OPTN Ad Hoc International Relations Committee Findings, Guidance on Overcoming Barriers to Evaluation of International Living Donors

Introduction

The evaluation and care of international living organ donors, including non-U.S. citizens/residents (NCR) and non-U.S. citizens/non-U.S. residents (NCNR), can pose unique challenges. Between January 2020 and June 2023, there was a total of 22,135 living donors. Of those, 692 (3.13%) were NCR, and 293 (1.32%) were NCNR. Access to living donors is limited and for some candidates, the only option for a living donor transplant may be family or friends who are NCR or NCNR. While international living donations account for a small portion of living donations, there is a need for scrutiny and attention to the barriers that affect the selection and care of international donors. A 2017 American Society of Transplantation (AST) Living Donor Community of Practice workgroup identified communication, logistics, and assessment of coercion, exploitation, and inducement as barriers in evaluating international living donors; the workgroup also identified unique challenges to international living donor follow-up.

The Organ Procurement Transplant Network (OPTN) Ad Hoc International Relations Committee (AHIRC) provides this guidance document to explore these barriers further and share common practices that transplant programs have used in evaluating international living donors and providing follow up. Some of the findings in this document reflect certain inherent limitations: the findings are limited and reflect self-selection by programs that chose to respond to the questionnaire on current practices; responses reflect the transplant programs' point of view, not donor's; centers may have been guarded in their responses, given the sensitivity of this subjects. Some of the responses may reflect duplicate responses from multiple respondents at the same transplant programs. Overall, the survey findings suggest options for transplant programs to consider, but are not statistically significant.
Achieving progress in reducing barriers requires sharing information on strategies to evaluate NCR and NCNR candidates of donation. Since each transplant program's needs are different, this guidance should be viewed as an educational resource for transplant programs to develop guidelines to evaluate and care for international living donors.

Background

OPTN Policy 14: Living Donation requires transplant programs to conduct a psychosocial and medical evaluation for all living donors before transplant donation. The evaluation process can be resource-intensive, and obtaining the necessary information to evaluate the potential living donor can present challenges, especially for international living donors. To explore the barriers transplant programs encounter when evaluating NCR and NCNR potential living donors, the AHIRC formed a Workgroup with representatives from the OPTN Ethics and Living Donor Committees. A questionnaire was sent to 205 living donor transplant programs with 66 centers responding. The results include 108 individual responses to questions about four specific barriers, which are reviewed in this document:

- Evaluation:
  - Communication barriers
  - Logistical barriers

- Risk of exploitation, coercion, and inducement barriers
- Post-donation follow-up barriers

The Workgroup used key findings from program practices and program experiences of barriers to evaluating NCR and NCNR potential living donors to provide an overview of current practices to suggest options for transplant centers to consider in creating policies for potential NCNR and NCR living donors. In developing the current resource, the Workgroup also considered an important resource in the AST workgroup publication by Shukhman et al that encapsulated the summary and evaluation of the AST effort.

Communication barriers

The components of communication include the method and the interpretation of information passing to the potential donor and responses to the transplant center. How this occurs may affect trust between the potential donor and the transplant program. A study of professional medical interpreters recommended that cultural competency training for physicians should make them more aware of sources of misunderstanding and the difficulties in medical interpreting. It stressed the need for physicians to know about the patient's country of origin and adapt to the patient's style of communication. There are significant challenges with understanding and interpreting the nuances and non-verbal cultural clues in communicating with potential donors. Examples might be if the potential donor felt it impolite to answer negatively for fear of disappointing or not having enough trust in the caller to answer truthfully. Research in obtaining consent highlights some of the pitfalls that exist, even with native language interpreters. Researchers conducting diabetes research in the Navajo nation used interpreters and Navajo language consultants to translate the standard consent form, translating exactly from English. Their early experience in recruiting subjects suggested that the consent process led to embarrassment, confusion and misperceptions. Differences in class, culture, and power may also impact communication barriers, with the clinician seen as the dominant player. The interpreter potentially becomes an active participant given the need to explain and act as a cultural broker.

Questionnaire Feedback

The range of responses from the feedback questionnaire inform discussions about methods for communication between transplant programs and donor candidates and the burden of responsibilities on the donor.

•**Communication Methods:** In the questionnaire, most respondents reported favoring conventional means for making first contact with potential donors by telephone or email. A few centers relied on cell phone video apps, web based social media platforms, web-based video conferencing. A couple of respondents made initial contact with web-based questionnaires. Many programs indicated concern about maintaining confidentiality through their use of encrypted email and/or HIPAA-compliant software. Most respondents used a trained medical interpreter, rather than providing material to the potential donor in English and relying on the potential donor to translate or run material through a machine learning translation program.

