for transplantation is a complex medical procedure requiring substantial expertise. This complexity raises concerns about whether a physician's degree of experience with SLT must be disclosed to a patient prior to obtaining informed consent, whether patients are capable of understanding enough about receiving a split, rather than whole, liver to make an informed choice, and whether informed consent for SLT must be obtained at more than one particular time during the transplant process.

#### A. *The Legal and Ethical Foundations for the Doctrine of Informed Consent*

Informed consent is intended to safeguard an individual's autonomy.<sup>163</sup> As Justice Benjamin Cardozo famously wrote in *Schloendorff v. Society of New York Hospitals*, “[e]very human being of adult years and sound mind has the right to determine what shall be done with his own body; and a person who performs an operation without his patient's consent commits an assault for which he is liable in damages.”<sup>164</sup> Soon after Justice Cardozo's

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162. See Moorlock et al., *supra* note 18, at 436 (“[E]thical concerns need to be explored and addressed if they are posing an unnecessary barrier to further increasing the number of life-saving transplantations.”).

163. See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 101 (7th ed. 2013) (“The autonomous individual acts freely in accordance with a self-chosen plan . . . .”); Michael Flynn, *Informed Consent: Does “OK” Really Mean “OK”*, 16 J. HEALTH & BIOMEDICAL L. 29, 30 (2019) (“[Informed consent] allows the patient to retain their autonomy in health care decisions and reinforces the legal principle of an individual's right to choose.”).

164. *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914); see *Matter of Conroy*, 98 N.J. 321, 486 A.2d 1209, 1222 (N.J. 1985) (“The doctrine of informed consent is the primary means developed in law to protect [the] personal interest in the integrity of one's body.”).

decision, U.S. courts universally accepted that physicians can be held liable for failing to obtain a patient's consent to the medical procedure performed.<sup>165</sup>

While the *Schoendorff* decision required patient consent, the first significant case to require "informed consent" was *Salgo v. Leland Stanford Junior University Board of Trustees*, decided in 1957.<sup>166</sup> In that case, the court mandated that physicians disclose "any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."<sup>167</sup> This expansion of the consent requirement further protected individual autonomy by ensuring that patients have sufficient information to knowledgeably evaluate a medical procedure before giving consent.<sup>168</sup> The mandate is based on the premise that individuals cannot meaningfully exercise their autonomy without understanding the risks and alternatives to a recommended medical procedure.<sup>169</sup> Indeed, the value of this information to the patient is considered so important that informed consent is now required in all fifty states by statutory or common law.<sup>170</sup>

Not only do physicians have a legal obligation to obtain informed consent from a patient, but they also have an ethical

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165. Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 703 (2012).

166. *Id.* at 705.

167. *Salgo v. Leland Stanford Junior Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957).

168. *See Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972); Derek Samz, *Face/Off: The Struggle Between Informed Consent and Patient Welfare in Facial Transplant Surgery*, 2007 U. ILL. J. L. TECH. & POL'Y 89, 91 (2007) ("The doctrine of informed consent functions to promote individual autonomy and encourage rational decision making in situations where the patient does not have the expertise necessary to determine his or her own course of treatment.").

169. *See Conroy*, 98 N.J. 32, 486 A.2d at 1222 ("The doctrine of informed consent presupposes that the plaintiff has the information necessary to evaluate the risks and benefits of all the available options and is competent to do so."); *id.* at 780 ("[The] right [of self-decision] can be effectively exercised only if the patient possesses enough information to enable an intelligent choice . . .").

170. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 167, at 706; Flynn, *supra* note 163, at 30.

obligation.<sup>171</sup> While both the legal and medical ethics requirements are based on respect for autonomy, a physician's ethical disclosure obligation is potentially broader than the legal mandate.<sup>172</sup> The American Medical Association (AMA) detailed the physician's ethical disclosure requirement explaining that "[t]he patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice . . . . Physicians should sensitively and respectfully disclose all relevant information to patients."<sup>173</sup>

### B. Traditional Disclosure Requirements

To comply with informed consent requirements, physicians must disclose the nature and purpose of the recommended medical treatment or procedure, the risks and alternatives, and the consequences if the medical treatment or procedure is not performed.<sup>174</sup> Although these specifications may at first seem straightforward, there can be many risks inherent in a medical procedure that are very unlikely to occur and many options that are clearly inadvisable.<sup>175</sup> Giving patients too much information may be overwhelming and obscure the information that is important to the patient in making an informed decision.<sup>176</sup> For

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171. BEAUCHAMP & CHILDRESS, *supra* note 163, at 101 ("The principle of respect for autonomous choices of persons runs as deep as the common morality as any principle.").

172. See I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, 108 GEO. L. J. 1425, 1452 (2020) ("[I]n many instances, it is not legally actionable to fail to make the disclosures that medical ethics would impose on physicians.").

173. AM. MED. ASS'N COUNCIL ON ETHICAL AND JUD. AFF., *Opinion 8.08 – Informed Consent*, <https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-informing-patients/2012-07> [<https://perma.cc/Z6R9-QNNV>] (last visited Oct. 19, 2022).

174. See *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 78–79 (N.J. 2002); *Duffy v. Flagg*, 905 A.2d 15, 20 (Conn. 2006).

175. *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir., 1972) ("It seems obviously prohibitive and unrealistic to expect physicians to discuss with their patients every risk of proposed treatment – no matter how small or remote – and generally unnecessary from the patient's viewpoint as well.").

176. *Duffy*, 905 A.2d at 23 ("[P]atients . . . would be burdened with immaterial information that many might find confusing" if "physicians would lack a clear understanding of the scope of

this reason, the courts use one of two rules – the physician-based standard or the patient-based standard – for determining when medical information needs to be disclosed.<sup>177</sup> U.S. states are approximately evenly divided in which rule they use.<sup>178</sup>

The physician-based standard, also known as the professional standard, was prevalent when informed consent first became a legal requirement.<sup>179</sup> Under this standard, a physician must disclose only the medical information that a reasonable physician in the same or similar community would disclose under similar circumstances.<sup>180</sup> This standard has been criticized because it gives “virtually unlimited discretion to the medical community to define the proper scope of disclosure.”<sup>181</sup>

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disclosure.”); *Canterbury*, 464 F.2d at 786 (“[T]he cases speaking in terms of ‘full’ disclosure appear to envision something less than total disclosure, leaving unanswered the question of just how much.”); Cohen, *supra* note 172, at 1453 (“[M]any believe that [‘]overdisclosure’ makes it difficult for patients to distinguish meaningful risks from trivial ones . . .”).

177. See Cohen, *supra* note 172, at 1468.
178. *Id.* at 1432–33; see Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 736.
179. Bryan Murray, *Informed Consent: What Must a Physician Disclose?*, AM. MED. ASS’N J. ETHICS 563, 563 (July 2012), <https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/hlaw1-1207.pdf> [<https://perma.cc/62SF-TAXA>] (“Traditionally, courts held that a physician’s duty to disclose information to the patient depended upon community disclosure standards—whether the majority of physicians within a particular community would customarily make such a disclosure.”); Cohen, *supra* note 172, at 1433 (“The physician-based standard . . . was more dominant in the early days of the doctrine [of informed consent].”); Zachery R. Paterick, Timothy Edward Paterick, & Barb Block Paterick, *Medical Informed Choice: Understanding the Element of Time to Meet the Standard of Care for Valid Informed Consent*, 96 POSTGRAD MED. J. 708, 710 (2020).
180. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 736; see Cohen, *supra* note 172, at 1442.
181. R. Jason Richards, *How We Got Where We Are: A Look at Informed Consent in Colorado – Past, Present, and Future*, 26 N. ILL. U. L. REV. 69, 97 (2005); *Scott v. Bradford*, 606 P.2d 554, 557 (Okla. 1979) (“[The professional standard would] perpetuate medical paternalism by giving the profession sweeping authority to decide unilaterally what is in the patient’s best interests.”).

To remedy this concern, approximately half the states decided to follow the more modern approach of using a patient-centered standard.<sup>182</sup> Under this approach, physicians must disclose information that a reasonable patient would consider material in choosing whether or not to undergo a particular treatment or procedure.<sup>183</sup> Materiality is defined as “information which the physician knows or should know would be regarded as significant by a reasonable person in the patient’s position . . . .”<sup>184</sup> This standard is objective – based on a reasonable person, rather than a specific patient<sup>185</sup> – to ensure that physicians can meet the disclosure standard without having to know the particular concerns of each individual patient.<sup>186</sup> “Thus, the physician-centered standard focuses on what the reasonable physician would disclose, while the patient-centered standard focuses on what the reasonable patient would want to know.”<sup>187</sup> Because the patient-centered standard approaches informed consent from the viewpoint of the patient, it is “more aligned with protecting patient autonomy.”<sup>188</sup>

*C. Current Law Regarding the Obligation of Physicians and Transplant Centers to Disclose Their Expertise with SLT*

Under both the physician-centered and patient-centered approaches, it would appear that physicians and transplant

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182. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 737.

183. Cohen, *supra* note 172, at 1443; *see* Andersen v. Khanna, 913 N.W.2d 526, 537 (Iowa 2018).

184. *See* Wheeldon v. Madison, 374 N.W.2d 367, 371-72 (S.D. 1985) (approving this construction of “materiality”).

185. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 739 (explaining that both the physician-centered and patient-centered disclosure standards “are objective and neither considers the needs and preferences of the individual patient”); *Duffy*, 905 A.2d at 20 (Conn. 2006) (“Our standard of disclosure for informed consent in this state is an objective standard that does not vary from patient to patient based on what the patient asks or what the patient would do with the information if it was disclosed.”).

186. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 739–40.

187. *Id.* at 738.

188. *Id.*

centers should be required to disclose their expertise regarding SLT because physician experience has a substantial effect on patient outcomes.<sup>189</sup> Due to the impact of experience on outcomes, a reasonable patient would find a physician's experience performing SLT material in choosing whether to accept a partial liver transplant from a particular surgeon, and reasonable physicians should customarily disclose their experience to patients because of its relevance and importance to the patient in choosing SLT.

However, with few exceptions, American courts do not require physicians to disclose their qualifications or experience.<sup>190</sup> The justification for this position is that only information directly relating to the medical treatment or procedure itself is material, not provider-specific information.<sup>191</sup> The AMA guidelines currently support this interpretation of the requirements for informed consent. The AMA's ethical guidance states that physicians' informed consent obligations are to "present the medical facts . . . and . . . make recommendations . . . in accordance with good medical practice."<sup>192</sup> Facts regarding physician characteristics, credentials, or experience are not included in the AMA's guidance.<sup>193</sup>

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189. See Bobbert, Primc, & Schafer, *supra* note 28, at 3.

190. Nadia Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 U. ILL. L. REV. 821, 833 (2016) ("[W]ith very rare exceptions, the physician's duty only extends to disclosure of medically material facts – not other types of information that may nevertheless be relevant to a patient's choice."); Cohen, *supra* note 172, at 1433 ("The substantial majority of courts have rejected the notion that failure to disclose the physician's experience or qualification breaches the duty of informed consent on the theory that only information about the procedure itself is material."); Flynn, *supra* note 163, at 42 ("[P]hysician disclosure under most informed consent laws appears limited to issues concerning medical treatment itself.").

191. See Sawicki, *supra* note 190, at 838; Howard v. Univ. of Med. & Dentistry of N.J., 800 A.2d 73, 84 (N.J. 2002) ("[P]hysician experience is not information that directly relates to the procedure itself [and so is not an] area[ ] of required medical disclosure concerning the procedure.").

192. AM. MED. ASS'N COUNCIL ON ETHICAL AND JUD. AFF., *supra* note 173.

193. See Sawicki, *supra* note 190, at 834.

Courts and scholars have focused on two major policy arguments to support limiting informed consent liability to failure to disclose information about a medical treatment or procedure and excluding physician qualifications and experience. The first is that medical risks are inherent in the medical procedure itself, while physician characteristics are risks that the individual physician brings into the treatment or procedure.<sup>194</sup> If disclosure of a physician's experience is required before obtaining informed consent, then, arguably, there is no logical basis for excluding other personal physician characteristics that may be material to patients in deciding whether to proceed with medical treatment.<sup>195</sup> For example, physicians might be required to disclose relevant disabilities, personal habits, religious beliefs, recent personal trauma such as a death in the family or divorce, and mental health issues, including alcoholism and addiction.<sup>196</sup> Patients might even find how much sleep the physician had the night before and the physician's medical school grades material in choosing whether to undergo a medical treatment.<sup>197</sup> Disclosing these types of personal information may be unduly burdensome<sup>198</sup> and also violate physicians' personal privacy with uncertain or minimal patient benefit.<sup>199</sup>

On the other hand, there is a strong argument that a physician's credentials and experience are more directly related

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194. See Ashley H. Wiltbank, *Informed Consent and Physician Inexperience: A Prescription for Liability?*, 42 WILLAMETTE L. REV. 563, 580 (2006) (noting that Washington and Texas "attempt to separate those risks that are a part of the surgery and cannot be avoided (i.e. inherent or primary risks) from those risks that the medical provider adds to the surgery through human intervention (i.e. acquired or secondary risks).").

195. *Whiteside v. Lukson*, 947 P.2d 1263, 1265 (Wash. Ct. App. 1997) ("In theory, the physician's own health, financial situation, even medical school grades, could be considered material facts a patient would want to consider in consenting to treatment by that physician.").

196. Sawicki, *supra* note 190, at 863; Flynn, *supra* note 163, at 50.

197. Sawicki, *supra* note 190, at 863.

198. See *id.* (noting that critics are likely to argue that disclosing physicians' personal characteristics renders informed consent too broad).

199. See *id.* ("Some facts that are uniquely known to the physician may be deemed too personal for disclosure.").

to the physician's medical practice than other types of personal information.<sup>200</sup> But requiring a physician to disclose their experience in performing a recommended medical procedure to a patient presents its own concerns. Some commentators have argued that if physicians must disclose their experience level, patients “may flock to more experienced physicians, who will [then] have heavy patient loads.”<sup>201</sup> Meanwhile, inexperienced physicians may not have enough patients to gain the expertise necessary to practice in their chosen medical fields.<sup>202</sup> This may negatively impact the healthcare system as a whole because newer medical providers will be unable to obtain the knowledge and experience they need to provide quality care.<sup>203</sup>

Despite these concerns, we recommend that only experienced transplant centers and physicians perform SLT. Physicians not affiliated with an experienced transplant center should disclose their inexperience to patients considering partial liver transplants and refer them to an appropriate center for SLT. Inexperienced physicians at transplant centers specializing in SLT can gain the training and experience they need by working with physicians who are experts in their field.<sup>204</sup> Patients at these centers can be told that trainees will be present and actively participate during the removal of the liver from the donor and/or during transplantation.<sup>205</sup> However, they should also be informed that

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200. Whether personal characteristics of the physician other than experience should be disclosed is beyond the scope of this article. *Id.* (“[I]nformation about experience levels or success rates with a particular procedure may be understood as more directly related to the physician’s medical practice.”).

201. *Id.* at 864.

202. *See id.*

203. *Id.* (explaining that requiring disclosure of experience “will make it difficult for newer providers . . . to develop their knowledge and ultimately may result in fewer experienced physicians overall . . .”).

204. *See Andersen v. Khanna*, 913 N.W.2d 526, 541 (Iowa 2018) (“[R]equiring physicians to disclose their experience will encourage physicians to gain as much training and experience with the procedure as possible.”).

