The Independent Living Donor Advocate Interview

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OBJECTIVES

- Define the role of the Independent Living Donor Advocate/Independent Living Donor Advocate Team (ILDA/ILDAT)
- Discuss regulatory requirements as it pertains to the ILDA/ILDAT role
- Describe the components of the ILDA interview

ROLE OF THE INDEPENDENT LIVING DONOR ADVOCATE/INDEPENDENT LIVING DONOR ADVOCATE TEAM (ILDA/ILDAT)

"…the ILDA is an advocate for patient autonomy and readiness, and a safeguard for aspects of informed consent unique to the living donor populations."

Rebecca Hays, MSW
AST, LDCOP (2015)

THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) GUIDELINES

- In 2007, CMS Conditions for Transplant Center Participation
- X-121 (Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)
  - §482.98(d) Standard: Independent Living Donor Advocate or Independent Living Donor Advocate Team. The transplant program that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team **to ensure protection of the rights of living donors and prospective living donors.**
  - Guideline §482.98 (d) Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) **prior to the initiation of the evaluation and continuing to and through the discharge phase.**

CMS GUIDELINES

- X122 (Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)
  - §482.98(d)(1) The independent living donor advocate or independent living donor advocate team **must not be involved in transplantation activities on a routine basis.**
  - Guideline §482.98(d)(1) Because of the conflict of interest which would be created for an advocate to perform any transplant activities, even on an infrequent basis, the ILDA or ILDAT **must not be associated with the transplant program in any capacity even on a temporary or intermittent basis.**

CMS GUIDELINES

- X-123 (Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)
  - §482.98(d)(2) The independent living donor advocate or independent living donor advocate team must demonstrate:
    - (i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and
    - (ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.
  - Guideline §482.98(d)(2) The advocate/team must be able to provide evidence of successful training which addressed the topics listed in the standard. Interviews with living donors confirm that the advocate/team provided information concerning:
    - Organ donation process;
    - Requirements of the informed consent process;
    - Immediate and long-term expectations following donation;
    - Immediate and long-term risks of donation;
    - Expected outcomes for the recipient;
    - Potential financial responsibilities related to donation; and
    - Any alternative treatment(s) for the potential transplant recipient, if available.
  - The living donor medical record should fully chronical the interactions between the advocate or advocate team and donor candidate including the assessed level of understanding by the donor candidate during interactions.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) POLICIES

POLICY 14: LIVING DONATION

The ILDA must:

- Function independently from the transplant candidate's team
- Advocate for the rights of the living donor
- Fulfill qualifications and training (both initial and **ongoing**) requirements specified in the recovery hospital's protocol regarding knowledge of:
  - Living organ donation
  - Transplantation
  - Medical ethics
  - Informed consent
  - Potential impact of family or other external pressure on the living donor's decision about whether or not to donate

OPTN POLICIES

POLICY 14: LIVING DONATION

The ILDA must:

- Review and document whether the living donor has received information on each of the following areas:
  - Informed consent process
    - Policy 14:3 Informed Consent Requirements
  - Evaluation process
    - Policy 14.1A: Living Donor Psychosocial Evaluation Requirements
    - Policy14.4.A: Living Donor Medical Evaluation Requirements
  - Surgical procedure
  - Follow-up requirements
    - Policy 18.1 Data Submission Requirements
    - Policy 18.5 Living Donor Data Submission Requirements
    - Policy 18.6 Reporting of Living Donor Adverse Events
- Assist the donor in obtaining additional information from other professionals

OPTN POLICIES

POLICY 14: LIVING DONATION

ILDA Protocols for Living Donor Recovery Hospitals

- Composition of the ILDA team
- Qualifications and training required for the ILDA
- Duties and responsibilities of the ILDA

OPTN POLICIES

Policy 14: Living Donation

ILDA Protocols for Living Donor Recovery Hospitals

Grievance

- The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interest of the living donor
- The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interest of the living donor

OPTN POLICIES

POLICY 14: LIVING DONATION

Living Donor Exclusion Criteria

- **Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgement, causes the donor to be unsuitable for organ donation**
- Living donor recovery hospital must exclude all donors who meet any of the following criteria:
  - Is both less than 18 years old and mentally incapable of making an informed decision
  - HIV, unless the requirements for a variance are met
    - Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

OPTN POLICIES

POLICY 14: LIVING DONATION

Living Donor Exclusion Criteria Continued

- Living donor recovery hospital must exclude all donors who meet any of the following criteria:
  - **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

OPTN POLICIES

POLICY 14: LIVING DONATION

- The hospital may refuse the living donor
  - Recovery hospital must inform the living donor that a different recovery hospital may evaluate the living donor using different selection criteria

