Informed Consent: What does the donor need to know?

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Objectives

Define	Define informed consent
Discuss	Discuss critical components of the informed consent process
Identify	Identify barriers to the consent process
Review	Review what donors want to hear
Identify	Identify strategies to improve the informed consent process

Informed Consent

❖Standard: Informed consent for living donors.

- ❖Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation.

- ❖Transplant centers must ensure that the prospective living donor is fully informed of elements pertaining to living donation.

Medicare Final Rule 2007
CFR 42 Living Donor Care

“The person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient.”

“Consensus Statement of the Live Organ Donor”: JAMA, December 12, 2000-Vol 284, No.22

Informed Consent

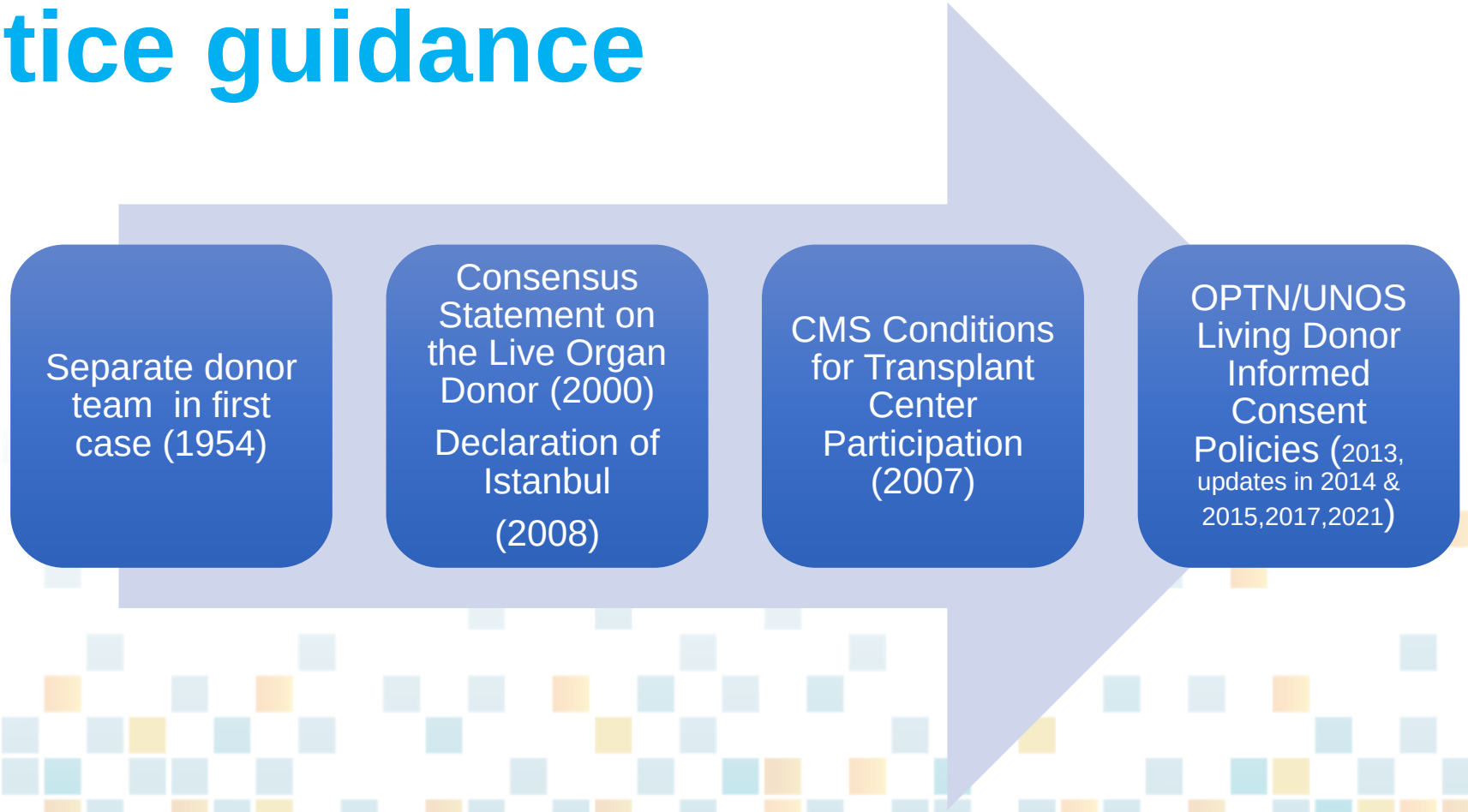
It is the primary mechanism in which ensures a person maintains control of what happens to their body

Consent procedures aim to ensure a choice free of coercion, rational deliberation and good understanding of consequences of the choice.