205. *See Wiltbank*, *supra* note 194, at 582.

experienced physicians will directly supervise, and actively participate in, the medical procedures to assure patients' safety.<sup>206</sup>

1. Case Law and Commentary Supporting Physician Disclosure of Expertise for SLT

While most American courts do not require physicians to disclose their experience with a particular medical procedure before receiving informed consent from a patient,<sup>207</sup> there is some strong ethical and legal support for our recommendation that physicians be required to disclose their expertise with SLT before receiving patient consent to a partial liver transplant. For example, case law and commentary relating to malpractice support imposing an obligation on physicians to disclose the alternative of SLT to all patients who would benefit from the procedure and refer them to a qualified care center with physicians who are experts in the field. Physicians may be held liable for malpractice if they fail to refer a patient to a specialist in a particular procedure when a referral would have improved the patient's chances of a favorable outcome.<sup>208</sup> In addition, the OPTN/Ethics Committee directly addressed SLT by issuing an opinion explicitly recommending that "informed consent should incorporate information about the national and the [transplant] center's experience and outcomes with liver splitting."<sup>209</sup> Most directly on point, a handful of courts have held that a provider's qualifications and experience should be disclosed,<sup>210</sup> particularly

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206. *See id.*

207. *See* Sawicki, *supra* note 190, at 838.

208. *See* DAN B. DOBBS ET AL., *Specialists and Different Schools of Medicine: Duty to Refer*, in THE LAW OF TORTS § 299 (2d ed. 2021) ("Medical doctors are generally under a duty to use reasonable care to . . . refer a patient to a specialist when the physician knows or should know treatment . . . is beyond his competency or that specialist care is needed."); BARRY A. LINDAHL, *Duty of Physician – Specific Duties – Referral*, MODERN TORT LAW: LIABILITY AND LITIGATION § 24:19 (2d ed. 2021) ("A physician has a duty to advise the patient to consult a specialist, or one qualified in a method or treatment which the physician is not competent to give, if the patient might enjoy better results by such referral.").

209. BOLTON, *supra* note 38, at 9.

210. Flynn, *supra* note 163, at 43 ("Some jurisdictions have started to recognize that doctors should reveal their own inexperience as part of obtaining informed consent.").

where there is evidence that lack of experience may lead to a significantly increased risk of injury related to the medical procedure.<sup>211</sup>

For example, in *Johnson v. Kokemoor*, the Supreme Court of Wisconsin held that a physician should have disclosed his lack of experience performing a complex surgical procedure because the surgical outcomes were significantly better when the procedure was performed by more experienced physicians at a well-equipped tertiary care center.<sup>212</sup> In that case, a physician failed to disclose his lack of experience with basilar bifurcation aneurysm surgery and his patient was rendered an incomplete quadriplegic after that surgery was performed.<sup>213</sup> At trial, the patient introduced evidence showing that basilar bifurcation aneurysm surgery is “among the most difficult [to perform] in all of neurosurgery”<sup>214</sup> and that the morbidity and mortality rates for experienced surgeons is approximately 15 percent, while for physicians with limited experience, those rates are close to 30 percent.<sup>215</sup> After reviewing the evidence, the Wisconsin Supreme Court held that “a reasonable person in plaintiff’s position would have considered [the physician’s experience level, the comparative risks to those with more experience, and the availability of a tertiary care center staffed with more experienced physicians in performing the same surgery] material in making an intelligent and informed decision about the surgery.”<sup>216</sup> The court further held that failure to disclose this information affected the patient’s evaluation of the viable alternatives, i.e. whether to choose surgery with the defendant or with a more experienced physician at a tertiary care center.<sup>217</sup>

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211. See Sawicki, *supra* note 190, at 841.

212. *Johnson*, 545 N.W.2d at 509 (“Articles from the medical literature introduced by the plaintiff also stated categorically that the surgery at issue should be performed at a tertiary care center . . . because of ‘the limited experience’ and lack of proper equipment and facilities available in [the community setting].”).

213. *Id.* at 499.

214. *Id.* at 505.

215. *Id.* at 506.

216. *Id.* at 505.

217. *Id.* at 497–98.

Similarly, in *Andersen v. Khanna*, the Supreme Court of Iowa relied on the difficulty in performing a surgical procedure, and the improved success rates when surgeons are experienced in performing that procedure, when it held that the defendant physician had an obligation to disclose his lack of experience before obtaining informed consent from his patient.<sup>218</sup> In that case, the defendant physician failed to disclose his limited experience in performing a Bentall heart procedure.<sup>219</sup> After he performed the procedure, plaintiff had to undergo a second heart surgery and eventually a heart transplant.<sup>220</sup> At trial, plaintiff presented evidence that the Bentall procedure is “very complicated . . . [and] . . . harder to perform than a heart transplant”<sup>221</sup> and the defendant’s “lack of experience and training on this Bentall procedure increased the odds of serious complications.”<sup>222</sup> In holding in favor of the plaintiff, the Iowa Supreme Court wrote, “[i]t is reasonable that anyone undergoing such a procedure would want to know his or her physician’s experience or training, or lack thereof, before consenting to such a procedure by that physician.”<sup>223</sup>

These cases strongly support requiring physicians who recommend SLT to disclose their inexperience with SLT and inform patients of qualified transplant centers staffed with physicians who are expert in the procedure. Research confirms that experienced surgical teams are likely to have significantly better outcomes with SLT and qualified care centers specializing in SLT are better equipped to handle split liver transplants than transplant centers that only occasionally perform SLT.<sup>224</sup> Requiring disclosure of physician experience with respect to complex procedures like SLT, where studies demonstrate that experience affects outcomes, would be a limited exception to the general rule that physician-specific information need not be

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218. *See Andersen v. Khanna*, 913 N.W.2d 526, 526 (Iowa 2018).

219. *Id.* at 531.

220. *Id.* at 530.

221. *Id.* at 542.

222. *Id.* at 541.

223. *Id.* at 542.

224. Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58.

disclosed.<sup>225</sup> In most cases, it would be difficult for a plaintiff to prove that a physician's experience level would be material to the reasonable person in deciding whether to undergo a particular medical procedure.<sup>226</sup>

2. Other Legal Issues Related to Holding Physicians Liable for Failing to Disclose Lack of Experience

The causation elements of informed consent also limit physicians' liability for failing to disclose their credentials or experience with a particular procedure. To succeed on an informed consent claim, the plaintiff must not only prove that the disclosure of information was inadequate, but also that the physician's failure to disclose the information would have caused a reasonable patient in the plaintiff's position to consent to a medical procedure that the reasonable patient would otherwise have refused.<sup>227</sup> This is called decision causation. Decision causation only establishes that the physician's failure to disclose material information would have caused a reasonable patient to consent to the medical procedure, but does not prove that the physician's inadequate disclosure caused any injury.<sup>228</sup> Therefore, in addition to establishing decision causation, the plaintiff must also prove that the undisclosed risk materialized,<sup>229</sup> resulting in

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225. See *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 84 (N.J. 2002) (noting that, in most cases, a physician's experience or credentials will not "be a material element affecting the risk of undertaking a specific procedure.").

226. *Id.*

227. See *Sawicki*, *supra* note 190, at 866; *id.* at 79; Tenenbaum, *supra* note 167, at 716 (pointing out that four states follow a subjective, rather than an objective, decision causation approach). Virginia's intermediate appellate court recently held that Virginia would also follow a subjective decision causation approach, becoming the fifth state to do so. *Pergolizzi v. Bowman*, 76 Va. App. 310, 323-33 (Dec. 29, 2022) (noting that "how a plaintiff proves proximate causation in an informed consent claim is a matter of first impression in Virginia" and holding that "the subjective approach better fits the basic principles of Virginia tort law").

228. See *id.* at 711.

229. See *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972) ("An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence."); *Andersen v. Khanna*, 913 N.W.2d

injury.<sup>230</sup> This is called injury causation. Both of these elements may present problems for the plaintiff-patient in an informed consent action based on failure to disclose lack of experience because experience is based on the personal characteristics of the physician, rather than on the risks inherent in the medical procedure itself.<sup>231</sup>

A plaintiff can only prove decision causation by presenting evidence that the physician's lack of experience created a significantly increased risk to the patient in undergoing the medical procedure. Otherwise, a reasonable patient would not be influenced to refuse a surgery based on the physician's experience level.<sup>232</sup> Although this aspect of informed consent would be difficult to prove in many informed consent cases based on lack of experience, it would not be a significant hurdle in a case involving SLT because there is research confirming that experienced surgical teams are likely to have significantly better outcomes.<sup>233</sup>

On the other hand, the plaintiff in an SLT case may have difficulty proving injury causation. For injury causation, most jurisdictions require that plaintiff prove the undisclosed risk that the physician should have revealed actually materialized.<sup>234</sup> It is unclear how provider-specific risks like experience would manifest themselves as compensable injuries as opposed to risks inherent in the medical procedure itself.<sup>235</sup> For example, if a physician fails to disclose that a medical procedure carries a significant risk of paralysis and the patient suffers paralysis from the procedure, it is clear that the undisclosed medical risk materialized. However,

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526, 546 (Iowa 2018) (“Some jurisdictions require the undisclosed risk to materialize . . .”).

230. See Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 711.

231. See *id.* at 709–11.

232. *Canterbury*, 464 F.2d at 790 (“A causal connection exists when, but only when, disclosure of significant risks incidental to treatment would have resulted in a decision against it.”).

233. See Bobbert, Primc, & Schafer, *supra* note 28.

234. Cf. *Andersen*, 913 N.W.2d at 546 (“In a couple of jurisdictions, the plaintiff's ‘injury’ from the physician's failure to obtain informed consent does not have to be physical or a result of the materialization of the undisclosed risk.”).

235. Sawicki, *supra* note 190, at 867.

if the physician fails to disclose their experience with the procedure, it is unclear what medical consequence could materialize that would satisfy the injury causation element.

Plaintiffs may overcome this hurdle by showing that the physician's lack of experience had a direct and demonstrable relationship to the harm that the plaintiff sustained. For example, in *Howard v. University of Medicine and Dentistry of New Jersey*, the New Jersey Supreme Court explained that the plaintiff could show by expert testimony that the "undisclosed risk posed by defendant's true level of qualifications and experience increased plaintiff's risk of paralysis from the . . . procedure."<sup>236</sup> Similarly, in *Andersen v. Khanna*, the Supreme Court of Iowa relied on expert testimony that "lack of experience and training . . . increased the odds of serious complications" from the medical procedure performed.<sup>237</sup> If the paralysis or serious complications materialized, this evidence would arguably meet the injury causation requirement.

With respect to SLT, a plaintiff could show, through expert testimony, that lack of experience increases the risk of complications and certain other negative outcomes. If the patient's injury resulted from a technically difficult aspect of the SLT, experts could testify that a more experienced physician would have had a significantly greater chance of avoiding that negative outcome.

All of the cases discussed above demonstrate that a patient could have a viable informed consent cause of action against a physician for failure to disclose their inexperience in performing an SLT. Indeed, SLT is the type of case that would have the best chance of succeeding because the surgery is technically demanding and complex and there is research demonstrating that inexperienced physicians have worse outcomes. More importantly, the law and cases regarding physicians' obligations to disclose their credentials and experience support our recommendation that SLT should be performed only at qualified transplant centers that are staffed by physicians who are expert in SLT and can provide patients with a significantly improved chance of a positive outcome.

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236. *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 84-5 (N.J. 2002).

237. *Andersen*, 913 N.W.2d at 541.

## 3. Physicians' Obligation to Refer Patients Who Would Benefit from SLT

If SLT is performed only at transplant centers with experienced physicians, then medical ethics and the law would also impose an obligation on physicians to disclose the alternative of SLT to all patients who would benefit from the procedure and refer them to one of these centers. These patients would include those whose chances of survival would increase by being eligible for SLT. Certainly, knowing about an alternative that might significantly increase the patient's chances of survival would qualify as material information necessary for the patient to make an informed and intelligent choice about treatment options.<sup>238</sup> The individuals who would benefit most from SLT would be individuals of short stature who are currently disadvantaged because they are too small to receive average and larger-sized grafts.<sup>239</sup>

While both men and women of short stature are currently disadvantaged by the liver allocation system,<sup>240</sup> women are disproportionately disadvantaged due to the greater likelihood that they will be shorter.<sup>241</sup> This disadvantage has serious

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238. See *Canterbury*, 464 F.2d at 786 (“[The patient’s right of self-decision] can be effectively exercised only if the patient possesses enough information to enable an intelligent choice . . .”).

239. Ge et al. *supra* note 65, at 1121 (“Women and men with short stature are . . . currently disadvantaged . . . by the [liver] allocation system due to inappropriate size matching.”); see Kyoto Fukazawa & Seigo Nishida, *Size Mismatch in Liver Transplantation*, 23 J. HEPATO-BILIARY SCI. 457, 458 (2016); Marc-Antoine Allard et al., *Extreme Large-for-Size Syndrome After Adult Liver Transplantation: A Model for Predicting a Potentially Lethal Complication*, 23 LIVER TRANSPLANTATION 1291, 1302 (2017) (Transplanting livers that are large in relation to the recipient’s anatomy can lead to serious “size mismatch” complications.).

240. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2078 (“[H]emiliver SLT appears to help provide more opportunities for small adults who are often bypassed on the waiting list due to size mismatch.”).

241. Nephew et al., *supra* note 49, at 1291–92; Lauren Nephew & Marina Serper, *Racial, Gender, and Socioeconomic Disparities in Liver Transplantation*, 27 LIVER TRANSPLANTATION, 900, 908 (2021) (“Women who make it to the first position on a match run were

consequences. Among patients who have been listed as in need of, and eligible for, a liver transplant, women are significantly less likely than men to have a liver transplant.<sup>242</sup> Women are significantly more likely to die on the waiting list and to be removed from the list because they become too sick to receive a liver transplant.<sup>243</sup> Studies consistently confirm that body size is a major factor contributing to the higher waitlist mortality for women awaiting a liver transplant.

Disclosure of the option of SLT could help reduce the disparity in mortality between men and women on the liver transplant waiting list because splitting livers provides size-appropriate grafts for smaller patients.<sup>244</sup> UNOS could further reduce the disparity in survival between women and men by

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significantly more likely than men to be declined because of height . . .”).

242. Alina M. Allen et al., *Reduced Access to Liver Transplantation in Women: Role of Height, MELD Exception Scores, and Renal Function Underestimation*, 102 *TRANSPLANTATION* 1710, 1711 (2018) (“Women are 30% less likely to undergo [a liver transplant] and the disparity has increased after the introduction of the MELD-based allocation system.”); Jin Ge et al., *Implementing a Height Based Rule for the Allocation of Pediatric Donor Livers to Adults: A Liver Simulated Allocation Model Study*, 27 *LIVER TRANSPLANTATION* 1058, 1058 (“In liver transplantation, adult women are more likely to die on the waitlist and less likely to receive a deceased-donor transplant compared to adult men.”); Lauren Nephew et al., *Sex Disparities in Waitlisting and Liver Transplant for Acute Liver Failure*, 3 *JHEP REPS.* 1, 4 (2020) (same).
243. See Allen et al., *supra* note 242, at 1715 (“Compared to men . . . , women were less likely to undergo [a liver transplant], more likely to die on the waitlist and to be removed from the list.”); Jin Ge et al., *Receipt of Pediatric Liver Offer as the First Offer Reduces Waitlist Mortality for Adult Women*, 68 *HEPATOLOGY* 1101, 1101 (2018) (“In liver transplantation in the United States, women continue to be significantly more likely than men to die or to be removed from the waitlist without transplantation.”); Giuseppe Cullaro et al., *Sex-Based Disparities in Delisting for Being “Too Sick” for Liver Transplantation*, 18 *AM. J. TRANSPLANTATION* 1214, 1216 (2017) (“Women were 10% more likely [than men] to be removed from the [liver transplant] waitlist for being too sick for liver transplantation.”).
244. Ge et al., *supra* note 65, at 1121 (“Secondary splits largely benefit smaller adults; the majority of secondary recipients were women (56%) with a median height of 163 cm (5 feet 4 inches).”).

facilitating more SLT and by prioritizing individuals of short stature for SLT.<sup>245</sup> By facilitating an increase in SLT and prioritizing individuals of short stature,<sup>246</sup> UNOS could not only help save more lives, but also gain the additional advantage of taking a further step towards fulfilling its mandate of allocating organs equitably.<sup>247</sup>

*D. Informed Consent for SLT Should Be Modified due to the Complexity of the Decisions Involved and the Waiting Time Before an Organ is Offered*

Choosing whether to accept a partial liver graft is such a complex decision that questions have been raised about whether a patient's decision can be an informed one.<sup>248</sup> Moreover, although the law only requires that physicians obtain informed consent from a patient once, liver transplant patients wait an average of 239 days for a suitable donor liver.<sup>249</sup> During patients' months on the waiting list, their medical condition generally deteriorates<sup>250</sup>

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245. Ge et al., *supra* note 65, at 1121 (“Secondary split livers could be prioritized for [individuals of short stature] as they often languished on the waitlist waiting for a size-appropriate graft to become available.”).

