Non-Directed Liver Donor: Creating a Standardized Approach to Candidacy

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Medical Director Living Donor Liver Transplant
Objectives

• Review published experience in non-directed living liver donation (ND-LLD)

• Highlight considerations in the evaluation & selection of non-directed donors (NDDs)

• Present a schema for NDD liver allocation among transplant waitlist candidates
Terminology

- **Altruistic** - describing those coming forward to donate whether directed or nondirected

- **Anonymous** - identity unknown to the recipient and vice versa

- **Directed** - donating an organ to a specified intended recipient

- **Related** - describing those with a blood relation to the intended recipient
  - Directed Unrelated Affiliated - specifies intended recipient with whom they have relationship but not blood relative
  - Directed Unaffiliated - specifies intended recipient who they have learned about but do not know directly “Social Media Donor”
    
    Susan Rubman Gold - Transplant Psychology, Yale University

- **Non-directed** - willing to donate to any appropriate recipient

- **Unspecified** - analogous to nondirected, favored term in European literature

Dynamic

Directed Donor

Compatible
- Donates to intended recipient

Incompatible
- Continues as Nondirected donor
  - Enters paired exchange
  - Recipient selected by center

Intended recipient transplanted with another donor

Anonymous D/R pair may choose to later disclose their identity
The Numbers

Number of non-directed living donor liver transplants per year (US)

The Numbers

Number of LDLTs per year by donor type (US)

The Numbers

- **2020**: 491 LDLT of 8,416 Total Liver Transplants = 5.5%,
- **58** unrelated, non-directed donors
- **NDD 58/total LLD 485 = 12%**

- **2021** OPTN Annual Data Report:
  - **72** unrelated, non-directed donors in the United States = **12.7%** of LDLT

Context
LDLT story line….
Attention to LDLT

Nationally publicized media campaigns

Center-specific programs to educate recipients on the benefits of LDLT and aid in identification of donors

Social media testimonials

Park A. UPMC's campaign for living-donor liver transplants resulted in 20,000 inquiries in its 1st year — 2 marketing leaders explain how. Becker's Hospital Review. November 20, 2019.
Center Activity & Interest in ND-LLD

- Kaplan et al Survey - 65% (n=33) of 51 US LT centers reported performance of ND-LLD, 78% of the 18 who hadn’t reported they would consider it.

- SRTR 3/2002 to 12/2020 - 35 centers performed at least 1 ND-LLD.

- Both DLD and NDD transplants were relatively concentrated at few centers; the concentration of NDD (Gini coefficient 0.84) was more pronounced than that of DLD transplants (Gini 0.66).


Personal Experience

- National (2020 OPTN/SRTR Annual Data Report) 491 LDLT of 8,416 Total Liver Transplants = 5.5%,
- NDD 58/ total LLD 485 = 12%

- **2022: Yale** 5 LDLT of 33 Total Liver Transplants = 15%,
- **NDD 3/ total LLD 5 = 60%**
- 2 Adult to Adult RL, 1 Adult to Pediatric LLS
- 1 was prior kidney donor

- 2023 thus far:  NDD 2/ total LLD 3
Reluctance

- Lack of awareness or acknowledgement of LDLT benefit
- Providers’ limited ability to accept such donor motivation
- Inherent complexity of developing & maintaining an NDD program
- Concern regarding potential regulatory and/or legal ramifications

14.6.B Placement of Non-directed Living Donor Organs

Prior to determining the placement of a non-directed living donor organ, including non-directed organs from domino donors and non-domino therapeutic organ donors, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center.

When a non-directed living donor organ is placed, the recovery hospital must document how the organ is placed and the rationale for placement.

This requirement does not apply to non-directed living kidney donors who donate a kidney through a Kidney Paired Donation (KPD) arrangement.
Experience NDD- LD

The Ethics Committee of the Transplantation Society endorsed the use of NDDS in 2006

Among the 11 highest volume LDLT countries, NDD was found to be explicitly legal in only 5 (Canada, India, US, Pakistan, Saudi Arabia)

