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Briefing to the OPTN Board of Directors on

Barriers Related to the Evaluation and Follow up of International Living Donors

OPTN Ad Hoc International Relations Committee

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OPTN

Barriers Related to the Evaluation and Follow up of International Living Donors

Sponsoring Committee: *Ad Hoc International Relations*
Public Comment Period: *January 21, 2025 – March 19, 2025*
Board of Directors Meeting: *June 9-10, 2025*

Executive Summary

The OPTN Ad Hoc International Relations Committee (the Committee) proposes a guidance document to share the Committee's assessment of common practices for evaluating and post-donation follow-up of international living donors, which include non-citizens/residents (NCR) and non-citizens/non-residents (NCNR). The Committee considered current literature and information provided through a feedback form to compile relevant practices that transplant programs may consider as they evaluate NCR and NCNR candidates for donation and provide post-donation follow-up. While international living donations represent a small percentage of total living donations,[1] the Committee understands the unique challenges that programs face when assessing and caring for this donor population. By compiling relevant practices from current literature and a feedback questionnaire, the Committee aims to provide programs with an educational resource to consider as they navigate the complexities of evaluating NCR and NCNR candidates for donation. The guidance document delves into practices and transplant program approaches for evaluating international donors, ensuring their physical and mental well-being throughout the donation process, and maintaining consistent post-donation follow-up care. This comprehensive guidance document aims to assist transplant programs as they often face additional communication, logistical, and coercion barriers that can impact the donor's ability to participate in organ donation. By sharing its assessment and practices, the Committee hopes to empower programs to make informed decisions and provide support to this unique donor population, ultimately facilitating more successful living donation and improving outcomes for international living donors.

[1] Meeting Summary for October 24, 2023, OPTN Ad Hoc International Relations Committee, https://optn.transplant.hrsa.gov (accessed December 2, 2024)

Purpose

The purpose of this guidance document is to provide useful practices and relevant literature for transplant programs to consider as resources for evaluating and managing 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.[2] The evaluation process can be resource-intensive, as programs must obtain a significant amount of information to properly assess the donor's suitability. A study conducted by the American Society of Transplantation (AST) Living Donor Community of Practice workgroup identified several key issues that can arise when evaluating international donors, including problems with communication, complex logistics, and concerns about potential exploitation and coercion of the donor.[3] The AST workgroup also noted unique challenges in conducting post-donation follow-up care for donors who live abroad. To further explore these barriers, the Committee formed a workgroup with representatives from the OPTN Ethics and Living Donor Committees. A feedback questionnaire was sent to 205 living donor transplant programs, with 66 programs participating and providing 108 responses about the specific obstacles they face with NCR and NCNR potential living donors, including:

- Evaluation:
    - Communication barriers
    - Logistical barriers
    - Risk of exploitation, coercion, and inducement barriers
- Post-donation follow-up barriers

The key findings from this feedback form are intended to provide an overview of current options that transplant programs can consider when assessing prospective living donors who do not reside in the United States, though the data gathered are not statistically significant. By illuminating these challenges, the OPTN workgroup aims to help transplant centers navigate the complex process of evaluating international living donors and facilitate more successful living donation outcomes.

Proposal for Board Consideration

The Committee proposes a guidance document for transplant programs to consider when conducting evaluation and post-donation follow-up of non-citizen/residents and non-citizens/non-residents.

Findings and Common Barriers

The barriers associated with the evaluation and care of international living donors include:

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

[2] OPTN Policy 14, Living Donation

[3] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

Communication barriers

The communication challenges associated with the evaluation of international living donors include the method and the interpretation of information passed to the potential donor and responses to the transplant center.[4] The process of assessing and approving an international donor is complex, requiring a clear and comprehensive exchange of information to ensure the donor fully understands the various elements involved. This can be complicated by differences in language, culture, and power dynamics between the medical staff and the donor candidate.