246. See Nephew & Serper, *supra* note 241, at 910 (noting that a height of less than 5 feet, 5 inches, “remained associated with an 8% increased risk of waitlist mortality.”).

247. See Elizabeth C. Verna & Jennifer C. Lai, *Time for Action to Address the Persistent Sex-Based Disparity in Liver Transplant Access*, 155 J. AM. MED. ASS'N SURGERY 545, 546 (2020) (“[A] factor that has been consistently associated with sex-based disparity in access to liver transplant is body size . . . .”); see Tenenbaum, *Swaps and Chains and Vouchers, Oh My!*, *supra* note 25; see Wahid et al., *supra* note 29, at 434 (“In a truly equitable system, two individuals with the same disease severity should have equal chances of obtaining a liver transplant regardless of demographic profile.”).

248. Moorlock et al., *supra* note 18, at 442 (“The lack of risk understanding is potentially concerning because it raises questions about the extent to which consent for transplantation can be considered informed, particularly with transplants that involve the more complex risks that split livers pose.”).

249. *Get Informed*, NAT'L FOUND. FOR TRANSPLANTS, <https://transplants.org/get-informed> [<https://perma.cc/GHN9-QBFF>] (last visited Sept. 23, 2022).

250. *Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies*, OPTN/UNOS,

and they have no idea about the quality of the liver they will eventually be offered.<sup>251</sup> For these reasons, physicians should be required to obtain informed consent from the patient at least three separate times during the SLT process. These and other modifications in the informed consent for SLT would go a long way in making the process more legally and ethically sound.

1. The Complexity Involved in Choosing SLT

The fact that many patients do not fully understand the risks involved in complex medical procedures is certainly not unique to SLT, but understanding the risks related to accepting a partial liver graft creates more concerns because it also involves weighing factors other than the transplant surgery itself. The patient must consider the characteristics of the specific organ offered and also the uncertain nature of the liver supply and whether the patient can afford to wait for another acceptable liver to become available.<sup>252</sup> Whether the patient can wait is dependent upon another uncertainty – what the patient’s health trajectory will be if the organ is refused.<sup>253</sup> These uncertainties are compounded by the fact that unique characteristics of the donor<sup>254</sup> and patient

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[https://optn.transplant.hrsa.gov/media/2500/ethics\\_whitepaper\\_201806.pdf](https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf) [<https://perma.cc/BF83-84LV>] (last visited Oct. 4, 2022).

251. See Moorlock et al., *supra* note 18, at 442.
252. See Feng et al., *supra* note 108, at 789 (noting that making the decision to accept a particular liver for transplant “requires facts about the risk posed by the particular graft being offered and the risk of death from progressive liver disease if the current offer is declined”); Samz, *supra* note 168, at 90 (“[P]hysicians cannot possibly explain certain transplant procedures in a way that will clearly inform the patient of the risks and consequences of undergoing the procedure.”).
253. See N.Y. STATE DEP’T OF HEALTH WORKGROUP, *supra* note 40, at 1190 (recommending that doctors discuss “[t]he risks/benefits/alternatives of using a donor vs. waiting for the next donor in the context of the candidate’s severity of disease and mortality risk”).
254. See Carlo Petrini, *Organ Transplantation from Marginal and Non-Standard Risk Donors: Ethical Requisites for Consent from Recipients*, 53 *ISTITUTO SUPERIORE DI SANITA* 350, 352 (2017) (“One of the reasons for [uncertainty about the risk of transplantation] is that it is generally difficult to acquire precise and exhaustive information regarding the donor’s lifestyle characteristics, of which even family members may not be aware.”);

may affect the success of the transplant<sup>255</sup> and the patient will have limited time to decide whether to accept a particular organ for transplant when that organ becomes available.<sup>256</sup> With SLT, the patient should also consider the added risk of post-operative complications when receiving a partial, rather than a whole, liver graft and the expertise of the physician, because a partial liver transplant is more technically challenging than a WLT.<sup>257</sup>

A study of patients waiting for liver transplants found that they were “generally aware of the dangers of remaining on the waiting list without [a] transplant.”<sup>258</sup> However, this knowledge often led to a simplistic understanding of other risks and an unduly optimistic attitude about receiving a transplant.<sup>259</sup> Many patients believed “that any liver offered to them would provide them with an opportunity for a better, longer life than not receiving a liver.”<sup>260</sup> On the other hand, transplant staff were more likely to be concerned about the quality of the organ accepted and believed it was important not only to increase the quantity

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Scott C. Halpern et al., *Informing Candidates for Solid-Organ Transplantation about Donor Risk Factors*, 358 NEW ENG. J. MED. 2832, 2834 (2008) (“[T]he veracity of reported behavioral risk factors [for donors] is limited because this information is typically obtained from grieving family members who may not know of or acknowledge their loved one’s behaviors.”).

255. See Moorlock et al., *supra* note 18, at 444 (“[S]ome livers carry increased risks, and these risks will also depend on an individual patient’s condition.”).
256. See Halpern et al., *supra* note 254, at 2834 (noting that patients have “little time to consider the risks and benefits of accepting or declining a particular organ before it [is] offered elsewhere”); Petrini, *supra* note 254, at 352 (“[P]roviding detailed information concerning a specific organ at the moment one becomes available requires time, an element in short supply at the moment when every effort is being made to keep delays to a minimum.”).
257. See Chan et al., *supra* note 16, at 2; MILLER, *supra* note 1, at 2 (“The recovery and the [SLT] are both more complex procedures than recovery and transplantation of the whole liver, requiring detailed knowledge of liver anatomy and expertise in hepatobiliary surgery.”).
258. Moorlock et al., *supra* note 18, at 438.
259. See *id.* at 439.
260. *Id.* at 438.

of liver transplants, but also to maximize “reasonable-quality transplants.”<sup>261</sup>

One solution that has been offered to help patients make more informed decisions about whether to accept a particular organ for transplant is to create a scoring system for donated organs.<sup>262</sup> If, for example, a donated liver was given a number between one and five – five being the lowest grade donated liver – patients would more easily understand the choice they were making.<sup>263</sup> A problem with this system is that it may mislead patients because the scoring ignores other important risks that may not be easy to quantify but that should also be considered.<sup>264</sup> The logical solution would be to explain the other risks related to SLT as well as possible. However, not only are these additional risks difficult to quantify, but patients often do not fully understand the information about risks and alternatives that is explained to them.<sup>265</sup> While it may seem that this would be a major concern for patients, a relatively recent study found that SLT patients generally believe that their understanding of the risks, combined with the recommendations of transplant teams, provide them with sufficient guidance to make an informed decision.<sup>266</sup>

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261. *Id.*

262. See Jesse D. Schold et al., *The Broad Spectrum of Quality in Deceased Donor Kidneys*, 5 AM. J. TRANSPLANTATION 757, 757 (2005) (“A more granulated scoring system that is easy to implement may be important to physicians and transplant recipients to make crucial decisions at the time of transplant.”).

263. See, e.g., *id.* (describing a scoring system for deceased donor kidneys).

264. See Petrini, *supra* note 254, at 352 (“[C]onsent for a specific organ generates a misplaced perception of knowing for certain how much each risk factor contributes to the absolute or relative risk associated with it, whereas the risk associated with individual factors is in fact not easy to quantify.”).

265. Moorlock et al., *supra* note 18, at 443 (“Our study suggests that although [information regarding the risks of SLT] may be explained to patients, it is not often fully understood or remembered by them to the extent that they can make fully informed decisions by themselves.”).

266. *Id.* at 446 (explaining that their “study suggests that deference to staff expertise rather than patient understanding of risk and benefit is what guides treatment decisions in many cases [of SLT]”).

Although patients may generally be satisfied with relying on the recommendations of their transplant team,<sup>267</sup> this satisfaction does not necessarily reduce physicians' obligations to provide them with clear explanations about the risks and alternatives to SLT in language that is as easy for the particular patient to follow as possible.<sup>268</sup> Most patients report wanting to know about the risks and benefits of receiving a transplant<sup>269</sup> and some patients will obviously have more understanding than others.<sup>270</sup> Patients – especially those who have difficulty understanding or processing the information on risks and benefits – should also receive recommendations from their transplant physicians.<sup>271</sup> Although some empirical literature has suggested that health professionals may regard “directive counseling” as a form of “undue influence,” the patient’s need for relevant expert information provides an ethical justification for sharing the physician’s “recommended course of action” in a direct, professional manner.<sup>272</sup> Concerns about impingements on patient autonomy are not unwarranted, but they logically center on conduct such as introducing information that is context-inappropriate, selectively presenting relevant facts or presenting them in a confusing manner, and making appeals that bypass the patient’s capacity for reason.<sup>273</sup>

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267. *See id.* at 438.

268. *See* Petrini, *supra* note 254, at 351 (noting that physicians should “consider such questions as . . . whether they have been diligent in ensuring that a particular patient knows everything that he or she would consider it useful to know”).

269. Moorlock et al., *supra* note 18, at 443 (noting that liver transplant “patients in our study *wanted* to know the risks involved [in SLT]”); Sara Kamran et al., *Patients’ Preferences in Transplantation from Marginal Donors: Results of a Discrete Choice Experiment*, 30 *TRANSPLANT INT’L* 589, 593 (2017) (noting that 76% of the respondents in a study preferred to be told that they would be receiving a marginal graft).

270. Moorlock et al., *supra* note 18, at 443 (“[S]ome patients may have better risk understanding than others, so taking a lowest-common-denominator approach may not be ideal.”).

271. *See id.* at 443 (“If patients are happy to defer to the expertise of the transplant staff . . . then limited understanding of significant risks is not necessarily a significant problem.”).

272. David Shaw & Bernice Elger, *Evidence-Based Persuasion: An Ethical Imperative*, 309 *J. AM. MED. ASS’N* 1689, 1689 (2013).

273. *Id.*; *see also* J.S. Blumenthal-Barby, *Between Reason and Coercion: Ethically Permissible Influence in Health Care and*

On the other hand, offering clear, well-reasoned, recommendations to patients to help them sort out complex information should help patients make sound medical decisions and reduce stress.

Since the deceased donor livers that will be split will be of good quality<sup>274</sup> and many of those receiving the transplants will receive a substantial survival benefit,<sup>275</sup> the fact that some patients may not fully understand all the information about risks and benefits should not be a major concern, especially if it is not of concern to them.<sup>276</sup>

2. Physicians Should Receive Informed Consent from Patients  
for SLT at Three Distinct Times

There is general agreement that patients should be informed of the risks and benefits of receiving a transplant,<sup>277</sup> but there is still some question about when that information should be given and the patient's consent obtained. This problem is peculiar to transplants because the patient is generally first informed of the risks and benefits of an organ transplant before placement on the transplant waiting list and there is often a substantial lag between this first discussion and the patient actually receiving an offer of an organ.<sup>278</sup> Because a patient's health condition deteriorates while waiting for a liver transplant,<sup>279</sup> physicians should obtain or confirm informed consent from the patient at three distinct times during the SLT process to protect the patient's right to autonomy and ensure efficiency in allocating partial liver grafts.

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*Health Policy Contexts*, 22 KENNEDY INST. ETHICS J. 345, 362–63 (2012); James L. Bernat & Lynn M. Peterson, *Patient-Centered Informed Consent in Surgical Practice*, 141 J. AM. MED. ASS'N 86, 90 (2006).

274. See Dalal, *supra* note 79, at 91.

275. See Chan et al., *supra* note 16, at 7–8.

276. See Halpern et al., *supra* note 254, at 2836 (going further and suggesting the elimination of the practice of organ-specific consent); Moorlock et al., *supra* note 18, at 446.

277. See Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 706 (“[A]ll fifty states [require] informed consent, either by statute or common law.”).

278. Moorlock et al., *supra* note 18, at 442.

279. Collett, O’Neill, & Neuberger, *supra* note 53, at 218.

*a. The First Informed Consent*

The option of accepting a partial liver graft should be discussed with patients who would benefit from SLT as soon as possible. This discussion could take place when the patient is added to the liver transplant list or even before listing.<sup>280</sup> Patients have a legal right to decide whether or not they will accept a partial liver graft and addressing the issue early gives the patient an opportunity to be considered for a partial liver graft should one become available. We recommend that there be a separate list of patients who are willing to consent to SLT so partial liver grafts can be fairly allocated to the best candidates as swiftly and efficiently as possible.<sup>281</sup> Thus, the physician should first receive informed consent for SLT from the patient before, or just after, the patient is added to the wait list and, if a patient consents to SLT, that patient should be added to a list of candidates who are willing to accept a partial liver graft.

While efficient and fair allocation of split liver grafts is the most important reason for obtaining a patient's informed consent for SLT early in the transplant process, there are other important reasons. As discussed earlier, physicians should be required to disclose the option of SLT to patients who would benefit from receiving a partial liver graft and refer them to a transplant center staffed by surgeons experienced in SLT if the patient is not already at one of those centers.<sup>282</sup> This disclosure should take place early in the transplant physician's relationship with the

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280. Moorlock et al., *supra* note 18, at 442 (recommending that “information on the risks and benefits of transplantation should be given prior to a patient joining the waiting list.”); BOLTON, *supra* note 38, at 8 (“[I]nformed consent should first be addressed while the patient is on the waiting list (ideally at the time of listing)[.]”).

281. Italy has already proposed a policy that would require a separate list for SLT. In the most recent Italian split liver policy, it explains that a national list will be compiled that will include the recipients of various transplant centers deemed suitable for an adult-adult split liver transplantation and who have signed an appropriate informed consent. See CENTRO NAZIONALE TRAPIANTI, *Split Liver Protocol in the National Setting – NTC Resolution No. 3*, [https://www.trapianti.salute.gov.it/imgs/C\\_17\\_cntPubblicazioni\\_414\\_allegato.pdf](https://www.trapianti.salute.gov.it/imgs/C_17_cntPubblicazioni_414_allegato.pdf) [<https://perma.cc/F6NL-RF9W>] (effective May 17, 2021).

282. See Hashimoto et al., *Split Liver Transplantation in Adults*, *supra* note 58, at 7504.

patient so the patient can decide whether to choose a physician with more experience in SLT.<sup>283</sup>

Further, patients should ideally make their own decisions regarding whether to accept the risks inherent in SLT.<sup>284</sup> However, liver transplant patients often become critically ill on the transplant waiting list, impairing their ability to make their own medical decisions and requiring surrogates – usually family members – to make decisions for them.<sup>285</sup> Discussing SLT early in the transplant process gives more patients the opportunity to consider the risks and benefits of SLT themselves before they become too ill to weigh their options.

Early discussion of SLT also gives patients more of an opportunity to fully digest the complex information about partial liver grafts that they receive, discuss that information with others, and arrange follow-up meetings to address their questions and concerns.<sup>286</sup> In this way, early disclosure of the risks and benefits of SLT can help achieve better patient understanding thereby promoting consent that is informed, and better protecting patient autonomy.<sup>287</sup> By contrast, waiting until a partial liver graft is available to obtain informed consent would require the patient's or surrogate's decision to be made very quickly and without adequate time for reflection.<sup>288</sup>

*b. The Second Informed Consent*

The fact that patients give informed consent when they are added to the wait list should not affect their right to refuse an

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283. See Valentino et al., *supra* note 2, at 3122; see HASHIMOTO & EGHTEHAD, *supra* note 59, at 95.

284. See BOLTON, *supra* note 38, at 8 (“Ideally, informed consent would involve discussion when candidates are capable of understanding the risks and benefits . . .”).

