Kidney Independent Living Donor Advocacy Training Documentation Manual

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The material contained within this document follows the Centers for Medicare and Medicaid Services X tags 121 through125 (d) Standard: Independent ILDA guidelines, as well as other CMS X tags related to living donation.

The goal of this manual is to provide the tools necessary to help the Independent Living Donor Advocate/Independent Living Donor Advocate Team work with the potential donor and be certain that all necessary information has been imparted to the potential donor. NATCO recognizes that at each transplant center many different individuals may fulfill this role. In preparing this manual, NATCO solicited input from many social workers, physicians, nurses and clergy who currently work as donor advocates in their institutions. While there are too many to name individually, we want to assure the reader that all points of view were considered.

LEGEND

The Independent Living Donor Advocate or Independent Living Donor Advocate Team will be referred to as ILDA throughout document.

1. POLICY AND PROCEDURES

Independence:

- Individual should function independently from the transplant team.
- Goal of the independent status is to avoid conflicts of interest.
- Factors to be considered when defining independence:
    - Position within the hospital. The ILDA may be an internal position or located outside of the hospital.
    - Does the position allow the ILDA to provide independent representation to the donor?

Qualifications:

- The ILDA will be approved and credentialed through the Transplant Center.
- The ILDA's background can include experience in the field of medicine, social work, pastoral care, psychology, nursing or other appropriate disciplines.
- The ILDA will complete center-specific orientation.

The ILDA will be able to demonstrate a general knowledge of living donation by:

- discussing the living donation process in general terms to include donor evaluation, donation surgery, post-donation recovery and follow up.
- discussing potential complications.
- discussing the donor's current medical history and its implications for the suitability of the donor (as indicated by the physician who performed the living donor screening exam), including possible long-term clinical implications of the organ donation. If additional clarification is needed, the donor should be referred to the physician who completed the exam, or a physician member of the transplant team to discuss the specific medical risks as they pertain to this individual donor identifying when the donor should be referred to the medical team or transplant team for clarification of how the donor's specific medical history affects his or her risks.
- identifying the current and future risks for the living donor using a multi-faceted framework and not solely a medical model.
- discussing the emotional / psychological aspects of living donation.
- understanding the importance of a psychosocial assessment to evaluate external pressures that may impact the donation decision.
- discussing the family support system regarding the donation decision and the risk of trying to proceed without the needed support.
- discussing in general the financial aspects associated with a living donor and emphasizing the need to have financial support in place prior to donation.
- apprising potential donors of potential difficulties obtaining new insurance post-donation.

The ILDA will be able to demonstrate a general knowledge of transplantation by:

- discussing options for the recipient other than organ donation from a living donor.

The ILDA will be able to demonstrate knowledge of medical ethics by:

- holding the donor's welfare of primary importance.
- respecting the decisions and autonomy of the donor and discussing the risks very thoroughly if the donor wishes to proceed despite team concerns that doing so would pose a risk. It should be noted that if it is the advocate or advocate team's consensus that donation may represent a significant risk, donor autonomy, usually a *sine qua non*, may not be absolute. The moral autonomy and moral stewardship of a transplant surgeon who may feel that proceeding with donation for a particular donor may violate his practice of "first do no harm" are important.
- maintaining donor confidentiality.
- setting and maintaining standards of competence and integrity.

The ILDA will be able to:

- demonstrate knowledge of informed consent by understanding the consent content and informed consent process assuring that the donor has been informed of:
- the fact that all communication is confidential.
- the evaluation process.
- the surgical procedure.
- alternative treatments for the recipient.
- medical and psychosocial risks.
- national and center outcomes.
- possible no coverage by insurance company following donation.
- right to opt-out.
- risk of recipient drug nonpayment and how it effects graft survival.
- chance of recipient having a successful outcome.
- the fact that the donor will be tested for infectious diseases, such as HIV and hepatitis, and if he or she is positive, some of the results may be reported to the local department of health.
- high-risk social behaviors that could lead to increased risk to recipient.
- evaluate the donor's understanding of informed consent.
- identify areas where additional information or clarification is warranted to documenting consent.
- define chain of command.
- explain the transplant program's process for grievances.
- define how/where the ILDA documents/communicates with the team.