Can this be achieved in living donation?

- ❖Different than other medical procedure consents because there is not a benefit to the donor
- ❖Nephrectomy/partial hepatectomy carries surgical risk and long-term medical risk and possible unknown risk as well as psychosocial and financial risk
- ❖In the setting of an ill loved one can rational deliberation occur?
- ❖Family relationships are complex, and coercion, pressure and guilt often exist

Evolution of LD informed consent practice guidance



Murray JE et al. Ann Surg 1958; Abecassis M et al. JAMA 2000 Dec 13; Pruett TL et al, Transplantation 2006 May 27; Medicare Program Final Rule; OPTN Policy 14.

Required Elements of Informed Consent

- The donor's signature on a document that confirms that the donor:
  - Is willing to donate
  - Is free from inducement and coercion
  - Has been informed that he or she may decline to donate at any time
  - An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

Required Elements of Informed Consent

- Instruction about all phases of the living donation process, which includes:
  - Consent
  - Medical and psychosocial evaluations
  - Pre- and post-operative care
  - Required post-operative follow-up according to Policy 18.5: Living Donor Data Submission Requirements

Required Elements of Informed Consent

The ILDA must be available to assist the living donor during the consent process, according to Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements

The recovery hospital must provide an ILDA.

Required Elements of Informed Consent

- It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations.

Informed Consent Surrounding Recipient Outcomes

- Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation. 4. A deceased donor organ may become available for the candidate before the recovery hospital completes the living donor's evaluation or the living donor transplant occurs.

- Transplant hospitals determine candidacy for transplantation based on existing hospital specific guidelines or practices and clinical judgment.

Informed Consent Surrounding Recipient Outcomes

The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and recipient.

Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality)that:

- ❖Exceed local or national averages,
- ❖Do not necessarily prohibit transplantation
- ❖Are not disclosed to the living donor

The recovery hospital can disclose to the living donor certain information about candidates only with permission of the candidate, including:

- ❖The reasons for a transplant candidate's increased likelihood of adverse outcomes
- ❖Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law

Informed Consent Surrounding Recipient Outcomes

The recovery hospital is required to:

- Report living donor follow-up information, at the time intervals specified in Policy 18.5: Living Donor Data Submission Requirements
- Have the donor commit to post donation follow-up testing coordinated by the recovery hospital.

Any infectious disease or malignancy that is pertinent to acute recipient care discovered during the donor's first two years of follow-up care:

- May need to be reported to local, state or federal public health authorities
- Will be disclosed to their recipient's transplant hospital
- Will be reported through the OPTN Improving Patient Safety Portal

Required Elements of Informed Consent

- **Medical evaluations & psychosocial evaluations are required to be a living donor risks associated with evaluation for living donation:**
  - Allergic reactions to contrast
  - Discovery of reportable infections or serious medical conditions
  - Discovery of adverse genetic findings unknown to the donor
  - Discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

Required Elements of Informed Consent

- **Risks of Surgery**
  - Death
  - Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
  - Abdominal symptoms such as bloating, nausea, and developing bowel obstruction
  - That the morbidity and mortality of the donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions

Required Elements of Informed Consent

- **Psychological risks:**
  - Problems with body image
  - Post-surgery depression or anxiety
  - Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies
  - Changes to the donor's lifestyle from donation
- **Financial Risks**
  - Personal expenses of travel, housing, childcare costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs
  - Need for life-long follow up at the donor's expense
  - Loss of employment or income
  - Negative impact on the ability to obtain future employment
  - Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance
  - Future health problems experienced by living donors following donation may not be covered by the recipient's insurance