285. *Id.*

286. See Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 744.

287. See *id.* at 743 (“[T]o achieve the purpose of informed consent . . . the focus must be on . . . delivering information designed to achieve patient understanding.”).

288. See Petrini, *supra* note 254, at 352.

SLT later on personal grounds or due to changes in their health.<sup>289</sup> A significant amount of time may elapse between being added to the wait list and actually receiving an organ transplant.<sup>290</sup> During this time period, the risks and benefits of receiving an SLT may shift due to changes in the patient's clinical status.<sup>291</sup> Because of these potential changed circumstances, the physician and patient should have continuing discussions about SLT while the patient remains on the wait list.<sup>292</sup> Researchers generally recommend that physicians engage in "shared decision-making, which emphasizes on-going collaboration between the physician and patient," rather than obtaining informed consent at one single point in time.<sup>293</sup>

At the very least, if the patient has been on the transplant waiting list for a substantial period of time, the physician should obtain a second informed consent for SLT when the patient reaches a point on the wait list where they may imminently receive an offer to accept a partial liver graft.<sup>294</sup> A substantial period of time should be defined as a period of time during which the patient's condition is likely to deteriorate.<sup>295</sup> Indeed, if the patient's condition has deteriorated, this second informed consent

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289. *See id.* (noting that consent to receiving an organ from a marginal or non-standard donor "should in no way affect a patient's right to review this decision at any time[.]").
290. Moorlock et al., *supra* note 18, at 442 (noting that there may be a "significant time lag between [a patient] being listed and transplanted.").
291. *See* BOLTON, *supra* note 38, at 8 ("[A] patient's or their center's circumstances might change while the patient is on the waiting list[.]").
292. *Id.* (recommending "recurring informed consent discussion regarding [willingness to accept a partial liver graft]").
293. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy*, *supra* note 165, at 743; Bernat & Peterson, *supra* note 273, at 86 ("Surgical consent is not an event or a signature on a form but is an ongoing process of communication that continues throughout the preoperative, perioperative, and postoperative care.").
294. *See* Moorlock et al., *supra* note 18, at 442 (noting that informed consent for transplantation is "slightly peculiar insofar as it is given when the patient joins the waiting list, and with a significant time lag between being listed and transplanted.").
295. *See* Collett, O'Neill, & Neuberger, *supra* note 53, at 218; Moorlock et al., *supra* note 18, at 442.

is legally required in order to give the patient important additional information about the risks and benefits of SLT given their current health status.<sup>296</sup> Certainly, this information would be material to the patient in deciding whether to go ahead with SLT.

A patient has the right to make an informed decision about having a medical procedure based on their current risks and benefits<sup>297</sup> rather than estimates of their probable health status made at the time they were added to the wait list.<sup>298</sup> Having a formal requirement for a second informed consent ensures that the patient receives a full disclosure of the risks, benefits, and alternatives given their current health status, rather than a more cursory discussion that may not fully inform the patient of all the material information. This second informed consent would also give patients some time to reconsider whether to accept a partial liver graft while having this additional information and improve the SLT process by avoiding unnecessary refusals of partial liver grafts and resulting harmful transplant delays.<sup>299</sup> As noted previously, livers begin to deteriorate outside the human body,<sup>300</sup> and one patient's uncertainty about whether to accept an offer

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296. See Moorlock et al., *supra* note 18, at 442 (noting that during the time the patient is on the transplant wait list, “the risks and benefits of [receiving a transplant] may change significantly . . .”).

297. See Danielle H. Chaet, *AMA Code of Medical Ethics' Opinions Related to Language and Hierarchy in Medicine* 19 AM. MED. ASS'N J. ETHICS 260, 261 (2017); Vulchev et al., *supra* note 67, at 1739 (“[P]atients are entitled to make effective decisions about their health . . . [s]pecifically, doctors and others must inform a patient, as accurately as possible, of the risks attending SLT . . .”).

298. See BOLTON, *supra* note 38, at 8 (noting that “[p]atients (or surrogates) may change their decisions about willingness to accept certain types of organs because of changes in clinical status or other reasons.”).

299. See Petrini, *supra* note 254, at 352 (explaining that time “is in short supply [when an organ becomes available and] every effort is being made to keep delays to a minimum”); BOLTON, *supra* note 38, at 8 (recommending “recurring informed consent discussions regarding [a patient’s willingness to accept a partial liver graft while the patient is on the wait list and] potential updating of their willingness with the OPTN[.]”).

300. See Edgardo E. Guibert et al., *Organ Preservation: Current Concepts and New Strategies for the Next Decade*, 38 TRANSFUSION MED. & HEMOTHERAPY 125, 126 (2011).

when it is made can potentially jeopardize another person's ability to benefit from SLT.

*c. The Third Informed Consent*

Patients also have the legal right to consent to a particular organ when it becomes available.<sup>301</sup> Obtaining a third informed consent at this point in the transplant process protects autonomy by ensuring the patient has the opportunity to consider the unique characteristics of the specific donated liver being offered.<sup>302</sup> It also ensures that the patient does not feel undue pressure to accept a partial liver graft because the patient consented to SLT earlier in the transplant process.<sup>303</sup>

It should be noted that with SLT, this third informed consent may not be as much of a concern as with other transplants. Only the best livers are suitable for splitting,<sup>304</sup> so the patient could arguably consent to receiving any partial liver graft that is offered, rather than having this third informed consent requirement.<sup>305</sup> As the law now stands, however, the physician apparently has a legal obligation to obtain informed consent from the patient for SLT three times during the informed consent process.<sup>306</sup>

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301. HASHIMOTO & EGHESAD, *supra* note 59, at 95 (“[R]ecipients have the unequivocal right to refuse an offer of a split graft.”); BOLTON, *supra* note 38, at 10 (noting that patients have the right to “refuse an organ, including a split liver.”).

302. Feng et al., *supra* note 108, at 789 (explaining that information about the characteristics of an organ at the time it is offered “is necessary to inform discussions of organ acceptance”).

303. See BOLTON, *supra* note 38, at 8 (“[T]ransplant candidates or their surrogates should not be put in a position of undue pressure, in which the transplant staff may be perceived as coercing them to accept a [SLT] at the time of the organ offer.”).

304. See Dalal, *supra* note 79, at 90.

305. See Petrini, *supra* note 254, at 352 (explaining that “[r]equesting consent for [a] whole category of ‘at risk organs’ rather than for a specific organ . . . offers practical advantages”).

306. *Id.* at 352 (“[I]t is . . . the duty of physicians to ask for consent at the time an organ becomes available.”).

#### IV. POTENTIAL FOR COERCION/MANIPULATION

With SLT, patients may be asked whether they would like to receive a WLT or whether they are willing to share a donor liver with another patient, thereby allowing that patient to also receive a liver transplant.<sup>307</sup> Patients presented with this choice may feel inherent pressure to choose the more socially acceptable alternative of sharing the donor liver, even though receiving a partial liver graft increases the patients' risks of complications.<sup>308</sup> They may also believe that the transplant team is pressuring them to accept a partial liver graft,<sup>309</sup> even if that is not the transplant team's intent.

Determining whether there is a danger of coercion when SLT is presented as a choice between taking a whole liver or sharing the donated liver with another person depends on how coercion is defined. At a minimum, coercion involves interfering with a person's autonomy or ability to self-rule.<sup>310</sup> Some commentators further assert that a decision is coerced if the will of another is forced on the individual or if the individual acts out of a sense of duty or obligation, rather than based on the individual's personal values and goals.<sup>311</sup>

In their foundational text, *PRINCIPLES OF BIOETHICS*, Tom Beauchamp and James Childress posit that there are three main components to exercising autonomy: (1) intentionality, (2) understanding, and (3) absence of "controlling influences that determine their action."<sup>312</sup> However, they further explain that full understanding and complete autonomy are not possible in the real

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307. BOLTON, *supra* note 38, at 8 (indicating that some liver transplant candidates are asked "whether they want the entire liver or a split liver").

308. *See* Dalal, *supra* note 79, at 90 ("There is increased risk of biliary complications with a split liver, and a recipient may wish to thus decline it.").

309. BOLTON, *supra* note 38, at 4.

310. BEAUCHAMP & CHILDRESS, *supra* note 163, at 101.

311. *See* Aaron Spital, *Ethical Issues in Living Organ Donation: Donor Autonomy and Beyond*, 38 AM. J. KIDNEY DISEASES 189, 189 (2001) ("[B]efore accepting a volunteer as an organ donor, we must first ask: how can we be sure that his offer reflects his own values and goals, [i.e.] that he is indeed acting autonomously?").

312. BEAUCHAMP & CHILDRESS, *supra* note 163, at 104.

world.<sup>313</sup> They base this determination, in part, on the fact that individuals often choose to accept the views of “an institution, tradition, or community . . . as a legitimate source of direction”<sup>314</sup> and argue that there is “no fundamental inconsistency” between accepting these views and acting autonomously.<sup>315</sup> Based partially on this reasoning, Beauchamp and Childress reject a broad definition of coercion<sup>316</sup> and determine that, to act autonomously, a patient “needs only a substantial degree of understanding and freedom from constraint, not a full understanding or a complete absence of influence.”<sup>317</sup> They conclude that “[c]oercion occurs only if an intended and credible threat displaces a person’s self-directed course of action . . . .”<sup>318</sup>

On the other hand, Beauchamp and Childress recognize that, even if an individual is not coerced under their definition, that person can be manipulated in a manner that will also affect their autonomy.<sup>319</sup> They define manipulation as “swaying people to do what the manipulator wants by means other than persuasion or coercion.”<sup>320</sup> As examples of manipulation, they point out that health care providers can frame the information they provide to a patient positively, thereby manipulating the patient’s understanding of the situation.<sup>321</sup> Health care providers can also manipulate a patient’s perception and response to information, for example, “by tone of voice, [or] by forceful gesture.”<sup>322</sup> To be a problem, the manipulation must have a significant effect on the

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313. *Id.*

314. *Id.* at 105.

315. *Id.*

316. *Id.* at 138 (“We reject a common tendency in biomedical ethics to use ‘coercion’ as a broad term of ethical criticism that obscures relevant and distinctive ethical concerns.”).

317. *Id.* at 104.

318. *Id.* at 138.

319. *Id.* at 139 (“Manipulation is a generic term for several forms of influence that are neither persuasive nor coercive.”).

320. *Id.*

321. *Id.* (giving as examples of framing positively – (“we succeed most of the time with this therapy”) rather than negatively (“we fail with this therapy in 35% of the cases”)).

322. *Id.*

patient's choices.<sup>323</sup> If the patient is acting based on his or her own values and beliefs, the individual is still acting autonomously.<sup>324</sup>

To determine the values and beliefs of liver transplant patients regarding SLT, Neal Barshes et al. performed a study in which they surveyed fifty adult liver transplant candidates.<sup>325</sup> The purpose of the study, published in 2005, was to determine whether, if given a choice, transplant candidates “would prefer to maximize their individual outcomes [or] increase the overall number of transplants that can be performed.”<sup>326</sup> In the study, 89.6% of the patients indicated that “they would participate in SLT [and share a donated liver] even if the survival benefit for adult recipients was inferior to [receiving a WLT].”<sup>327</sup> Almost all of the participants (98%) indicated that “they would feel good about sharing a part of their liver graft with a pediatric liver transplant candidate”<sup>328</sup> and 69% expressed a willingness to “participate in SLT even if it conferred only seven years survival benefit for every ten conferred by [a WLT].”<sup>329</sup>

In another study, published in 2016, Greg Moorlock et al. similarly found that patients were willing to share a donated liver with children even if a partial liver graft increased their risks of dying or suffering complications from the surgery.<sup>330</sup> Some of the participants also indicated that sharing a donated liver helped them feel more positive about using a scarce resource to save their own lives.<sup>331</sup> According to the authors, the views of the

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323. *See id.* (referencing “the point at which influence threatens autonomous choice”).

324. *See* Spital, *supra* note 311, at 189.

325. Barshes et al., *supra* note 62, at 2047.

326. *Id.*

327. *Id.* at 2050.

328. *Id.* at 2048.

329. *Id.*

330. *See* Moorlock et al., *supra* note 18, at 445.

331. *See id.* at 441 (quoting one patient who stated: “You know you’re giving two people a chance instead of one . . . . But I think everybody, as many people as possible, deserve a chance . . . .”); *see also* Barshes et al., *supra* note 62, at 2047 (“Several candidates named the ‘shortage of organs’ for their willingness to participate in SLT . . . .”).

participants in this study also supported adult/adult SLT “as an acceptable way to increase the number of people receiving transplants if there were no suitable pediatric recipients available.”<sup>332</sup>

These studies indicate that the values and goals of most patients support SLT. If the patients’ values and goals support their decision to accept a partial liver graft, there would be no coercion under either the definition of coercion used by Beauchamp and Childress or the broader conception of coercion that they consider and reject.<sup>333</sup> However, there are limitations to both the Barshes and Moorlock studies. Notably, both studies were based on hypothetical scenarios presented to patients when they were not actually facing the reality of accepting a partial liver graft and the added risks connected with that choice.<sup>334</sup>

More importantly, both the Barshes and Moorlock studies indicate that there is a risk of conscious or unconscious coercion or manipulation. The Moorlock study stressed that the liver transplant patients who participated in the study did not have a full understanding of the risks of SLT.<sup>335</sup> In addition, in both the Moorlock and Barshes studies, many liver transplant candidates indicated that they would rely heavily on their health care providers in making decisions about whether or not to accept a partial liver graft.<sup>336</sup> Moreover, the Moorlock study confirmed that

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332. Moorlock et al., *supra* note 18, at 446.

333. BEAUCHAMP & CHILDRESS, *supra* note 163, at 106 (noting that autonomous agents have the “right to hold views, make choices, and to take actions based on their values and beliefs.”); Morley, *supra* note 24, at 250 (“A patient is not coerced into a decision when she acts in accordance with her personal moral beliefs . . .”).

334. *See* Barshes et al., *supra* note 62, at 2047 (explaining that questionnaires were administered “to 50 adult liver transplant candidates.”); Moorlock et al., *supra* note 18, at 437 (selecting adult participants who had either “had a liver transplant in the previous five years or were on the liver transplant waitlist at the time of recruitment”).

335. *Id.* at 438 (“The first theme to emerge from the data was [the transplant candidates’] poor understanding of risk . . .”).

336. *Id.* at 446 (“[O]ur study suggests that deference to staff expertise[,] rather than patient understanding of risk and benefit[,] is what guides treatment decisions in many cases.”); Barshes et al., *supra* note 62, at 2048–49 (“Virtually all patients (98%) indicated that they would trust their transplant surgeon and transplant

transplant staff “were generally supportive of [SLT] and felt that, given the shortage of transplantable livers, efforts should be made to increase the number of opportunities for patients to receive a transplant.”<sup>337</sup> The patients’ lack of understanding and corresponding reliance on health care staff in making decisions,<sup>338</sup> combined with the staff’s support of SLT and making more transplants available for patients, provide fertile ground for conscious or unconscious coercion or manipulation of patients’ decisions.

For some patients, especially individuals of short stature, accepting a partial liver graft will be the best option because it gives them the best chance of survival.<sup>339</sup> However, no liver transplant candidates should be placed in a position where there is even the appearance of undue pressure to choose SLT.<sup>340</sup> To avoid the danger of manipulation or coercion, physicians should be diligent in disclosing the risks of SLT compared to receiving a whole liver graft.<sup>341</sup> Transplant centers should also consider using independent counselors to work with the patients because they will not have any monetary or other personal interest in having the split liver transplant performed.<sup>342</sup> In addition, transplant

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coordinator to help them decide if SLT would be a good option in their situation.”).

337. Moorlock et al., *supra* note 18, at 446.

338. *Id.* at 443–44 (noting “[p]atients’ simplistic understanding of risk, and optimism toward transplantation”); see BEAUCHAMP & CHILDRESS, *supra* note 163, at 107 (“Respect for autonomy obligates professionals in health care to . . . ensure understanding and voluntariness, and to foster adequate decision making.”).