•**Access to records:** Most programs relied on the donor to send medical records. Eight programs said they communicated directly with the potential donor's local healthcare provider; three programs said they asked the potential donor to allow them to access the patient's electronic medical record (EMR) portal. Three programs tried all methods, depending on circumstances. Over half of respondents said they were not conducting telehealth follow-up visits with donors. Centers conducting telehealth visits

indicated the use of a variety of methods: telephone, web-based video conferencing, email, or cell phone video apps.
•**Donor understanding of financial implications:** Whether programs rely on the donor candidate to pay for international travel and lodging varies according to feedback received. Ensuring that donor candidates understand what costs they may incur is therefore an important question.
•**Appropriate resources:** When asked whether their transplant programs have access to the linguistically and culturally appropriate resources to support NCR/NCNR, most respondents stated that they did (46 of 57). However, two respondents indicated that they did not, and nine responded that they were not sure.

AHIRC Findings and Common Program Practices
Transplant programs should consider the following common strategies that were reported:

•Using Health Insurance Portability and Accountability Act (HIPAA)-compliant secure communication to make initial contact with international donor-candidate and understand privacy laws in candidate's home country
•Using trained medical interpreters to ensure accurate communication
•Being clear with donor candidates about the potential financial costs that may be incurred prior to receiving donor consent

Logistical barriers

This section focuses on the logistical barriers to be considered for evaluating international potential living donors and following international donors who have donated and are living abroad. The primary logistical barriers identified are travel, financial, obtaining medical records and labs from overseas, and donor follow up.

International donors living outside of the U.S. are a heterogeneous group who may have emotional and social challenges involved with travel, visas and health outcomes. For example, the distance from the home of an NCR or NCNR living donor to the program is a major factor logistically. For potential living donors who live near U.S. borders, programs may be within a reasonable car ride, while other potential international living donors must take long plane trips to visit the transplant center.

Questionnaire Feedback

•**Visa application:** The questionnaire results indicated that most donor centers reported they wrote a letter supporting the visa application to the U.S. Embassy in the potential donor's home country. About a third of respondents indicated that the program left it up to the potential recipient to make certain the donor candidate could legally enter the U.S.
•**Travel:** Programs take varied approaches as to when to bring potential donors to the U.S. A few only brought the potential donor to the program when the donor candidate completed the workup, while a couple programs brought potential donors in as soon as they expressed interest and had them complete the entire workup at the program. About a third of respondents said they brought the potential donor for in-person evaluation once the person had completed lab work on blood type, tissue typing, donor specific antibody, and it was clear the pair were a match, while over 40% said they waited for the donor-candidate to complete basic lab work to bring them to the program but brought the potential donor in for higher level testing such as a CT scan and tissue typing. In the event the pair were not a histocyte leukocyte antigen match or the recipient had donor specific antibodies to the potential donor,

discovered after the potential donor arrived in the U.S., just under 39% of programs reported they entered the pair in the OPTN Kidney Paired exchange program or the National Kidney Registry. Almost 30% said at that point they cancelled the transplant, and the donor candidate returned home. 28% said they looked for an internal paired exchange; one center said it looked for a compatible recipient on their wait list. One program said it could go ahead with transplant after desensitizing the intended recipient. It is essential that programs be clear that even following the early evaluation and travel to the U.S., it is not guaranteed that the individual will be approved to donate or to donate directly to the intended recipient.

•**Lab results:** Beyond the complexities of bringing potential donors to the U.S., programs use various means to obtain lab results from abroad. Almost 73% reported that the potential donor was responsible for sending lab results, 14% of centers relied on a hospital to send the results, and 18% indicated that a physician was responsible for sending the lab results.

•**Financial considerations:** With respect to financial barriers, most survey respondents reported that the donor was responsible for the costs while only a few respondents indicated that the recipient's insurance covered these costs. Additional reported sources of funding included GoFundMe or other fundraising campaigns, as well as seeking support from Donor Shield , the potential donor's home country embassy, or foundations or grants or family.

