

Essential Components to Start a New Living Donor Liver Transplant Program

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Disclosure:

I am the current VP of the *United Network of Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) but the views expressed here are my own*



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Your Hospital Leadership wants to start offering LDLT at your center!

- Institutional Commitment for Successful LDLT program
- Resources
 - Financial
 - Personnel
 - Transplant department
 - Other departmental
- Experience
- Policies
- “Buy-In”
 - Team
 - Patient
 - Referring providers
- Team/Candidate/Donor education and support

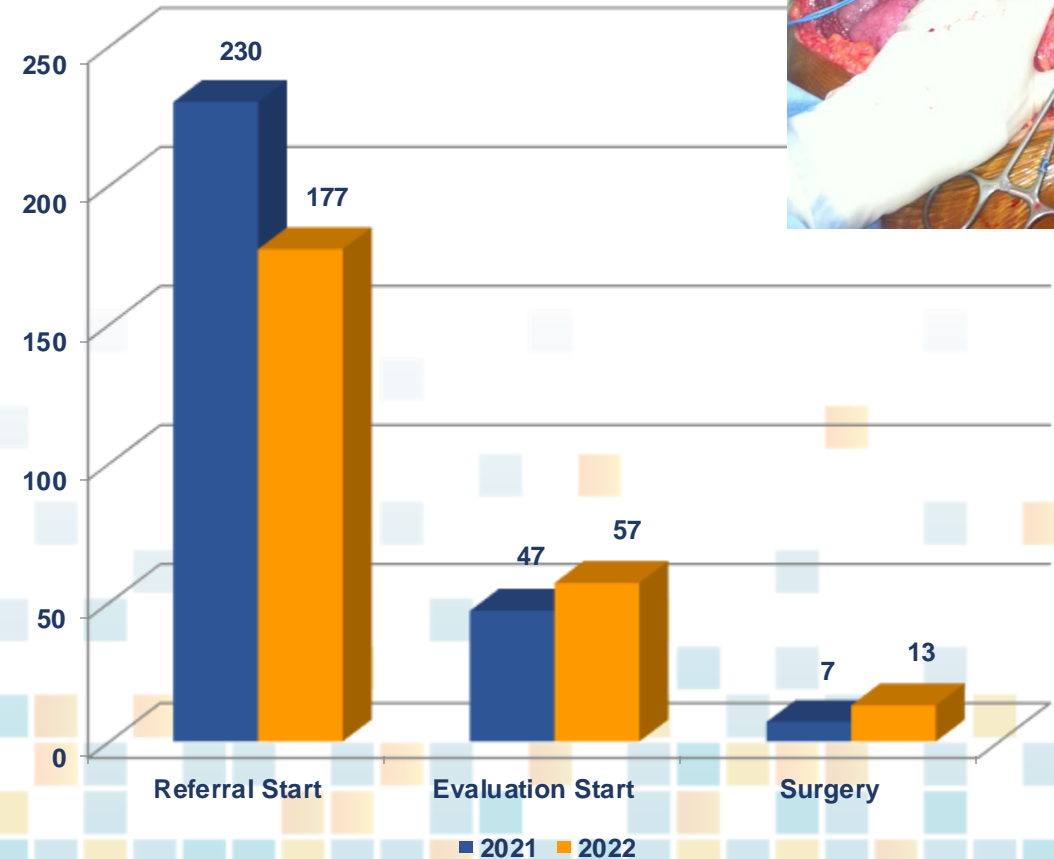
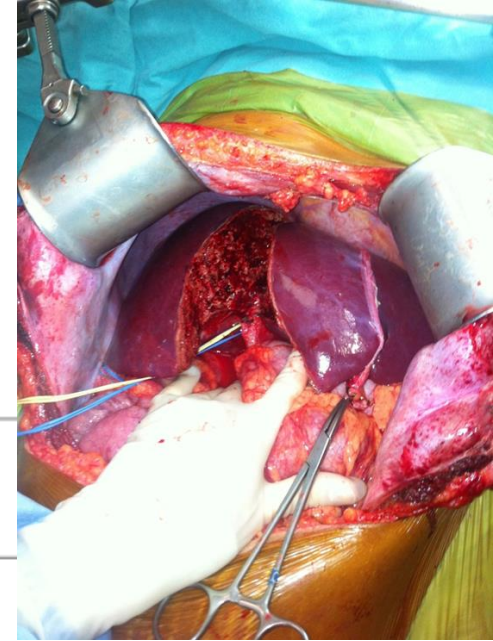


