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The Development of Practice Guidelines for Independent Living Donor Advocates

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Living donors contribute to nearly half of all kidney transplants and increasing numbers of liver, lung, and intestine transplants.¹ In 2000, a consensus statement recommended that all transplant centers which perform living donor surgeries retain an Independent Living Donor Advocate (ILDA) “whose only focus is on the best interest of the donor.” In 2007, the Department of Health and Human Services (DHHS) and the United Network for Organ Sharing (UNOS) required all transplant centers to retain an ILDA.² According to the UNOS and the DHHS, the primary elements of the ILDA’s role include: [1] ensuring the protection of current and prospective living donors (DHHS); [2] being knowledgeable about living organ donation, transplantation, medical ethics, and the informed consent process (DHHS and UNOS); [3] not being involved in the transplant recipient activities on a routine basis (DHHS and UNOS) and being independent in the decision to transplant the potential recipient (UNOS); [4] representing and advising the donor, protecting and promoting the interests of the donor, respecting the donor’s decision, and ensuring that the donor’s decision is informed and free of coercion (DHHS); and [5] assisting the potential living donor in understanding the consent and evaluation process, surgical procedures, and the benefit and need for post-surgical follow-up (UNOS).³⁻⁴ Although the evaluation of living donors is a multidisciplinary process, the ILDA can have a significant impact on the donor, and indirectly the transplant candidate, particularly if the ILDA has “veto” power with regard to the surgery as recommended in the consensus statement.

A recent national survey of ILDA’s in the U.S. found that a wide range of educational backgrounds, disciplines (e.g., social workers, physicians, clergy), and practices exist across ILDA’s.⁵ The recommendations for the development of practice guidelines are outlined in Table 1 and were, in part, based on the results of a national survey of ILDA’s.⁵ The details of the survey results can be found elsewhere, however a summary of the findings, followed by recommendations for practice guidelines, can be found below.⁵

Summary of the National Survey of Living Donor Advocates in the U.S

The Qualifications and Role of the ILDA

The survey was conducted between January and March of 2011. One hundred and twenty ILDA’s completed the survey (68% response rate). The ILDA’s reported an education and training as a nurse (35.8%), social worker (33%), clergy (13.2%), psychologist (3.8%), and a variety of other disciplines (14.2%). More than half of the ILDA’s reported dual roles, for example, serving as both the living donor social worker or nurse coordinator as well as the ILDA. When asked to define “independent” as it refers to their role as an “Independent” Living Donor Advocate, the majority of ILDA’s (54%) reported that “independent” referred to the ILDA not evaluating transplant candidates. The remaining 46% of ILDA’s reported a variety of other definitions for “independent” elucidating the variability in how ILDA’s themselves define their role (see original report for further details).⁵

Training and Continuing Education

With regard to training as an ILDA, nearly half of the ILDA’s (48.5%) reported being trained by the transplant team at their center which may be considered a conflict of interest if “independent” refers to the ILDA’s autonomy or “independence” from the transplant team as some ILDA’s reported.⁵ The ILDA’s reported receiving training through various means including: [1] serving on ethics or selection committee, [2] conducting their own research,

[3] consulting with other health care professionals, [4] learning from patients and families; [5] attending conferences; [6] reviewing the research literature; [7] reviewing CMS and UNOS policies; [8] receiving little or no training; [9] attending a training course or receiving a checklist to follow; [10] receiving training in bioethics; or [11] being involved with the National Kidney Foundation listserv.

