

Chapter 8

Findings from a National Survey of Living Donor Advocates

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Introduction

The inadequate supply of organs in the U.S. and other countries continues to drive the need for living donor transplantation [1]. Although living donor surgeries have been performed since the 1950s, it was not until 2000 that representatives from the transplant community convened for a meeting on living donation to develop a consensus statement to promote the welfare of living donors [2]. As a part of the consensus statement, it was recommended that transplant centers retain an independent living donor advocate (ILDA) whose primary focus be on the best interest of the donor [2].

The two primary governing bodies of transplantation include the Department of Health and Human Services (DHHS) and the United Network for Organ Sharing (UNOS). After the consensus statement was published in 2000, the DHHS and UNOS began to develop guidelines for the qualifications, professional boundaries, and practices of the ILDA [3, 4]. Similar to other medical specialties who evaluate transplant candidates and living donors, the guidelines developed by these organizations provided a broad interpretation of the role of the ILDA.

Although the DHHS and UNOS have similar guidelines for the ILDA, the organizations emphasized different aspects of the role. For example, the DHHS included guidelines that ILDAs' responsibilities were to (1) ensure the protection of current and prospective living donors; (2) be knowledgeable about living organ donation, transplantation, medical ethics, and the informed consent process; (3) not be involved in transplantation activities on a routine basis; and (4) represent and advise the donor, protect and promote the interests of the donor, respect the donor's decision, and ensure that the donor's decision is informed and free of coercion [3].

Similarly, the UNOS included in their bylaws, the same year that all transplant centers must have, an ILDA who is (1) not involved with potential recipient evaluation on a routine basis; (2) independent of the decision to transplant the potential recipient; and (3) a knowledgeable advocate for the potential living donor [4]. According to the UNOS, the responsibilities of the ILDA are to advocate for potential living donors; promote their best interests; and to assist the potential living donor in obtaining and understanding the consent and evaluation process, surgical procedures, and the benefit and need for postsurgical follow-up [4].

Despite the requirements set forth by the DHHS and the UNOS, and the costs of ILDAs to medical centers (approximately US\$ 9 million annually) [3], the so-

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ciodemographic characteristics, selection and training, and clinical practices of ILDAs are not well understood. As a result, our team aimed to better understand the ILDAs' background, professional boundaries, clinical responsibilities, and how ethical challenges encountered by ILDAs are managed.

The study that was conducted was a survey of ILDAs across transplant centers performing living donor surgeries in the U.S.. Each of the 201 transplant centers in the U.S. that perform living donor surgeries was contacted to identify the ILDA at their center. The survey included 63 quantitative and qualitative items that queried the ILDA with regard to sociodemographic information (e.g., age, gender, and education), roles and responsibilities (e.g., number of hours worked and timing of contact with donors), and ethical challenges associated with living donor advocacy (e.g., descriptions of when the ILDA felt as though the donor was being pressured or coerced). For greater details regarding the design and methods of the study, please refer to the original paper [5].

The findings of this study suggest that there is a marked variability in the sociodemographic characteristics, definition of the role of the ILDA, the clinical practice of ILDAs, and how ILDAs manage ethically challenging issues associated with living donation. A wide range of educational backgrounds, including those with less than high school diploma to professional degrees (MDs/PhDs), were reported; however, the majority of ILDAs reported having a Bachelor's or Master's degree and were trained as either nurses or social workers. A small percentage of ILDAs (2%) were from ethnic or racial minority backgrounds, which reflects the disparity also observed of transplant candidates and donors.

The position of the ILDA is quite recent, and many of the ILDAs were appointed by the transplant team and were often someone whom the team worked with in some capacity prior to becoming the ILDA (e.g., social worker or nurse; Fig. 8.1). Depending on the size of the transplant center, the ILDA role is sometimes combined with another role of the living donor team, most often a social worker or nurse. Approximately 53% of ILDAs perform a second role within transplant.

The definition of the "independent" living donor advocate has been previously debated [6]. The findings of this survey suggested that ILDAs themselves may have many definitions regarding the term "independent" as it refers to their role as an ILDA. Figure 8.2 depicts the responses the ILDAs reported when queried about the definition of "independence" as it refers to their role as the ILDA.

