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Evaluation and Care of International Living Kidney Donor Candidates: Strategies for Addressing Common Considerations & Challenges

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Abstract

End-stage kidney disease patients in the United States may have family members or friends who are not U.S. citizens or residents but are willing to serve as their living kidney donors in the United States (“international donors”). In July 2017, the American Society for Transplantation (AST) Live Donor Community of Practice (LDCOP) convened a multidisciplinary workgroup of experts in living donation care, including coordinators, social workers, donor advocates, administrators and physicians, to evaluate educational gaps related to the evaluation and care of international donors. The evaluation of the international living donor candidates is a resource intensive process that raises key considerations for assessing risk of exploitation/ inducement, and addressing communication barriers, logistics barriers and access to care in their home country. Through consensus-building discussions, we developed recommendations related to: 1) establishing program guidelines for international donor candidate evaluation and selection; 2) initial screening; 3) logistics planning; 4) comprehensive evaluation; and 5) postdonation care and follow-up. These recommendations are not intended to direct formal policy, but rather as guidance

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to help programs more efficiently and effectively structure and execute evaluations and care coordination. We also offer recommendations for research and advocacy efforts to help optimize the care of this unique group of living donors.

Keywords

Medical Evaluation; International Donor; Living Donor Kidney Transplantation; Living Kidney Donation; Logistics

Introduction

Living donor kidney transplantation (LDKT) is the best treatment for most patients with end-stage kidney disease (ESKD), conferring improved length and quality of life compared to dialysis or deceased donor kidney transplantation (DDKT), at lower costs to the healthcare system.^{1–3} While 2018 marked the first substantial increase in living donation in more than a decade,^{4–6} there is still a need for monitoring and attention to barriers and disincentives to donation and LDKT.^{7,8} Further, racial disparities in LDKT in the United States have heightened over time. After adjustment for baseline clinical factors, the relative likelihood of LDKT in Hispanic compared to white candidates declined from 17% lower access in 1995–1999 to 48% lower access in 2010–2014.⁹ Among Asian versus white candidates, LDKT was 44% less likely in 1995–1999, and 58% less likely in 2010–2014.⁹ In 2014 the American Society of Transplantation (AST) Live Donor Community of Practice (LDCOP) “Consensus Conference on Best Practices in Live Kidney Donation” issued a recommendation to create a mechanism to remove barriers to donation by U.S. non-residents.¹⁰

Approximately 100 to 150 LDKT from persons who are neither U.S. citizens nor U.S. residents (“international donors”) are performed in the United States each year.¹¹ In 2015–2016, the most frequent countries of origin for persons serving as international kidney donors in the United States were Mexico (N = 55), Kuwait (N = 22), Canada (N = 16), India (N = 16), Qatar (N = 15), the Dominican Republic (N = 14), the Philippines (N = 11), and the United Arab Emirates (N = 10); 63 other countries were represented, including 29 countries with a single donor each.¹¹ Generally, international donors are family members or friends of patients with ESKD who visit the United States to serve as living kidney donors. Whereas some countries prohibit international donors due to concerns for organ trafficking or transplant commercialism, the U.S. has no such prohibition.^{12,13} A recent study of U.S. Organ Procurement and Transplantation Network (OPTN) registry data found that international living kidney donors were tightly clustered among a small number of transplant centers.¹¹ Resources for helping transplant programs understand and address challenges to assessment and care of international donor candidates may improve consideration of international donors for U.S. kidney patients, but to date, the nature of these challenges, and strategies to address them, have not been well described.

In July 2017, the AST LDCOP convened a multidisciplinary workgroup of experts in living donation care, including coordinators, social workers, donor advocates, administrators and physicians, to evaluate educational gaps related to the evaluation and care of international

donors. Given the paucity of published literature on this topic, workgroup objectives included developing and administering a survey of transplant program staff regarding concerns and challenges (reported separately¹⁴), and monthly conference calls to discuss core principles of international donor candidate evaluation based on experiences of the workgroup and the community (Figure 1). The workgroup identified 4 areas specific to the care of international donors that warrant special attention: assessment of risk factors for inducement or exploitation; communication barriers; logistics barriers; and follow-up care options.