Activity has been documented only in the US and Canada*


### TABLE 2 Published experience of anonymous nondirected living liver donation

<table>
<thead>
<tr>
<th>First author and year of publication</th>
<th>Country</th>
<th>Center</th>
<th>Year</th>
<th>N</th>
<th>Age range</th>
<th>Surgery (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. Jendrisak, 2006^22</td>
<td>United States</td>
<td>Washington University, Washington University Medical Center</td>
<td>a</td>
<td>1</td>
<td>35</td>
<td>LLS</td>
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<tr>
<td>L. Wright, 2007^13</td>
<td>Canada</td>
<td>University of Toronto, Toronto General Hospital</td>
<td>a</td>
<td>1</td>
<td>46</td>
<td>LLS</td>
</tr>
<tr>
<td>J-B. Otte, 2009^14</td>
<td>Belgium</td>
<td>Université Catholique de Louvain, Cliniques Saint-Luc</td>
<td>2004</td>
<td>1</td>
<td>50</td>
<td>LLS</td>
</tr>
<tr>
<td>TW Reichman, 2010^15</td>
<td>Canada</td>
<td>University of Toronto, Toronto General Hospital</td>
<td>2005-2009</td>
<td>12</td>
<td>20-54</td>
<td>RTH (7), LLS (5)</td>
</tr>
<tr>
<td>N. Goldaracena, 2019^16</td>
<td>Canada</td>
<td>University of Toronto, Toronto General Hospital</td>
<td>2005-2017</td>
<td>50</td>
<td>20-59</td>
<td>RTH (21), LLS (24), LL (5)</td>
</tr>
</tbody>
</table>

*Abbreviations: LL, left hepatectomy; LLS, left lateral segmentectomy; RTH, right hepatectomy.

^aNot provided.
Published Experience

O063 NON-DIRECTED ALTRUISTIC LIVING LIVER DONATION: EVALUATION AND OUTCOMES
Leeds Teaching Hospitals NHS Trust, HPB and Transplant Unit, Leeds, United Kingdom

Results: Since beginning our liver transplant (LT) program in 1985, we have performed 2574 adult and 319 paediatric LT. We began LDLT in 2007 and we have had 821 enquiries that converted into 321 live donor assessments and 84 LDLT. Of those enquiries, 85 represented NDAD (10%). They were predominantly males (63%), median age 40 years (range 18-60); 7 had previously donated a kidney. The main reasons for not progressing to donation were failure to engage after an initial enquiry (45%), or medical conditions precluding donation (30%). 11 progressed to donation (13%): 8 males, median age 26 years (19-54), all Caucasian, 8 single, and 1 after kidney donation. 10 donated a left lateral segment graft and 1 a right liver graft. The median hospital stay was 4 days (4-7), and the post-operative complications rate was 18%, all Clavien-Dindo grade I.

Conclusion: Our donor cohort was demographically diverse but they all shared a common desire to help others; we found them to be intellectual, psychologically well balanced, self-aware, and with a universal sense of social and personal responsibility. We were able to carry out the surgery safely. We suggest that experienced LDLT programs should consider NDAD liver transplantation.
Published Experience

- Non-directed living liver donation in prior living kidney donors
- Non-directed living liver donors to facilitate paired exchange


TABLE 1 Characteristics of all ND-LLDs in the United States, 1998-2018. Data obtained from SRTR and given in n (%) 

<table>
<thead>
<tr>
<th>Variable</th>
<th>N - 105 total patients, N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD), years</td>
<td>39.2 ± 10.3</td>
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<tr>
<td>Gender, male</td>
<td>51 (49)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>98 (93)</td>
</tr>
<tr>
<td>Black</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>2 (2)</td>
</tr>
<tr>
<td>BMI (mean ± SD), kg/m²</td>
<td>25.2 ± 3.5</td>
</tr>
<tr>
<td>Type of donation</td>
<td></td>
</tr>
<tr>
<td>Left lateral segment</td>
<td>33 (31)</td>
</tr>
<tr>
<td>Left lobe</td>
<td>19 (18)</td>
</tr>
<tr>
<td>Right lobe</td>
<td>46 (44)</td>
</tr>
<tr>
<td>Not reported</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Transfusion</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>13 (12)</td>
</tr>
<tr>
<td>Attended college/technical school</td>
<td>20 (19)</td>
</tr>
<tr>
<td>Associate/bachelor’s degree</td>
<td>43 (41)</td>
</tr>
<tr>
<td>Graduate degree</td>
<td>20 (19)</td>
</tr>
<tr>
<td>Not reported</td>
<td>9 (9)</td>
</tr>
</tbody>
</table>

Employment status
- Full time: 79 (89)
- Part time: 7 (8)
- Not reported: 3 (3)

Insurance status
- Medicaid: 1 (1)
- Medicare: 2 (2)
- Public-CHIP (Children’s Health Insurance Program): 3 (3)
- Unknown: 99 (94)

Current donor status
- Alive: 89 (85)
- Deceased: 0
- Unknown: 16 (15)