According to the governing bodies of Center for Medicare and Medicaid services (CMS) and UNOS, the role of the ILDA includes both "advocating" and "protecting" the donor. It is unclear at this time if an ILDA can necessarily perform both of these tasks. With regard to the ILDA advocating and protecting the donor, the ILDAs were queried about how they would proceed with regard to the following scenario:

How would you proceed if you felt that the donor having surgery would be detrimental to their physical or psychological well-being, but (1) this had been explained to the donor in detail and the donor understood the potential consequences; (2) the donor has been approved to proceed with surgery by the medical and psychosocial team members; and (3) the donor wants to proceed with surgery despite the potential risks?

We found that 29% of ILDAs responded that they would document their concerns but would "approve" the donor for surgery ("advocate" for the donor). However,

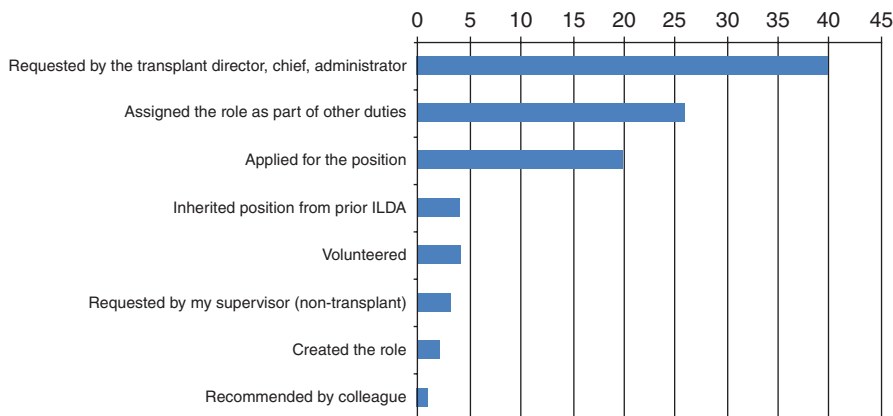


Fig. 8.1 Percentage of ILDAs reporting how they were selected as an ILDA at their transplant center

the majority of ILDAs reported that they would document their concerns and “not approve” the donor for surgery (51%; “protect” the donor). The remaining ILDAs (20%) had a variety of responses, including not being aware they were involved in the selection process (see Chap. 22 for further discussion regarding the dilemma of advocating versus protecting).

Most would agree that the primary responsibilities of the ILDA are to confirm that the donor (1) is willing to donate; (2) is competent to donate; (3) is not under any undue pressure or coercion to donate; (4) is not being compensated to donate; and (5) understands the informed consent process including the medical, psychosocial, and financial risks of donation. Further, the ILDAs were queried about any issues they have had when evaluating the potential donors for competency. The ILDA

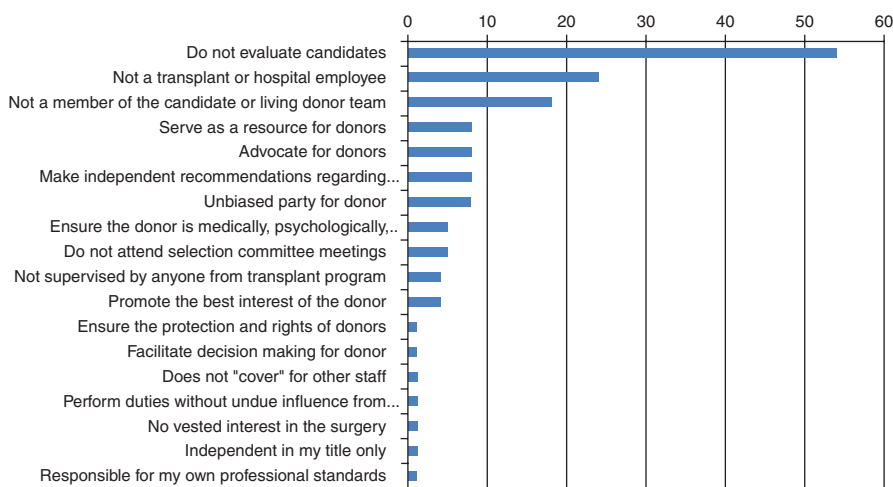


Fig. 8.2 Percentage of ILDAs reporting their definition of “independent”

Table 8.1 Examples when the ILDA declined a donor for issues concerning competency to donate

A belief that risks did not apply to the donor because of God protecting him absolutely

A donor who had a ninth-grade education, unstable home life, although temporarily living with a girlfriend, wanted to donate to a friend. It was not clear if the donor was just trying to please his friend and if he totally understood informed consent process

Donor with an extensive alcohol abuse history and who had served a prison sentence. Poor historian, her stories did not match up between the team members. She did not seem to understand the process and we excluded her from donation