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

Required Elements of Informed Consent

- Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:
  - On average, living donors will have a 25-35% permanent loss of kidney function after donation.
  - Although risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors.
  - Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in midlife (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young living donor cannot predict lifetime risk of CKD or ESRD.
  - Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
  - Dialysis is required if the living donor develops ESRD.
  - Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to Policy 8.3: Kidney Allocation Points

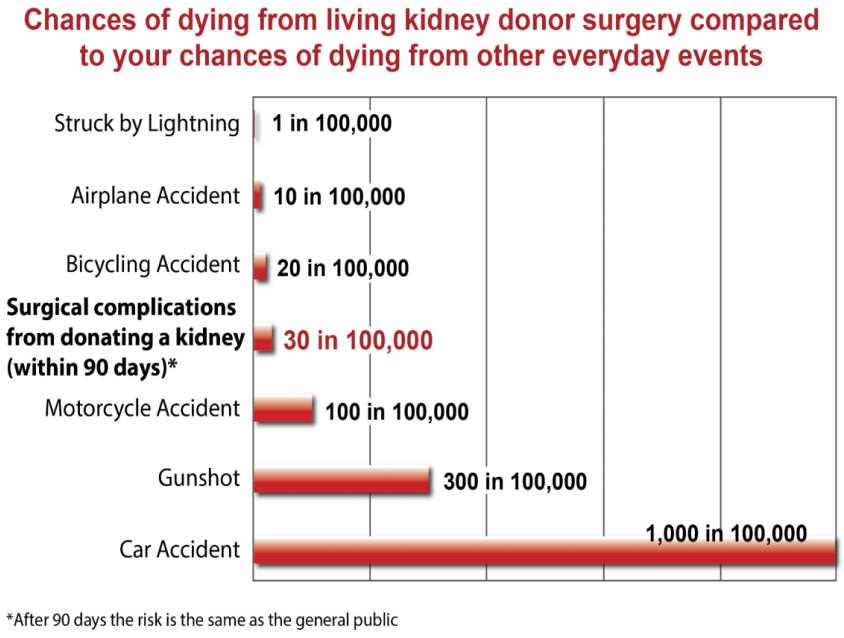
Additional Aspects of Kidney Donor Consent

- Surgical risks may be transient or permanent and include but are not limited to:
  - Potential medical or surgical risks:
  - Decreased kidney function
  - Acute Kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
- Additional Risks to the Female Kidney Donor:
  - Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation

Required Elements of Informed Consent

- The hospital may refuse the living donor. In such cases, the recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria

Patient friendly interpretations of risk



Group	Chances of getting kidney disease	What this means
General population	326 out of 10,000 (3.3%)	Highest chance
Living donors	90 out of 10,000 (0.9%)	Low chance
Healthy non-donors	14 out of 10,000 (0.14%)	Lowest chance

Additional Aspects of Liver Donor Consent

- Surgical risks may be transient or permanent and include but are not limited to:
  - Acute liver failure with need for liver transplant.
  - Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation.
- Risk of red cell transfusions or other blood products.
- Biliary complications, including leak or stricture that may require additional intervention.
- Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.

Required Elements of Informed Consent

- The hospital must provide the living donor with the hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program specific reports
- The hospital's 1-year living donor recipient's survival and recipient's graft survival rates

OPTN Requirements

For any KPD exchange, the paired donor's transplant hospital is responsible for obtaining and documenting informed consent from the paired donor according to Policy 13: Informed Consent Requirements.

If a different transplant hospital performs the organ recovery, the recovery hospital must also obtain and document informed consent according to Policy 13

https://optn.transplant.hrsa.gov/media/1205/kpd_informed_consent

Kidney Paired Donation

- Components of the KPD program must be reviewed with the donor separately from the intended recipient.
- Risks of shipping a kidney must be disclosed, as applicable.
- Separate elements for bridge donors:
  - Process for determining whether a chain ends with a bridge donor (Policy 13.6.6.2)
  - Possibility of needing another medical evaluation prior to donation
  - Verbal consents at multiple stages of the ‘bridging’ process

http://optn.transplant.hrsa.gov/media/1203/kpdpp_operational_guidelines.pdf

Summary of Live Kidney Donor Education Content

❖Best Practice in Living Kidney Donation Consensus Conference

Table 1. Topics reviewed by the workgroup committee to be included in the education of potential living kidney donors

Topics
Benefits to recipients of living donor kidney transplantation
Timing of transplantation
Risk assessment and counseling in living kidney donation
Surgical risks
Long-term medical risks
ESRD and mortality
Racial variation in risk estimates
Hypertension
Risks during pregnancy
Psychosocial considerations
Transplantation of donors who subsequently develop ESRD

Tan et al. CJASN 2015

Can informed consent be achieved?