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Institutional Commitment

- LDLT is a low volume high stakes endeavor
- Commitment from senior hospital leadership is essential
- Success is highly resource dependent
- Risk Tolerance/experience
- Staff, equipment, external resources
- Patient support services



Sound Financial Structure

- Funding for experienced surgical and medical team,
- Funding for travel for education/training/mentorship
- SAC fee: you might just use your DD SAC for first year and then model it from experience
- The hospital needs to contract with managed care providers so fees and rates can be negotiated with each payer.
- Determine policies for coverage of VNS and Complications
 - Donor complications are handled on a case by case basis, and for most, department covers the costs unless these occur while the donor is still in hospital
 - The payer contracts for donors typically ends on the day of discharge and they are only covered for that finite time period on the recipient's plan.
 - Most 90 day global periods do not cover donor complications. We ask departments to accept the Medicare rate as payment in full.
- Goals for donor financial neutrality



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Personnel Resources

- Medical/surgical
- Living donor/ recipient
- Transplant/ Non-transplant
- Clinical/Administrative



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Roles/Resources Required by Regulation (in addition to those required for a liver program)

- Living donor surgeon
- Living donor medical evaluation resources
- Independent living donor advocate



Living Donor Surgeon/s

- Must meet the primary liver surgeon requirements
 - MD or DO with license
 - Part of hospital medical staff
 - Credentialed
 - Board certified
 - Fellowship or experience
- Required additional experience
 - 20 major liver resections
 - 7 living liver donors
 - 10 as primary or co-surgeon
- Things to consider
 - How much experience is sufficient?
 - Will the same surgeon do both sides?
 - Do you have additional surgical resources; PA fellow



Independent Living Donor Advocate

- **Center must provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.**
- Function independently from the transplant candidate's team.
- Advocate for the rights of the living donor.
- Fulfill the qualification and training requirements specified in the hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the living donor's decision about whether to donate.
- Review and document whether the living donor has received information on each of the following areas and assist the donor in obtaining additional information from other professionals as needed about the:
 - Informed consent process and Evaluation process
 - Living Donor Psychosocial Evaluation and Living Donor Medical Evaluation Requirements
 - Surgical procedure
 - Follow-up requirements
- Things to consider:
 - Does the ILDA believe in benefits of LDLT?
 - Do they have sufficient life experience to participate assist the donor during the donor decision making process?
 - Do they have adequate mentorship, training and support?



Essential Transplant Team Personnel

- **Live Donor Nurse Coordinator***
 - Education, support and coordination in all phases of care
 - Should just care for Living donors
- **Live Donor /Recipient Hepatologist**
 - Experience with LDLT
 - Experience with ERCP
- **Live Donor Social Worker***
 - Psychosocial evaluation
 - Assist in support in all phases
 - Travel and logistics
- **Psychiatrist/Psychologist**
 - Psychiatric evaluation
 - Mental health/addiction screening
- **Dietitian***
 - Should be integral part of all phases particularly patient with steatosis or body mass index (BMI) issues
- **Pharmacist***
 - Medication review and counseling
- **Designated Live Donor Administrative staff**
 - Screening
 - Scheduling testing
 - Tracking progress
 - Help with post donation follow-up compliance

****Required by regulation - All need specialized training in liver donation***

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LDLT: Separate Teams with Great Working Relationship



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Other Programmatic Supports to Consider