Chain of Command for the Independent ILDA

- The keyword for the ILDA is Independent. This is not to say that the ILDA works totally independent of the transplant team but he or she must remain non-biased during the donor evaluation process.

- The ILDA must communicate directly to the Living Donor Transplant Coordinator all unanswered questions, concerns or complaints by the living donor candidate. Communication between the ILDA and the Living Donor Transplant Coordinator should be conducted on an ongoing basis to ensure proper communication between the two individuals.

- In the event that the Living Donor Transplant Coordinator cannot answer questions, concerns or complaints, the ILDA must take those issues to the transplant program administrator for investigation. It will be the transplant program administrator's responsibility to determine if the ILDA concerns must be elevated to a higher authority level or can be resolved internally.

- The living donor candidate must be given the right to file a grievance/complaint to an outside agency (i.e., Organ Procurement and Transplant Network (OPTN) and State Department of Health) if the grievance/complaints cannot be resolved by the transplant program. It will be the responsibility of the transplant program to provide the necessary information or forms to the living donor candidate to file such a grievance/complaint to an outside agency during the initial donor evaluation process.

Documentation

- The ILDA should document all meetings with the living donor candidate as part of the living donor candidate's medical record as determined by individual transplant program policy. The ILDA must document its discussion with the living donor about the required elements to be discussed that include the following:
    - (i) Consent process(the discussion must include all of the required CMS elements for informed consent as listed in the previous section);
    - (ii) Evaluation process;
    - (iii) Surgical procedure;
    - (iv) Benefit and need for follow-up;
    - (v) Grievances/Complaints.

Process for Grievances

- With the help of the ILDA the living donor candidate will be able to submit the proper grievance form utilized by the specific transplant center.
- In the event that the living donor candidate has experienced a grievance that the organ transplant program cannot resolve, the transplant program must have a policy and procedure in place for the living donor candidate to file a grievance against the transplant program/institution.

2. KNOWLEDGE OF PROCESS

2a. Donor Medical History Effects

While it is the physician who will assess individual risk based on past medical history, the ILDA must know how the donor medical history affects his or her long-term survival/organ function in order to be certain that the donor understands his or her individual risks. The ILDA should refer the donor to the transplant team if there is any question regarding the donor's understanding or his or her individual risks.

Summary Points:

- Hypertensive Live Kidney Donors
    - Blood pressure increases with age.
    - Healthy adults with normal blood pressure who donate a kidney are more likely than non-donors to develop a 6 mm/hg increase in systolic blood pressure and 4 mm/hg increase in diastolic blood pressure, which is higher than what is considered normal for aging.
    - Potential donors with borderline hypertension, positive family history or obesity are at greater risk for blood pressure elevation from uninephrectomy.
    - While an increase in blood pressure following nephrectomy may not measurably increase the risk of ESRD, it will increase the risk of heart attack and stroke, and it must be meticulously controlled.
    - United States data prompt consideration of hypertensive donors if they have hypertension (HTN) that is well-controlled, age older than 50, white and have normal kidney function.
        - A recent study noted 25 donor deaths 90 days post-surgery out of 80,347 live kidney donors in the United States between April 1, 1994, and March 31, 2009. Though the overall death rate remained 3.1 in 10,000, donors with HTN also had a statistically significantly higher surgical mortality than donors without HTN (36.7 per 10 000 donors; 95% CI, 4.4-132.6; vs. 1.3 per 10 000 donors; 95% CI, 0.4-3.4; RR, 27.4; 95% CI, 5.0-149.5; *P*_.001), although this was based on only two deaths among 545 donors with HTN; therefore, as indicated by the wide CI, the magnitude of the excess surgical risk remains quite uncertain.

