The Living Donor Process: Intake Through Long Term Follow-up

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Disclosure

none

Objectives

- Discuss Practice Guidelines for the medical evaluation of the live organ donor
- Identify the CMS and OPTN regulations for the Live Donor Evaluation
- Review Goals of the phases of the evaluation
- Discuss key components of the live donor medical evaluation
- Describe key issues in the donor's past history that should be explored
- Discuss general and organ specific testing
- Identify the importance of anatomical assessment
- Review donor disease transmission risks.
- Review in-patient and long term care

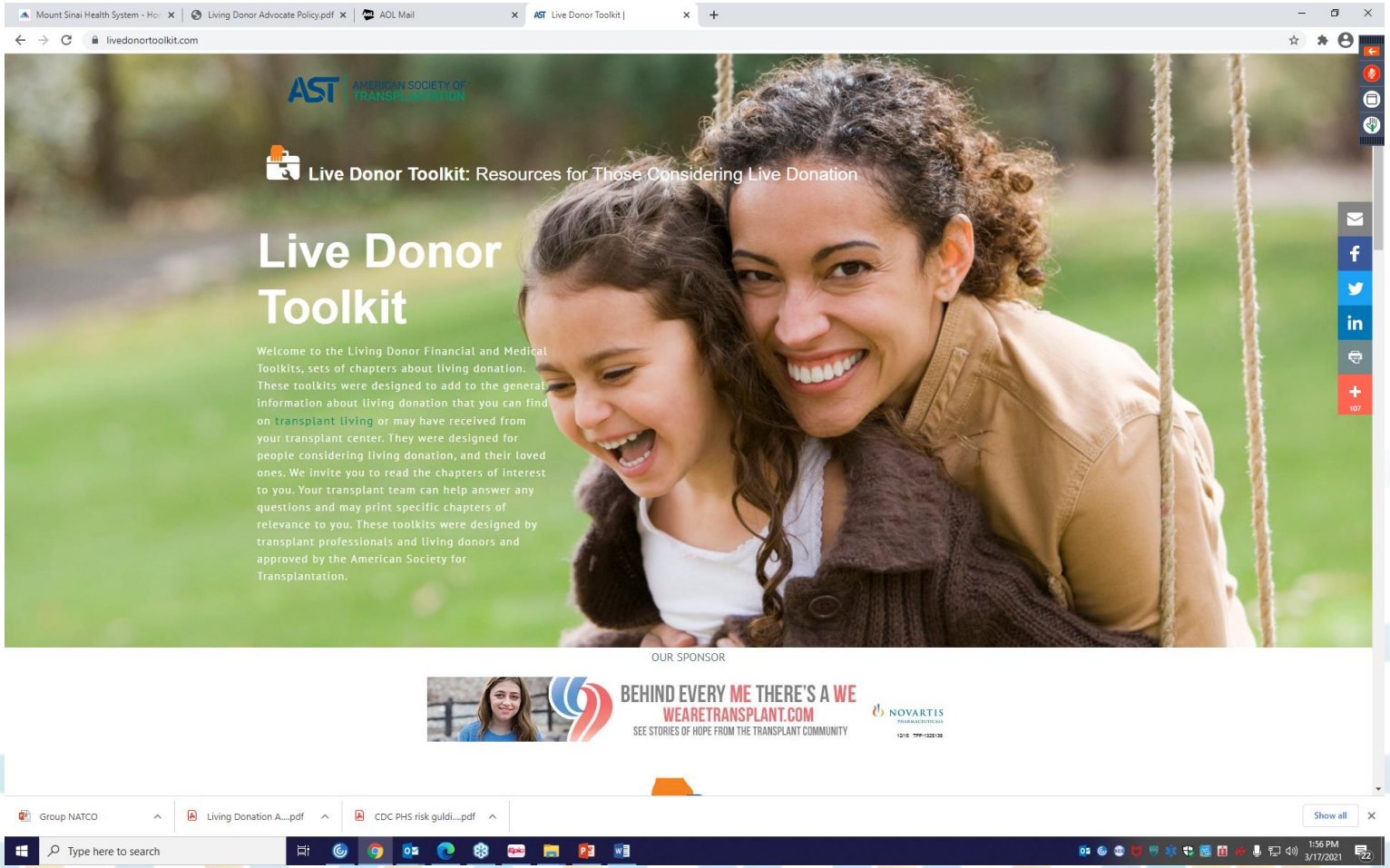
Practice Guidelines to Assess the Live Organ Donor