- Ethics
- Regulatory/Quality
- Crisis planning
- Radiologist with hepatobiliary experience
- Pathologist with liver experience
- Designated Surgical OR team; nurses, techs
- Liver Anesthesia; consider 2 separate teams
- Adequate House Staff coverage with 24 hr 7 days a week coverage with experience in care of donor and recipient ; consider PAs/NPs
- Designated Donor Nurses for the in-patient unit



Designated Donor Nurse

- LDLT is a low volume high stakes event.
- Policies and regulations surround the safety and education of those considering donation and long term out patient follow-up.
- But the most critical care occurs during the immediate post operative phase delivered by an inpatient medical team and bedside nursing staff who are not as familiar with the policies regulations and standards of care.
- The infrequency of living donor liver transplantation makes it nearly impossible to have all transplant program staff on a nursing unit be “experts” in live donor care.
- Designated Donor Nurses:
 - Donor champions on the nursing unit to mirror to goals of the living donor team.
 - Care for and advocate for live donors during the in patient stay
 - serve as a resource to their colleagues.

Quality improvement in the care of live liver donors: implementation of the Designated Donor Nurse Program

Publications on living donor liver transplant have focused on the medical aspects of donor selection, postoperative management, surgical procedures, and outcomes, but little attention has been given to the nursing implications for care of live liver donors during their inpatient stay. Donor advocates from various disciplines are involved during the initial education and evaluation, but most care after surgery is delivered by an inpatient medical team and bedside nursing staff who are not as familiar with the donor and concepts related to donor advocacy. In an effort to improve the overall donor experience and provide safe, high-quality care to patients undergoing elective partial hepatectomy, our academic medical center began a quality improvement project focused on improving the inpatient stay. Inpatient nursing standards and policies and procedures were developed to ensure that consistent care is delivered. However, the infrequency of living donor liver transplantation makes it nearly impossible to have all transplant program staff on a nursing unit be “experts” on donor care. Therefore, our center determined that, similar to the Independent Donor Advocacy Team, a transplant program needs live donor champions on the nursing unit to mirror the goals of the team. To that end, we developed the concept of the Designated Donor Nurse to care for and advocate for live liver donors during the inpatient stay and also to serve as a resource to their colleagues. (*Progress in Transplantation*. 2010;20:XXXX-XXX)