- Obese Living Kidney Donors
    - Obesity is commonly defined as BMI > 30 kg/m3.
    - Obesity is an independent risk factor for renal failure when you have two kidneys. BMI AND RISK FOR ESRD: BMI 30-35 – 3.6-fold higher risk BMI 35-40 – 6.1-fold higher risk BMI > 40 – 7.1-fold higher risk compared to individuals with BMI 18.5-25.
    - Kidney donors who are obese may have increased blood pressure within the remaining kidney. Higher filtration pressure increases the long-term risk of renal damage. This is treatable when identified.
    - Obesity is a risk factor for the development of diabetes, respiratory insufficiency, cardiovascular disease and also wound problems or venous embolization after surgery.
    - In a series of 871 kidney donors, a body weight over 100 kg was significantly associated with perioperative complications.
    - Many programs regard a BMI of 30 – 35 as a relative contraindication to donation and those with a BMI >35 will be considered on a case-by-case basis.
    - Recent study noted 25 donor deaths 90 days post-surgery out of 80,347 live kidney donors in the United States between April 1, 1994, and March 31, 2009. Increased surgical mortality was not associated with obesity.

- ESRD Risk in Live Kidney Donors
    - GFR decreases with age in all people.
    - Live kidney donors lose 20-30% of their predonation GFR permanently.
    - Adaptive hyperfiltration stabilizes creatinine clearance to 70-80% of predonation values.
    - If a donor has a predonation GFR of 80 cc/min, you cannot reliably predict the stability of function over 20-30 years of time.
    - The absolute ability to increase GFR is dependent on age and obesity. Young donors who are obese do not retain the ability to fully compensate for the loss, and, although older donors do increase single kidney GFR, the absolute increase is comparatively less.
    - Further study comparing the risk of ESRD in the general public to that in living kidney donors is needed. Because there has been no national systematic long-term data collection on the risks associated with living organ donation, the risk of renal dysfunction for the living kidney donor is not well known. However, recent OPTN data reveal the following: The risk of end-stage kidney disease, and the need for dialysis or to receive a kidney transplant is between 0.10 and 0.52%; this risk may be higher if the prospective donor is African-American; between January 1996 and February 2008, there were 172 candidates on the kidney waiting list who were identified to be previous living kidney donors. The median time from donation to listing was 19 years.
    - Risks of post-donation ESRD are unequal among various ethnic/racial groups and mirror the increased risk of ERSD that these higher risk groups experience within the general population.

- Older Live Kidney Donors

- The numbers of living donors older than age 50 has increased 3-fold since 1995.
- Graft survival from living kidney donors older than age 55 was 85% (3 years) and 76% (5 years) compared to 89% and 82% from donors younger than age 55.
- Current guidelines do no set an upper age limit. However, older donors require close attention to underlying renal function and latent cardiovascular disease or malignancy.
- Older age and higher body mass index were associated with a GFR <60 mL/min/1.73 m2 and HTN post-donation.

- Donors who Smoke
  - Smoking (current and previous) increases cardiovascular risk and is associated with preoperative respiratory events, cardiovascular events and post-op wound complications.
  - It is advised for potential donors to abstain from smoking 2-4 weeks before surgery.

- Donors with Nephrolithiasis
  - Kidney stones are common and affect up to 5% of the population with a lifetime risk of 5-10%.
  - Overall risk of stone recurrence is 50% in 5 years.
  - Donors should be advised of general measures to reduce risk of recurrent stone formation (adequate hydration, reduce dietary intake of animal proteins, salt and oxalate-rich foods).
  - Donor must understand the slight increased risk to the donor's remaining kidney.
  - Each transplant center will have its own policies and procedures regarding suitability of donors with kidney stones and which kidney will be transplanted (if the center opts to utilize donors with stones). The ILDA must be familiar with its transplant programs policy regarding utilizing donors with kidney stones or history of kidney stones.
  - Donors with recent stone history or metabolic disorders such as hyperparathyroidism and gout may need to be excluded.

- Proteinuria in Live Kidney Donors
  - Only a fraction of live donors develop proteinuria despite the occurrence of some degree of hyperfiltration in donors following nephrectomy.
  - Yearly surveillance will identify incipient glomerular disease which can be treated appropriately if needed (ACEIs and ARBs).