For example, a potential donor from a culture where it is considered impolite to refuse a request may be hesitant to truthfully express any reservations or concerns they have, fearing they will disappoint their family or friends. Similarly, differences in social class or the perception of clinicians as dominant authority figures can create barriers that inhibit open and honest communication. The use of interpreters, while necessary, adds another layer of complexity, as the interpreter must not only translate the words being spoken, but also act as a cultural broker to help bridge gaps in understanding.[5] Additionally, there are also challenges with understanding and interpreting the nuances and non-verbal cultural clues in communicating with potential donors.

Compounding these issues are the legal and privacy considerations that vary by country, requiring transplant programs to carefully navigate the appropriate means of initial contact and information sharing. Overcoming these challenges is critical to facilitating a successful donor evaluation process and ensuring the donor is fully informed to make the best decision for their circumstances.

To address these concerns, the Committee suggests that programs use Health Insurance Portability and Accountability Act (HIPAA)-compliant secure communications to make initial contact with international donor candidates. The Committee also stresses the importance of understanding the privacy laws in the candidate's home country.[6] The Committee also suggests using trained medical interpreters to ensure accurate communication.[7] The Committee further recommends that programs maintain transparency with donor candidates regarding any potential obligations that may be incurred prior to receiving donor consent, such as financial expenses.[8]

Logistic barriers

Evaluating potential living donors who reside outside the United States presents a unique set of logistical challenges that programs should carefully navigate. These international donors are a varied group, hailing from various countries and backgrounds, each with their own unique circumstances and needs. A key issue is the significant geographic distance that often separates these donors from the transplant program, which can create major hurdles. For some, the program may be just a reasonable

[4] Meeting Summary for August 22, 2023, OPTN Ad Hoc International Relations Committee, https://optn.transplant.hrsa.gov (Accessed December 8, 2024)

[5] Kaufert JM, Putsch RW. "Communication Through Interpreters in Healthcare: Ethical Dilemmas Arising from Differences in Class, Culture, Language, and Power" J Clin Ethics. 8, no. 1(1997):71-87. PMID: 9130112 https://pubmed.ncbi.nlm.nih.gov/9130112/.

[6] Office of Ethics, Risks, and Compliance Services, Oercs.berkeley.edu. (Accessed December 11, 2024) https://oercs.berkeley.edu/privacy/international-privacy-laws.

[7] Juckett G, Unger K. "Appropriate Use of Medical Interpreters". AM Fam Physician. 2014; 90, no.7:476-480 https://www.aafp.org/pubs/afp/issues/2014/1001/p476.html.

[8] Guidance for the Informed Consent of Living Donors, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov (Accessed December 10, 2024)

car ride away if they live near the U.S. border. However, for others, reaching the facility may require a lengthy flight spanning multiple time zones. This distance creates travel difficulties and expenses and can exacerbate the emotional and social stresses that living donors already face. Leaving their home, family, and support systems to undergo medical evaluations and procedures in an unfamiliar country adds considerable anxiety and disruption to the process.

There are also logistical complexities around obtaining necessary medical records, lab work, and other documentation from healthcare providers in the donor's home country. Ensuring seamless communication and coordination across borders is critical. Additionally, programs should be mindful that the financial assistance and insurance coverage available to living donors within the U.S. is often not extended to international donors, potentially creating an added financial burden.

To address these multifaceted challenges, programs are suggested to conduct as much of the preliminary donor evaluation as possible remotely. This includes initial screenings, lab tests, medical history reviews, and educational sessions - all of which can help determine a donor's suitability and minimize the risk of disqualification after they have traveled to the transplant center. Maintaining transparency about all potential costs is also essential.

Risk of exploitation, coercion, and inducement barriers

When evaluating international living donors, it is crucial to assess NCR/NCNR donor candidates for any evidence of exploitation, inducement, or coercion. This assessment is vital in determining the donor's true motivation for organ donation. It is currently required in OPTN *Policy 14* that all living donors be evaluated for this risk.[9] Central to this assessment is determining the relationship between the donor candidate and the recipient.