A donor who stated that he had not read any of the donation education information but he had signed and returned an agreement of understanding. My assessment was that I was not sure he could read and/or he lacked ability to understand the material. Patient was ruled out for medical reasons but I would have recommended neuropsychological assessment if he had been able to proceed with evaluation

We had a donor who was a relative and had suffered traumatic brain injury in a motor vehicle accident. We did the regular evaluation with a complete psychiatric evaluation as to cognition and competency. It was determined that this person was capable of making decision regarding surgery

I had one case where a potential donor was a foreign national visiting the recipient and my initial interview needed to be interpreted by the donor's wife on the spot due to time being limited. I had no way of knowing if the translation was accurate or not. I did get the sense that the donor truly wanted to help his friend and understood there were some risks always involved with surgery

Donor was donating to his cousin, with whom he resided and who was providing financial support to the donor (who was not working at the time). Donor reported a history of special education courses in school. Donor did not appear to understand any of the medical aspects of surgery or the long-term implications of his decision. He had limited knowledge of his own personal finances (e.g., did not know if he had health insurance) and appeared generally cognitively impaired. Donation was advised against. The cousin later called and yelled at the coordinators, who subsequently requested a reevaluation. A more in-depth psychological and cognitive evaluation was completed, which revealed borderline intellectual functioning of the donor

I evaluated a donor under 20 years of age developmentally disabled man who wanted to donate a kidney to his sister. His family was in full support, and I believe that he was quite close to his sister. Although he was fairly high functioning in some ways, I did not fully believe that he understood all of the risks and benefits or that he could make a decision without the influence of his very involved family

Younger sibling was to donate to older, more successful sibling. Donor was on a very low developmental level and was not able to articulate or describe the risks that would be faced. This donor just kept repeating again and again, "I am not being pressured, I am not being paid." The donor was not even able to understand the evaluation or results or the work-up process

A woman once called me and wanted to be a donor for her mother. During the entire telephone interview, the potential donor's mother was in the background responding to questions. When I asked a question, the mother would answer and she would repeat that answer to me. The donor was on disability, but could not explain to me why donor was disabled. She said that it was from "when I was a little girl" but could not name the disorder. When I asked her who her MD was, she gave me a name and told me she took "little black and yellow pills"

may not formally assess the donor's competency but may refer a donor for further neuropsychological or psychiatric evaluation for concerns regarding competency. TheILDAs described several examples in which they may decline a donor for surgery due to issues of competency and understanding of the information consent process (Table 8.1).

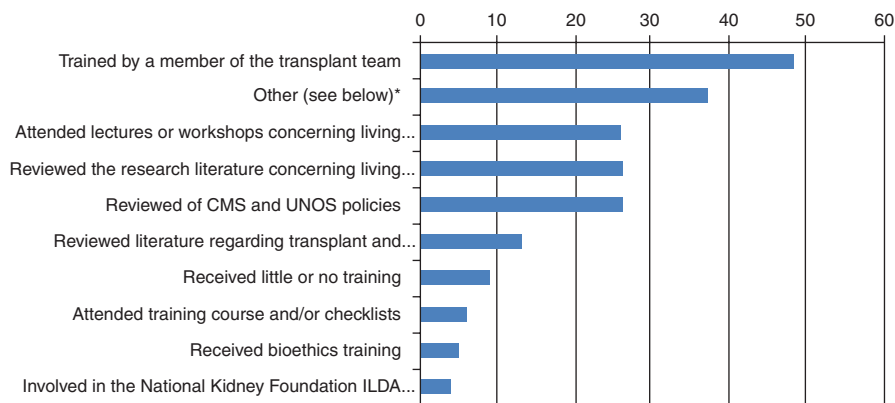


Fig. 8.3 Percentage of ILDAs reporting how they were trained as an ILDA. *Other* ILDAs serve on ethics or selection committee, own research and writing, consult with other health care professionals, learned from patients and families

Since the inception of this position in 2007, no formal training for ILDAs has existed. Many of the ILDAs, when queried as a part of this survey, stated that they had received training from a variety of sources and the type and duration of training varied greatly among ILDAs (Fig. 8.3).

As the field of living donation and the guidelines and requirements set forth by the DHHS and UNOS continue to evolve, formal training and continuing education are recommended. Because of the diversity of professional backgrounds of ILDAs, it may be a challenge to identify a common forum (e.g., professional meeting) for training and continuing education. The development of written and/or web-based educational materials for ILDAs could be an approach that would facilitate consistency in knowledge and practices of ILDAs.