•**Legal status:** Most respondents (84 %) stated they accept non-US citizens residing in the US with some legal protection, while a smaller but still substantial proportion (61%) indicated their programs accepted non-US citizens in the US without legal protection as potential donors. Around three-quarters of responding programs stated that the recipients' legal status had no impact on the non-citizen's donor candidacy. The questionnaire further queried respondents as to the level of legal status which were required to be a living donor, with 64% indicating that they do not require any level of legal status. Of the remaining respondents, 32% required a green card/legal permanent residence; 27% required a long-term visa; 16% accepted deferred action or temporary protected status; 7% accepted asylees awaiting hearing status; and 7% required a social security number. More than half of respondents indicated that barriers existed related to donors' concerns regarding their legal statuses.

AHIRC Findings and Common Program Practices

Transplant programs should consider the following common strategies that were reported:

•Programs may determine if a potential donor holds a visa for legal entry to U.S. If not, the programs could advise the donor to begin application for B-2 visa (a tourism visa). Some programs supplied letters of support to further facilitate the process.

•Centers should consider how much of the work-up potential donors must have completed before travel to the U.S., it is advantageous to have completed as much of the early evaluation as possible, such as initial screening, blood work, medical history, required cancer screenings, education, and discussions to assess that the living donor is voluntarily willing to donate as detailed in a separate section of this document. These assessments assist in determining if the candidate is suitable for additional evaluation and can help reduce the possibility of being disqualified following travel to the program. Consider when the donor should travel to the transplant program. For labs required prior to travel, determine how these will be ordered and received. Programs should also consider what approach to take if they find donor candidate and recipient are not an HLA match after the donor arrives in the US.

•Of special importance prior to international travel is the discussion of financial considerations. Beyond the challenges faced by all living donors, such as time off from work for recovery, international living donors may incur substantial costs for obtaining a visa, international travel, housing in the U.S., transportation within the U.S., and required medical testing. Programs should provide full transparency regarding costs, especially as financial support that is available for living donor (LD) in the U.S. is often

not available for international living donors. For instance, the recipient's insurance might not cover international lab work, and the living donor may not qualify for funding from the National Living Donor Assistance Center(NLDAC) as NLDAC requires that both the recipient and donor be U.S. citizens or U.S. residents. Consider the estimated total costs and share information with donor. Early conversations with the program's financial manager should make fully clear to the potential donor the costs that may be incurred. Programs should consider whether funding by the potential recipient represents an inducement to donation, an issue discussed in the following section.

•Programs also found success in educating potential donors and having conversations with them about any concerns associated with their NCR or NCNR status.

Risk of exploitation, coercion, and inducement barriers

The Shukhman article described the "risk of exploitation/inducement" as follows:

- •Power and resource differentials between international donor candidates and U.S. recipients are common.
- •Donor candidates may have limited resources, limited access to medical care, and may be at risk of
pursuing donation in the hopes of remuneration or migration opportunities.

The definition of three critical terms helps to ground this discussion. Exploit means "to make use of meanly or unfairly for one's own advantage." Induce means "to move by persuasion or influence." Coerce means "to compel to an act or choice"; "to achieve by force or threat." Ultimately, the intent is to detect and prevent any coercion or inducement that would exploit a potential living donor. Assessing the NCR/NCNR donor candidate for evidence of exploitation, inducement, or coercion is important in determining their motivation for donating an organ. It is currently required in OPTN Policy 14 that all living donors be evaluated for this risk. Central to this assessment is determining the relationship between the donor candidate and the recipient and is required to evaluate potential international donors for Human Trafficking for Organ Donation (HTOD). The donor candidate-recipient relationship can have an influence on the donor's motivation for donating an organ. Broadly these relationships are either: familial (biologically) or emotionally related; or unacquainted with no pre-existing relationship between the donor candidate and recipient.

Duties and obligations associated with family relationships often weigh heavily on the decision to donate, as do emotional bonds within the family and cultural familial influences. Attention should be given to family systems and dynamics, and assessment for the presence of coercion, undue pressure, or financial motivation . For example, if the relationship is familial, cultural norms might place undue influence on the donor candidate, such as children expected to donate unquestionably to a parent or wives expected to defer unquestionably to husbands.

Unacquainted donor candidate-recipient relationships can be difficult to assess as to their motivations to donate. This group may be vulnerable to being exploited or coerced. An example are the concerns regarding solicitations for a living donor on the internet.

In addition to donor candidate-recipient relationship, the socio-economic status of the donor candidate may influence their motivation to donate. For example, considering whether the donor candidate is a fully enfranchised resident of his or her home country. Another example would be if they are vulnerable class of persons such as a refugee, a persecuted religious or ethnic minority, or a socially disvalued person.