Familial relationships, whether biological or emotional, often come with a sense of duty and cultural expectations that can weigh heavily on the decision to donate an organ. Family dynamics and the potential for coercion or undue pressure from family members should be carefully examined.[10] For example, in some cultures, children may feel obligated to donate to a parent without question, or wives may be expected to defer to their husband's wishes, even if it goes against their own desires.[11] On the other hand, unacquainted donor-recipient relationships, where no prior relationship exists, can be particularly concerning, as these individuals may be more susceptible to exploitation or inducement, such as through internet solicitations for living donors.[12]

To address these concerns, the Committee suggests that donor candidates be assessed for risk of inducement, especially for vulnerable populations who may seek either asylum or financial remuneration.[13] Programs may refer to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA)*

[9] OPTN Policy 14.1.A, *Living Donor Psychosocial Evaluation Requirements* (December 10, 2024)
[10] Hartsock JA, Helft PR. "International Travel for Living Donor Kidney Donation: A Proposal for Focused Screening of Vulnerable Groups". Transplantation. 2019 Dec; 103(12):2576-2581. doi: 10.1097/TP.0000000000002875. PMID: 31356577. https://pubmed.ncbi.nlm.nih.gov/31356577/.
[11] Ibid.
[12] Institute of Medicine. "Organ Donation: Opportunities for Action". Washington, DC: The National Academies Press. 2006. https://doi.org/10.17226/11643.
[13] Hartsock JA, Helft PR. "International Travel for Living Donor Kidney Donation: A Proposal for Focused Screening of Vulnerable Groups". Transplantation. 2019 Dec; 103(12):2576-2581. doi: 10.1097/TP.0000000000002875. PMID: 31356577. https://pubmed.ncbi.nlm.nih.gov/31356577/.

Requirements to evaluate and assess voluntariness of decision to donate.[14] Furthermore, programs are encouraged to verify the relationship between the NCR/NCNR living donor candidate and the U.S. transplant candidate and explore any power concerns in the relationship.

Post-donation follow-up barriers

The post-donation follow-up challenges associated with evaluating international living donors are important social determinants of health that need to be addressed to improve healthcare access and ensure the long-term health of NCNR donors. It is essential that the ability of an NCNR donor to obtain the necessary follow-up care in their home country is thoroughly evaluated and planned for during the pre-screening process. As the initial medical evaluation and pre-donation work-up begins, the framework for the crucial post-donation follow-up phase should be carefully mapped out.

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 which includes lab results, on living kidney donors at 6, 12, and 24 months post-donation. Oftentimes, 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.

To address these concerns, the Committee suggests that programs develop a follow-up plan for care in the donors' home country prior to donation. This suggestion aligns with the AST Living Donor Community of Practice workgroup's publication by Shukhman et al., which recommends creating such a plan.[15] 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.

This includes involving the donor's local physician in the planning of the follow-up care before donation. Programs should 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. Additionally, transplant programs could consider helping with travel costs for the donor to return to the program for complications related to donation or help pay for their care in their home county, if they are unable to travel back to the program.

Improving compliance with OPTN requirements for living kidney donor follow-up care supports an opportunity to expand telehealth and local healthcare partnerships, ultimately enhancing pre- and post-organ donation care for international living donors.

[14] OPTN Policy 14.2, *Independent Living Donor Advocate (ILDA) Requirements* (Accessed December 19, 2024)
[15] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

Overall Sentiment from Public Comment

The proposal was released for public comment from January 21, 2025 – March 19, 2025. The Committee welcomed all input on the proposed guidance document, and asked for the following specific feedback during public comment:

- Are there additional challenges that should be considered when evaluating international living donors?
- Are there additional strategies/practices that can be shared to address these barriers?

The proposal received support from regional meetings and various stakeholder societies, including, AST, American Society of Nephrology (ASN), and American Nephrology Nurses Association (ANNA). Additionally, it was endorsed by several OPTN Committees including the Living Donor Committee, Minority Affairs Committee, and the Transplant Coordinators Committee.

Sentiment in Public Comment

Sentiment by Region (OPTN Regional Meetings)

Sentiment is collected on public comment proposals and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5).