- Required to know
- Need to know
- Want to know

Kortram et al: Transplantation 2014

- Performed a systematic review of informed consent practices:
  - 21 manuscripts included
  - Significant variation exist is practice between centers and providers
  - Donors often make decisions based on moral reasoning rather than balancing risks and benefits.
  - Stressed importance of accurate uniformed information
  - Recommended initiatives to minimize differences in donor education

Informed Consent

- Practices vary among US Transplant Programs
- Written consents vs checklists
- Elements omitted from consent by centers utilizing checklists
- Majority of programs do not incorporate all the CMS or OPTN mandated elements
- Consent should do more than merely document informational disclosures or informed consent
- Well-crafted consent forms play an integral role in facilitating donor comprehension
- **Proposal:**
  - **UNOS to develop a uniform consent incorporating all required elements**

Written informed consent for living kidney donors: practices and compliance with CMS and OPTN requirements.

Thiessen C[1], Kim YA, Formica R, Bia M, Kulkarni S. AJT 2013

Informed Consent

- Informed Consent is a critical aspect of living organ donation
- Safeguarding the individual donor is a central tenet of safe clinical practice
- Protecting the donor's autonomy is a major legal and ethical concern
- Process that occurs through-out the donation trajectory with focus on the donor rather than the recipient

Proposal:

- **Culturally congruent education**
- **Each team member focus on their individual specialty & educate on that topic only**
- **Involvement of clinical ethicist in consent process**

Living Organ Donation and Informed Consent in the United States: Strategies to Improve the Process.
Henderson ML[1], Gross JA[1].

Informed Consent

- Transplant programs have ethical imperative & federal mandate to ensure that potential donors are fully appraised of risks
- Many donors make the decision under stressful circumstances
- Donors reported:
  - Limited usefulness of certain CMS mandates topics
  - Desire for additional information about donation
  - Efforts to standardize should incorporate:
    - Donors' perspectives on the specific topics
    - Quantity of information
    - Mode of communication found most useful
- **Proposal:**
  - **Standardized informed consent practices**

Living Kidney Donors' Information Needs and Preferences.
Traino HM[1], Nonterah CW[2], Gupta G[3], Mincemoyer J[4].

Process of Informed Consent

The Process of Informed Consent

- Learners retain:
  - 10% of what they read
  - 20% of what they hear
  - 30% of what they see
  - 50% of what they see and hear
  - 70% of what they see hear and speak
  - 90% of what they say and do

Cupples and Ohler 2016

Fundamental Components of Informed Consent

- Decision making capacity
- Voluntariness
- Disclosure
- Understanding
- Consent

Addressing Live Donor Learning and Understanding

Everyone plays a role !
Particularly for centers using the IDAT model

Medical Team - Surgeon, nephrologist, nursing

- Provision of medical risk educational content
- Review of documents

Social work assesses:

- Cognitive & learning barriers?
- Need for teaching accommodations?

ILDA:

- Understands risks?
- Expected outcomes for donor and recipient?