Practices of ILDAs

When queried at what point the ILDA evaluates the donor, the ILDAs reported that they were involved with donors at varying times throughout the process including during the screening phase (45.2%), during the evaluation (79.8%) during the post-evaluation period (58.3%), and during the post-surgical phase (56%). Only 20% of ILDAs followed the donors for longer than 6 months. A minority of ILDAs billed for their services (14.5%). With regard to educational materials provided to donors, 17.2% of ILDAs reported using materials developed by national organizations such as UNOS or the American Society of Transplantation (AST). Fifty-one percent of the ILDAs reported having the donor sign a document stating they understood the risks of donation and/or were not receiving compensation.⁵

Of the 120 ILDAs who participated in the study, 53.7% of the ILDAs reported attending the selection committee meeting when living donors were presented, 38.8% attended the selection committee when both donors and candidates were discussed, 7.5% did not attend these meetings; and 9% only attended the selection committee meetings occasionally. The ILDAs reported that the reasons for declining donors from surgery included: [1] several different reasons (e.g., age, motivations; 53%); [2] coercion (38%); [3] psychiatric diagnoses (37%); [4] poor understanding of risks (25%); [5] lack of support or family issues (24%); [6] medical reasons (22%); [7] low socioeconomic status (22%); [8] substance use (21%); [9] donor fear or uncertainty (16%); [10] suspected compensation (12%); and [11] cognitive or intellectual functioning (2%). Several of the reasons described above to decline a donor from surgery may not be considered to be related to the ILDA's role.

At a minimum, the ILDA may be responsible for evaluating the following areas including: (1) willingness to undergo surgery, (2) relative competence, (3) the lack of undue pressure or coercion, (4) compensation or valuable consideration for donation, (5) understanding the medical, psychosocial, and financial risks of donation, (6) understanding of the informed consent process, (7) the understanding that there are other options for the transplant candidate, and (8) understanding of the importance and benefit of long-term medical follow-up.

Ethical Issues

The consensus statement concerning living donation published in 2000 suggested that the ILDA should have the power to "veto" the surgery.² It was clear from the findings of the survey that some ILDAs do have the power to veto the surgery, while other ILDAs were not aware that this was possible.⁵ At this time, the UNOS and DHHS do not include in their guidelines that the ILDA has "veto" power with regard to the donor proceeding with surgery, however the guidelines suggest the ILDA's role is to advocate ("promoting the interests of the donor, respecting the donor's decision") as well as to protect the donor. As indicated by the survey, more than half of the ILDAs tended to protect rather than advocate for the donor if they felt it was not in the donor's best interest to donate, even when the donor understood the risks and wanted to proceed with surgery.⁵

The ILDAs were queried with regard to whether the transplant team had access to the ILDA's written evaluation of the donor. Ninety-one percent of ILDAs reported that the team

had access to their evaluation of the donor, however 29% reported they kept separate confidential notes. It is likely that in some institutions, not only the transplant team but other health care professionals may have access to the ILDA-donor evaluation and progress notes.

Recommendations for Practice Guidelines

Practice guidelines, including uniform training of ILDAs, would greatly improve the consistency of practice across transplant centers, which is of particular importance if the ILDAs are involved in the selection process and/or has the ability to “veto” the surgery.^{2,5} The impact of a donor being “vetoed” from surgery would likely affect the life of the donor and recipient significantly, possibly resulting in the candidate’s death.

Practice guidelines may be defined as generally accepted, informal or formal, standardized or evidence-based techniques, methods, or processes.⁷ The goals of developing practice guidelines for ILDAs are to set standards, delineate the division of labor, create boundaries, and educate patients and health care professionals regarding the practices of ILDA. Regardless of these benefits, practice guidelines also have disadvantages. For example, those spearheading the guidelines may bring biases from their own disciplines, and recommendations may not reflect the local or regional needs or circumstances of the center. Practice guidelines may also limit innovation and advances in the field, and standardize practice based on the “average,” rather than “best” practice. Furthermore, practice guidelines can result in a more cumbersome and/or restrictive process and if not developed appropriately, may have legal implications. Table 1 provides a list of the areas that warrant further discussion and consensus by the transplant community to improve consistency across ILDA practices and to ensure appropriate service delivery.