Marital status
- Married: 54 (55)
- Single: 34 (34)
- Divorced/separated/widowed: 10 (10)
- Not reported: 1 (1)

Donor-experienced complications
- Biliary: 3 (3)
- Other complications: 10 (10)
- Readmission: 6 (6)
- Not reported: 7 (7)

30 (29%) prior kidney donors

Published Experience:

Health Related Quality of Life
Keck School of Medicine USC

FORUM

The nondirected live-kidney donor: ethical considerations and practice guidelines
A National Conference Report

Adams, Patricia L.; Cohen, David J.; Danovitch, Gabriel M.; Edington, Reverend Mark D.; Gaston, Robert S.; Jacobs, Cheryl L.; Luskin, Richard S.; Metzger, Robert A.; Peters, Thomas G.; Siminoff, Laura A.; Veatch, Robert M.; Rothberg-Wegman, Lynn; Bartlett, Stephen T.; Brigham, Lori; Burdick, James; Gunderson, Susan; Harmon, William; Matas, Arthur J.; Thistlethwaite, J. Richard; Delmonico, Francis L.

Author Information

Published Experience:

“Second Chance St. Louis Donor Evaluation Protocol”

A program established within regional OPO (Mid-America Transplant Services) to evaluate potential NDDs (liver & kidney) prior to transplant center referral

Planning committee- transplant surgery, medicine, hospital administration, psychiatry, bioethics, OPO

Review committee- bioethics, law, religious community, media, lay public

Data reported from the initial 30 months of program operation

## Published Experience:
“Second Chance St. Louis Donor Evaluation Protocol”

<table>
<thead>
<tr>
<th>Stage</th>
<th>N</th>
<th>NFA</th>
<th>MRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inquiry</td>
<td>731</td>
<td>600</td>
<td>N/A</td>
</tr>
<tr>
<td>Call-back</td>
<td>131</td>
<td>44</td>
<td>40</td>
</tr>
<tr>
<td>Phase I</td>
<td>47</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>Phase II</td>
<td>25</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Phase III</td>
<td>19</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Phase IV</td>
<td>19</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Phase V</td>
<td>19*</td>
<td>2**</td>
<td>2</td>
</tr>
<tr>
<td>Phase VI</td>
<td>7</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NFA = no further action, MRO = medical rule out. *7 donated (6 kidney, 1 liver), 5 pending donation (2 kidney, 3 liver). **Intended liver recipients unexpectedly receive deceased donor transplant. Three liver donor candidates were declined referral by transplant center for lack of need and are under evaluation for kidney donation.

Published Experience: “Second Chance St. Louis Donor Evaluation Protocol”

Psychological Testing and Personal Evaluation:

- Minnesota multiphasic personality inventory (MMPI-2) - validated measure of psychopathology
- Temperament and character inventory (TCI) - validated measure of personality traits
- Standard psychiatric interview using DSM-IV clinical criteria for major psychiatric disorders
- Mini mental status exam (MMSE)
- Assessment of donor motivation
- Interview of family for support

In total, the interview, MMPI-2 and TCI provided convergent evidence that these donor candidates were without psychiatric disorder, were not thrill seekers and appeared to be very self-confident and socially aware individuals. They chose to be donors on their own without influence from others.

Considerations in the Donor Evaluation

Dichotomous Decision with Multiple Points for Consideration with Unknowns

Miller CM, Transplantation Reviews 2008
Across the domains of evaluation: Medical, Surgical, & Psychosocial, should the acceptable risk threshold for non-directed donors differ from that of directed donors? Points to consider:

- Emphasis on donor safety should be equivalent
- Role of shared decision making
- Risk may be modified by recipient selection
- An early negative outcome in NDD will have significant negative impact not only for the donor but for living donation in the US.


Donor Evaluation: Thresholds

Medical

• Attention to “grey zones” - age, metabolic profile, hypercoaguable assessment

Surgical
“Moral” Focus

In addition to donor safety, the primary “ethical” or “moral” focus in NDD need be on attention to strict avoidance of coercion, assurance of informed consent, transparency, and respect for donor autonomy.

• Avoid transplant center generated coercion
  • awareness vs. marketing initiatives
  • upfront education re: all donation options*

• Education in informed consent
  • use of standard programs
  • disclosure re: options
  • discussion of risks specific to NDD
  • review of graft allocation algorithm

• Maintenance of confidentiality & anonymity
  • protocols to minimize a breach of confidentiality
  • recipient’s insurance explanation of benefits
  • process for disclosure of identity if mutually desired

Discussion of Donation Options

Statement vs. Ask?