- Long-term Survival of Living Donors
  - Prior studies from Sweden, Switzerland, Minnesota and UNOS conclude that living kidney donors live longer and are healthier than the aged-matched patients in the general public. This likely reflects the earlier selection bias of only healthy white people serving as donors.
  - The use of more medically complex donors of diverse ethnicity will require long-term investigation. However; live donors were drawn from UNOS of 80 347 live kidney donors in the United States between April 1, 1994, and March 31, 2009. Median (interquartile range) follow-up was 6.3 (3.2-9.8) years. A matched cohort was drawn from 9,364

participants of the third National Health and Nutrition Examination Survey (NHANES III) after excluding those with contraindications to kidney donation. One of the conclusions was: among a cohort of live kidney donors compared with a healthy matched cohort, the mortality rate was not significantly increased after a median of 6.3 years.

- Surgical Mortality
  - 3.1 per 10, 000 surgeries (25 deaths per 80, 347 surgeries).
  - Surgical mortality was higher in men than in women (5.1 vs. 1.7 per 10 000 donors).
  - Higher in black versus white and Hispanic individuals (7.6 vs. 2.6 and 2.0 per 10 000 donors).
  - Higher in donors with HTN versus without HTN (36.7 vs. 1.3 per 10 000 donors based on two deaths in 545 hypertensive donors).

- Surgical Morbidity: Information from UNOS Cohort Study Living Donor Registration Forms (covers events that occur within 6 weeks of donation) 2005-2007; n=19,037
  - Median age of donors : 41.0 years
  - Median BMI of donors: 26.6
  - History of HTN: 1.3% yes, 2.2% unknown, 96% no
  - History of diabetes: 2.3% unknown, 97.6% no
  - Surgical outcomes: one donor death, 5% required blood transfusion
  - Adverse events: readmission= 353, required interventional procedure = 115, re-operation = 85, vascular complications requiring intervention = 56, other complications requiring intervention = 393
  - Reoperation: bleeding (n=28), bowel obstruction (n=13), and hernia repair (n=10)

- Reasons for Readmission
  - Abdominal problems (nausea vomiting, gastroenteritis, ileus, constipation, abdominal pain or bowel obstruction).

- Less Frequent Reasons
  - Chylous ascities, pancreatitis, SOB, PE, subphrenic fluid and infection (wound, pneumonia UTI).

- OPTN Limitations
  - > 50% of forms are submitted less than 6 weeks post-donation, so all rated should be considered minimum rates.

- Pregnancy
  - The research revealed that a woman who has donated a kidney does not face any additional risks of developing conditions such as HTN during a future pregnancy compared with women in the general population. In addition, female kidney donors do not face any increased risk of miscarriage or of giving birth prematurely.

- Additional Complications
  - Some men will experience testicular swelling that will resolve without intervention.

- Urinary retention when foley is removed.
- Chronic pain/nerve entrapment.
- Depression/post-traumatic stress disorder (PTSD).
- Conversion from lap to open procedure < 3%.
- Hernia.

2b. **Explain the General Surgical Procedures and Have a General Knowledge of Potential Risks of Surgery**

- The information given to potential donors should be dependent of Living Donor Advocate or Living Donor Advocate Team primary role (RN, SW, MD, pastoral care, etc). ILDA will need to assess a potential donor's understanding of the procedures/risks and answer basic questions. Detailed information of procedures/risk should be directed to the living donor coordinator and/or transplant surgeon.
- Laparoscopic Donor Nephrectomy.
- Laparoscopic nephrectomy, also known as "keyhole surgery," is a minimally invasive surgical procedure for obtaining a kidney from a living donor that can make the process easier.
- In this procedure, the surgeon makes two or three small incisions close to the belly button. The kidney is removed through the central incision. Through one of the other openings, a special camera called a laparoscope is used to produce an inside view of the abdominal cavity. Surgeons use the laparoscope, which transmits a real-life picture of the internal organs to a video monitor, to guide them through the surgical procedure.
- In comparison to the standard operation, it results in a smaller incision, reduces recuperation time and usually shortens hospital stays. Many donors are discharged from the hospital after two days and return to normal activity within two to four weeks. A small percentage of donors may have a longer recovery period.
- Not all donors can undergo laparoscopic nephrectomy. Donors may not qualify for the procedure if they:
    - had multiple previous abdominal surgeries.
    - are significantly overweight.
    - have abnormal anatomy of the kidney.
- The transplant surgeon will determine if laparoscopic nephrectomy is a possibility.