Qualifications and Role of the ILDA

At this time, the only qualifications to serve as an ILDA is “being knowledgeable about living organ donation, transplantation, medical ethics, and the informed consent process” (DHHS and UNOS, 2007). The definition of “knowledgeable” in areas can range from an individual who has no formal training in these areas (e.g., volunteer who has donated an organ) to a transplant surgeon who has years of specialized training in the area of transplantation. The ILDA training should include a basic foundation of knowledge in transplantation, organ donation, bioethics, the guidelines of governing bodies such as UNOS and DHHS, and the informed consent process is recommended.

Both UNOS and DHHS have made recommendations with regard to professional boundaries. The recommendation is that the ILDA cannot be routinely involved in transplant candidate activities, so as to reduce potential bias while evaluating the living donor for surgery. However, only 54% of the ILDAs at the time of the survey interpreted “independent” with reference to this professional boundary.

Furthermore, more than half of the ILDAs reported a dual role (e.g., social worker, nurse, or physician and ILDA). Advantages to a dual role may include that the ILDA may have greater breadth and depth of knowledge of the donor by performing a full psychosocial or medical evaluation and/or have more frequent contact with the donor as with a nurse coordinator. As reflected in the findings of the survey, disadvantages may be the lack of differentiation between the two roles, particularly if the ILDA is involved in the selection process. It was apparent that some ILDAs may make recommendations for the donors’ suitability for surgery based on their non-ILDA role. Further clarification is recommended regarding the role of the ILDA in the selection process as well as the separation of roles when dual roles exist.

Training and Continuing Education

The lack of formal training of ILDA's was evidenced by the national survey of living donor advocates. The majority of ILDA's reported that they were trained by a member of the transplant team (48.5%), which may be considered a conflict of interest but potentially the most relevant training with regard to the region and/or center practices. The remaining ILDA's reported various other methods of being trained which included training themselves, or receiving little or no training.⁵ This lack of training translates to the significant variability in practices observed across centers. Ideally, a separate organization or subcommittee within an organization (e.g., UNOS, ATS) that is not connected to the ILDA's own transplant center would provide training to ILDA's. The standards of training may include a certain number of hours and/or an examination and certification process to provide evidence for at least a minimum knowledge base. The content and duration of training as well as fiscal issues associated with training should be carefully considered. Web-based training may be optimal as the wide range of ILDA disciplines (e.g., nursing, clergy) make annual meetings as a potential venue for training and continuing education challenging. Continuing education for ILDA's is also recommended as the field of living donation evolves, as do the guidelines and requirements set forth by the DHHS and the UNOS. Similar to other professions, a certain number of continuing education credit hours could be required every 2 years to facilitate the ongoing education of ILDA's.

Once practice guidelines have been developed and consistent training across ILDA's has been established, performance standards and methods to measure performance can be implemented. Without practice guidelines, it is difficult for transplant centers, governing bodies, and the donors themselves to know if donors are receiving the appropriate services from the ILDA.

Practice of ILDA's

According to the results of the national survey, the timing of the evaluation greatly varied across ILDA's greatly with some ILDA's being involved in the screening process of donors while others in the evaluation. Some ILDA's reported being involved with all phases of the processes. Only 56% of ILDA's were involved in the post-operative follow-up period. At a minimum, it is recommended that ILDA's be involved in the evaluation and the immediate post-operative phase of donation. The ILDA's involvement during the screening process could be cost-effective if the donors who did not meet the ILDA criteria were screened out prior to the completion of several medical tests and meetings with the transplant team members.

It is also recommended that the ILDA be available after the face to face evaluation but before the surgery in case issues arise prior to the surgery in which the donor needs the ILDA's assistance (e.g., decision not to proceed with surgery). Furthermore, the ILDA should follow some donors after being declined from donation as new medical (e.g., cancer) or psychiatric conditions (e.g., bipolar disorder) may have been diagnosed during the evaluation and warrant treatment. The donor may need further clarification with regard to his/her diagnosis or may experience barriers to accessing the treatment that was recommended. Furthermore, in instances where donors' recipient has poor outcomes or loses their loved one during the surgery or shortly after transplant, longer follow-up of donors is recommended by the ILDA or other transplant team members (e.g., psychology, social work).