With regard to ILDA practices, approximately half of the ILDAs combined the ILDA evaluation with other responsibilities (e.g., psychosocial, medical, or nursing evaluation). The advantages of combining the ILDA evaluation include a more comprehensive understanding of the donor and family dynamics, which in turn can facilitate the decision-making process regarding the donors' suitability for surgery. Disadvantages may include the ILDA's role becoming diffuse and unable to "advocate" for the donor if she/he believes that there is a psychosocial, financial, or medical contraindication for surgery secondary to their other role.

The educational information the donor receives may be important in his or her decision to proceed with surgery and therefore materials developed by and vetted through health care professionals should be provided to donors rather than information developed by individuals including ILDAs. The ILDAs who provided educational information to donors reported that only a small percentage (20%) of materials were developed by UNOS or other national organizations related to transplantation and vetted through health care professionals working in transplantation.

With regard to the ILDA’s practices, the majority of ILDAs reported attending multidisciplinary selection committee meetings in which donor, and sometimes transplant, candidates were discussed. The consensus statement published in 2000 suggested that the ILDA should have the power to “veto” the surgery [1]. It is clear from the findings of this study that a minority of ILDAs have the power to “veto” the surgery, while some ILDAs were not even aware that this was an option for them. If the ILDA is a part of the selection process, the ILDA may be obligated to disclose to the medical team(s), the reasons for recommending against surgery, both verbally and as part of the donor’s medical record. It is unlikely that the donor candidates are aware that information disclosed to the ILDA will be shared with the transplant team(s) and possibly with other health care professionals who may have access to their medical records. If ILDAs are involved in the selection process, this should be included in the informed consent process so that the donors are aware that the information disclosed to the ILDA may be shared with other health care professionals. If members of both the donor and candidate transplant teams are present at the selection committee meetings, and the ILDA discloses information discussed with the donor, there may be an increased risk of the donor’s confidentiality being breached to family members and/or recipients through members of the candidate team.

As part of the survey, we queried ILDAs regarding reasons provided for declining donors for surgery (Fig. 8.4). Although declining donors for surgery with regard to specific ILDA-related reasons was rare, it was observed that some ILDAs would decline a donor for reasons that may not be associated with the role of the ILDA (e.g., psychiatric diagnosis and medical reasons).

LaPointe Rudow and colleagues suggested that ILDAs be involved in both the short- and long-term follow-up of living donors; however, this may have fiscal implications for the transplant and/or medical center supporting the ILDAs [7]. At least for some donors, long-term follow-up by the ILDA may be recommended, particularly for those who experienced medical, psychosocial, or financial complications surrounding donation; loss of their loved one during or shortly after the

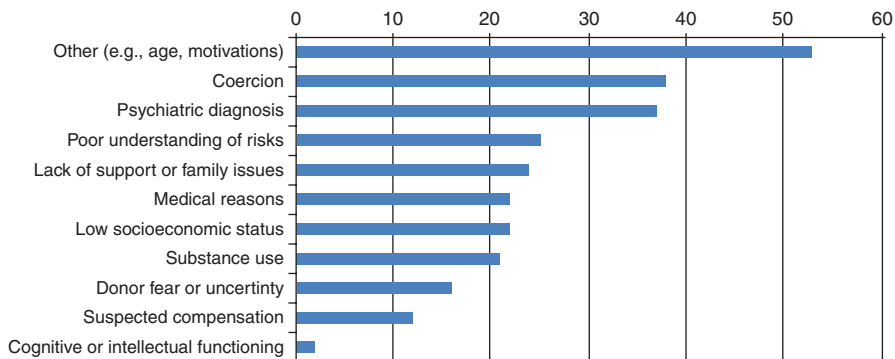


Fig. 8.4 Percentage of ILDAs reporting the reasons for declining donors for surgery

transplant; or when the donor may be facing a new medical diagnosis as a result of the donor evaluation process (e.g., cancer and Hepatitis C).

One of the most controversial areas in living donation is “valuable consideration” [8–10]. The role of the ILDA is to ascertain if a donor is receiving compensation for their organ and to inform the donor of the law associated with valuable consideration. The National Organ Transplantation Act (NOTA, P.L. 98–507) permits living and deceased organ donation but prohibits the sale of organs. Section 301 of NOTA specifically prohibits the exchange of *valuable consideration* (money or the equivalent) for organs [11]. 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.” [10] The penalty for such a violation is “a fine not more than \$50,000 or imprisonment not more than five years, or both.” [11] Because of the potential consequences to the donor for being compensated for the donation of their organ, the ILDA’s understanding of this law is important to help guide the donor. However, before the donor can understand this law, the ILDA must also understand this law to be able to appropriately inform donors. As part of the survey, we queried ILDA with regard to how they would respond to hypothetical scenarios that may or may not involve valuable consideration (Table 8.2).