Open Nephrectomy

- Open nephrectomy has been the standard for the past 35 years and involves a five-to-seven-inch incision on the side of the chest and upper abdomen. A surgical instrument called a retractor is usually needed to spread the ribs to gain access to the donor's kidney. Sometimes it is necessary to remove part of a rib for better exposure.
- The operation typically lasts three hours, and the recovery in the hospital averages four to five days. Donors can usually return to normal activity within four to 12 weeks.

Risks and Potential Complications

- In-depth information regarding general risk/complications, risk and complications specific to the individual donor based on medical history and lifestyle choices, and expected donor outcomes should be given by the living donor transplant coordinator/transplant surgeon. In addition, it is important for the ILDA to tell a potential donor to take an active role in learning more about these potential surgical risks and long-term complications.

General Risks for Living Kidney Donation:

- Pain
- Infection of the wound
- Incisional hernia
- Pneumonia
- Blood clots
- Hemorrhaging
- The need for blood transfusions
- Side effects associated with allergic reactions to the anesthesia
- Death

Long-Term Organ Specific Donor Complications

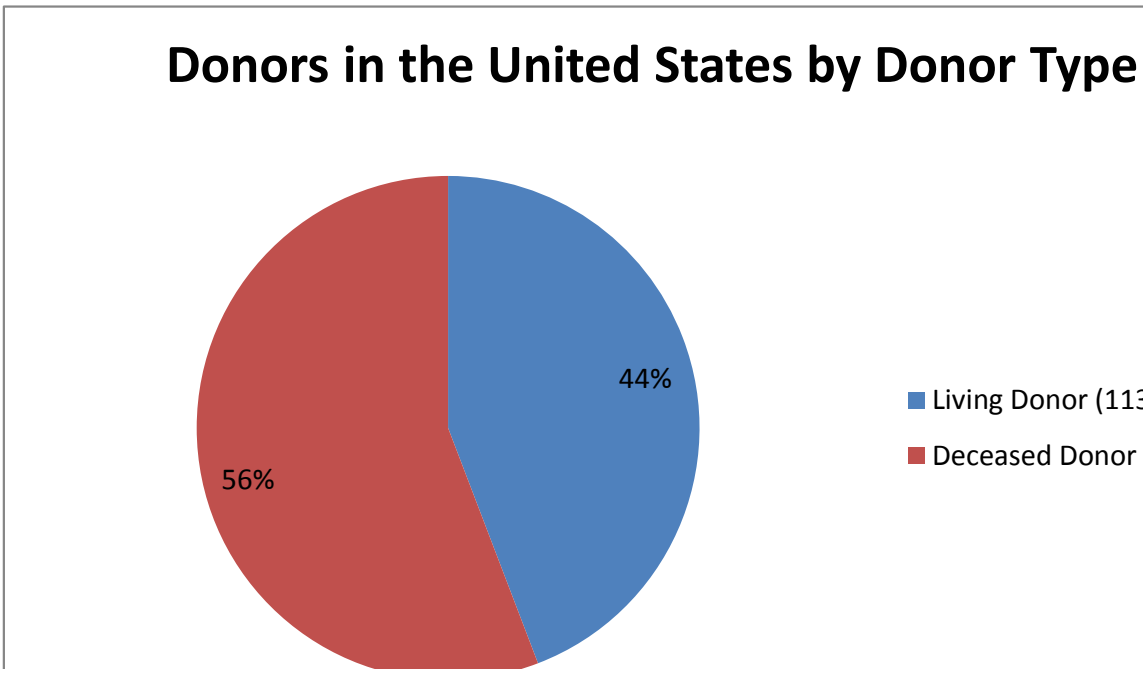
- HTN
- Kidney failure
- Proteinuria

Alternatives

- The ILDA will demonstrate a general knowledge of alternative modalities for patients with ESRD besides living donation.
    - Deceased donor transplantation
    - Hemodialysis
    - Peritoneal dialysis
        - CCPD continuous cyclic peritoneal dialysis
        - CCPD- continues ambulatory peritoneal dialysis

Donors in the United States by Donor Type

The chart below shows total donors in the United States organized by donor type to date.
Donors Recovered: January 1, 1988 - July 31, 2011.