Consensus regarding the content of the evaluation, follow-up of donors as well as the documentation is warranted. At the minimum, the ILDA evaluation should include that the donor: [1] is willing to donate and displays competence to make the decision to donate; [2]

has been explained the potential medical, psychosocial, and financial risks of donation; [3] appears to be free from pressure or coercion to donate; [4] has not reported that s/he will profit from donating their organ; [5] has been explained the informed consent process; and [6] has been educated about the importance of long-term post-surgical follow-up. In addition, it is recommended that ILDAs also assess the donor's motives to donate. An ILDA may provide a donor with a document describing the laws related to valuable consideration and have the donor sign it if there are any concerns regarding compensation for donating their organ. Understanding if there are any family members or friends that may not be supportive of the donation is also important to prevent potential psychosocial consequences to the donor.

The documentation of the ILDA-donor evaluation in the medical record may include only a checklist of the items above (yes or no) with a separate confidential file that includes the details of the ILDA-donor discussion. If the ILDA-donor evaluation is not confidential, the donor should be informed that the information they share may be placed in the medical record and may be discussed with the transplant teams.

Consistency and quality of educational materials given to donors should be addressed, as printed information can have an impact on the donor's decision to proceed with surgery, and the accuracy of the document is essential. Although some of the ILDAs reported use of contracts with the donor, this seems contrary with the role as the "advocate". For example, a contract stating the donor needs to complete the 2-year follow-up recommended by UNOS may be viewed as pressure and cannot be enforced. Nonetheless, the long-term follow-up should be encouraged by all members of the transplant team and the donor should be allowed flexibility on where the medical follow-up can be performed.

Due to the importance of the ILDA being present to hear the discussion regarding donor suitability for surgery, it is recommended that the ILDA attend the selection committee meetings during at least the donor presentations. The ILDA should be present so s/he can serve as the donor's voice, present donor's concerns, ask questions, and understand the reasons the donor is declined. The ILDA may also be involved in the selection process of donors, however issues regarding the informed consent process (e.g., donor made aware of the ILDA's involvement in the selection process) and clarification of the ILDA's role to "advocate and protect" donors would be beneficial if the ILDA was involved in the selection process. If applicable, in rare cases, understanding the family dynamics including the donor-candidate relationship may be important and having the ILDA meet other family members and/or discuss the donor-candidate with the donor and recipient teams may be warranted.

If the ILDA will be a part of the selection process (e.g., authority to "veto" the surgery), the donors' understanding of the ILDA's role in the selection process should be made known to them so that they are aware that what is said to the "advocate" may be used in the decision for determining their suitability for donation. Optimally, the informed consent should include information about the ILDA's role and if decided that the ILDA be involved in the selection process, then this should also be included in the donor's informed consent process.

Ethical Issues

While there are several ethical challenges within the field of transplantation that warrant further discussion and consensus (e.g., valuable consideration, competence to make informed decisions), several ethical issues directly related to the role of the ILDA remain unresolved. First, consistent training of all ILDAs in the principles of bioethics and decision making would be optimal. Secondly, in cases where the ILDA may be obligated to disclose the reasons to the transplant team for recommending against surgery, verbally during the selection committee meeting and/or as part of the donor's medical record, the donor should

be made aware of the ILDA's role. This could be done similarly to the other transplant team members by including a description of the ILDA's role in the informed consent as well as the ILDA explaining this to the donor. Furthermore, if the details of the evaluation are included in an electronic medical record system where other health care professionals outside of transplantation may have access to this information, the donor should be made aware that this will occur.

The DHHS recommends that the ILDA "protects" as well as "respects" the donor's decision for surgery. Based on the results of the national survey, the majority of ILDAs favored "protection" of the donor (e.g., the ILDA believes that it is not in the donor's best interest to proceed with surgery even if the donor wants to proceed, and the ILDA recommends against the surgery; 51%), while the minority of ILDAs may "advocate" for the donor (e.g., the ILDA recommends surgery if this is the donor wants to proceed despite the risks; 29%).⁷ While "protection" of the donor is important under certain circumstances (e.g., pressure or coercion), a paternalistic role of the ILDA was not likely the intention of those who suggested that donors have an "advocate" that act in their best interest.