The ILDAs were also asked to describe some of the problems or controversies that they experienced in their role as the ILDA (Fig. 8.5). As the field of living donation continues to evolve as well as the role of the ILDA, attention should be given to the difficulties ILDAs may encounter in their positions. Development of methods to resolve such disagreements between the ILDAs and the transplant team would provide the ILDAs with autonomy and the ability to protect and advocate for the living donors (See Chap. 15 for further details). A national ombudsman appointed through the DHHS or UNOS could be available for ILDAs who are not able to resolve conflicts at their transplant center.

The ILDA were also asked to provide examples where they had observed pressure and/or coercion of the donor by the candidate or the medical team. The ILDAs provided the examples presented in Table 8.3. Although the donor likely experiences a degree of pressure or obligation as a family member or friend, the role of the ILDA is to ascertain if the donor is experiencing undue pressure or coercion from the candidate, candidate’s family, or medical team.

By nature of the position, the ILDA experiences not only ethical challenges as described earlier (e.g., compensation for donation and advocate versus protection of donor) but also other ethical issues such as the examples described in Table 8.4.

This survey identified marked variability in the position and practice of the ILDA in transplant centers. Although practice variability exists in all disciplines, many professions have practice guidelines to provide a minimum standard. Practice guidelines are often recommended for legal and regulatory issues, consumer and/or public benefit (e.g., improved service delivery, avoiding harm to the patient, and decreasing disparities in underserved or vulnerable populations), and for professional guidance (e.g., risk management issues and advances in practice).

Table 8.2 ILDA responses to hypothetical scenarios

Scenarios considered “acceptable” by the ILDAs	Percentage
Receiving financial assistance from the transplant candidate (or candidate’s family) for the flight, to be evaluated for donation or for the surgery	7.1
Receiving financial assistance from the transplant candidate (or candidate’s family) for unemployment benefits lost while recovering from surgery	47.1
Receiving financial assistance from the transplant candidate (or candidate’s family) for wages lost while recovering from surgery	64.7
If the transplant candidate is an employer and the donor is the employee, the donor receives from the candidate, time off for the surgery and recovery with pay	35.3
Receiving financial assistance from the transplant candidate (or candidate’s family) for a vacation with the candidate’s family	2.9
Receiving financial assistance from the transplant candidate (or candidate’s family) for the expenses for lodging and food while being evaluated for donation or surgery	85.3
Receiving financial assistance from the transplant candidate (or candidate’s family) to cover the mortgage/rent, car payment, and utilities while recovering from surgery	41.2
Receiving financial assistance up to US\$ 5,000 from the transplant candidate (or candidate’s family) for expenses related to the donation	25.3
Receiving financial assistance from the transplant candidate (or candidate’s family) for the donor’s discretion	2.9
<i>ILDA independent living donor advocate</i>	

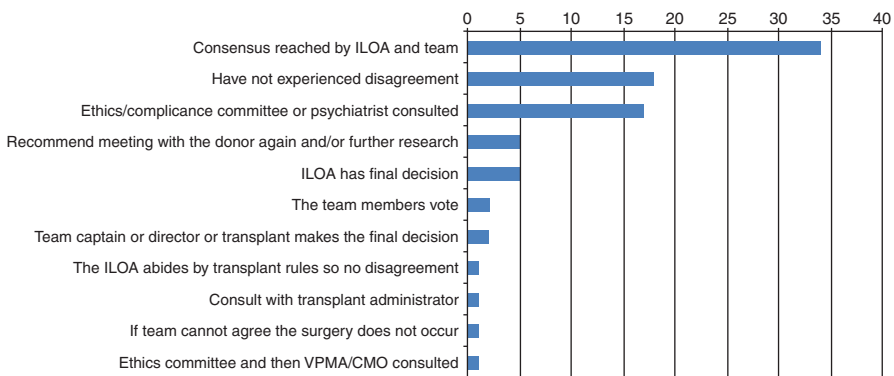


Fig. 8.5 Percentage of ILDAs reporting the methods used to resolve disagreements between the transplant team and ILDA