Figure 1 shows the overall sentiment captured during OPTN regional meetings, based on a total of 227 responses. Overall, feedback was supportive of the proposal, reflected in an average sentiment score of 3.9.

Figure 1: Overall Sentiment (OPTN Regional Meetings)

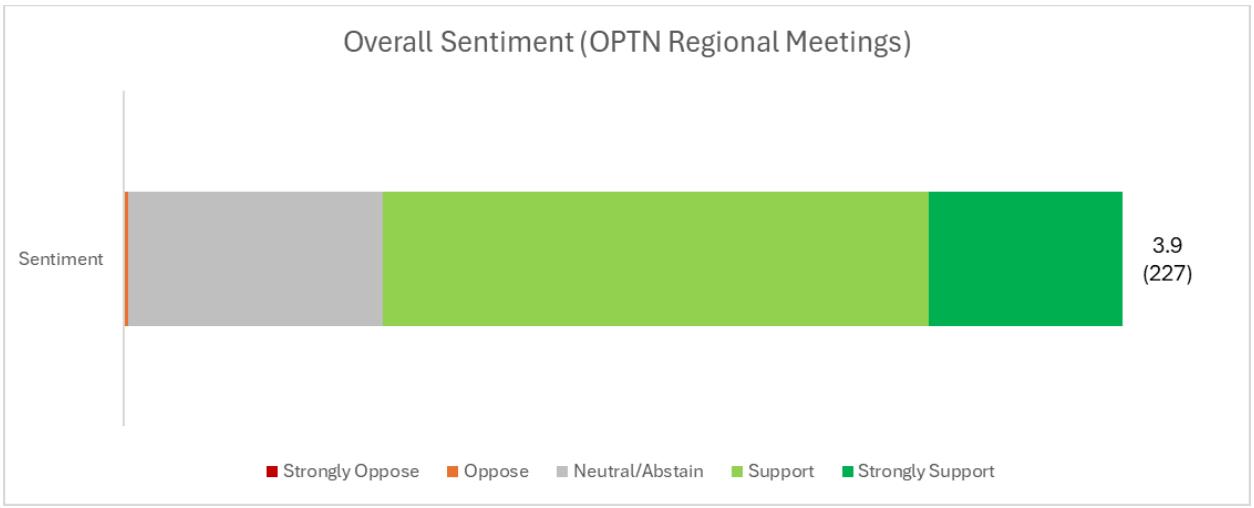
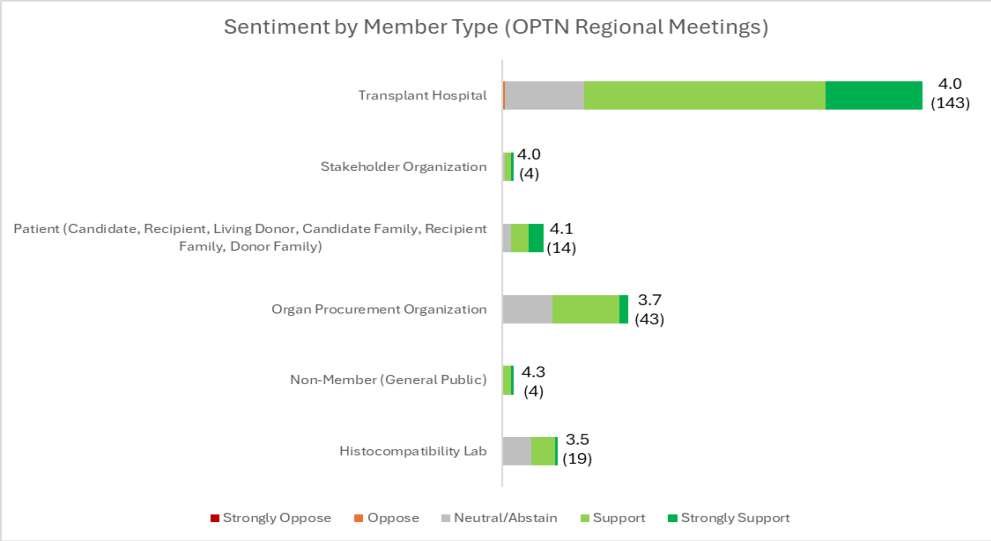