- No Practice Guidelines for the live donor evaluation exist
- No randomized controlled clinical trials to determine testing required for the evaluation of live organ donors have been performed
- Recommendations are based on review of existing data in the literature and consensus
- The evaluation is to determine risks for the donor, contraindications to donation and if the donated organ is healthy to transplant
- Normal testing cannot accurately predict future risk of developing end stage organ disease

Existing Live Donor Guidelines

- The Evaluation of the Living Renal Transplant Donors: Clinical Practice Guidelines. Journal of the American Society of Nephrology 1996; 7(11) 2288-2313.
- Consensus Statement of the Live Organ Donor": JAMA, December 12, 2000-Vol 284, No.22
- New York State Committee on Quality Improvement in Living Liver Donation at http://www.health.state.ny.us developed in 2002
- A Report of the Amsterdam Forum on the Care of the Live Kidney Donor: Data and Medical Guidelines. Transplantation 2005;79 s53-s66.
- A Report of the Vancouver Forum on the Care of the Living Organ Donor: lung, liver, pancreas and intestine: Transplantation 2006;81(10):1373-1385
- Summary of the British Transplantation Society/Renal Association U.K. guidelines for living donor kidney transplantation. Transplantation 2012; 93: 666-673
- https://kdigo.org/guidelines/living-kidney-donor/ last updated 2017
- AST Live Donor Medical Tool Kit 2017 : https://www.myast.org/patient-information/live-donor-toolkit (Kidney donors current. Liver available late 2021)
- Application of the 2017 KDIGO Guideline for the Evaluation and Care of Living Kidney Donors to Clinical Practicehttps://kdigo.org/wp-content/uploads/2017/07/KDGO-CJASN-LD-GL-review-in-press.pdf CJASN 2020

AST Tool Kit for Provider and Patients regarding evidenced based care of living donors.



https://www.livedonortoolkit.com/

OPTN Policy: Live Donor Evaluation

14.1	Psychosocial Evaluation Requirements for Living Donors
14.2	Independent Living Donor Advocate (ILDA) Requirements
14.3	Informed Consent Requirements
14.4	Medical Evaluation Requirements for Living Donors
14.5	Living Donor Blood Type Determination and Reporting
14.6	Placement of Living Donor Organs
14.7	Living Donor Pre Recovery Verification
14.8	Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials
14.9	Requirements for Domino Donors and Non-Domino Therapeutic Donors
14.10	Living Donor Organ Check-In
14.11	Living Donor Pre Transplant Verification
14.12	Reporting Requirements
15.3	Informed Consent of Transmissible Disease Risk
15.6	Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy
13:	Kidney Paired Donation (KPD)

CMS Conditions of participation

42 C.F.R. 482.72 OPTN Membership
42 C.F.R. 482.74 Notification to CMS
42 C.F.R. 482.76 Pediatric Transplants
42 C.F.R. 482.80 Data Submission, Clinical Experience and Outcome Requirements for Initial Approval
42 C.F.R. 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval
42 C.F.R. 482.90 Patient and Living Donor Selection
42 C.F.R. 482.92 Organ Recovery and Receipt
42 C.F.R. 482.94 Patient and Living Donor Management
42 C.F.R. 482.96 Quality Assessment and Performance Improvement (QAPI)
42 C.F.R. 482.98 Human Resources
42 C.F.R. 482.100 Organ Procurement
42 C.F.R. 482.102 Patient and Living Donor Rights
42 C.F.R. 482.104 Additional Requirements for Kidney Transplant Centers