Donor candidates that come from resource-poor areas may be at a higher risk of being exploited/induced. This group may also be at risk to be inadequately informed or giving manipulated consent.
Given the potential nature of the power and resource differentials between NCR/NCNR donor candidates and U.S. citizen recipients, it is essential that transplant programs take particular care in assessing motivation for donation. As indicated by transplant programs themselves, this involves deliberately assessing the potential for coercion.

Questionnaire Feedback:

•**Voluntariness:** Six respondents identified concerns about coercion and local situations after communication. Three respondents couldn't verify the relationship, and two respondents identified power concerns in the relationship. A smaller number of respondents mentioned issues like third-party completed questionnaires and tried to control communication,
recipient alluded to payment beyond travel and accommodation, or visa issues.
Respondents indicated a need for additional support and resources to ensure the voluntariness of the donor candidate. These included interpreters (28%), an Independent Living Donor Advocate (ILDA) (14%), and in some cases, more in-depth evaluation, psychiatric assessment, or ethics review. However, 39% of respondents said they did not require any extra resources and relied on their standard protocols. Note that respondents were able to select more than one concern, so answers are not mutually exclusive. Most centers found it equally challenging to assess voluntariness and understanding of the process for non-citizen non-residents of the U.S. and non-citizens residing in the U.S. Notably, about a third of respondents said they did not proceed with transplants due to concerns about voluntariness. While many programs used an outside agent to assess voluntariness, several centers relied on the ILDA, as required by OPTN Policy 14.2:Independent Living Donor Advocate (ILDA) Requirements, which mandates the involvement of the ILDA to evaluate voluntariness, regardless of whether the transplant program conducts the assessment itself or uses a professional in the donor's home country.
•**Motivation:** 16% of respondents shared reasons that contributed to the decision not to proceed with a transplant involving an NCR/NCNR living donor as motivational concerns (e.g., coercion, payment, means to come to U.S.). A quarter of respondents used local psychologists or social workers to evaluate motives. Some respondents relied on the potential donor to affirm voluntariness. A small proportion of programs relied on the ILDA. Several programs said they conducted interviews in person to establish voluntariness, with one program stressing that the potential donor was alone when questioned about voluntariness.

Additionally, several questions looked at differences in communication between NCR and NCNR. Almost 55% of respondents said assessing the two groups for voluntariness was equally difficult. 63% of respondents said it was equally difficult to make certain patients in either group understood the risks of donation. Of the centers that said they considered potential living donors who were non-citizen resident or non-citizen non-resident, but did not carry out the transplant, 31% cited concerns over voluntariness.
•**Assessing coercion:** Respondents shared ways in which they would discern non-verbal clues of coercion or ask in a culturally sensitive manner: native language interpreter on video call, relying on local psychologist/social worker to evaluate and provide written report, or relying on potential donor to affirm they are not being coerced.

AHIRC Findings and Common Program Practices
Transplant programs should consider the following common strategies that were reported:

•It is important that donor candidates be assessed for risk of inducement especially for vulnerable populations who may seek either asylum or financial renumeration.
•Comply with OPTN Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements in the process of evaluating and assessing voluntariness of decision to donate
•Cases where recipient candidates pay for transportation and lodging costs, or evidence of any other monetary or non-monetary compensation, require additional scrutiny for coercion.
•NCNR donor candidates residing in the United States may be the only available living donors for family and friends who have also migrated to the U.S. These potential donors must be subjected to the same scrutiny applied to all living donors to assure there is no coercion involved in the decision to donate, and that the donor procedure is safe and will not impair the donor's long-term health.
•Some programs found success with having the independent living donor advocate (ILDA) discuss voluntariness alone with the potential donor.
•Verify the relationship between the NCR/NCNR living donor candidate and the U.S. citizen transplant candidate, and explore any power concerns in the relationship.
•Programs should apply multiple methods, relying on the expertise of culturally relevant resources, to ensure that coercion is not in play.
Transplant programs should consider whether these approaches would be effective or appropriate for their review of donor candidates.

Post-donation donor follow-up barriers

NCNR donors face unique barriers that US citizens do not in the organ donation process. These barriers represent important social determinants of health that need to be addressed to improve healthcare equity and ensure the long-term health of NCNR donors. Ideally, the ability of a NCNR to obtain follow-up should be established during the donor pre-screening phase. As the pre-donation work up is initiated, the groundwork for the follow-up phase should be planned. If the living donor can successfully complete the initial lab work in their county and communicate with the living donor coordinator in a timely fashion, then follow-up post-donation may not be an issue. The article by Shukhman et. al recommends creating a follow-up plan for care in the donor's home country prior to donation. This plan should address the donor's medical and psychosocial concerns and be documented in advance of donation reflecting the donor's willingness to comply. The donor's local physician should be involved in the planning of the follow-up care prior to donation.