Figure 2 shows sentiment received during OPTN regional meetings, stratified by member type. Again, there was overall support for the guidance document

Figure 2: Sentiment by Member Type



Support on OPTN Website

The public comments submitted on the OPTN website were categorized based on the sentiment expressed in the text submitted. Each comment was analyzed to identify whether it conveyed support, opposition, or neutrality towards the proposal. The following definitions were used to ensure clarity and consistency in the categorization process:

- **Support:** The text of the public comment expressed a positive stance towards the proposal. Supportive comments typically contained language that endorsed, agreed with, or advocated for the proposal.
- **Do Not Support:** The text of the public comment expressed a negative stance towards the proposal. Comments that do not support the proposal contained language that opposed or disagreed with the proposal.
- **Neutral:** The text of the public comment did not clearly express a positive or negative stance towards the proposal. Neutral comments lacked definitive "support" or "not support" language or presented balanced viewpoints on the proposal.

Figure 3 shows overall support from the OPTN website, with 55% (6) of comments being supportive and 45% (5) of comments being neutral.

Figure 3: Overall Support (OPTN Website Comments)

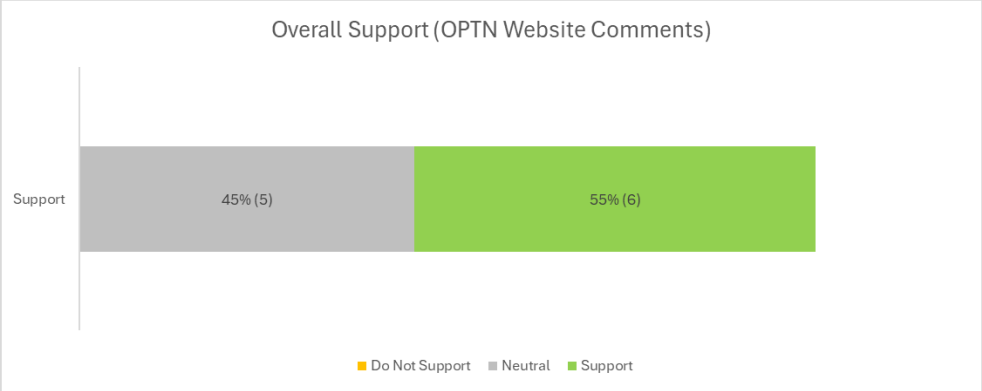
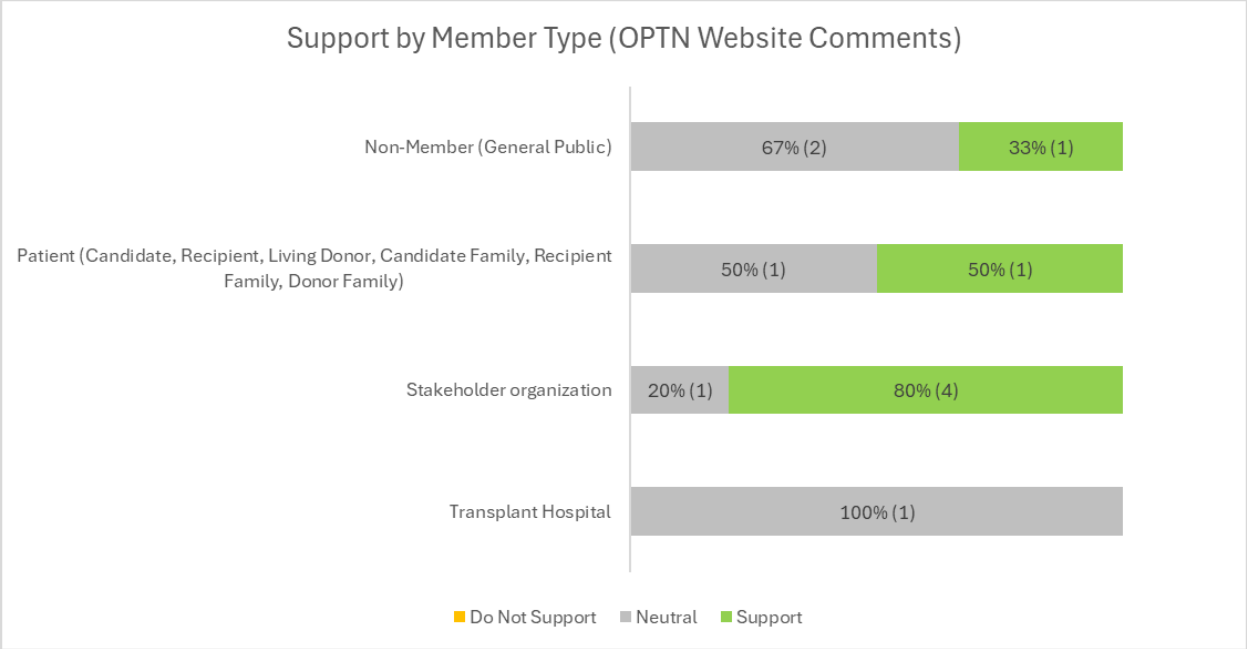