Phases of the Live Donor Evaluation Must Comply With Policy

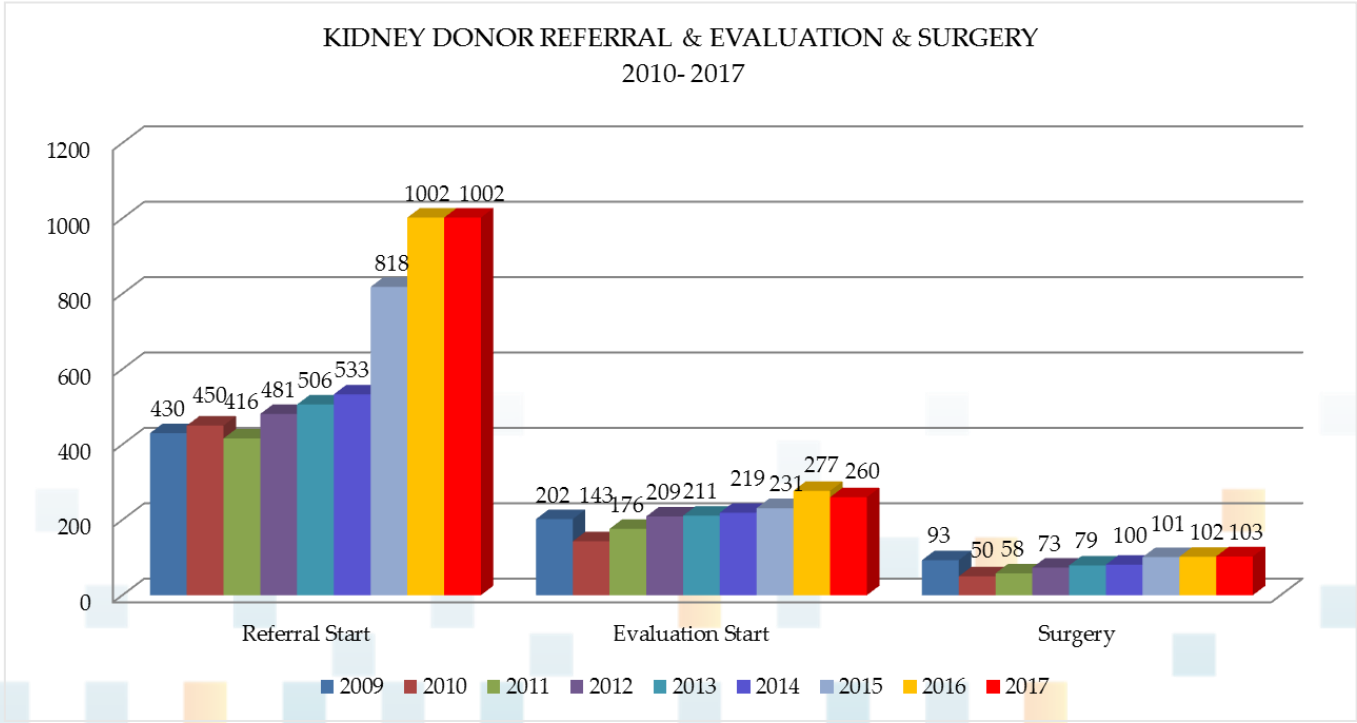
- In practice (varies by center)
  - Pre donation
    - Donor screening
    - Evaluation
    - Cleared for surgery
  - Donor Inpatient stay
    - Peri op
    - Post op
    - Discharge
  - Post donation
    - OPTN required 2 year FU
    - Long term
- QAPI
  - Pre donation
  - Peri operative
  - Post donation

- CMS: §482.98 Standard: Independent Living Donor Advocate of Living Donor Advocate Team X121
  - Recent interpretation Guideline:
  - *Living Donor ILDA Interview: "Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or (ILDAT) prior to the initiation of the evaluation and continuing to and through the discharge phase.*
    - Clarification provided: CMS cannot define the "interview", including what it entails, how it is conducted, etc. The intent is to make sure there isn't any coercion, that the potential living donor understands what they are getting involved with. The advocate needs to see what the potential donor's thought process is about donation. ,
    - Timing of the interview is that must take place before any testing, including pre-screening such as ABO, labs, etc.
    - There are a lot of things that can happen once you have taken blood including HIV status, not a biological parent.