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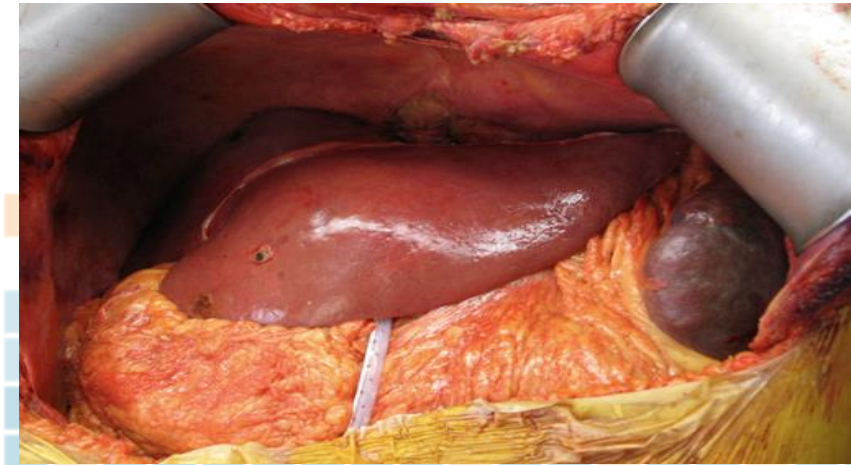
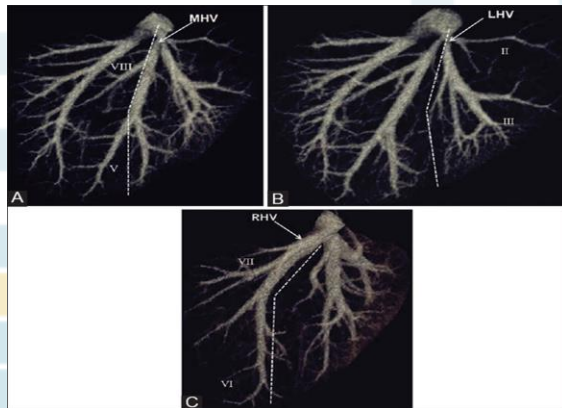
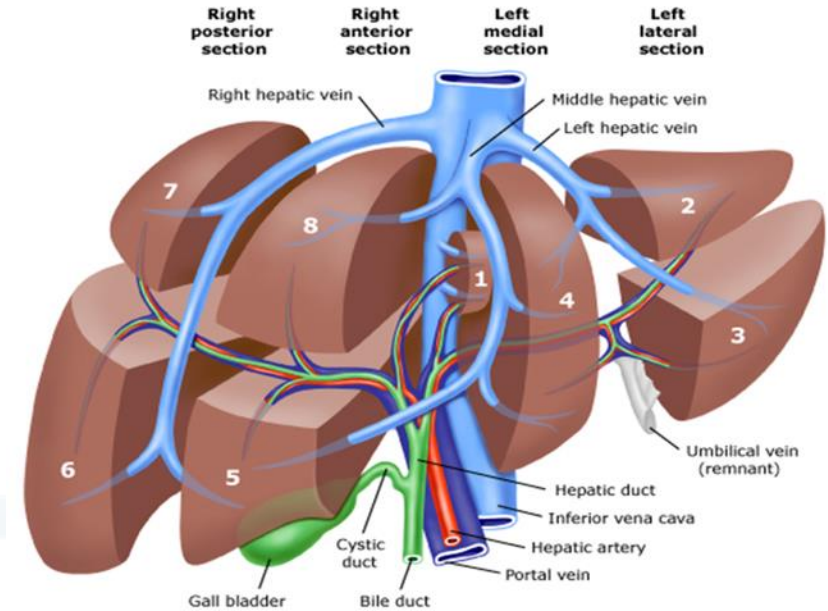
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Specialized Radiologist and Equipment

Anatomical Assessment is critical for success

- Radiologist who understands the LDLT surgeries
- Modality may vary by radiologist expertise
- CTA verses MRI/MRA/MRCP
 - Biliary and Vascular Mapping
 - Presence of steatosis and Iron
 - Size and volume determination



Operating Room Equipment

- Operative C-arm for fluoroscopy to do intra op cholangiograms
- Cell saver auto transfusion device
- Two OR teams
- Two Anesthesia teams
- If back to back and simultaneous, storage equipment for liver



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Location for living donor recovery

- Where will the donor recover from anesthesia? PACU, ICU TICU
- Will they be on the transplant unit? Other surgical unit?
- Will they be proximally close to the transplant recipient ? Are there special considerations for pediatric candidates?
- What is the level of care on the unit?
- What training needs to take place?



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Living Donor Liver Transplant Policies

- Living Donor Informed Consent policy
- Living Liver Donor Evaluation policy
 - protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease
 - Protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for: Cervical cancer, Breast cancer, Prostate cancer, Colon cancer, Lung cancer
 - protocol for hypercoagulable state evaluation
 - protocol for testing for genetic
 - protocol for screening for autoimmune disease
 - protocol for predonation liver biopsy
 - Protocol for Domino living donation (if applicable)
- Living Donor Psychosocial Evaluation policy
- ILDA Policy
- Living donor specimen storage policy
- Post operative care and Follow up of the living liver donor



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Living Donor Reportable Events

- Policy for reporting living donor events through the Improving Patient Safety Portal within 72 hrs
 - A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.
 - A living donor dies within 2 years after organ donation
 - aware A living liver donor is listed on the liver wait list within 2 years after organ donation
 - A living kidney donor is listed on the kidney wait list or begins regularly administered dialysis as an ESRD patient within 2 years after organ donation
 - A living donor organ is recovered but not transplanted into any recipient
 - A living donor organ is recovered and transplanted into someone other than the intended recipient
 - If the hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy,