Figure 4 illustrates the sentiment collected from the OPTN website with varying levels of support across different member types. Overall, the feedback was supportive of the guidance document. Several stakeholder organizations, including the ANNA, AST, ASN, and Alpha-1 Foundation, expressed their support.

Figure 4: Support by Member Type



Themes in Public Comment

While there was overall support for the guidance document, there was additional commentary related to the feedback requested, including 1) agreement with the barriers and consideration for additional guidance, and 2) additional strategies/practices that can be shared to address these barriers.

Agreement with barriers and consideration for additional guidance

Public comment feedback concurred with the barriers identified in the guidance document. Although no new barriers were proposed, members underscored the importance of the challenges outlined in the document. Additionally, there was support for providing further guidance related to these barriers. Specifically, the Transplant Coordinators Committee asked for further guidance on:

- Cultural competency in language translation.
- Navigating foreign healthcare systems, including understanding these systems, dealing with language barriers, and managing healthcare costs and insurance issues.
- Ethical and practical considerations for living organ donations between donors and candidates who do not know each other.

Additionally, the AST noted that more robust guidance is needed on aspects of the screening process, such as language barriers, cultural cues, coercion, and informed consent comprehension. While the committee considered these additional requests and recognized that additional guidance would be beneficial, there is a lack of available data and resources to provide additional guidance at this time.

Additional strategies and practices for consideration

Overall, the feedback received from regional meetings and societies including the ANNA, AST, and ASN, endorsed the current practices mentioned in the document and suggested additional practices. Regional meeting feedback recommended fostering international partnerships with hospitals in the donor's home country for improved evaluation and follow-up. Other regional meeting comments recommended creating a specialized team to facilitate the evaluation and follow-up process for international donors. The AST recommended that transplant hospitals develop toolkits and policies to support the initiative and educate their staff. Given the scarce literature on the topic of evaluating and following up with international living donors, the committee considered the public comment feedback received and decided that it complements the strategies that currently exist in the document. Therefore, no changes were made to the guidance document in response to public comment. However, the committee discussed future opportunities to enhance the guidance document with additional strategies and practices as more literature becomes available.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this project under the broad authority of the National Organ Transplant Act of 1984 (NOTA), as amended, and the Secretary's direction to the OPTN "to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule."[16] This project will promote patient access to transplants by offering guidance to transplant programs to consider when implementing practices of the evaluation and care of international living donors in the United States.

OPTN Strategic Plan

The proposed guidance document supports the strategic plan to increase opportunities for transplant. It aims to identify and understand the barriers that transplant programs face when evaluating NCR and NCNR for living donation transplants. The goal is to raise awareness of these challenges and provide transplant programs with effective practices to address them, thereby increasing transplant opportunities.