ILDA/ILDAT ROLE Continued

- Disciplinary background of ILDA/ILDAT varies
  - Dual Role
  - Skillset to be consistent with core competencies and roles as defined by the OPTN Policy
  - Hays et al. (2015)
    - Assessment, communication, and advocacy skills
    - Effective health care systems navigator
    - Cultural humility
    - Grounding in medical ethics

Steel et al., 2013; Hays et al., 2015

COMPONENTS OF THE ILDA INTERVIEW

- Informed Consent
  - Information, comprehension, voluntariness
    - “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.”
  - Relative competency
    - Formal evaluation of competency may be warranted if donor has a history of a traumatic brain injury or developmental disorder
- Evaluation process
  - Health Insurance Portability and Accountability Act (HIPAA)
  - Medical Risks
    - Misattributed relationship
  - Surgical Risks
  - Psychosocial Risks
  - Financial Risks
  - Non-directed and paired exchange programs
    - Evaluate understanding of the process
  - Domino Donors and Non-Domino Therapeutic

Gordon, 2017 ; Organ Transplantation and Procurement Network, 2021

COMPONENTS OF THE ILDA INTERVIEW

- Alternate procedures or courses of treatment for the recipient
- Donor Motivation
  - Relationship to intended recipient
  - Knowledge of the need for transplant
  - Circumstance of decision to pursue donation
- Undue pressure or coercion
  - “Coercion pertains to when an explicit threat of harm is presented by one person to obtain compliance by another. Undue influence pertains to an offer of ‘an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance (Belmont Report)’.”

Rudow et al., 2015; Gordon, 2017

COMPONENTS OF THE ILDA INTERVIEW

- Understanding of how health affects ability to donate
- Donor may be declined at anytime
- Scientific Registry of Transplant Recipients (SRTR)
  - Risk of recipient candidate’s morbidity and mortality

US LAWS GOVERNING LIVING DONATION

LAW	MAIN OUTCOME
1984 National Organ Transplant Act	Banned acquisition or transfer of human organs for “valuable consideration”
1999 Organ Donor Leave Act	Federal employees guaranteed paid leave for organ donation
2004 Organ Donation and Recovery Improvement Act	Grant program to reimburse donor travel and subsistence expenses
2007 Charlie Norwood Living Donation Act	Paired kidney donation determined not to constitute valuable consideration

Hays et al., 2015

COMPONENTS OF THE ILDA INTERVIEW

National Organ Transplant Act (NOTA)

42 U.S. Code § 274e - Prohibition of organ purchases

(a) PROHIBITION
It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.

(b) PENALTIES
Any person who violates subsection (a) shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) DEFINITIONS
For purposes of subsection (a):
(1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.
(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.
(3) The term "interstate commerce" has the meaning prescribed for it by section 321(b) of title 21.
(4) The term "human organ paired donation" means the donation and receipt of human organs under the following circumstances:

- **(A)**An individual (referred to in this paragraph as the "first donor") desires to make a living donation of a human organ specifically to a particular patient (referred to in this paragraph as the "first patient"), but such donor is biologically incompatible as a donor for such patient.
- **(B)**A second individual (referred to in this paragraph as the "second donor") desires to make a living donation of a human organ specifically to a second particular patient (referred to in this paragraph as the "second patient"), but such donor is biologically incompatible as a donor for such patient.
- **(C)**Subject to subparagraph (D), the first donor is biologically compatible as a donor of a human organ for the second patient, and the second donor is biologically compatible as a donor of a human organ for the first patient.
- **(D)**If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a human organ for a patient in such group.
- **(E)**All donors and patients in the group of donor-patient pairs (whether 2 pairs or more than 2 pairs) enter into a single agreement to donate and receive such human organs, respectively, according to such biological compatibility in the group.
- **(F)**Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the human organs referred to in such subparagraph.

(Pub. L. 98–507, title III, § 301, Oct. 19, 1984, 98 Stat. 2346; Pub. L. 100–607, title IV, § 407, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 110–144, § 2, Dec. 21, 2007, 121 Stat. 1813.)

- Assess for any signs of monetary/financial gain or valuable consideration
- Clear understanding of what is classified as valuable considerations
  - Money
  - Intangible goods or services
- Travel, housing, and lost wages **are not** considered valuable consideration

COMPONENTS OF THE ILDA INTERVIEW

- Long-term follow-up care after surgery
- Donor must be informed that they can decline to donate at any time
  - Discontinue the living donor consent or evaluation process in a way that is protected and confidential
  - Medical out, excuse, or alibi
    - No consensus on its use
    - General statement describing donor's unsuitability
  - Rehearsal or role play
  - Electronic medical record systems

Rudow et al., 2015; Gordon, 2017

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QUESTIONS