Purpose: determine if donor has obvious medical or psychosocial contraindications to donation, gather past medical record, and educate regarding the process

No longer perform preliminary screening tests

- Who
  - Live donor coordinator
  - Administrative Assistant
- Where
  - Electronically
  - Face to face
  - Remotely
- How
  - Before or after recipient listed
  - One at a time
  - More than 1
  - Is there a maximum
- What does it entail
  - Review of history
  - Education
  - Individual/group



Once approved By ILDA can do ABO,HLA, Vital signs

Live donor selection and evaluation protocol

Based on:

- Data
- Consensus
- Policy
- Center preference
- Witch craft?
- Should be tailored to the individual

- Center specific protocols with selection criteria, contraindications and components of the evaluation

Dear Sir:

Over the past 10 years I've approached 4 hospitals and each has ruled me out for a different reason--melanoma (center A.), center B (altruistic donor + migraines), center C(not ruled out, but Dr. was concered about my HX of endometrial cancer), center D (kidney stone). What's weird is, each knew about all four problems, but ruled me out on different ones. Thus center D said the melonoma and endometrial cancer were fine, but not the stones. Center C thought the melanoma and stones were okay but were concerned about the endometrial. Center B thought the stones and both cancers were fine.

Recommend:

1) develop uniform national standards and let everyone know what they are, or
2) publish the differences so that potential donors know where they'd be accepted and where they wouldn't

Goals of the Medical Evaluation

OPTN Evaluation Plan: Those performing a medical evaluation are physicians and surgeons experienced in living donation

- Determine Suitability
  - Assess immunological compatibility
  - Assess general health of the donor
  - Assess surgical risk for the donor
  - Identify if there are any diseases present that may be transmitted from the donor to the recipient
  - Assess anatomy of and function of intended organ for donation
  - Educate donor on individual risks (perioperative and long term) based on assessment and existing data

Key components of the live donor medical evaluation

- Medical and Psychosocial history
- Physical exam
- Laboratory testing
- Radiological testing.
- Health maintenance
- Age appropriate screening tests
- Organ specific testing

Key issues in the donor's past history that should be explored

- Existing medical conditions
- Personal history of medical conditions
  - HTN, DM, Lung Disease, Heart Disease, GI Disease, Autoimmune Disease, Neurological Disease, GU Disease, Hematologic Disorders, Bleeding/clotting disorders, History of Cancer including melanoma
- History of infections
- Active or past medications used that are toxic to the organ intended to donate (nephrotoxic/hepatotoxic)
- Use of pain medication
- Allergies
- Family history: liver/kidney disease, cardiac disease, diabetes, cancer, clotting/bleeding disorders

Organ Specific History

Kidney Specific History

- A personal history of significant medical conditions which include, but are not limited:
  - Genetic renal diseases
  - Kidney disease, proteinuria, hematuria
  - Kidney injury
  - Diabetes including gestational diabetes
  - Nephrolithiasis
  - Recurrent urinary tract infections
- Family History:
  - Kidney disease
  - Diabetes
  - Hypertension
  - Kidney Cancer

Liver Specific History

- Family History
  - Liver diseases
  - Bleeding or clotting disorders

Living Donor Exclusion Criteria

OPTN Policy 14: Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.

Must Exclude:

- Is both less than 18 years old and mentally incapable of making an informed decision
- HIV (unless variance in Policy 15.6)
- Active malignancy, or incompletely treated malignancy
- High suspicion of donor coercion
- High suspicion of illegal financial exchange between donor and recipient
- Evidence of acute symptomatic infection (until resolved)
- Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
- Kidney: Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage or Diabetes
- Liver: HCV RNA positive, HBsAg positive ,donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes , expected donor remnant volume less than 30% of native liver volume, prior living liver donor

The Social History

- Occupation
- Employment status
- Health insurance status
- Living arrangements
- Social support
- Smoking, alcohol and drug use and abuse
- Psychiatric illness, depression, suicide attempts
- Risk behavior as defined by the *U.S. Public Health Services (PHS) Guideline (March 2021 new criteria)*

Discuss general and organ specific testing

General laboratory tests

- OPTN Policy 14 required:
  - ABO and Subtype if necessary
  - CBC with platelets
  - Comprehensive metabolic panel
  - Pt Inr and PTT
  - Chest x-ray
  - Ekg
  - HCG
- Other testing
  - Lipid panel (fasting)
  - Evaluation for coronary artery disease and need for further testing
    - (American College of Physicians)
  - Evaluation for pulmonary disease for smokers and need for further testing
    - (American College of Anesthesia and American Lung Association)