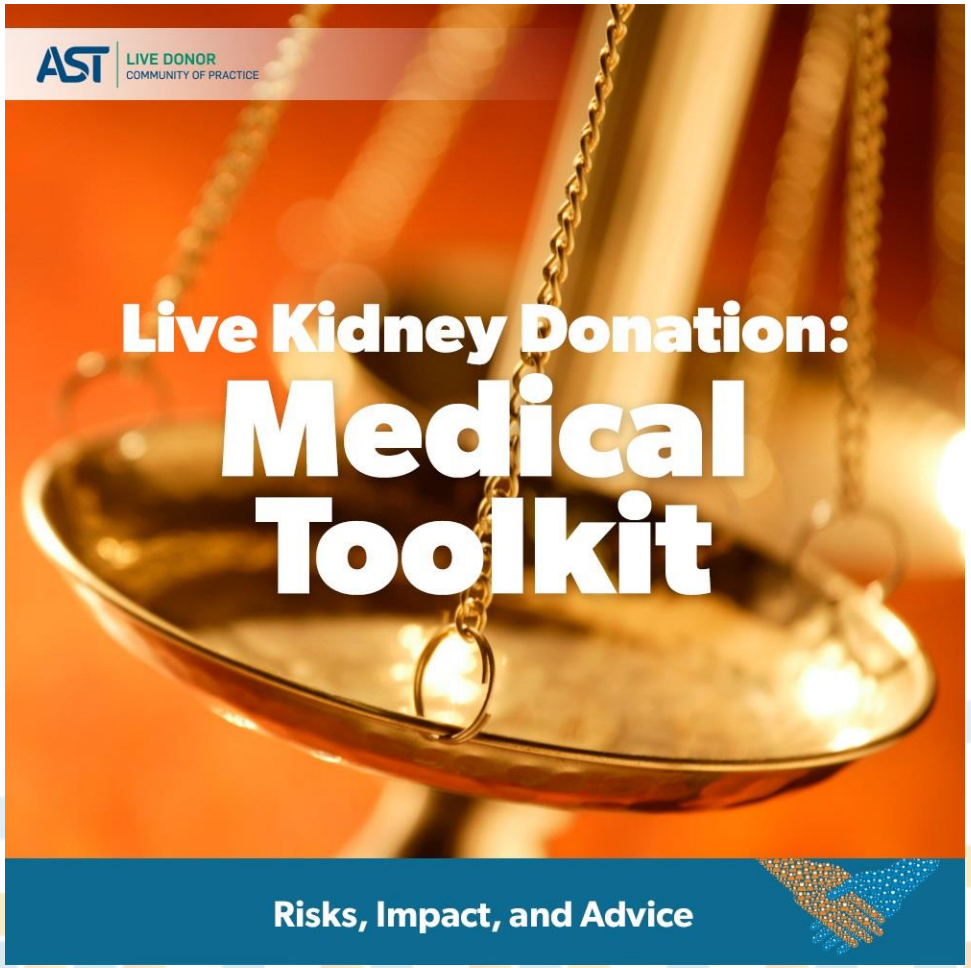
Abecassis M, et al. Live Organ Donor **Consensus** Group. JAMA. 2000 Dec 13;284(22):2919-26.

Required Elements of Informed Consent

- Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the living donor is able to engage in meaningful dialogue with recovery hospital's staff.