Based on current OPTN data as reported on September 30, 2011. Data subject to change based on future data submission or correction. For updated information, visit the OPTN HRSA website: http://optn.transplant.hrsa.gov/data/about/.

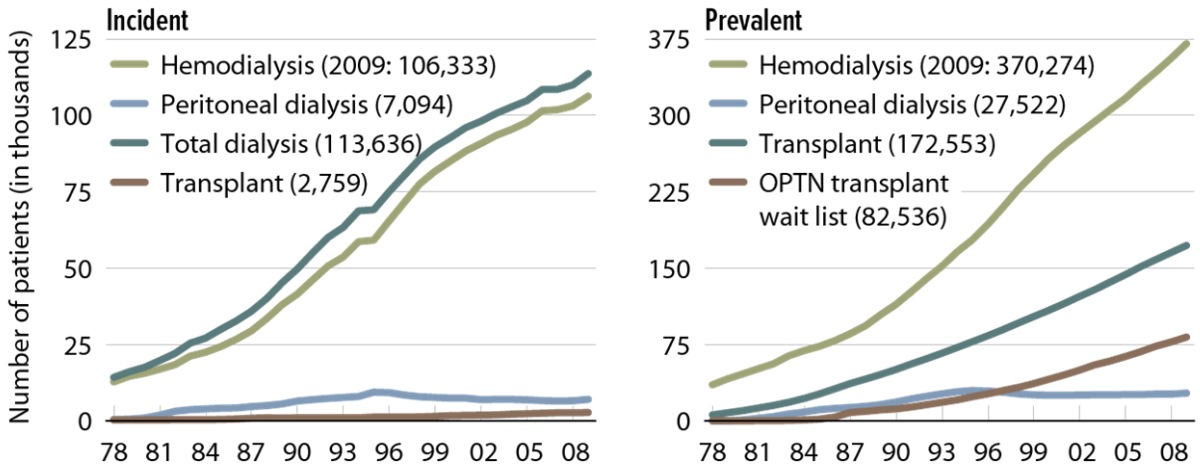
United States Renal Data Systems 2011 Annual Report data reported the number of incident dialysis cases rose 3.3% in 2009 to 113,636; with 2,759 patients receiving a pre-emptive transplant as their first ESRD modality, 116,395 total patients began ESRD therapy in 2009.

More than 106,000 dialysis patients started ESRD treatment on hemodialysis, and 7,094 started on peritoneal dialysis---6.1% of patients with known dialysis modality. The rate of new ESRD cases per million population has been relatively stable since 2000, and rose just 1.1% in 2009 to 355. Growth in the incident population continues to be driven by a linear increase in the number of patients age 45 to 64; growth in the population age 65 and older, in contrast, has slowed considerably.

The December 31, 2009 prevalent population included 370,274 patients on heomodialysis and 27,522 on peritoneal dialysis, as well as 172,553 with functioning kidney transplant; the total treated ESRD population thus rose above 570,000. The rate of prevalent ESRD cases reached 1,738 per million population, an increase of 2.1% from 2008, and consistent with a similar rise per year since 2002.

Incident & prevalent patient counts (USRDS), by modality

Figure 1.1 (Volume 2)



Incident & December 31 point prevalent patients.

Based on the United States Renal Data Systems 2011 Annual Report Data.

Waitlist Data

Current number of people waiting for transplant in the United States as of September 2011.

- 121,805 – all organs
- 96,005 – Kidneys
- 10% of adults on the waiting list will die before receiving an organ transplant.

Kidney Transplant Data (2010-2011) based on OPTN/UNOS HRSA data 2010

Transplant	As of September 30, 2011	2010
Total	**9,687**	**16,900**
DD Transplant	**6,356**	**10,622**
LD Transplant	**3,331**	**6,278**

Based on OPTN data as of September 30, 2011. Data subject to change based on future data submission or correction.