339. See Vulchev et al., *supra* note 67, at 1737 (“[I]n some contexts, there is no SLT dilemma because [maximizing the number of patients receiving organ transplants, and maximizing the individual patient’s survival] do not conflict.”).

340. See BOLTON, *supra* note 38, at 8 (“[T]ransplant candidates or their surrogates should not be in a position of undue pressure in which the transplant staff may be perceived as coercing them to accept a [SLT] at the time of organ offer.”).

341. See Petrini, *supra* note 254, at 352.

342. Using independent counselors for SLT would be unusual because counselors generally work with organ donors, rather than recipients. See, e.g., Spital, *supra* note 311, at 192 (“I believe that . . . all [potential donors] should be evaluated in private by an experienced mental health professional who has no vested interest

staff should refrain from giving the transplant candidate information about who will receive the other partial liver graft should the patient choose SLT.<sup>343</sup> This will help avoid potential psychosocial complications including an exaggerated sense of personal responsibility or guilt that may result from the belief that one has denied a transplant to a particular patient.<sup>344</sup>

Another way of avoiding this potential manipulation or coercion, which we advocate on equitable and utilitarian grounds, is to have mandatory splitting of acceptable livers.<sup>345</sup> With a mandatory splitting policy, a patient's only choice will be whether to accept a partial liver graft or wait for a whole liver to become available.<sup>346</sup> Mandatory splitting also reinforces the prevailing message that "deceased donor livers – whether transplanted as whole or split organs – are a community [, not an individual,] resource . . . ." <sup>347</sup>

## V. ETHICAL CHALLENGES ARISING FROM THE CURRENT STRATEGY OF OFFERING WHOLE ORGANS

Transplant programs, including the surgeons and administrators who set the tone and tempo of liver transplantation, operate within a complex matrix of ethical

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in the welfare of the intended recipient or the transplant program.”).

343. This suggestion tracks the recommendation that bridge donors in kidney chains should not know how many individuals will benefit from their donation as this may subject them to an increased degree of perceived coercion. See E.S. Woodle et al., *Ethical Considerations for Participation of Nondirected Living Donors in Kidney Exchange Programs*, 10 AM. J. TRANSPLANTATION 1460, 1466 (2010); Tenenbaum, *Bartering for a Compatible Kidney Using Your Incompatible Live Kidney Donor*, *supra* note 20, at 160.
344. See Tenenbaum, *Bartering for a Compatible Kidney Using Your Incompatible Live Kidney Donor*, *supra* note 20, at 160.
345. See Petrini, *supra* note 254, at 350; BOLTON, *supra* note 38, at 8 (pointing out that offering SLT “to candidates as the only transplantation option with that organ . . . avoids candidate (or surrogate) coercion . . .”).
346. BOLTON, *supra* note 38, at 8.
347. *Id.*; Ahearn, *supra* note 33, at 129 (“[W]hat’s optimal for society (i.e., the maximum survival benefit from the marginal liver) might not be what’s best for the patient (who could be better off waiting for a better liver).”).

obligations, discretionary choices, and incentive structures.<sup>348</sup> Within this constellation, as it is presently constructed, divisible livers are offered to clinical teams as whole livers for specified patients.<sup>349</sup> Predictably, the decision whether to split an acceptable liver (to the extent it is contemplated) is shaped by the surrounding milieu. This Section examines two ways in which whole organ offers present ethical challenges for teams that might offer SLT. The first challenge implicates a tension between clinicians' obligation to look out for their patients' best interests and the more systemic values advanced by SLT. The second challenge stems from the practical reality that performing SLT may destabilize a transplant program by adversely affecting its regulatory performance metrics.

The Section will show that these ethical conundrums for transplant professionals are not inevitable consequences of liver scarcity but rather a modifiable artifact of how livers are offered whole through the OPTN. As such, these professional dilemmas can be obviated by instead offering select livers to qualifying teams as hemilivers only. Finally, we will consider a possible ethical objection to this alternative approach—that it would impermissibly abandon the sickest patients—and explain why we find it unconvincing.

#### A. *Transplant Professionals' Fiduciary Duties and SLT*

The OPTN is charged with allocating deceased donor organs, including livers, in a way that equitably balances utility and non-utilitarian considerations of justice.<sup>350</sup> This balance necessarily involves normative judgments, but the guiding values and principles are different from those characterizing the physician-patient relationship.<sup>351</sup> A basic distinction between the proper

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348. *See generally* Richard J. Howard, *The Challenging Triangle: Balancing Outcomes, Transplant Numbers and Costs*, 7 AM. J. TRANSPLANTATION 2443 (2007).

349. *See* BOLTON, *supra* note 38.

350. *See supra* notes 142–50 and accompanying text.

351. *See generally* BEAUCHAMP & CHILDRESS, *supra* note 163, at 5–9, 255 (distinguishing the ethical norms governing physician conduct from value-laden public policy decisions and characterizing the development of principles governing organ allocation in the United States as a societal exercise in public deliberation); *see also* ROBERT M. VEATCH & LAINIE F. ROSS, *TRANSPLANTATION ETHICS* 273, 296 (2d ed. 2015) (stating “[i]t is the public’s responsibility to make

roles of transplant clinicians in the physician-patient relationship and public oversight bodies<sup>352</sup> is central to both the philosophical literature on organ allocation<sup>353</sup> and the legal organization of the system that connects patients with organs. Under the existing division of labor, the OPTN's Board of Directors is responsible for establishing "minimum [medical] criteria . . . for adding candidates to, and removing candidates from, organ transplant waitlists," as well as principles for prioritizing patients for organ offers.<sup>354</sup>

Within these broad lines, transplant centers maintain their own eligibility criteria and list individual patients according to administrative prerogatives and professional judgment.<sup>355</sup> When donated organs are recovered by a regional Organ Procurement Organization (OPO), the OPO performs a match run to determine who will be offered an available organ under OPTN

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sure that the UNOS allocation formulas reflect the proper moral principles" and contrasting this role with clinical decision making at the bedside).

352. See VEATCH & ROSS, *supra* note 351, at 295–96 (mentioning that these bodies, of course, may include physicians or other healthcare professionals as members).
353. *Id.* at 296; see also ROBERT M. VEATCH, *Revisiting A Theory of Medical Ethics: Main Themes and Anticipated Changes*, in *THE STORY OF BIOETHICS: FROM SEMINAL WORKS TO CONTEMPORARY EXPLORATIONS* 69–74 (Jennifer K. Walter & Eran P. Klein eds., Geo. Univ. Press 2003) (elaborating a contractarian model of biomedical ethics that distinguishes the contract between the public and the professions from that between the individual patient and clinician).
354. 42 C.F.R. § 121.8(b)(1)–(2) (1998).
355. Huma Zarif, *Distributive Injustice and Organ Transplant Waitlists*, 7 HASTINGS SCI. & TECH. L. J. 75, 82–83 (2015); Katharine Secunda et al., *National Survey of Provider Opinions on Controversial Characteristics of Liver Transplant Candidates*, 19 LIVER TRANSPLANTATION 395, 395–96 (2013); see José R. Maldonado et al., *The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT): A New Tool for the Psychosocial Evaluation of Pre-Transplant Candidates*, 53 PSYCHOSOMATICS 123, 125–26 (2012) (mentioning that the Centers' optimization and listing of transplant candidates is informed by relevant scientific and professional literature. Also providing an example of a published assessment tool).

policies.<sup>356</sup> As noted, match runs for livers employ a MELD-based algorithm, incorporating variables such as acuity and geographic proximity.<sup>357</sup> The OPO then notifies the patient’s transplant center that it is offering an organ for a particular patient. The center must respond to the initial notification and provide more detailed follow-up information within finite timeframes.<sup>358</sup> The decision whether to accept an offer, which may be less than ideal in terms of organ characteristics, logistical considerations, or other factors,<sup>359</sup> is “shared” in the sense that the surgeon and patient must both be willing to proceed on the basis of the available information.<sup>360</sup> Some of the deliberative process can be frontloaded, through patient education, values-eliciting conversations, and directive counseling before an offer is on the line.<sup>361</sup> If a center does not accept an offered organ within the

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356. See ORGAN PROCUREMENT AND TRANSPLANT NETWORK, POLICY 1: ADMINISTRATIVE RULES AND DEFINITIONS 1, 10 (2022) (defining “match run”). See ORGAN PROCUREMENT AND TRANSPLANT NETWORK, POLICY 5: ORGAN OFFERS, ACCEPTANCE, AND VERIFICATION 81, 84–85 (2022) (describing match runs are to be conducted for livers and other organs).
357. See *supra* notes 140–142 and accompanying text. The precise contours of the OPTN’s approach to matching have been in flux and contested. See Kayla Goggin, *New Liver Transplant Policy Cleared to Go Despite Pending Court Battle*, COURTHOUSE NEWS SERV. (Jan. 16, 2020), <https://www.courthousenews.com/new-liver-transplant-policy-cleared-to-go-despite-pending-court-battle/> [<https://perma.cc/BH5S-G528>] (noting that the precise contours of the OPTN’s approach to matching have been in flux and contested).
358. ORGAN PROCUREMENT AND TRANSPLANT NETWORK, POLICY 5, *supra* note 356, at 87 (§ 5.6: Receiving and Accepting Organ Offers).
359. James Neuberger & Chris Callaghan, *Organ Utilization – The Next Hurdle in Transplantation?*, 33 TRANSPLANT INT’L 1597, 1602 (2020) (enumerating a wide variety of reasons why offered organs may be declined).
360. Lainie Friedman Ross, Stefanos Zenios, & J. Richard Thistlethwaite Jr., *Shared Decision Making in Deceased-Donor Transplantation*, 368 THE LANCET 333, 336 (2006).
361. See Cory R. Schaffhausen et al., *Designing a Liver Transplant Patient and Family Decision Support Tool for Organ Offer Decisions*, 7 TRANSPLANTATION DIRECT 1, 3–7 (2021) (noting such opportunities); see also Jennifer Cindy Lai, Sandy Feng, & John Paul Roberts, *An Examination of Liver Offers to Candidates on*

allotted time window, the OPO may offer it for the next ranked candidate.<sup>362</sup>

Center variations in patient listing and organ acceptance practices have been criticized on distributive justice and consequentialist grounds.<sup>363</sup> So long as differences in philosophy and expertise exist among transplant centers, though, transparency about this heterogeneity can enable patients to choose the most appropriate programs for them based on differences in center characteristics such as experience and “aggressiveness.”<sup>364</sup> However, within the existing allocation framework, SLT seems unlikely to be offered or discussed at all. Key to understanding why is the distinction between the public values implicated by OPTN policies (specifically how organs are offered) and the ethics of the physician-patient relationship (specifically how clinicians help patients navigate offers). Although wider adoption of SLT would almost certainly represent a net benefit to patients in need of a liver transplant by reducing waitlist mortality, when a surgeon is offered a liver for a particular patient, “what’s optimal for society . . . might not be what’s best for the patient.”<sup>365</sup> And the welfare of the individual relying on the learned professional has long been a “cornerstone” of medical ethics,<sup>366</sup> even if the nature of medical decision making has become less centralized with the proliferation of stakeholders

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*the Liver Transplant Wait-List*, 143 GASTROENTEROLOGY 1261, 1265 (2012) (proposing greater education and “prospective” assessment of patients’ willingness to accept increased risk organs).

362. ORGAN PROCUREMENT AND TRANSPLANT NETWORK, POLICY 1, *supra* note 356, at 6; ORGAN PROCUREMENT AND TRANSPLANT NETWORK, POLICY 9: ALLOCATION OF LIVERS AND LIVER INTESTINES, 212–13 (Oct. 27, 2022), [https://optn.transplant.hrsa.gov/media/eavh5bf3/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf) [<https://perma.cc/KG3X-EU2E>] (§ 9.10 Expedited Liver Offers).
363. *See, e.g.*, Amit K. Mathur et al., *Variation in Access to the Liver Transplant Waiting List in the United States*, 98 TRANSPLANTATION 94, 95 (2014); David S. Goldberg et al., *Liver Transplant Center Variability in Accepting Offers and Its Impact on Patient Survival*, 64 J. HEPATOLOGY 843, 844 (2016).
364. Cory R. Schaffhausen et al., *Tool to Aid Patients in Selecting a Liver Transplant Center*, 26 LIVER TRANSPLANTATION 337, 346 (2020).
365. Ahearn, *supra* note 33, at 129.
366. *Id.* at 128.

whose interests exert a gravitational pull on the healthcare system.<sup>367</sup>

Stated as an ideal in the starkest terms, “Physicians are required to do everything they believe may benefit each patient without regard to costs or other societal considerations. In caring for an individual patient, the doctor must act solely as that patient’s advocate, against the interests of society as a whole, if necessary.”<sup>368</sup> When a patient establishes a relationship with a transplant team, the patient’s doctors on the team become fiduciaries with duties of loyalty and care.<sup>369</sup> In the biomedical ethics literature, there is debate over whether respect for patient “autonomy” has eclipsed the traditional duty of “beneficence,” or whether beneficence rightly understood includes enabling the patient to realize their own values.<sup>370</sup> Either way, the clinician must be attentive to the patient’s physiological well-being, values, and preferences.<sup>371</sup> This intense focus on the individual case extends to allied professions: Social workers, for example, may play a screening role in transplant assessment that is different from pure patient advocacy, but the ostensible unit of analysis is

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367. See DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING* 1–3 (Basic Books 1991).

368. Norman G. Levinsky, *The Doctor’s Master*, 311 *NEW ENG. J. MED.* 1573, 1573 (1984); see also Robert D. Truog, *Patients and Doctors — The Evolution of a Relationship*, 366 *NEW ENG. J. MED.* 581, 584 (2012) (noting that the problem of allocating access to dialysis machines and other expensive technology pressured this traditional ideal).

369. See generally Maxwell J. Mehlman, *Why Physicians are Fiduciaries for Their Patients*, 12 *INDIANA HEALTH L. REV.* 1, 2–14 (2015) (for a nuanced overview of the relevant case law).

370. Edmund D. Pellegrino, *Patient and Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship*, 10 *J. CONTEMP. HEALTH L. & POL’Y* 47, 50 (1994).

371. Norman Daniels, *National Health-Care Reform*, in *MEDICAL ETHICS* 415–36 (Robert M. Veatch ed., Jones and Bartlett 2d ed. 1997) (asserting that, for there to be voluntary, informed consent, “physicians must invest the time to discuss alternative, available treatments with patients so they can make informed choices that reflect their own values and preferences.”) (emphasis omitted).

still the patient in their social circumstances and not a pool of patients.<sup>372</sup>

To be sure, in practice, “physicians have always had competing pressures that prevent them from providing everything that might be of medical benefit to a patient, beginning with the fact that no physician can spend an unlimited amount of time with any one patient.”<sup>373</sup> Further, duties to individual patients are not necessarily absolute in regulated healthcare ecosystems. For example, some moral philosophers’ work suggests that, if refraining from immediately prescribing an antibiotic for a mild infection imposes a small burden on the ill patient, this burden might be defensible or required on the basis of mitigating the potential externality of antimicrobial resistance borne by other members of the public.<sup>374</sup> Yet, in such cases, the limit on the exercise of fiduciary authority is typically imposed by the state,<sup>375</sup> and the appreciable distribution of benefits and burdens differs markedly from the prospects confronting a surgeon who has just received a liver offer for an individual suffering from potentially fatal liver failure. In this latter scenario, there is little reason to think the physician would advocate treating the patient with less than the whole liver if this represents the standard of care thought to maximize individual outcomes.

In theory, the possibility of sharing an available liver might be explored in relation to the patient’s own values, but it is

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372. See, e.g., Jack Rothman et al., *Client Self-Determination and Professional Intervention: Striking a Balance*, 41 *SOCIAL WORK* 396, 396–405 (1996) (on ethical principles in social work); Katrina A. Bramstedt, Annette Chalfant, & Carol Wright, *Emergency Consults in the Setting of Transplant Medicine: Dilemmas for Social Workers and Bioethicists*, 17 *PROGRESS IN TRANSPLANTATION* 36, 38 (2007) (discussing the role of social workers in transplant assessment); see generally Sinthu Srikanthan, *Values Not Our Own: Interrogating Psychosocial Suitability in the Transplant Social Work Assessment*, 46 *HEALTH & SOC. WORK* 308, 308–11 (2021) (for a critique of individualism in transplant social work).