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Additional Living Donor Liver Transplant Policies

- Adverse event plan in case of donor death or near death.
- Educational packets and informed consent document development
- Develop note templates/order sets for protocol adherence and regulatory compliance
- Set up quality metrics: compliance, efficiency, and clinical/safety



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Things to Consider

- Will you perform LDLT for fulminant failure?
 - If yes; need ability to work up donors and perform surgery 7 days a week, 24 hr a day
 - Who will perform workup?
 - Policies need to reflect practice
- Will you utilize non-directed liver donors?
 - For adult and peds or peds only
 - Develop transparent process for allocation
 - Develop policies
- Will you allow previous kidney donors to be liver donors
 - Develop policies
- Will you participate in Liver Paired exchange?
 - Internal/ external
 - Develop policies
- When will you begin the donor evaluation?
 - At candidate evaluation or when listed
 - Will you work up more than 1 donor at a time
- Special populations: obese donors, donors for colorectal cancers patients etc
 - Each require special resources



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Transplant Candidate Team “Buy IN”

- Surgeons
 - Which patients do they want to consider LDLT for
- Hepatologist
 - Do they believe in LDLT, do they agree with surgeons on who is best served by LDLT
- Nursing/social work
 - Do they feel comfortable discussing LDLT, can they answer the candidates questions about the benefits and process?
- Referring MDs
 - Do they understand who best benefits from LDLT?
- Patients
 - Need education about why LDLT is best for them
 - Will this be 1on 1, group face o face or zoom, who will do the education? When will it occur? At evaluation, when listed



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Barriers to Selection and Engagement of the Liver Transplant Candidate for LDLT

Table 1: Candidate Selection and Engagement (n=46, 90.2% response rate)

# Priority Strategy(ies)	Importance of Barrier	Consensus Responses Mean (SD); Median (IQR)
#1	Gaps in the knowledge on benefits, risks and timing of LDLT and the risks/benefits to the living liver donor among transplant physicians and referring providers.	Importance: 8.39 (0.93); 9 (8, 9)
#2	Lack of uniform consideration of the benefit of LDLT in select patients with low MELD-Na among transplant and referring providers. For example, many transplant providers are unaware that low MELD-Na (<15) patients with sarcopenia, frailty, decompensating events, infections, or women benefit from LDLT, compared to waiting for rise in MELD-Na or DDLT.	Importance: 8.19 (0.87); 8 (8, 9)
#3	LDLT in the United States and some other regions is not always considered a first choice for many pediatric patients eligible for liver transplant	Importance: 8.02 (1.05); 8 (7, 9)
#4	Limited institutional commitment to enable the liver transplant program to develop optimal living donor liver transplantation practices to benefit a large proportion of candidates on the waiting list.	Importance: 8.02 (1.03); 8 (8, 9)
#5	In critically ill patients, centers need sufficient surgical/medical experience to provide optimal pre- and post-surgical management.	Importance: 7.79 (1.55); 8 (7, 9)
#6	Accurately knowing which patients with extended HCC criteria (without vascular invasion and extrahepatic mets), based on disease burden and tumor biology, will benefit from a LDLT from a survival perspective.	Importance: 7.54 (1.19); 8 (7, 8)**
#7	Pediatric transplant clinicians lack agreement on the benefits of pediatric LDLT.	Importance: 7.53 (1.52); 8 (6, 9)
#8	Ethical concerns regarding donors' risks and recipients' benefit limits the possibility of LDLT in patients with relative poor/unknown prognosis (non-resectable colorectal liver metastases and intrahepatic cholangiocarcinoma)	Importance: 7.52 (1.53); 8 (7, 9)
#9	There is a low level of acceptance of LDLT among candidates on the liver transplant waiting list.	Importance: 7.40 (1.64); 8 (7, 9)
#10	Lack of data on LDLT for non-resectable colorectal liver metastases and intrahepatic cholangiocarcinoma outcomes to justify exposure of a healthy donor to a major surgery.	Importance: 7.09 (1.53); 7 (6, 8.5)**