Initial touch point

Thank you for your courage in stepping forward to be evaluated as a potential living liver donor for xxx. I do not see any absolute contraindication in proceeding based on your health screening assessment. We will begin with blood typing and a liver panel (add others as applicable) to see if you are compatible as a donor for xxx and contact you when we have results. Should we note that your blood type is not compatible or if there is another anatomical reason noted further into your evaluation that limits you from being a directed donor for xxx, if you wish, and at your request, we can discuss potential paired donation, and/or consider you as non-directed donor (willing to donate to any eligible transplant waitlist candidate). If you are interested in this option should the need arise, we would be honored to continue to work with you.

Intended recipient transplanted

Thank you for your courage in stepping forward to be evaluated as a potential living liver donor for xxx. I am calling to let you know that xxx has now successfully undergone transplantation. At xxx we do consider non-directed donors (someone willing to donate to any eligible transplant waitlist candidate). If you are interested in this option, we would be honored to continue to work with you. Please contact us back if this is the case.
Evaluation & Allocation

- Kaplan et al Survey - Inquired re: respondents' thoughts on NDD evaluation and graft allocation......

## Allocations - NDD Kidney

### Table 2: Organ allocation models in kidney transplantation

<table>
<thead>
<tr>
<th>Model</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor-Centric</td>
<td>To the recipient with the highest likelihood of success.</td>
</tr>
<tr>
<td>Recipient-Centric</td>
<td>To the recipient with the lowest likelihood of receiving any other organ.</td>
</tr>
<tr>
<td>Utilization-Centric</td>
<td>To facilitate paired exchange transplants.</td>
</tr>
<tr>
<td>Socio-Centric</td>
<td>To the recipient at the top of the waiting list.</td>
</tr>
</tbody>
</table>

Ethical Principles of Allocation

Minimize Donor Risk

https://www.transplantmanitoba.ca/transplant-program/kidney-allocation
Proposed algorithm for allocation of NDD liver grafts to promote higher utility within the bounds of non-futility, to be just, and to fairly distribute grafts to those in greatest need, who have significant mortality risk, who will derive maximal benefit, and who are without adequate access to donor organs otherwise.
Principles to Guide NDD Graft Allocation

- Potential recipients of NDD grafts should be **medically appropriate to receive a partial liver graft**.

- Potential recipients of NDD grafts should have **standard indications for LT**.

- The use of NDD grafts for patients with **MELD score exceptions** should be **guided by anticipated access** to deceased donor transplantation relative to the recipient’s risk of waitlist dropout.

- Potential recipients who have **approved directed living donors** should be considered for NDD grafts if they are participating in **LPE** or initiation of a chain where NDD grafts could increase the donor pool and provide access to a patient without such an option.

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Principles to Guide NDD Graft Allocation

• Potential recipients who have an approved yet incompatible (size or ABO) living donor should be given first priority for NDD grafts and the approved donor allocated to a compatible recipient (pediatric, if available) to allow for two transplants to occur.

• Pediatric recipients should share first priority for NDD grafts because pretransplant mortality rate is highest for pediatric candidates, especially those aged younger than 1 year.

• The remaining eligible candidate pool should be considered by a multidisciplinary transplant team.

• Assessment of appropriate graft weight to body weight ratio is complex and must include consideration of not only size but other factors such as recipient MELD, donor age, and graft steatosis.