Table 8.3 Examples that the ILDA provided with regard to instances of pressure/coercion from the candidate or medical teams

Pressure from the transplant candidate
Donor came forward to donate a kidney to an immediate family member. Before surgery took place, donor reported that the recipient was calling her everyday demanding that donor donate a kidney. Recipient also lied to donor about risks and recovery time
A woman who had known her boss for a long time, were friends, and she felt obligated to give her kidney. He gave her a bonus out the blue, gave her all time off whenever she wanted and treated her differently from the team
A donor candidate who was under the age of 25 and a veteran with PTSD whose father expects him to donate, cannot let his father down. The father got very angry when we turned down his son's application to donate
I had the donor tell me that the recipient was forcing him to do it. He did not want to proceed. "How could we get him out of this?" We told the recipient that he was not a suitable candidate without giving any details
Younger sibling was pushed to donate when the older sibling was screened as unsuitable. Donor was told by the family that she was the only one who could donate
Pressure from the medical team
The transplant team tells the donor that this was the recipients' only option
Not emphasizing "opt outs" or "medical outs"
When the health of the recipient or the wait on the list for a cadaveric donor is mentioned regularly
Donor is unwilling but feels responsible or guilty if he/she did not agree to proceed
Demanding the left kidney when the donor team only approves the right kidney secondary to risk and or complexity
Team not listening to donor's verbal and/or nonverbal cues
I do not really ever see any pressure on the donor from the medical team(s); just pressure on me detected by frequent calls to reverse my decision
Either subtle or direct suggestions about which family or friends would be the most ideal donors
If the team is making multiple phone calls to a potential donor who has not continued the evaluation. If a recipient physician urges the potential donor team to expedite the evaluation
Pressing forward with donation in the face of objections from team members. Suggesting to someone directly that he/she would make a good donor
When there is a need for a specific type of blood/tissue or if it has been a long time since we have had approvals.
When deep concerns from living donor advocate or social worker are overlooked by the transplant team
<i>PTSD</i> post-traumatic stress disorder

Without such practice guidelines, there is a possibility that donors (and indirectly, candidates) may be negatively affected through the screening and/or selection process. The ILDA's decisions can have a significant impact on a donor (e.g., felony charge for valuable consideration) and/or the transplant candidate (e.g., candidate death). Even though the evaluation of living donors is a multidisciplinary process, the development of uniform practice guidelines for ILDAs is critical for decreasing potential disparities, particularly if the ILDA has "veto" power, as was evidenced by some ILDAs.

Table 8.4 Examples of ethical challenges reported by the LDAs

Donor with developmental disorders, the family wants the donor to proceed although donor advocate is concerned if the donor can provide informed consent
Donor with drug and alcohol issues but the medical committee wants to proceed with surgery
Donor who recently attempted suicide but the transplant candidate and team wanted donor to proceed with surgery
A donor who is under 18 years of age donating to her child
Donor wanting other surgical interventions (hernia repair) during donation surgery
Donors found candidate on the Internet/Facebook
Transplant candidate was HIV positive but had not disclosed HIV status to donor
Donors who do not have health insurance coverage
Donors diagnosed with serious illness such as pancreatic or breast cancer and have no insurance
Misattributed paternity
Physician with end-stage organ disease soliciting his patients for organ donation
An ILDA being pressured by the team to approve someone who the he/she strongly believes is not acceptable. This is usually in the form of pressure from the surgeon that is handed down to the coordinators, which is then passed on to the ILDA
Protecting privacy of donors when recipients try to insert themselves into donor evaluations/care
Supporting and educating donors who know that their recipients are not eligible for deceased donor transplants and are deemed “living” donor only candidates
Supporting and educating donors who suspect that their recipients are not being truthful about the progression of their disease, nonadherence, or other treatment options
Introduction/facilitation of meetings between nondirected donors and their recipients
Transplant candidate paying third party to find a donor
Foreign immigrant with citizenship, returned to native country, found a wife willing to donate organ, brought her back to the U.S. to be tested (prior to getting married)
Donors who come from other countries and admit they have no access to follow-up care in their country of origin
Unemployed and no source of income
Donor with a diagnosis of bipolar disorder, which was untreated and the desire to donate was likely related to symptoms of grandiosity
Need for ongoing psychotropic medications
Responded to an ad in a bar for a donor. Donor was an unemployed drifter with no visible plan for after care
Young donor to older candidate (60-year difference between donor and candidate)
Convicted of felony, wanting to donate without job or insurance

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