373. Truog, *supra* note 368, at 584.

374. Alberto Giubilini & J. Savulescu, *Moral Responsibility and the Justification of Policies to Preserve Antimicrobial Effectiveness*, in *ETHICS AND DRUG RESISTANCE: COLLECTIVE RESP. FOR GLOBAL PUB. HEALTH* 141, 143 (Euzebiusz Jamrozik & Michael Selgelid eds., Springer 2020).

375. See *id.* at 149.

unlikely that an untrained physician would be confident in their ability to present this option in an unbiased, non-coercive way.<sup>376</sup> The OPTN, for its part, currently provides for two “variances” (i.e. special allocation procedures) to facilitate the sharing of livers suitable for SLT, but neither *requires* surgeons to split livers or offer patients a segmental transplant.<sup>377</sup> Thus, the variances problematically rely on the goodwill of transplant programs (or other incentives) to consider SLT while simultaneously fulfilling their obligations to their patients. It is not hard to understand why many physicians, faced with this conflict, would favor a WLT to minimize potential complication for their patient,<sup>378</sup> even though this is probably not the best option for the larger community of patients in need.

*B. Competing Aims Within Transplant Programs and Conflicting Regulatory Incentives*

As previously noted, a transplant surgeon has a fiduciary obligation to act in the best interest of a patient receiving an organ, but that obligation can stand in tension with the value that the larger allocation system places on minimizing preventable deaths across a larger population.<sup>379</sup> The tension

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376. See *supra* notes 308–34 and accompanying text. See Nat’l Kidney Registry, *Compatible Pairs*, [https://portal.kidneyregistry.org/compatible\\_pairs.php](https://portal.kidneyregistry.org/compatible_pairs.php) (last visited Oct. 29, 2022) (A somewhat analogous opportunity would be offering a compatible living donor-recipient pair the opportunity to help other patients in need by participating in chain kidney donation). *Id.* (In that context, anticipated physiological benefits to the individual recipient still tend to be central to the discussion).

377. See ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, *OPTN Database*, <https://optn.transplant.hrsa.gov/data/about-data/optn-database/> [<https://perma.cc/NJN2-25J7>] (last visited Oct. 29, 2022) (defining “match run”); ORGAN PROCUREMENT AND TRANSPLANT NETWORK, POLICY 9: ALLOCATION OF LIVERS AND LIVER INTESTINES, 214–15 (Oct. 27, 2022), [https://optn.transplant.hrsa.gov/media/eavh5bf3/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf) [<https://perma.cc/M9Q9-VTTR>] (§ 9.12 Variances: §§ 9.12.A and 9.12.C).

378. See Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2078 (finding that 15% of deceased donor livers utilized at one transplant center that performs SLT “could have been split;” in practice, “the majority were used for [WLT]”).

379. See *supra* note 148 and accompanying text.

between what is optimal for the individual patient and what is optimal for a larger class of patients (some of whom are in the care of the same transplant program) can be analyzed as an exercise in applied moral philosophy, compelling us to define and prioritize goals.<sup>380</sup> In practice, however, surgeons' and hospital administrators' decision-making is not so neatly abstracted from the institutional pressures and incentives that can affect the growth and viability of transplant programs.<sup>381</sup> For this reason, a second powerful deterrent to offering SLT confronts transplant programs: Even if it can be reconciled with clinicians' fiduciary obligations, *and even if it is compatible with a patient's own values, goals, and preferences*, performing SLT when whole livers are offered can jeopardize a transplant center's outcomes data, and by extension its future.

Transplant centers and affiliated staff stand to gain revenue, prestige, and career opportunities from performing higher volumes of procedures, at least if quality and costs are well-

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380. See Peter A. Ubel & George Loewenstein, *Distributing Scarce Livers: The Moral Reasoning of the General Public*, 42 SOC. SCI. MED. 1049, 1051–52 (1996) (documenting how members of the public in one county reasoned morally about allocating scarce livers); *but see* AMA Council on Ethical and Jud. Affs., *Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients Policy H-370.982*, <https://policysearch.ama-assn.org/policyfinder/detail/Organ%20Donation?uri=%2FAMADoc%2FHOD.xml-0-3140.xml> [<https://perma.cc/YHK6-NYTR>] (last modified 2012) (identifying ethically acceptable criteria and processes for allocating scarce organs while cautioning that practicing “physicians . . . should not make the actual allocation decisions”).
381. See Bertram L Kasiske, et al., *Potential Implications of Recent and Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States*, 16 AM. J. TRANSPLANTATION 3371, 3371 (2016) (noting a concern that public reporting of surgical outcomes could lead to “more discarded organs and fewer patients benefiting from transplant” if the risk of “a poor public evaluation” dissuades programs from “higher risk, but clinically justified, transplants”); *see also* David A. Axelrod, Editorial, *Balancing Accountable Care with Risk Aversion: Transplantation as a Model*, 13 AM. J. TRANSPLANTATION 7, 7 (2012) (“The decision to list a patient for transplantation and subsequently accept a deceased donor organ rests at the intersection of many competing priorities.”).

managed.<sup>382</sup> Conversely, worse-than-expected surgical outcomes as evaluated by the OPTN or other external benchmarking can lead to increased regulatory scrutiny,<sup>383</sup> negative publicity among potential donors and recipients,<sup>384</sup> loss of insurer funding,<sup>385</sup> and even program closures.<sup>386</sup> Notably, among the many conditions of federal program participation set by the U.S. Center for Medicare & Medicaid Services (CMS), CMS judges the acceptability of a center's one-year "patient and graft survival rates" in relation to "expected" outcomes using data from the Scientific Registry of Transplant Recipients (SRTR).<sup>387</sup> Although the methodologies

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382. See Richard J. Howard, *The Challenging Triangle: Balancing Outcomes, Transplant Numbers and Costs*, 7 AM. J. TRANSPLANTATION 2443, 2444 (2007) (discussing how center volumes are associated with institutional revenue, "professional prestige," individual compensation, and research opportunities); see also Makenzie Cook & Edward Zavala, *The Finances of a Liver Transplant Program*, 24 CURRENT OP. IN ORGAN TRANSPLANTATION 156, 160 (2019) (discussing the importance of "maintain[ing] quality" while containing costs).
383. See Colleen Jay & Jesse D. Schold, *Measuring Transplant Performance: The Goals are Not Controversial but the Methods and Consequences Can Be*, 4 CURRENT TRANSPLANT REPS 52, 53 (2017); see also John Gever, *Transplant Program at U. of Pittsburgh Put on Probation*, MEDPAGE TODAY (Nov. 16, 2011), <https://www.medpagetoday.com/surgery/transplantation/29729> [<https://perma.cc/7ZEK-Q43T>] (for a case illustration).
384. See Andrew Conte, *Registry: UPMC Liver Transplant Outcomes Languish*, TRIBLIVE (Jan. 18, 2012, 5:00 AM), <https://archive.triblive.com/news/registry-upmc-liver-transplant-outcomes-languish-2/> [<https://perma.cc/LS9F-U32Y>].
385. See Casey Ross, *Hospitals are Throwing Out Organs and Denying Transplants to Meet Federal Standards*, STAT (Aug. 11, 2016), <https://www.statnews.com/2016/08/11/organ-transplant-federal-standards/> [<https://perma.cc/5Q49-JGH3>].
386. See Tracy Weber & Charles Ornstein, *Transplant Centers Penalized*, L.A. TIMES (Nov. 29, 2006, 12:00 AM), <https://www.latimes.com/archives/la-xpm-2006-nov-29-me-transplant29-story.html> [<https://perma.cc/NEA5-56V2>].
387. CTRS. FOR MEDICARE & MEDICAID SERV., *Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants*, 72 Fed. Reg. 15198, 15263 (2007). See U.S. DEP'T. HEALTH & HUM. SERVS. ADMIN., *The Scientific Registry of Transplant Recipients*, <https://srtr.transplant.hrsa.gov/> [<https://perma.cc/N2Z6-X9GB>] (explaining the SRTR).

employed take into account donor and recipient risk factors, members of the transplant community have questioned the adequacy and comprehensiveness of the risk adjustment.<sup>388</sup> Additionally, UNOS, working in conjunction with the Secretary of HHS, wields substantial enforcement powers with respect to hospitals participating in the OPTN under the mantle of quality assurance. While the focus of this oversight is on compliance with formal rules and policies, UNOS “identif[ies] programs that need closer scrutiny” by comparing expected to observed outcomes data using SRTR reports.<sup>389</sup> In theory, either UNOS or CMS could initiate a regulatory action resulting in a hospital’s loss of Medicare certification on the basis of transplant outcomes.<sup>390</sup> Less drastically, the OPTN Board of Directors might require a transplant program deemed non-compliant to implement a Corrective Action Plan.<sup>391</sup> Combining these pressures with clinicians’ “limited ability to accurately assess risk” and documented risk aversion, the result is likely to be a cautious

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388. See Michael M. Abecassis et al., *Transplant Center Regulation—A Mixed Blessing? An ASTS Council Viewpoint*, 8 AM. J. TRANSPLANTATION 2496, 2500 (2008) (questioning whether the approach then employed adequately adjusted for transplants involving antibody pre-sensitization, “marginal donors,” and the sickest patients); see also Richard J. Howard et al., *CMS Oversight, OPOs and Transplant Centers and the Law of Unintended Consequences*, 23 CLINICAL TRANSPLANTATION 778, 780 (2009) (specifying factors influencing transplant outcomes that are not taken into account by SRTR).

389. Bing Ho et al., *Should Both UNOS and CMS Provide Regulatory Oversight of Kidney Transplantation?*, 2 CURRENT TRANSPLANTATION REP. 127, 128–29 (2015) (text and Table 1).

390. *Id.* at 129. But see Charles Ornstein & Tracy Weber, *Transplant Monitor Lax in Oversight*, L.A. TIMES (Oct. 22, 2006, 12:00 AM), <https://www.latimes.com/archives/la-xpm-2006-oct-22-me-transplant22-story.html> [<https://perma.cc/CF8V-QQKA>] (noting that some observers have criticized UNOS’s approach to enforcement as spotty and excessively protective of established transplant centers); see Lenny Bernstein & Todd C. Frankel, *70 deaths, many wasted organs are blamed on transplant system errors*, WASH. POST (Aug 3, 2022, 2:30 PM) <https://www.washingtonpost.com/health/2022/08/03/transplant-deaths-mistakes-senate-finance/> [<https://perma.cc/Z26E-K8WA>] (documenting the variety of responses to “patient safety complaints” received by UNOS).

391. Ho et al., *supra* note 389, at 129.

posture toward organ offers, where one's willingness to risk undertaking a procedure reflects not only the potential recipient's interests but also the perceived implications for center statistics and, by extension, sustainability.<sup>392</sup>

This approach to balancing competing values—which itself appears to be a source a moral distress based on the volume of published commentary it has elicited—is likely to dampen enthusiasm for SLT, along with other procedures characterized by risk and uncertainty. As noted, SLT represents an innovative set of surgical techniques with evolving outcomes, the appeal of which lies in its potential to maximize the number of lives saved using scarce donated livers rather than maximizing outcomes for a smaller, fortunate selection of patients.<sup>393</sup> To the extent that concerns about outcomes data undercut the expansion of SLT at centers that are well equipped to offer it, there is a tragic irony to this situation. The asserted rationales for collecting and assessing surgical outcomes—guiding quality improvement,<sup>394</sup> ensuring that available organs are not squandered,<sup>395</sup> and screening out programs that fail at basic safety measures<sup>396</sup> – are oriented toward making the best use of available organs on a

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392. Axelrod, *supra* note 381, at 7.

393. See Joel T. Adler & David A. Axelrod, *Regulations' Impact on Donor and Recipient Selection for Liver Transplantation: How Should Outcomes be Measured and MELD Exception Scores be Considered?*, 18 AM. MED. ASS'N J. ETHICS 133, 139 (2016) (warning that, without allowances to support innovative procedures, “[transplant] programs face strong disincentives for generating novel approaches to the most difficult problem facing transplant clinicians: the need to expand the supply of available organs”).

394. Amit K. Mathur & Jayant Talwaker, *Quality measurement and improvement in liver transplantation*, 68 J. HEPATOLOGY 1300, 1300–04 (2018) (associating regulatory reporting requirements with healthcare “quality”).

395. See Suzie Lee et al., *Identifying Predictors of Outcomes in Combined Heart and Liver Transplantation*, 51 TRANSPLANTATION PROC. 2002, 2007 (2019) (noting, in a different context, that risk-based recipient selection criteria can help transplant professionals “expand the candidate pool while remaining good stewards of scarce organs”).

396. Mathur & Talwakar, *supra* note 394, at 1304 (noting that one possible function of identifying poor transplant performance is the “removal of consistently underperforming programmes in the interest of patient safety”).

system level. Individual case outcomes are the unit of measurement, but transplant programs are the focal point of intervention.<sup>397</sup> The problem arises when use of the metric runs counter to its presumptive purpose. So long as programs are effectively evaluated on the basis of one-year survival data (which may be influenced by serious complications), rather than, say, waitlist mortality or lives saved per organ offer, programs that improve net organ utilization with SLT risk being stigmatized and penalized as low performers due to the higher rate of case complications.

In light of the scarcity of donated organs, directing those available to the best surgical candidates, defined in terms of expected patient and graft survival, can be defended as a utilitarian salvage exercise, akin to minimizing casualties on an active battlefield.<sup>398</sup> If one takes this view, then a system of checks and balances<sup>399</sup> that promotes careful recipient selection might be regarded as a legitimate means of holding transplant programs accountable for the responsible stewardship of organs they will be offered. Researchers and commentators note, however, that risk-aversion on the part of transplant teams does not simply prioritize one category of plausible recipients over others; another possible consequence is that usable organs are not placed during their

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397. CTRS. FOR MEDICARE & MEDICAID SERV., *Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants*, *supra* note 387, at 132 (“Since we will be using outcomes data, along with other data and information on transplant center performance, to make decisions on initial approvals and re-approvals of transplant centers, we believe the thresholds are sufficiently rigorous to ensure we can identify transplant centers whose performance is unacceptable.”).

398. Some scholars have made the case for such a “battlefield” approach to allocation. See Rosamond Rhodes, Charles Miller, & Myron Schwartz, *Transplant Recipient Selection: Peacetime vs. Wartime Triage*, 1 CAMBRIDGE Q. HEALTHCARE ETHICS 327, 328–29 (1992).

399. See THE FEDERALIST NO. 51 (James Madison) (“Ambition must be made to counteract ambition. [. . .] This policy of supplying by opposite and rival interests, the defect of better motives, might be traced through the whole system of human affairs, private as well as public.”).

finite lifespan because of programs' unwillingness to run the risk of transplanting a particular organ into a particular patient.<sup>400</sup>

Whereas reasonable people can disagree about how best to allocate scarce lifesaving resources, the underutilization of available organs is widely treated as scandalous, as evidenced by recent attention to the United States' high kidney discard rate compared to France and the implications for patients' lives.<sup>401</sup> Likewise, a decision whether to perform SLT does not merely affect *which* patients receive transplants; it affects *how many* patients receive transplants. On a population level, performing a WLT when two patients could receive hemilivers represents a lost transplant opportunity, roughly akin to discarding a usable hemiliver. Yet, so long as surgeons have reason to think hemiliver transplants may be associated with inferior one-year outcomes in individual cases, the confluence of regulatory incentive structures and human decision psychology can be expected to yield a pattern of just such missed opportunities to save more lives.<sup>402</sup>

Recent changes in the oversight of organ retrieval and placement show that it is possible to revise how outcomes are measured and evaluated to better align them with desired behaviors and mitigate unintended consequences. Historically, OPOs were "evaluated on the basis of how many organs [were] recovered per 'eligible death,'" the designation of "eligible" being left to the OPOs. This approach created a disconnect between maximizing statistical outcomes and "actually getting people

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400. Adler & Axelrod, *supra* note 393, at 139; *but see* Jesse D. Schold et al., *The Association of Performance Evaluations and Kidney Transplant Volume in the United States*, 13 AM. J. TRANSPLANT 67, 73 (2013) (finding "no marked changes in known characteristics of recipients and donors" in kidney programs that received low performance evaluations).