3. MEDICAL ETHICS AND INFORMED CONSENT

Informed Consent for Independent Living Donor Advocates or Living Donor Advocate Team
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- Informed consent is a term that came into existence in response to the trial of Nazi physicians at Nuremberg. A criticism of the physician-researchers -- seemingly mild compared to the atrocities they committed -- was that they did not give the subjects of their research the opportunity to choose voluntarily whether to be involved. Prosecutors at the trial claimed that voluntarily consent to participation in a research study was an international standard of medical research. The term "informed consent" arose several years later to describe this standard. It is worth noting that the standard of voluntary consent under conditions of full understanding was often violated in the decades before and even after WWII. One of the most well-documented examples is the National Health Service study of syphilis in African-American men, which lasted for five decades from the 1920s to the 1970s. Poor, rural farmers from Tuskeegee, Alabama, were misled about the nature of the research study and were prohibited from receiving treatment for syphilis in the name of learning about the natural course of the disease. Informed consent is grounded in the larger ethical principles of respect for persons (sometimes also called respect for patient autonomy). The principle of respect for persons says, broadly speaking, that health care professionals should respect the values and decision-making authority of patients.

- In the United States, specific rules for obtaining informed consent were first developed for medical research. However, in the 1970s the concept was adopted as important to protect patient rights in making treatment decisions. The basic idea is that a patient's body is his or her own, and he or she should be in control of the types of medical treatments that he or she receives. A person who gives his or her informed consent to a treatment is in control because he or she understands the treatment being offered and freely accepts it. A string of cases (*Schloendorff v. NY Hospital*, *Salgo v. Leland Stanford*, *Jr,*; *Donald Cowart, Nancy Cruzan, Canterberry vs. Spence*) established informed consent as a requirement for the provision of medical treatments. Courts and regulatory bodies developed procedures for obtaining informed consent;- simply put, these procedures are meant to ensure that the patient is in control.

- No one would dispute that living donor candidates should be in control of whether they donate or not. Thus, informed consent procedures are important because they help to ensure that the donor candidate is in control of the decision, rather than someone else. What is it, specifically,

for a person to be in control of his or her choice? The basic idea is that a person fully understands what he or she is being asked to do, and he or she chooses to do it (or not) based on the core values that he or she holds to be important in life. If someone holds career advancement to be the highest value in his or her life, and if donation somehow inhibits his or her career, then he or she has a strong reason not to donate based on his or her core values. If a person values commitment to the well-being of family members as especially important, then he or she has a strong reason to donate based on his or her core values. Of course, each of us has multiple core values, and negotiating among them to come to a decision sometimes is not an easy task. However, what should not happen is that someone lacks the knowledge about donation so they cannot evaluate how donation fits with their core values. Nor should someone be rushed into donation without the time to process what donation means to them. Nor should someone be coerced into donation by an aggressive family member. The list of barriers to providing valid informed consent could go on.

- It is useful to divide informed consent into five elements of informed consent:
    1) competence,
    2) voluntariness,
    3) disclosure,
    4) understanding, and
    5) consent.

    Each element is necessary for informed consent, and if each element is satisfied, this shows that informed consent has been sufficiently obtained. The elements are summarized below. Together they provide a useful checklist for determining whether informed consent has been obtained in a specific case.

    1) **Competence:** To be eligible to give informed consent, a person must be mentally competent. Generally speaking, persons are assumed to be mentally competent to consent to medical care or research unless they demonstrate characteristics that bring their capacity for decision making into question. When it is unclear whether someone has the capacity to understand information and make a reasoned choice based on their values, a physician (typically a psychiatrist) can formally evaluate a person for decision-making capacity. A determination that a person lacks decision-making capacity is a clinical judgment, and thus is made by a health care provider such as a physician. A determination that a person is not competent is a legal determination made by a judge; though the judge will consider as evidence the evaluation for capacity made by a clinician. State laws vary on the specifics related to determinations of capacity and competency. For living donor informed consent, it is not necessary to have a court determine competency. Indeed, a formal medical evaluation for capacity should occur only if questions arise during the routine donor evaluation.