Implementation Considerations

Histocompatibility Laboratories

Operational Considerations

This guidance document will have no operational impact on histocompatibility laboratories.

Organ Procurement Organizations

Operational Considerations

The guidance document will have no operational impact on organ procurement organizations.

Transplant Programs

Operational Considerations

As this is an OPTN Guidance document, there is no direct operational impact on transplant programs. However, transplant programs should reference the guidance document when considering, evaluating, or coordinating follow-up care for an international living donor

[16] Department of Health and Human Services, Health Resources and Services Administration, "Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines," 71 Fed. Reg. 34946 No. 116 (June 16, 2006). https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurement-andtransplantation-network-optn-living-donor (accessed June 23, 2020).

Fiscal Impact

OPTN

Resource Estimates

It is estimated that $7,829 would be needed to implement this proposal. Implementation would involve preparing implementation communications and educational materials, community outreach, and updates to the OPTN website. There is no expected cost for ongoing support. The total for implementation and ongoing support is estimated to be $7,829.[17]

Conclusion

The proposed guidance document outlines the challenges that transplant programs may encounter when evaluating and following up with non-citizens/residents and non-citizens/non-residents (international living donors). It aims to offer common practices and relevant literature to help transplant programs effectively assess and manage these donors.

[17] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

Guidance Document

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.[18] 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.[19]

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 donors'; centers may have been guarded in their responses, given the sensitivity of this subject Some of the responses may reflect duplicate responses from multiple respondents at the same transplant programs. Overall, the questionnaire 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

[18]Meeting Summary for October 24, 2023, OPTN Ad Hoc International Relations Committee, https://optn.transplant.hrsa.gov (accessed December 10, 2024)

[19] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

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 programs 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.[20]

Communication barriers

The components of communication include the method and the interpretation of information passing to the potential donor and responses to the transplant program . 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.[21] 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.[22] 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.[23]

[20] Ibid.
[21] Hudelson Patricia, "Improving Patient-Provider Communication: Insights from Interpreters". Fam Pract. 2005 Jun; 22(3):3116. doi: 10.1093/fampra/cmi015. Epub 2005 Apr 1. PMID: 15805131. https://pubmed.ncbi.nlm.nih.gov/15805131/.
[22] McCabe M, Morgan F, Curley H, Begay R, Gohdes DM. "The Informed Consent Process in a Cross-Cultural Setting: Is the Process Achieving the Intended Result?" Ethn Dis. 2005 Spring;15(2):300-4. PMID: 15825977. https://pubmed.ncbi.nlm.nih.gov/15825977/.
[23] Kaufert JM, Putsch RW. Communication Through Interpreters in Healthcare: Ethical Dilemmas Arising from Differences in Class, Culture, Language, and Power" J Clin Ethics. 8, no. 1(1997):71-87. PMID: 9130112 https://pubmed.ncbi.nlm.nih.gov/9130112/.

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 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[24]
- Using trained medical interpreters to ensure accurate communication[25]
- Being clear with donor candidates about the potential financial costs that may be incurred prior to receiving donor consent[26]

[24] Office of Ethics, Risks, and Compliance Services, Oercs.berkeley.edu. (Accessed December 11, 2024) https://oercs.berkeley.edu/privacy/international-privacy-laws.

[25] Juckett G, Unger K. "Appropriate Use of Medical Interpreters". AM Fam Physician. 2014; 90, no.7:476-480 https://www.aafp.org/pubs/afp/issues/2014/1001/p476.html.