Organ specific testing

- <u>Kidney</u>
  - UA
  - Urinary Protein and albumin secretion
  - Fasting Glucose
  - Glucose tolerance or HGBa1c in first degree relatives with DM or HR pts
  - Measurement of GFR
  - Policy for PKD Screen
  - Screen for nephrolithiasis with 24 ur urine in pts at risk
- <u>Liver</u>
  - Cerulaplasm with FH Wilson's Disease
  - Screen for hepatitis
  - Iron studies
  - Alpha 1 antitrypsin level and phenotype
  - Written protocol for Autoimmune liver disease, genetic liver disease and need for liver biopsy
  - Protocol for Hypercoaguable workup

Anatomical assessment

- Modality utilized varies based on center comfort and expertise
- Kidney
  - Determine if equal size
  - Evidence of mass, stone, cyst
  - Identify arterial and venous structures
  - Examine collecting system
  - Determine of other anatomical defects exist
  - Determine which kidney is suitable for donation
- Liver
  - Determine if the liver is anatomically suitable for transplantation
  - Assess safety of resection for the donor
  - Assessment of projected graft volume,
  - Donor’s remnant volume,
  - Vascular anatomy
  - Presence of steatosis

Assessment of donor disease transmission risks

- Infectious Disease
- Cancer
- Genetic disease of the organ transplanted

Infectious Disease Screening

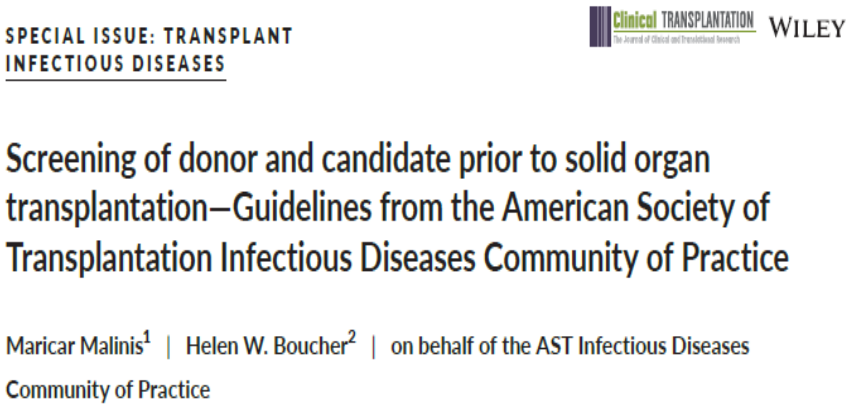
- Infectious disease testing must be performed in a CLIA-certified laboratory or equivalent as determined by CMS using FDA-licensed, approved tests.
- Extensive personal history of risks of transmission including , travel, exposure and risk behavior.
- If a living donor is identified having a risk for HIV, HBV, and HCV transmission according to the *U.S. Public Health Services (PHS) Guideline*, this must be disclosed to the transplant candidate.
- Risk criteria changed in 2021

- <u>LABS</u>
- CMV (Cytomegalovirus) antibody
- EBV (Epstein Barr Virus) antibody
- HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery
- Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery
- Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery
- HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery
- Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery
- HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery
- Syphilis testing
- If at risk for TB
  - Intradermal PPD
  - Interferon Gamma Release Assay (IGRA)
- Develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation

Recommendations for screening for infectious disease screening

Endemic Transmissible Diseases

Clinical Transplantation. 2019;33:e13548 https://doi.org/10.1111/ctr.13548



PHS Risk Screening

The United States Public health Service (USPHS) recommends that during the donor evaluations the clinician should ascertain whether any of the following 10 risk criteria were present in potential living donor candidate:

1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection in the last 30 days
2. Man who has had sex with another man in the last 30 days?
3. Sex in exchange for money or drugs in the last 30 days
4. Sex with a person who had sex in exchange for money or drugs in the last 30 days
5. Drug injection for nonmedical reasons in the last 30 days
6. Sex with a person who injected drugs for nonmedical reasons in the last 30 days
7. Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours in the last 30 days
8. Child breastfed by a mother with HIV infection in the last 30 Days
9. Child born to a mother with HIV, HBV, or HCV infection in the last 30 Days
10. Unknown medical or social history

Effective June 1 2021: All Live donors must consent to blood drawn within 24 hrs of living donor procurement and stored for ten years, only to be used for investigation of potential donor-derived disease

Screening for COVID 19: process is evolving …

as of April 2021

- All living donors should:
  - Have viral testing by NAT for SARS-CoV-2 as close to donation as possible, but no longer than 3 days prior to surgery.
  - Be counseled on preventative strategies (masking, distance hand hygiene) especially 14 days prior to surgery
  - Self quarantine is recommended, not mandatory, as some may not have option to work at home
- As no data currently supports the use of COVID positive organs, any positive test would result in delay of donation.
- For living donors who were previously infected
  - Consult transplant infectious diseases team to assist with the decision about when to proceed with surgery.
  - Donation should proceed only when repeat NAT is negative, symptoms have completely resolved and at least 21-90 days have passed since initial infection.
- Vaccination is encouraged prior to living donor transplant

https://www.myast.org/covid-19-information

Cancer Screening

Live donor programs must develop and comply with 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

The American Cancer Society recommends these screening guidelines for most adults.

- http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer

Live donor selection committee

Goals:

CMS COP 482.90

- Selection criteria must be consistent with principles of medical ethics and contain the following:
- LD received a psychosocial evaluation prior to donation
- The medical record documents suitability for donation
- Live donor was given information needed to make an informed consent

Practicalities:

- Committee Constructs
  - Free from influence of the recipient and its team
    - Can be challenging
  - Multidisciplinary
  - ILDA present
    - Practice varies
- Collect and evaluate medical, psychosocial, and financial data for team review
- Determination of suitability for donation according to OPTN policy and center protocol
  - Identify further testing
  - If exception to protocol documentation is required
- Communicates outcome to the donor
  - Verbally and in writing
- Communicates outcome with the recipient team

Pre Surgical Visit:

The process of pre surgical visit may vary but should include:

- Informed consent
- Review that evaluation remains current
- Final immunological compatibility testing
- Infectious disease screening
  - Nat testing
  - Review of PHS risk criteria
- Pre operative medical assessment
- Medication review; ASA NSAID, OCT

Education and Support

- Education
  - Gaps about donation
  - Process for day of surgery
  - Need for protected sex

Role of the SW/ ILDA

Coordination with the recipient surgical team

- Process for side selection (kidney)
- Anatomical issue discussions

Documentation

Day of Surgery

- Is the donor still willing to proceed?
- Final medical check
  - Donor and recipient
  - Recipient should be present and medically stable prior to donor induction of anesthesia
- Pay attention to the alphabet
  - ABO, K, HCG

In-Patient Stay

- Living donor advocate involved
- Housed in a unit with competency in LD
- Medically sophisticated team to care for the donor
- Labs and UA prior to discharge
- Sufficient discharge plan
  - Discharge instructions
  - Diet plan
  - Activity
  - Wound care
  - Follow-up
  - Need for Primary care
- Consistent messaging

OPTN Policy 18: Donor Follow-up reporting

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first This does not apply to VCA transplants.
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date This does not apply to VCA transplants.

OPTN Required Elements for FU

Kidney Donor Follow-up

Donor status and clinical information for at least 80% of their living kidney donors

kidney laboratory data using the LDF form for at least:

- **70% of their living kidney donors**

Required kidney donor status and clinical information includes *all* of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDR or LDF form was submitted?
5. Kidney complications
   - Maintenance dialysis
   - Donor developed hypertension requiring medication
   - Diabetes
   - Cause of death, if applicable and known

Required kidney laboratory data includes *all* of the following:

- 1. Serum creatinine
- 2. Urine protein

Liver Donor Follow-up

Donor status and clinical information for 80% of their living liver donors.