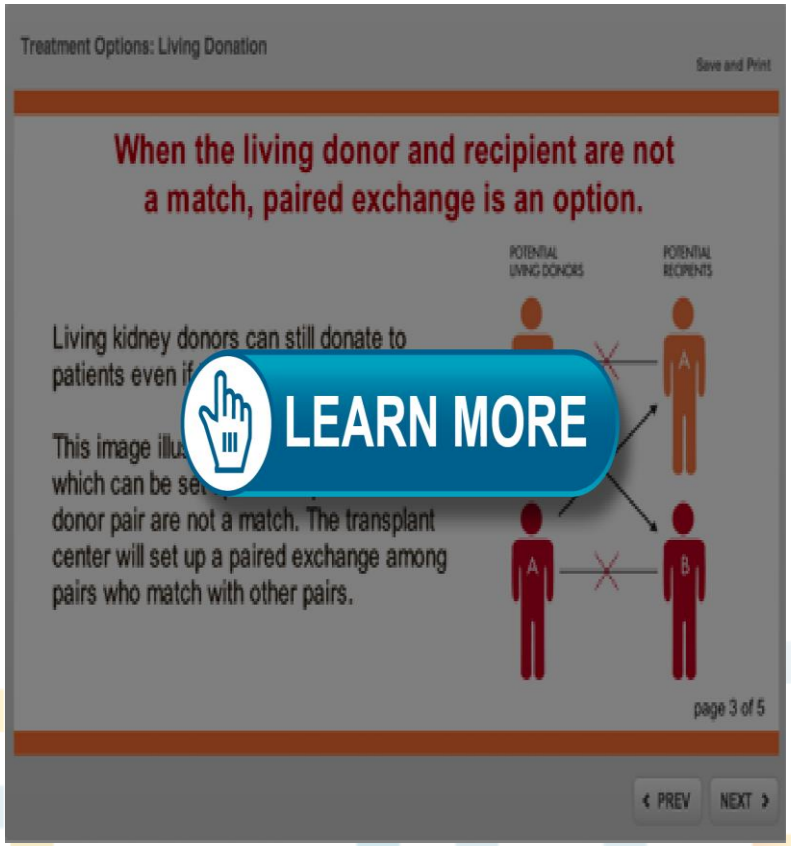
http://www.livedonortoolkit.com/

Medical Toolkit Table of Contents



Tools to Improve Understanding

- Environment conductive to learning sufficient time, quiet area with limited interruptions
- Limit amount of information given at one time
- Teaching material: video, group sessions
- Repeat education at various time points throughout the process



https://transplantliving.org
https://informate.org
Gordon EJ, Mullee J et all Surgery 2016 Sept

Create climate conducive to informed, autonomous decision-making

- Affirm the opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
- Integrate the ILDA role to assist the donor during the consent process
- Teaching must be provided in a language in which the donor is able to engage in meaningful dialogue with staff.
- Teaching modalities are not prescribed
  - Any media
  - Group or one-on-one
  - Methods to assess understanding not specified
- Provide instruction about all phases of the living donation process including:
  - Consent itself
  - Medical and psychosocial evaluation processes
  - The procedure, including pre and post operative care
  - Required post-operative follow up

Addressing Barriers to Informed Consent

- Decreased Health Literacy
  - Language required for compliance is not at the fifth grade learning level
  - Not all donors are at the 5th grade level
  - Need to use terms they understand
- Ambivalence
  - Not uncommon
  - Donation must be an affirmative decision
  - Interventions to address: Cooling off period, motivational interviewing, counseling, reeducation, mentorship
- Coercion
  - Explore consistency in motivation
  - Presence of realistic expectations
  - Offer medical “Out”

Shared Decision Making

- Integrate donor values and preferences in shared decision-making regarding eligibility
  - " providing care that is respectful of and responsive to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions" (IOM)
- Useful in the medically complex, younger and more educated donors
- Donors surveyed would accept a higher risk of HTN, CVD and ESRD than professionals
- In certain circumstances donors would be allowed to attend selection committee and present reasons for donating (elect an advocate to do , video and appeal or write a letter)
- Donor team can decide to decline donor or send for another opinion

Thiessen, Gordon, Reese and Kulkarini AJT 2015

Often re-education is required
Overcoming Myths about Living Donation

- **Common myths about kidney donation**
  - Living kidney donors won't live a healthy life with just one kidney.
  - After donating, living kidney donors can't have children.
  - Living kidney donors don't choose which person they want to donate their kidney to.
  - Living kidney donors live a shorter life.
  - The Catholic Church opposes organ donation.
  - Living kidney donation harms the donor's sex life.
  - Living kidney donors are more likely to get kidney disease after donating.
  - Living kidney donors have to take anti-rejection medicines.
  - Only younger people should be able to get a kidney transplant.
  - Adults over age 50 can't donate.
  - Gay (homosexual) people can't be living kidney donors.
  - People with tattoos can't donate a kidney.

http://informate.org/cultural_beliefs_and_myths/

Perform Informed Consent as a Process

- Donor decision making, readiness, and understanding changes over time
- As options and plans change, so may the patient's wishes
- This is particularly true in complex medical evaluations, or in paired exchange

Adapted from Rebecca Hays

Conclusions

- Regulations dictate much of the informed consent practices
- Patient preferences regarding education needs must be considered
- Partnerships between donors and providers are crucial to good donation decisions
- Informed consent is a process with multiple points in times and modalities required.
- Research is needed on enhancing the communication of risk, and understanding donor preferences

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