[26] Guidance for the Informed Consent of Living Donors, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov (Accessed December 10, 2024)

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[27] or other fundraising campaigns, as well as seeking support from Donor Shield[28], 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)[29] 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 the donor. Early conversations with the program's financial manager should make fully clear to the potential donor the costs that may

[27] GoFundMe. (Accessed December 17, 2024)
https://www.gofundme.com/

[28] Donor Shield. (Accessed December 17, 2024)
https://www.donorshield.com/

[29] National Living Donor Assistance Center. (Accessed December 17, 2024)
https://www.livingdonorassistance.org/

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[30] 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."[31] Induce means "to move by persuasion or influence."[32] Coerce means "to compel to an act or choice"; "to achieve by force or threat."[33] 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 that all living donors be evaluated for this risk.[34] Central to this assessment is determining the relationship between the donor candidate and the recipient and evaluating potential international donors for human trafficking for organ donation.[35] 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[36]. 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.[37]

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[30] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

[31] Merriam-Webster. (n.d.). Exploit. In Merriam-Webster.com dictionary. Retrieved September 11, 2024, from https://www.merriam-webster.com/dictionary/exploit.

[32] Merriam-Webster. (n.d.). Induce. In Merriam-Webster.com dictionary. Retrieved September 11, 2024, from https://www.merriam-webster.com/dictionary/induce.

[33] Merriam-Webster. (n.d.). Coerce. In Merriam-Webster.com dictionary. Retrieved September 11, 2024, from https://www.merriam-webster.com/dictionary/coerce.

[34] OPTN *Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements.*

[35] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

[36] Hartsock JA, Helft PR. "International Travel for Living Donor Kidney Donation: A Proposal for Focused Screening of Vulnerable Groups". Transplantation. 2019 Dec; 103(12):2576-2581. doi: 10.1097/TP.0000000000002875. PMID: 31356577. https://pubmed.ncbi.nlm.nih.gov/31356577/.

[37] Ibid.

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.[38] An example are the concerns regarding solicitations for a living donor on the internet.[39]

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 a vulnerable class of persons such as a refugee, a persecuted religious or ethnic minority, or a socially disvalued person.[40]
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 to give manipulated consent.[41]
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 requires the

[38] Ibid.
[39] Institute of Medicine. "Organ Donation: Opportunities for Action". Washington, DC: The National Academies Press. 2006. https://doi.org/10.17226/11643.
[40] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.
[41] National Academy of Science, "Advanced Research Instrumentation and Facilities". Washington, DC: The National Academies Press. https://doi.org/10.17226/11520.
https://nap.nationalacademies.org/catalog/11520/advanced-research-instrumentation-and-facilities.

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 donors 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.[42]
- Comply with OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements* in the process of evaluating and assessing voluntariness of decision to donate[43]
- 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 ensure 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.

[42] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

[43] Guidance for the Informed Consent of Living Donors, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov (Accessed December 10, 2024)

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 an 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.[44] The article by Shukhman et. al recommends creating a follow-up plan for care in the donor's home country prior to donation.[45] 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.[46] 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.

Questionnaire Feedback:

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

[44] Lentine, K., et al. "Care of International Living Kidney Donor Candidates in the United States: A Survey of Contemporary Experience, Practice, and Challenges." Clinical Transplantation 34, no. 11 (2020):e14064. doi: 10.1111/ctr.14064 https://doi.org/10.1111/ctr.14064.

[45] Shukhman, E., et al. "Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges." Clinical Transplant 34, no. 3 (2020):e13792. doi: 10.1111/ctr.13792 https://pmc.ncbi.nlm.nih.gov/articles/PMC8761064/.

[46] Orandi, BJ. et al. "Donor Reported Barriers to Living Kidney Donor Follow up." Clinical Transplantation 36, no. 3 (2022):e14621. doi: 10.1111/ctr.14621 https://pubmed.ncbi.nlm.nih.gov/35184328/.

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, an 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.[47] 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

[47] Hartsock JA, Helft PR. "International Travel for Living Donor Kidney Donation: A Proposal for Focused Screening of Vulnerable Groups". Transplantation. 2019 Dec; 103(12):2576-2581. doi: 10.1097/TP.0000000000002875. PMID: 31356577. https://pubmed.ncbi.nlm.nih.gov/31356577/.

they are unable to travel back to the center. Of course, any acute or life-threatening issue should be addressed locally.

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