Liver laboratory data for at least:

- **75% of their living liver donors on the 6 month LDF**
- **70% of their living liver donors on the one year LDF**

- Required liver donor status and clinical information includes *all* of the following:
  1. Patient status . Cause of death, if applicable and known
  3. Working for income, and if not working, reason for not working
  4. Loss of medical (health, life) insurance due to donation
  5. Hospital readmission since last LDR or LDF was submitted
  6. Liver complications, including the specific complications
     - Abscess
     - Bile leak
     - Hepatic resection
     - Incisional hernias due to donation surgery
     - Liver failure
     - Registered on the liver candidate waiting list

Required liver laboratory data includes *all* of the following:

- 1. Alanine aminotransferase
- 2. Alkaline phosphatase
- 3. Platelet count
- 4. Total bilirubin

Is two year data reporting sufficient? Is it follow-up Data or Care?

No and Both ….

Education to Focus on Health after Donation

- Living kidney donors, as a consequence of having a decreased GFR due to renal mass loss rather than an underlying renal disease,
  - should not be classified as having CKD.
- Living kidney donors in general have excellent long-term outcomes.
  - Even when their GFR is < 60 ml/min/1.73m^2, it is reassuring that this does not usually worsen over time, as occurs with CKD patients.
- Living donors should have an annual measurement of BP, and an assessment of their eGFR, and urine protein.
- Female donors and their providers should be aware that there is a higher risk of pre-clampsia after donation, 3-11% compared to 0.5-5% in non-donors. Fetal outcomes are similar.

Adapted from Serur et al in press by the LDCOP

Strategies to Comply with Follow-up

- Remove disincentives to follow-up
  - Minimizing Cost
    - Attempt to ensure donors do not receive a bill if follow up is at center
    - Parking passes
  - Multiple ways to follow-up
  - Designated staff to provide efficient visit
  - Capture data with each interaction
- Collect accurate contact information at each visit
- Switch in paradigm:
  - Follow-up is health promotion not identification of disease
  - Nursing focus
- Establishing relationships with team
- Added a 6 week follow-up visit
  - NP, Dietitian, Social worker
  - Referral to fee for service primary care clinics if uninsured
- Policy on follow-up appointments

Clinical Follow-up: benefit of a 6 week visit

- Ensure that donor is back to baseline
- Normalize symptoms of recovery
- Ensure active
- Review medications, supplements etc
- Re-educate about the post operative outcomes
- Reinforce need for health maintenance, healthy living and follow-up
- Consult with dietitian , meal planning BMI assessment
- Review laboratory data creatinine, EGFR, Microalbumin, LFTS liver regeneration
- Assess for psychosocial dysfunction
- The “New Normal”

LIVING DONOR COLLECTIVE

DATA DRIVEN TO IMPROVE OUTCOMES

Pilot completed:

- HRSA agreed to have the SRTR continue and add sites over time
- First attempt to capture comprehensive meaningful long term data on living donors

Living Donor Transplants at Pilot Sites in 2015			
	Kidney	**Liver**	**Total**
Kidney and liver programs: 6			
Rochester Methodist Hosp, Mayo Clinic	153	20	173
Johns Hopkins Hospital	67	12	79
University of Pittsburgh Med Center	70	19	89
Univ. of Minnesota Medical Center	71	9	80
Baylor University Medical Center	50	17	67
Mount Sinai Medical Center	101	20	121
Kidney-only programs: 4			
Emory University Hospital	94	0	94
UCLA Medical Center	124	0	124
Hennepin County Med Center	17	0	17
Saint Louis University Hospital	11	0	11
Total participating programs: 10	758	97	855

Summary

- Few clinical trials exist regarding donor evaluation components,
- Practice guidelines exist for certain aspects of the live donor evaluation but much is based on consensus in the community and federal guidelines
- Comprehensive history and testing is needed to determine donor suitability
- Practice and acceptance criteria varies
- More evidence based studies are needed to determine utility of much of the testing performed
- Despite comprehensive testing, donor risk and recipient risks exist as no evaluation can determine ones life time risk of developing disease
- Role of education and consent is critical
- Our community needs to reflect about the best practice for donor follow up care short and long term

American Foundation for Donation and Transplantation
Science Education Organ Donation Preservation Fraternity Since 1963