Given the challenges in adherence to follow-up recommendations of transplant programs and donors within the U.S., concern exists regarding the logistics of how NCNR and NCR donor follow-up will be completed. The OPTN requires that transplant centers report follow-up data, including lab results, on living kidney donors (LKD) at 6, 12 and 24 months post-donation. Despite this requirement, almost half of all U.S. transplant programs are not in compliance with this requirement for all living donors. Follow-up rates for NCR theoretically should be no different than for U.S. citizens, since they are living in this country. Many times, the living donor is contacted by the program but then fails to complete the requested lab work. Often, the living donor is unable to be contacted after every effort of communication is exhausted, including telephone, email, and patient portals. Improving compliance with OPTN requirements for living kidney donor follow up care supports an opportunity to expand telehealth and local healthcare partnerships and to improve pre and post organ donation care for living donors.

<u>Questionnaire Feedback:</u>

Feedback questionnaire results indicated that most of respondents agreed or strongly agreed that access to healthcare after donation for donation-related complications is a barrier when evaluating non-citizen residents without any or some legal protections. This was an especially strong barrier for non-US citizens without any legal protection and was reported to be a barrier for 79% of respondents in this category.

•**Follow up data:** The questionnaire results indicated that 43% of transplant program respondents reported that the follow-up rate of international living donors as somewhat lower, and 24% was much lower compared to U.S. living donors. Programs reported experiencing challenges with obtaining follow up for OPTN required lab reporting for 56% of NCR and 79% of NCNR living donors. The responding programs overwhelmingly report email as the preferred mode of providing lab orders to international living donors at 70%. Where the donors obtain the lab work is evenly split between a local hospital, local lab, or their primary care physician, with the donor owning responsibility of sending the results to the program in 73% of the responses. Findings showed that programs expect the donor to cover the cost of the follow-up lab work rather than covering the expense through the center, while a few still try to cover the cost with the recipient's insurance.

•**Telehealth:** 57% of the responding programs indicated that they do not conduct a telehealth follow-up. Thus, a NCNR may be required to travel from another country for a 10-minute appointment. If the trip back to the U.S. for the follow-up is the responsibility of the donor, most will not return. Of the centers performing telehealth follow-up visits, the majority are conducted via telephone or web-based video conferencing. This questionnaire of communication has its own challenges due to time differences and in many cases the need for translators. These challenges in NCNR follow up care may lead to missed complications related to the organ donation for the NCNR or a delay in diagnosis and subsequent care.

•**Communication methods:** The responding transplant programs report email as the most widely used form of contact between NCNR living kidney donors and the center due to time differences between countries at a rate of 84%. Although LKD complication risks are relatively low, identifying them early is key to preventing progression. Without proper follow-up post donation, complications such as hypertension, decreased kidney function, hernia, organ failure, depression, anxiety, and even death could be missed. In the event of donor complications, 68% of programs report they are willing to assist the donor with obtaining a visa to return to the U.S., if necessary, but the cost is the donor's responsibility according to 59% of programs.

•**Post-transplant considerations:** About half of centers indicated the donor would remain in the U.S. for follow-up for as long as it took the donor to recover whereas others used specified durations: 33% for one month, 16% for two months and 5% for three months. Once the donor has returned home, more than half reported not conducting telehealth visits with donors; of those doing follow-ups, most used the telephone, followed by video conferencing, email, or cell phone video apps. In the event of a post-operative complication after returning home, 68% reported helping the donor to get a visa to return to the U.S., but again held the donor (59%) or the recipient (44%) responsible for travel related to donor complications.

AHIRC Findings and Common Program Practices

Transplant programs should consider the following common strategies that were reported:

•Develop a follow up plan for care in donors home country prior to donation.

•Involve the donor's local physician in the planning of the follow-up care before donation.

•Consider providing the donor with information for billing of any post-donation lab work back to the transplant center prior to the donor leaving the U.S. to return to their home country.

•Transplant programs could consider helping with travel costs for the donor to return to the center for complications related to donation or help pay for their care in their home county, if they are unable to travel back to the center. Of course, any acute or life-threatening issue should be addressed locally.

Conclusion

NCR and NCNR potential living donors are vulnerable populations facing unique barriers that require an integrated and thoughtful approach to both evaluation and donor follow up. Transplant programs should consider the options adopted by their peers for integration into their own effective practices for their individual candidate.