Further, if the ILDA can "veto" the surgery, and the donor wants to proceed despite understanding the potential risks, it also calls into question whether the ILDA is an "advocate" for the donor if the donor understands the risks and still wants to proceed with surgery.⁷ The ILDA should make the donor aware if there is the ability to "veto" the surgery. However, in the case in which an ILDA does decline a donor from surgery and the donor wanted to proceed, the donor-ILDA relationship may be negatively affected and the donor may no longer want assistance from the "advocate".

The survey queried the ILDAs regarding how they managed conflicts between the ILDA and transplant team if they did not agree with the decision for the donor to proceed with surgery. The majority of the ILDAs reported that a consensus was reached (34%), while others reported that they had not experienced a disagreement (18%) or the ethics/compliance committee/psychiatrist was consulted (17%). A national ombudsman connected with UNOS or the DHHS could be appointed for cases in which a disagreement cannot be reached or due to pressure experienced by the ILDA (e.g., political, financial), creating a higher level of protection for the ILDAs' autonomy.

Fiscal Issues

The implementation of an ILDA has considerable costs associated with it, and on average each center pays approximately 80,000 USD per year for this service.³ New guidelines or changes in existing policies concerning the ILDA recommended by governing bodies may be associated with an increased number of hours per week for the ILDA as well as increased costs to the transplant or medical center supporting the ILDA. Although few ILDAs reported billing for their services, it is unclear if the services provided by the ILDA should be billable services reimbursed by insurance companies or Medicare and Medicaid. If a donor is billed and the services are not reimbursed, the candidate and/or donor may become responsible for the costs. This was not likely intended when this role was conceptualized and it remains unclear if the candidate and/or donor or their insurance company should pay for an "advocate". In addition, although most medical professionals who are employed by the transplant center and/or hospital may be covered with the hospital's malpractice insurance, those ILDAs practicing independently may want to consider the liability associated with their position, particularly if involved in the selection process or post-surgical follow-up.

Summary

The practice recommendations discussed here are based on the findings of the national survey summarized above as well as the opinions of the authors. The recommendations that are proposed here are not exhaustive and are aspirational in intent and are likely to evolve with time. Practice guidelines are recommended for legal and regulatory issues (e.g., state or federal laws), consumer or public benefit (e.g., improving service delivery, avoiding harm to the patient, decreasing disparities in underserved or vulnerable populations), and for professional guidance (e.g., new role, professional risk management issues, advances in practice).⁵ Without such practice guidelines, donors, and indirectly the candidates, may be at increased risk for possible bias or undue harm.

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Table 1

Recommendations for Practice Guidelines

Area	Recommendations
1.0. Qualifications and Definition of Role	
	Define minimal qualifications and professional boundaries
	Define roles and responsibilities
2.0 Training and Continuing Education	
	Consistent and formal training of ILDAs
	Continuing education for ILDAs
	Certification process of ILDAs
	Peer supervision
	Development of measures of practice standards and outcomes
3.0 Practice	
	Timing of ILDA evaluations (e.g., screening, evaluation, post-op)
	Content of evaluation
	Attendance and participation in selection committee meetings
	Documentation of donor evaluation and follow-up
	Contracts and educational information provided to donors
	ILDA involvement in the selection process of donors
	Long-term follow-up of donors by ILDA
4.0 Ethical Issues	
	Types of donors and exclusions (e.g., valuable consideration)
	Resolution of disagreements between transplant center and ILDA
	Informed consent regarding ILDA-donor communication
	Limits of confidentiality in disclosure of donor evaluation
	Limits of confidentiality in documentation of donor evaluation
5.0. Fiscal Issues	
	Malpractice insurance for ILDAs
	Financial reimbursement for ILDA services