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ORIGINAL ARTICLE

Living donor liver transplant candidate and donor selection and engagement: Meeting report from the living donor liver transplant consensus conference

Michelle T. Jesse¹ | Whitney E. Jackson² | AnnMarie Liapakis³ | Swaytha Ganesh⁴ | Abhinav Humar⁴ | Nicolas Goldaracena⁵ | Josh Levitsky⁶ | David Mulligan⁷ | Elizabeth A. Pomfret⁸ | Daniela P. Ladner⁶ | John P. Roberts⁹ | Alisha Mavis¹⁰ | Carrie Thiessen¹¹ | James Trotter¹² | Gerald Scott Winder¹³ | Adam D. Griesemer¹⁴ | Anjana Pillai¹⁵ | Vineeta Kumar¹⁶ | Elizabeth C. Verna¹⁷ | Dianne LaPointe Rudow¹⁸ | Hyosun H. Han¹⁹ | on behalf of the AST LDLT Consensus Working Group

- Center need to determine who will best be served by LDLT at their center
- Collaboration among providers so that all send the same message to the candidates



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Barriers to Transplant Candidate “Buy-In”

- Transplant candidate concerns
 - Barriers associated with their denial and avoidance of the severity of their disease
 - Lack of knowledge, information and awareness of patients and families
 - Reluctance, hesitancy and discomfort to approach and discuss with the potential donors
 - Concerns about the donor’s health
 - Candidates desire to maintain the privacy of their health status
 - Psychological barriers (Guilt, Fear)
 - Risk perception of the donor surgery



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Educational Initiatives

- Assess your current programmatic views on LDLT: Do you need to educate expand views
- How big do you want your LDLT program to be? Best to start slow with low risk cases
- Which candidates does your team believe will get the most benefit from LDLT
 - All candidates
 - Low MELD patients
 - Cancer patients
 - Emergent indications for LDLT
- What processes are in place or need to be in place for candidate /donor education
- Customize a process based on your current “culture of LDLT” and where you want to be



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Educational Resources

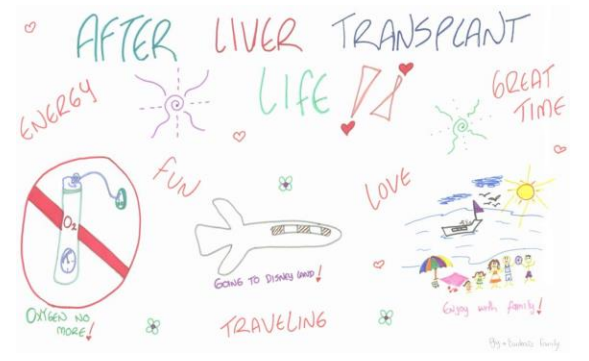
- AST Liver Donation Provider tool kit: <https://www.myast.org/education/specialty-resources/living-donor-provider-toolkits>
- AST Patient Live Donor Tool Kit: <https://www.livedonortoolkit.com/>
- Financial Toolkit for donors <https://www.livingdonortoolkit.com/financial-toolkit>
- AST Q&A Video: <https://power2save.org/community-education/>
- ASTS Live donor video: <https://asts.org/resources/living-liver-donation-english#.ZC8L0XbMJJaQ>
- American Liver Foundation : <https://liverfoundation.org/liver-diseases/treatment/living-donor-liver-transplant-information-center/a-donors-guide-to-living-donor-liver-transplant/>
- <https://transplantliving.org/living-donation/>
- UNOS Liver Paired Donation Program: <https://unos.org/transplant/liver-paired-donation/>
- NLDAC: <https://www.livingdonorassistance.org/>
- Living Donor Collective: <https://www.srtr.org/about-srtr/living-donation/>



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Questions?



Mount Sinai Living Donor Celebration



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Session Survey

Dianne LaPointe Rudow, ANP-BC, DNP, CCTC | April 19th 1:15 PM-2:00 PM



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