401. *See, e.g.*, Adrianna Rodriguez, *US Discards Thousands of Donated Kidneys Each Year as Patients Die on Waitlist, Study Says*, USA TODAY, <https://www.usatoday.com/story/news/nation/2019/08/29/us-throws-away-3-500-donated-kidneys-per-year-study-says-heres-why/2139644001/> [<https://perma.cc/K587-WCPQ>] (last updated Aug. 30, 2019, 10:47 AM) (depicting a "broken system that costs lives").

402. *See id.*; *see also* Raymond L. Heilman, et al., commentary, *Potential Impact of Risk and Loss Aversion on the Process of Accepting Kidneys for Transplantation*, 101 TRANSPLANTATION 1514, 1514 (2017).

more organs.”<sup>403</sup> In 2020, as part of a more comprehensive update of OPO funding conditions, CMS replaced that metric with one focusing on instances in which at least one organ is recovered “as a percentage of inpatient deaths” in circumstances permitting organ donation.<sup>404</sup> Per CMS, “the revised measure will encourage OPOs to pursue all potential donors, even those who are only able to donate one organ.”<sup>405</sup> Even more directly analogous to revisiting regulatory deterrents to SLT, CMS, by jettisoning “the potential for termination of transplant programs that [do] not achieve the highest possible success rates,” conjectured that it had “remove[d] a strong disincentive for accepting and using all transplant quality organs.”<sup>406</sup>

Tension between a transplant professional’s duty to the individual patient and the allocation system’s orientation toward the health of a larger population is in some sense inherent in a universe of finite resources. In contrast, the apparent tension between regulatory incentives and optimizing SLT on a population level is a modifiable consequence of imperfect outcomes metrics, akin to the OPO assessment problem. Because SLT and minimum outcome standards for network participation

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403. Dylan Matthews, *A New Trump Executive Order on Kidneys Could Save Thousands of Lives*, VOX (Jul. 10, 2019, 8:30 AM), <https://www.vox.com/future-perfect/2019/7/10/20687507/trump-kidney-disease-transplant> [<https://perma.cc/TCC9-W9RG>].
404. CTBS. FOR MEDICARE & MEDICAID SERV., *Fact Sheet: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020), <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos> [<https://perma.cc/H5Y8-L9QD>].
405. *Id.*; See Kevin O’Connor & Alexandra Glazier, editorial, *OPO Performance Improvement and Increasing Organ Transplantation: Metrics Are Necessary But Not Sufficient*, 21 AM. J. TRANSPLANTATION 2325, 2325 (2021) (for a critical analysis embracing the objectives of incentive alignment and accountability while calling for further refinements).
406. CTBS. FOR MEDICARE & MEDICAID SERV., *Organ Procurement Organizations Conditions for Coverage Final Rule: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations* (Nov. 20, 2020), <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos> [<https://perma.cc/X7QJ-XD6Z>].

share a common goal, the OPTN/UNOS and CMS are well-positioned to encourage fuller realization of SLT through policy reforms. Specifically, these bodies could make the small percentage of livers suitable for splitting between two adults available first to qualifying transplant programs for appropriate patients exclusively on a split basis. We do not here attempt to prescribe the specific set of criteria that would govern transplant programs' eligibility to participate; these considerations will likely evolve over time. Rather, we emphasize that they should reflect public interests, rather than interests of particular transplant programs, and note that this kind of standard-setting is a familiar role of CMS and the OPTN.

The team with the highest priority patient offered SLT would choose the hemiliver to excise, and the remaining half would be available beginning with the next highest priority recipient (subject to geographic and other logistical constraints).<sup>407</sup> Transplant programs would have access to these organs for WLT only if no program accepts a hemiliver. Given the complexities of allocating and transporting liver tissue during its finite period of viability outside the body, if only one half of a liver can be placed,<sup>408</sup> that program that accepted the hemiliver would have the option of using the entire liver for the same patient. Priority would be retained for patients at imminent risk of death from *acute* liver failure, even if they require a whole liver.<sup>409</sup>

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407. See Alexander Polyak, Alexander Kuo & Vinay Sundaram, *Evolution of Liver Transplant Organ Allocation Policy: Current Limitations and Future Directions*, 13 *WORLD J. HEPATOLOGY* 830, 833 (2021).

408. Published data on adult recipients at one center show one- (and five-) year graft survival ratios of 70% for left hemilivers and 86.7% for right hemilivers, contrasted with 81.5% with whole liver grafts. Thus, one would expect that remaining left hemilivers may be more difficult to place. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2016.

409. Individuals with ALF [acute liver failure] who are listed for orthotopic liver transplantation in the US have 'status 1A' priority, above that of patients with cirrhosis . . . ." R. Todd Stravitz & David J. Kramer, *Management of Acute Liver Failure*, 6 *NATURE REVIEWS GASTROENTEROLOGY & HEPATOLOGY* 542, 549 (2009). ALF patients represent approximately 6% of liver transplant recipients in the United States. UCSF DEPARTMENT OF SURGERY, *Acute Liver Failure (ALF)*, <https://transplantsurgery.ucsf.edu/conditions-->

Additionally, the OPTN could separate out SLT outcomes from broader program evaluation metrics to alleviate any anxiety on the part of surgeons and administrators that challenges in SLT could jeopardize other transplant activities such as WLT.<sup>410</sup>

By effectively creating a central clearinghouse for SLT, this proposal may raise concerns that decisions conventionally left to surgeons' professional judgment are being preempted by a regulatory body. Locating a technical decision with the OPTN rather than the surgical team is not in itself remarkable. With public input, the OPTN ordinarily develops, employs, and adjusts organ allocation algorithms.<sup>411</sup> Clinicians, who have historically been "well represented" on bodies that set allocation policies including UNOS's board of directors, would still be able to bring their expert perspectives to the table, albeit a step further upstream.<sup>412</sup> By addressing the essential question of whether to split before any transplant program receives an offer for a specific patient, this approach sidesteps the ethical quagmire of "bedside rationing,"<sup>413</sup> instead encouraging greater adoption of SLT by better aligning interests and removing regulatory disincentives.

### C. *SLT and Society's Commitment to the Sickest*

Since liver transplant candidates with high MELD scores are not good candidates for SLT,<sup>414</sup> and current practice prioritizes

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procedures/acute-liver-failure-(alf).aspx [https://perma.cc/9CZT-8NG6] (last accessed Mar. 11, 2022).

410. Such a bifurcation should be straightforward, since the whole-split distinction is binary and one-dimensional. *See* Gerd R. Silberhumer et al., *The Difficulty in Defining Extended Liver Criteria for Grafts: The Eurotransplant Experience*, 26 *TRANSPLANT INT'L* 990, 991 (2013).
411. *See, e.g.*, ORGAN PROCUREMENT AND TRANSPLANT NETWORK, *Reassess Inclusion of Race in Estimated Glomerular Filtration Rate (eGFR) Equation*, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/> [https://perma.cc/K6TF-HL62] (last visited Mar. 10, 2022).
412. VEATCH & ROSS, *supra* note 351, at 273.
413. *See* Morten Magelssen, Per Nortvedt, & Jan Helge Solbakk, *Rationing at the Bedside: Immoral or Unavoidable?*, 11 *CLINICAL ETHICS* 112, 112–21 (2016) (discussing the practice and ethical implications of "bedside rationing").
414. *See supra* note 113.

candidates with the highest MELD scores, “pulling” some livers from the ordinary distribution process for SLT will potentially reduce the sickest patients’ access to liver transplantation. This foreseeable effect poses difficult questions of distributive justice. For reasons that will be discussed, we maintain that the proposed pathway is defensible in a range of circumstances.

Distributive justice is a major yet deeply contested theme of applied moral philosophy, including healthcare ethics.<sup>415</sup> One taxonomy distinguishes between libertarian approaches that emphasize personal independence, redistributive approaches that seek to correct societal inequities, and “egalitarian” approaches that aim to treat similar medical cases equally. “Practice guidelines and clinical pathways implicitly adopt an egalitarian concept of justice.”<sup>416</sup> In the transplant context, this statement is perhaps unsurprising given the interpersonal dependence inherent in transplant medicine, which poses a challenge for the libertarian framework, and the intense, but limited nature of surgical interventions, which render them ill-suited for addressing many societal disparities. Even confining our purview to egalitarian schools of thought, there remains a wide range of tendered answers to the basic question, “equality of what?”<sup>417</sup> One influential school of egalitarianism, associated with the philosopher John Rawls, poses a particular problem for SLT, though. Adherents to this approach evaluate possible states of affairs by comparing the welfare of those people who are worst off within each arrangement.<sup>418</sup> Adopting this lens, one would presumably look askance at a system of liver allocation that disfavors eligible patients with the highest acuity and urgency.<sup>419</sup>

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415. LAWRENCE B. McCULLOUGH ET AL., *PRINCIPLES AND PRACTICE OF SURGICAL ETHICS* 2–11 (McCullough, Jones, & Brody eds., Oxford U. Press 1998) (cautioning that appeals to “justice” in surgical ethics should be “made with care” given “historical and deep philosophical disagreement”).

416. *Id.* at 11.

417. AMARTYA SEN, *Equality of What?*, THE TANNER LECTURE ON HUMAN VALUES AT STANFORD UNIVERSITY 197 (1979).

418. *See id.* at 206–07 (exploring different versions of the “Rawlsian Difference Principle”).

419. *See* SAMUEL FREEMAN, *LIBERALISM AND DISTRIBUTIVE JUSTICE* 108, 150 (2018) (emphasizing that Rawls’ account was concerned foremost with the basic structures ordering societies.) Arguably, the choice among reasonably defensible organ allocation policies is

Our response to such objections is multifold. Technical factors prevent the transplant “waitlist” from truly operating like a ranked queue according to disease severity.<sup>420</sup> Transplant candidates have heterogeneous and nonlinear diagnoses and prognoses.<sup>421</sup> A patient with localized carcinoma that spreads, for example, may rapidly decline from among the best off physiologically to too sick to transplant.<sup>422</sup> When organs become available, they are offered based on donor, liver, and recipient characteristics like size and blood type.<sup>423</sup> A simplifying model that illuminates some of these dynamics is that of a rescue operation in which individuals stranded at sea are ferried to shore in a boat that can either transport one large person or two small people on each trip. In such an iterative scenario, there will be situations where “equal consideration” is best approximated by taking the one person who is in the most jeopardy and other

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not such a scenario, but rather a discrete downstream problem arising in circumstances where it not possible to guarantee everyone a minimal level of an essential health resource simultaneously.

420. *Frequently Asked Questions, “What is the Waitlist?”*, UNITED NETWORK FOR ORGAN SHARING (2022), <https://unos.org/transplant/frequently-asked-questions/> [<https://perma.cc/P5SB-8V6C>] (“When a donor organ becomes available, the matching system dynamically generates a new, specific list of potential recipients based on the criteria defined in that organ’s allocation policy (e.g., organ type, geographic local and regional area, genetic compatibility measures, details about the condition of the organ, the candidate’s disease severity, time spent waiting, etc.)”).
421. See generally Zobair M. Younossi et al., *Nonalcoholic Steatohepatitis is the Most Rapidly Increasing Indication for Liver Transplantation in the United States*, 19 CLINICAL GASTROENTEROLOGY & HEPATOLOGY 580 (2021) (discussing the evolution of indications for liver transplantation and respective outcomes).
422. Francis Yao et al., *Liver Transplantation for Hepatocellular Carcinoma: Lessons From the First Year Under the Model of End-Stage Liver Disease (MELD) Organ Allocation Policy*, 10 LIVER TRANSPLANTATION 621, 621 (2004) (“Since patients with HCC may have preserved hepatic function and consequently a MELD score predicting low risk of death from liver disease alone, an adjustment would need to be made to allow for the anticipated risk of dropout and death due to HCC.”).
423. *Understanding the Liver Transplant Waitlist*, UPMC HEALTH BEAT (Jan. 17, 2018), <https://share.upmc.com/2018/01/liver-transplant-waiting-list/> [<https://perma.cc/G7VH-BMWP>].

situations in which two should be taken.<sup>424</sup> As Kim and colleagues note, this “balancing” strategy also has the virtue of aligning with the OPTN’s current dual orientation toward fairness *and* utility,<sup>425</sup> which carries the imprimatur of democratic legitimacy in our pluralistic society. Importantly, given the relatively small percentage of donated livers suitable for splitting,<sup>426</sup> the impact of SLT on the supply of livers offered for WLT is likely to be modest.

We take the position here that establishing a program offering certain livers on a “split first” basis is consistent with the equitable balance that the OPTN aims to achieve—probably more so than the existing approach to liver allocation with its built-in ethical tensions. Even viewing allocation through a Rawlsian lens, in many cases SLT will be justified. Our preferred choice architecture would locate the authority to identify prime livers for splitting within the OPTN, or a similarly-appointed clearinghouse, and retain absolute priority for patients in acute liver failure to receive a WLT. In this case, the system can promote fuller utilization of SLT while reinforcing professional integrity among clinicians, ensuring voluntary informed consent among patients, and advancing distributive justice among the population on the waitlist.

## VI. RECOMMENDATIONS FOR IMPROVING THE CURRENT SPLIT LIVER TRANSPLANT POLICIES AND CONCLUSION

### A. *Mandatory Splitting of Suitable Deceased Donor Livers*

The most significant of the policies we recommend is requiring all qualifying livers to be offered first on a split basis.<sup>427</sup> The narrow exceptions to the mandatory splitting policy would be patients with acute liver failure that occurs rapidly, placing them in urgent need of a transplant, and possibly patients in need

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424. Tae Wan Kim et al., *Ethics of Split Liver Transplantation: Should a Large Liver Always be Split if Medically Safe?*, 48 J. MED. ETHICS 738, 739 (2021).

425. *Id.* (drawing on the work of Frances Kamm, Thomas Scanlon, and Thomas Nagel).

426. Hashimoto et al., *Split Liver Transplantation Using Hemiliver Graft in the MELD Era*, *supra* note 55, at 2078 (15% of deceased donor livers utilized at one transplant center “could have been split;” in practice, less were).

427. Bobbert, Primc, & Schafer, *supra* note 28, at 5.

of multiorgan or multivisceral transplantation.<sup>428</sup> These exceptions have also been approved in other countries with SLT policies.<sup>429</sup> We also recommend a separate waitlist for liver transplant candidates who qualify for SLT.<sup>430</sup> This list would make finding the appropriate recipients for hemiliver grafts easier and help avoid unnecessary delays in transplantation.<sup>431</sup> A well-designed mandatory splitting policy, along with a separate SLT waiting list, would not only increase the number of lives saved by

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428. See *infra* note 446, tbl.1.