US Recipients of NDD

**TABLE 3.** Multivariable analysis of factors potentially associated with receipt of NDD liver transplant among adults

<table>
<thead>
<tr>
<th>Factor</th>
<th>aOR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–34</td>
<td>Ref</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>35–49</td>
<td>0.98</td>
<td>(0.43-2.29)</td>
<td>&gt;0.9</td>
</tr>
<tr>
<td>50–64</td>
<td>1.58</td>
<td>(0.71-3.54)</td>
<td>0.3</td>
</tr>
<tr>
<td>65–79</td>
<td>0.62</td>
<td>(0.23-1.64)</td>
<td>0.3</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>Ref</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Female</td>
<td>2.31</td>
<td>(1.44-3.7)</td>
<td>&lt;0.01</td>
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<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>Ref</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Black</td>
<td>1.51</td>
<td>(0.53-4.29)</td>
<td>0.4</td>
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<tr>
<td>Hispanic/Latino</td>
<td>0.48</td>
<td>(0.21-1.11)</td>
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<td>Other</td>
<td>1.37</td>
<td>(0.47-3.99)</td>
<td>0.6</td>
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<td>Primary diagnosis</td>
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<td>Alcohol-related disease</td>
<td>Ref</td>
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<tr>
<td>Viral hepatitis</td>
<td>0.62</td>
<td>(0.23-1.68)</td>
<td>0.2</td>
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<td>Fatty liver disease</td>
<td>3.43</td>
<td>(1.63-7.22)</td>
<td>&lt;0.01</td>
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<tr>
<td>Primary sclerosing cholangitis</td>
<td>4.23</td>
<td>(1.9-9.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HCC</td>
<td>2.99</td>
<td>(1.24-7.24)</td>
<td>0.02</td>
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<td>Other</td>
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<td>(1.17-4.7)</td>
<td>0.02</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&lt;25</td>
<td>Ref</td>
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<tr>
<td>25–30</td>
<td>0.6</td>
<td>(0.46-1.32)</td>
<td>0.4</td>
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<tr>
<td>&gt;30</td>
<td>0.32</td>
<td>(0.17-0.58)</td>
<td>&lt;0.001</td>
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<tr>
<td>MELD/PELD</td>
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<tr>
<td>&lt;20</td>
<td>Ref</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>20–29</td>
<td>0.69</td>
<td>(0.02-0.15)</td>
<td>0.1</td>
</tr>
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</table>

**TABLE 6.** Multivariable analysis of factors potentially associated with receipt of NDD liver transplant among children

<table>
<thead>
<tr>
<th>Factor</th>
<th>aOR</th>
<th>95% CI</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
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</tr>
<tr>
<td>0–1</td>
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<td>1–5</td>
<td>0.18</td>
<td>(0.07-0.46)</td>
<td>&lt;0.001</td>
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<td>6–11</td>
<td>0.08</td>
<td>(0.02-0.31)</td>
<td>&lt;0.001</td>
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<td>12–17</td>
<td>0.06</td>
<td>(0.02-0.21)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>Ref</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Female</td>
<td>0.39</td>
<td>(0.18-0.87)</td>
<td>0.02</td>
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<td>Race</td>
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</tr>
<tr>
<td>White</td>
<td>Ref</td>
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<td>–</td>
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<tr>
<td>Black</td>
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<td>(0.75-5.89)</td>
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<td>Hispanic/Latino</td>
<td>0.86</td>
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<td>0.7</td>
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<td>Other</td>
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<td>(0.16-1.84)</td>
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<td>Biliary atresia</td>
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<td>(0.71-4.19)</td>
<td>0.2</td>
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<tr>
<td>Other</td>
<td>Ref</td>
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<td>–</td>
</tr>
<tr>
<td>MELD/PELD</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>Ref</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>20–29</td>
<td>1.23</td>
<td>(0.41-3.68)</td>
<td>0.7</td>
</tr>
<tr>
<td>30–39</td>
<td>0.4</td>
<td>(0.14-1.13)</td>
<td>0.06</td>
</tr>
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<td>&gt;40</td>
<td>0.87</td>
<td>(0.22-2.04)</td>
<td>0.5</td>
</tr>
<tr>
<td>Status 1a/b</td>
<td>1.01</td>
<td>(0.26-3.85)</td>
<td>&lt;0.9</td>
</tr>
</tbody>
</table>

Conclusions:

• ND-LLD is increasing in the United States though currently activity is concentrated at distinct centers.
• NDDs in comparison to directed donors are older, more often Caucasian, and college educated.
• Prior kidney donation is prevalent among NDDs.
• NDDs have been utilized in liver paired exchange.
• Short time outcomes of NDDs are comparable to directed donors.
• Attention to “grey zones” in donor evaluation is advised, center thresholds vary.
• The North American Living Liver Donor Innovations Group has provided a suggested graft allocation algorithm.
• Current US NDD recipients are more often pediatric, female, and less likely to have Etoh related liver disease or viral hepatitis.
Future Directions

Ensured access for NDDs to health and life insurance
Donor reimbursement for lost wages and travel
Registry enrollment to follow NDDD outcomes over time
Consensus for allocation targeting those patients most disadvantaged on the waitlist
Innovative approaches to increasing utility of an NDD through paired exchange and chains
Exploration of the roles of education, advertising, and recruitment of donors in an ethical context

Non-Directed Living Liver Donors

QUESTIONS

THANK YOU
Session Survey

AnnMarie Liapakis, MD | April 20th 10:30 AM-11:00 AM