    2) **Voluntariness:** Consent is valid only if it is given voluntarily. A choice that is coerced, that is made under the duress of an explicit or implied threat, is not given voluntarily. A physician who angrily threatens to abandon his or her patient unless the patient accepts the treatment he or she recommends is acting coercively. Likewise, a grandparent is acting coercively if he or she threatens to disinherit a grandson unless he "steps up to the plate" to donate a kidney to an uncle. The grandparent may be within his or her

rights to disinherit his or her grandson. Even so, the threat itself is coercive and it calls into question whether the grandson can give a valid informed consent. Asking potential donors about why they are motivated to donate helps to rule out coercion: a person who speaks lovingly about wanting to help a friend or relative is probably not being pressured into the decision by a forceful relative. Sometimes, promise of reward is thought to be coercive. For example, offering to pay a mother whose children are starving $10,000 to donate a kidney is thought by some to be coercive because the mother literally "could not resist" this reward even if she did not want to donate. Concern about the coercive nature of payment is in part what is behind federal laws prohibiting compensation for organ donation (See NOTA, 1984).

Potential donors need time to make a final decision. Some donors initially feel a measure of ambivalence and need time to work through those emotions, which the advocate/team must be prepared to allow. Donors may start out with hesitation and arrive, after a thorough education about donation, at the point of wanting to be a donor once everything is fully understood. In general, ambivalence that is rigid is incapacitating and usually means the donor should not go forward, but most patients present with at least a small measure of mixed feelings and advocates and the team should allow time to process the many emotions involved. This can be a challenge in a busy program where the thrust is to push forward, but allowing all the time needed is essential. It goes without saying, conversely, that central to the role of the ILDA is the responsibility of encouraging donors to share negative thoughts about donation, avoid shame and make the best decision for themselves, extricating themselves in a way that is protective of their privacy, and with the help of donor advocates and others if that is the their ultimate decision."

3) **Disclosure:** A person makes an "informed" choice only if he or she has the information needed to make the choice. For treatment decisions, the information needed includes diagnosis, prognosis, the treatment options available (including the option of doing nothing) and the risks, benefits and burdens of each option. For research studies in which the subject does not expect to benefit, the information needed includes a description of the research and its potential to advance knowledge, what is expected of subjects who participate and the risks of participating. Because living donors do not benefit medically from the removal of their kidneys, the information they require is similar to that of research subjects. They need information on the nature of donation and how it is expected to benefit the recipient, what is expected of them if they donate, and most importantly about the short-term and long-term risks of donation. Living Donor Advocacy Programs should develop a list of information that is important to explain to donor candidates.

4) **Understanding:** Presenting information to someone does little good unless the person understands the information. After all, the purpose of presenting information is so that patients and research subjects can make a reasoned choice about whether consenting to an activity is consistent with their core values. If understanding is not present, consent is not valid. Persons in charge of obtaining informed consent must thus evaluate a person's understanding of the information presented. The "tell back" or "teach back" method is an effective and efficient way to evaluate understanding. One

simply prompts patients to explain the information they just heard. Within a few sentences it is usually easy to evaluate a level of understanding of the material. If understanding is lacking, it is important to return to the disclosure process, varying one's approach and technique to successfully communicate the information to patients.

5) **Consent:** All too often, "consenting" a patient means getting a signature on a piece of paper. A signature alone is not adequate to ensure that a person has given informed consent (although legally the signature may play this role). Giving consent means that a person has taken a mental action—they have made a choice to accept a treatment option, to become a research subject or to donate a kidney. Making the choice—voluntarily, under conditions of full understanding, and for reasons that make sense internally to the person giving consent—should be an active and engaged process. Signing a form may be a necessary part of the process, but it should not be misunderstood to be the entire process.

   Informed consent should be a part of all procedures (e.g., tests). It is important to underscore that it is a process rather than product. For the donor to arrive at that point may entail many additional discussions with donor advocates as well as other team members. Related to this is the need to ensure that informed consent not only signifies that a potential donor understands the donation process and its flow but also that the donor can **interpret** the effects of donation on all parts of his or her life and has been encouraged to voice all thoughts and feelings related to the ultimate decision in a safe and supportive and non-judgmental environment with the living donor advocate. Thus, it is not enough simply to say that he or she understands because intellectual comprehension without emotional buy-in does not enhance true informed consent.

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