429. In Italy, super-urgent patients that have priority over SLT patients are those “with severe medical conditions” who need a transplant to survive. There is also an exception for patients who are “waiting for a multiorgan transplant.” Silvia Trapani et al., *Analysis of the Trend Over Time of High-Urgency Liver Transplantation Requests in Italy in the 4-Year Period 2014-2017*, TRANSPLANT PROC. 2280, 2883 (2019). A similar prioritization model was implemented in Australia and New Zealand. The TSANZ developed an urgent waiting list, which puts patients that “have a high risk of dying” on the waitlist and “a short window of opportunity for transplantation” on the top of the waitlist for mandatory transplantation. *2nd Annual Report ANZLITR*, AUSTL. & N.Z. LIVER & INTESTINAL TRANSPLANT REGISTRY, 1, 13 (2020), [https://www.anzlitr.org/wp-content/uploads/2021/12/32ndANZLITR\\_AnnualReport.pdf](https://www.anzlitr.org/wp-content/uploads/2021/12/32ndANZLITR_AnnualReport.pdf); *Liver Allocation Policy – POL195*, NHS BLOOD & TRANSPLANT, 1, 18, <https://nhsbtddb.blob.core.windows.net/umbraco-assets-corp/27372/pol195-120822.pdf> (last visited April 2021). In the UK and the Republic of Ireland, only Category 1, super-urgent patients have priority over split liver transplantation. This includes (1) patients who have acute liver failure or acute graft failure, (2) patients who require a multivisceral graft containing the liver, bowel and pancreas, and (2) patients who require a multiorgan (combined heart liver or lung/liver) transplant. See also *Liver Allocation Policy – POL196*, NHS BLOOD & TRANSPLANT, 1, 12, <https://nhsbtddb.blob.core.windows.net/umbraco-assets-corp/26684/pol196.pdf> (last visited Oct. 2021); see also NHS Blood and Transplant, *Liver Allocation Policy - POL196/11*, 1, 8, <https://nhsbtddb.blob.core.windows.net/umbraco-assets-corp/28053/pol196.pdf> [<https://perma.cc/DLU9-KDUQ>] (effective Oct. 25, 2022). For more information on these countries’ policies, see *infra* note 437 and accompanying text.

430. See *supra* note 282 and accompanying text.

431. *Id.*

liver transplants,<sup>432</sup> but would also reduce the ethical concerns related to SLT.

Mandatory splitting would obviate the issues related to potential coercion or manipulation of patients because patients would no longer be given the choice of either accepting a whole deceased donor liver or sharing the liver with a child or an adult.<sup>433</sup> The transplant candidate's only choice would be whether or not to accept a hemiliver transplant. In making this choice, the patient would be free to consider only what is in the patient's own best interests. A mandatory splitting policy would also eliminate the conflict inherent in transplant physicians' desires to split a donated liver to benefit the liver transplant community as a whole, while also honoring their fiduciary duty to their individual patients, who are less likely to have post-surgery complications if they receive a whole, rather than a hemiliver, graft.<sup>434</sup> Mandatory splitting would take the choice of whether to split out of the physicians' hands so the physician's only role would be to advise his/her individual patient on whether or not to accept a hemiliver graft.<sup>435</sup>

While mandatory splitting may seem like an extreme departure from UNOS's current allocation policies, other countries have already implemented mandatory splitting policies.<sup>436</sup> Italy, the United Kingdom, and South Korea require splitting of eligible deceased donor livers if the hemiliver grafts can be used to benefit a child and adult recipient.<sup>437</sup> Italy was the

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432. See Bobbert, Primc, & Schafer, *supra* note 28, at 5; see Chan et al., *supra* note 16, at 7–8.

433. See *supra* notes 346–47 and accompanying text.

434. See *supra* notes 147–50 and accompanying text.

435. *Id.*

436. See tbl.1 and discussion accompanying note 437.

437. See CENTRO NAZIONALE TRAPIANTI, *supra* note 281; NHS BLOOD AND TRANSPLANT DECEASED DONOR LIVER DISTRIBUTION AND ALLOCATION - POL196/10.1, § 2.9.1 (2022), <https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/> [<https://perma.cc/W78P-AULY>]; Gil-Chun Park et al., *Prognosis of Split Liver Transplantation Compared with Whole Liver Transplantation in Adult Patients: Single-center Results under the Korean MELD Score-based Allocation Policy*, 35 J. KOREAN MED. SCI. 1, 3 (2020) (“The KONOS policy requires donor organ splitting as mandatory only for a combination of adult and child recipients. That is if a candidate deceased donor fulfills the

first country to also propose a national allocation policy that requires splitting eligible deceased donor livers for two adult recipients.<sup>438</sup> Under this proposed policy, adult-adult SLT would only be appropriate when “there are no pediatric patients in need of a SLT.”<sup>439</sup> In addition, the Italian proposal called for compiling a national list of individuals “deemed suitable” for an adult-adult split liver transplant.<sup>440</sup> Before being placed on this separate waitlist, liver transplant candidates would be required to sign an informed consent form agreeing in advance to SLT.<sup>441</sup>

Some other countries, while not having a mandatory splitting policy, have a commitment to fostering SLT. For example, Australia’s and New Zealand’s national organ transplant policy expresses “a commitment . . . [to] ‘split’ [low risk livers] wherever possible.”<sup>442</sup> In Argentina, national OPOs are “encourage[d] . . . to set regulations to directly assign a liver for a split procedure when a ‘split-able’ donor is identified.”<sup>443</sup> If the liver cannot be split, the recommendation is that it should be allocated using the nation’s regular MELD score-based allocation.<sup>444</sup> Taiwan and Saudi Arabia both promote the increased use of adult-adult split liver transplantation, partially

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criteria for SLT, the KONOS selects appropriate adult and child recipients on the waitlist list.”).

438. See Angelico et al., *supra* note 106.

439. *Id.*

440. *Id.*

441. *Id.*

442. The Transplant Society of Australia and New Zealand, *Clinical Guidelines for Organ Transplantation from Deceased Donors – Version 1.7*, 1, 116 (Sep. 2021), [https://tsanz.com.au/storage/documents/TSANZ\\_Clinical\\_Guidelines\\_Version-17.pdf](https://tsanz.com.au/storage/documents/TSANZ_Clinical_Guidelines_Version-17.pdf).

443. Sabrina Gambaro et al., *Right Extended Split Liver Transplantation Compared with Whole Liver Transplantation: Lessons Learned at a Single Center in Latin America – Results From a Match Case-Control Study*, 49 *TRANSPLANT PROC.* 2122, 2127 (2017); Esteban Halac et al., *Split Liver Transplantation: Report of Right and Left Graft Outcomes From a Multicenter Argentinean Group*, 22 *LIVER TRANSPLANTATION* 63, 64 (2015).

444. *Id.*

due to the shortage of small or pediatric deceased donors in the area.<sup>445</sup>

*Table 1: National Split Liver Policies/Recommendation*

Country/ Territory	Manda- tory Splitting Policy	Form of SLT Alloca- tion	Adult/ Adult SLT Suggested	Excep- tion for Urgent/ Super- Urgent Patients <sup>446</sup>	Exception for Multi- visceral or Multiorgan Transplant Patients
Italy	Yes	Child/ Adult	Yes	Yes	Yes
Australia & New Zealand	No	Child/ Adult	No	Yes	Yes
UK <sup>447</sup>	Yes	Child/ Adult	No	Yes	Yes
South Korea	Yes	Child/ Adult	No <sup>448</sup>	----	---- <sup>449</sup>

445. See Faisal A. Abaalkhail et al., *Clinical Practice Guidelines for Liver Transplantation in Saudi Arabia*, VOL. 42 SAUDI MED. J. 927, 928 (2021), <https://smj.org.sa/content/smj/42/9/927.full.pdf>; Chan et al., *supra* note 16, at 2096.

446. See *supra* note 436 and accompanying text.

447. The United Kingdom does not use the MELD allocation system. See Mitra K. Nadim et al., *Inequity in Organ Allocation for Patients Awaiting Liver Transplantation: Rationale for Uncapping the Model for End-Stage Liver Disease*, 67 J. HEPATOLOGY 517, 519 (2017) (“In the United Kingdom, [allocation criteria] is based on the United Kingdom End-Stage Liver Disease Score, which directs organs to candidates who have a realistic chance of surviving more than 5 years post transplantation.”).

448. Although South Korea does not have a national policy promoting the use of adult-adult SLT, individual transplant centers encourage its use. See Jung et al., *supra* note 93, at 239; see also Park et al., *supra* note 437, at 11.

449. The Nat’l Inst. of Organ Tissue and Blood Mgmt., *Living Donor*, KONOS, [https://www.konos.go.kr/page/subPage.do?page=sub1\\_1\\_2\\_4](https://www.konos.go.kr/page/subPage.do?page=sub1_1_2_4) [<https://perma.cc/M483-LS4U>] (last visited Feb. 21, 2022).

We also recommend that the mandatory splitting policies in the U.S. be flexible so that hemiliver grafts can be allocated to liver transplant candidates who are not critically ill and would benefit most from SLT.<sup>450</sup> While this would alter MELD-based national allocation systems somewhat, only approximately 12.6% of livers are suitable for splitting<sup>451</sup> so the additional wait times for those at the top of the national waitlists should be minimal.

*B. Separate Outcome Assessments for SLT*

We also recommend that organizations engaged in the evaluation of transplant centers' performance, particularly the SRTR, UNOS, and CMS, collect and assess data on SLT separately from data on whole liver transplantation. This approach will give transplant professionals the confidence to embrace SLT by helping to assure them that possible complications associated with a complex, innovative procedure will not be held against other vital services their centers offer. Although federal regulations presently set standards for transplant "centers,"<sup>452</sup> in practice current performance standards are largely *organ*-specific. Thus, in 2005, a California academic hospital lost its Medicare certification for liver transplantation due to unacceptable case management, but the hospital's kidney and pancreas transplant programs were unaffected.<sup>453</sup> Given the unique physiological and ethical implications of SLT, we maintain that further disaggregation is needed within liver program metrics, distinguishing split from whole liver transplants.

Breaking out outcomes data at this greater level of granularity is not unprecedented. Existing federal regulations, direct CMS to "review adult and pediatric outcomes separately when a program requests approval to perform both adult and pediatric transplants."<sup>454</sup> Additionally, CMS imposes some participation requirements on living donor programs that are not applicable to programs only performing deceased donor organ

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450. See Angelico et al., *supra* note 106, at 2037–38.

451. See Ge et al., *supra* note 65, at 1116.

452. See, e.g., CTRS. FOR MEDICARE & MEDICAID SERV., *supra* note 387, at 15199.

453. See *Liver Program at UCI Closes*, ORANGE CNTY. REGISTER (Nov. 11, 2005), <https://www.oregister.com/2005/11/11/liver-program-at-uci-closes/> [<https://perma.cc/6R8G-HJ97>].

454. 42 C.F.R. § 482.80(c) (2019).

transplantation.<sup>455</sup> Given the foreseeable learning curve for SLT, a distinct structure for outcomes review and supplementary program approval requirements would promote accountability for outcomes while also acknowledging relevant nuances. If in time SLT becomes less exceptional, the scope of the carve-out could be refined to reflect the maturation of the field.<sup>456</sup>

### *C. Modifications of Informed Consent*

Next, we recommend that SLT be performed only at qualifying transplant centers with experienced physicians who are expert in SLT because of the complexity of SLT and the significantly better results at these centers.<sup>457</sup> We also recommend that the requirements for informed consent be adapted to facilitate the transfer of appropriate candidates for liver transplants to these centers and to comply with the intent of informed consent laws.

Physicians should be required to disclose the alternative of SLT to all patients who would benefit from receiving a hemiliver graft.<sup>458</sup> If the patient is an appropriate candidate for SLT and is amenable to receiving a hemiliver graft, the patient should be informed of the physician's experience in performing SLT and referred to a qualified transplant center specializing in SLT if the patient is not already at one of those centers.<sup>459</sup> Because individuals of smaller stature – mainly women – have a significantly higher mortality on the waitlist than men generally,<sup>460</sup> UNOS should help facilitate more SLT and prioritize

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455. See 42 C.F.R. § 482.102 (2019).

456. CMS has incrementally blurred the distinction between adult and pediatric transplantation programs by effectively allowing transplant programs approved for one of these classifications to perform some transplants in the other category. See CTRS. FOR MEDICARE AND MEDICAID SERV., NOTICE TO TRANSPLANT PROGRAMS: APPLICATIONS AND APPROVAL FOR ADULT AND PEDIATRIC TRANSPLANT PROGRAMS (Dec. 14, 2007).

457. See generally *supra* note 138.

458. See generally *supra* note 241–51 and accompanying text.

459. *Id.*

460. Nephew et al., *supra* note 49, at 1 (noting that women have a higher mortality on the liver transplant waiting list than men and that this higher mortality is believed to be due to “difficulty finding appropriately sized organs for smaller statured women”).

individuals of short stature as recipients.<sup>461</sup> Not only will prioritizing these patients lead to a more equitable distribution of donor livers,<sup>462</sup> but individuals of short stature are generally the best candidates for hemiliver grafts clinically.<sup>463</sup>

Physicians should also obtain informed consent from candidates for liver transplants at three distinct times during the transplant process.<sup>464</sup> First, physicians should obtain informed consent from patients before they are added to the waitlist – preferably a special waitlist for those who have agreed to accept a hemiliver graft.<sup>465</sup> The second time physicians should obtain informed consent is when the patient reaches a point on the waitlist when the offer of a deceased donor liver is imminent.<sup>466</sup> Because the patient can remain on the waitlist for a substantial period of time before being offered a donor liver,<sup>467</sup> this second informed consent will give the patient an opportunity to determine whether to accept a hemiliver graft given the patient’s current medical condition and will also help avoid unnecessary refusals of split liver grafts and corresponding delays.<sup>468</sup> Finally, the third informed consent is necessary because patients are entitled to refuse a specific deceased donor liver after being informed of the characteristics of that donor organ.<sup>469</sup>

## VII. CONCLUSION

While we contend that SLT should be mandated, we also believe that the additional suggestions outlined above will facilitate more adult/adult hemiliver transplants and help alleviate important ethical concerns. It now appears that, in the not-too-distant future, transplant patients may be able to receive engineered organs or genetically modified animal organs

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461. *See generally supra* note 248.

462. *See generally supra* note 1.

463. *See generally supra* note 91.

464. *See supra* Section III(D)(2).

465. *See supra* note 253 and accompanying text.

466. *See generally supra* note 298.

467. *See* UPMC HEALTH BEAT, *supra* note 423.

468. *See generally supra* note 303 and accompanying text.

469. *See supra* note 302 and accompanying text.

(xenotransplantation), instead of human donor livers.<sup>470</sup> Indeed, the first technically successful transplants of genetically modified animal organs into human bodies took place just this past year.<sup>471</sup> However, these innovations are still years away from being offered to patients on a large scale.<sup>472</sup> In the meantime, the technology and skill to save additional lives through SLT exist now.<sup>473</sup> As William Blake reputedly said, “[h]indsight is a wonderful thing, but foresight is better, especially when it comes to saving life . . . , or some pain!”<sup>474</sup> Research has shown that implementing a mandatory SLT policy will save additional lives.<sup>475</sup> The time to act is now.

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470. See Roni Caryn Rabin, *Patient in Groundbreaking Heart Transplant Dies*, N.Y. TIMES (Mar. 9, 2022) (stating that a “genetically modified pig heart” was successfully transplanted into a 57-year-old man, but he died “two months after the transplant surgery”) [<https://perma.cc/U8UK-AZQP>]; Roni Caryn Rabin, *In a First, Surgeons Attached a Pig Kidney to a Human, and It Worked*, N.Y. TIMES (Oct. 21, 2021), (noting that a genetically modified pig kidney was attached to “a brain-dead patient who was sustained on a ventilator” and that “the organ worked normally, a scientific breakthrough that one day may yield a vast new supply of organs for severely ill patients.”) [<https://perma.cc/8QEB-HR2W>]; Joshua Gershlak, *Engineering New Tissues and Organs: How We Can Eliminate the Massive Organ Shortage in the United States*, 14 J. HEALTH & BIOMEDICAL L. 83, 100 (2018) (noting that “tissue and organ engineering have shown great promise in addressing the organ shortage.”).

471. Roni Caryn Rabin, *In a First, Surgeons Attached a Pig Kidney to a Human, and It Worked*, N.Y. TIMES (Oct. 21, 2021), <https://www.nytimes.com/2021/10/19/health/kidney-transplant-pig-human.html> [<https://perma.cc/5AP5-KWTJ>].

472. *Id.* (noting that pig organs will not be available for transplant “any time soon, as there are significant medical and regulatory hurdles to overcome”).

473. See *supra* note 162.

474. *Governance and Regulations: Contemporary Issues, in* 99 CONTEMP. STUDIES IN ECON. AND FIN. ANALYSIS 289 (Simon Grima & Pierpaolo Marano eds., 2018).

475. See *supra* note 95.