Final recommendations were endorsed unanimously by all workgroup members. Herein we describe recommendations related to areas of vulnerability and unique challenges in the international donor population, organized across the care continuum (Table 1). We recommend: 1) establishing program guidelines for international donor candidate evaluation and selection to promote consistency, transparency, & efficiency; 2) in-depth and tailored initial screening processes; 3) logistics planning and navigation; 4) comprehensive evaluation; and 5) planning for postdonation care and follow-up. These recommendations do not direct policy, but rather serve as guidance to help programs structure and execute international donor candidate care. We also offer recommendations for research and advocacy to advance the care of international living donors. This manuscript is a work product of the AST LDCOP.

Establishing Program Guidelines for International Donor Candidate Care

Recommendation #1: Transplant programs should develop guidelines for the evaluation and selection of international living donors that assess this population’s specific vulnerabilities and meet care needs.—Communication, education, and screening of the international donor candidate is a complex process with many inherent challenges. To conduct these evaluations efficiently and effectively, transplant programs should establish guidelines addressing key considerations, and train staff members to understand and address potential challenges in their workflows (Table 2).

Define any program-specific candidacy criteria differences for international donors—Many international donor candidates come from resource-poor areas, may have power or resources differential with the intended recipient, and may be at associated higher risk of being induced or exploited in relation to living organ donation. As a result, some transplant programs have defined relationship candidacy criteria for international donors, which may mean mandating a familial relationship with the transplant candidate; others require evidence of an established personal relationship with the transplant candidate. Programs should decide whether persons who are not biological relatives or do not have established personal relationships with the transplant candidate will be considered for international donation, and whether kidney paired donation (KPD) is an option, and if so, whether “difficult to match” pairs will be considered. Program-specific international donor evaluation guidelines should address whether candidacy depends on the healthcare system and availability of care in country of origin, or on type of visa a donor candidate has or needs. The guidelines should also define the screening information needed prior to the donor candidate’s travel to the United States for evaluation. Transparency about these guidelines

is essential when interacting with those who inquire about donation, and with the transplant candidate.

Initial Screening of the International Donor Candidate

Recommendation #2: Upon an international donor candidate's self-referral, detailed pre-screening and initial education should be completed.—It is recommended that programs provide preliminary screening and linguistically attuned basic education about donation including the process (all phases, including evaluation, donation surgery, recovery and follow-up), risks and benefits prior to travel to the United States so that only very motivated and appropriately healthy candidates undertake the time and expense of travel for donation. It must be decided if the prescreening tests required are different depending on the country of origin. Use of multidisciplinary team members (who may include the living donor coordinator, social worker, ILDA, psychologist/psychiatrist, and/or ethicist) is encouraged to gain a comprehensive understanding of the potential international living donor in the preliminary stages. This approach can assist in efficient identification of eligible donors and increase preparedness for both the living donor candidate and the living donor team.

Pre-screening components—For international donor candidates, prescreening may include aspects that would typically be assessed during in-person donor evaluation. This includes review of medical and surgical history, assessment of current psychosocial situation and socioeconomic status. It also includes education components that would typically be covered in-person. In addition, assessment of donor candidate comprehension is critical, given potential communication barriers (described below) and because U.S. health systems and U.S.-style medical care may be unfamiliar. The ease of completing pre-screening testing may vary based on the structure of the healthcare system in the country of origin.

Assessment of the nature of the relationship between donor and recipient, and the donor candidate's own description of motivations are essential. Careful scrutiny of both submitted documentation and responses to questions on donor-recipient relationship and motivation for donation are required to evaluate potential international donors for Human Trafficking for Organ Donation (HTOR).¹⁵ Care must be taken to assess risk of inducement, especially for potentially vulnerable populations who may seek either asylum or financial remuneration beyond that allowed by the National Organ Transplant Act (NOTA).¹⁵

Performing a preliminary medical evaluation in the home country, prior to travel to the United States, can be beneficial in identifying potential concerns or barriers to donation. The transplant program should recommend specific tests, such as blood pressure, body mass index, metabolic panel to estimate glomerular filtration rate, and urinalysis. Advance planning may minimize the need for duplication of testing and associated costs. Identified concerns may warrant early intervention, further consideration, or may preclude donation. Efficient prescreening prior to acquiring additional medical testing can be helpful to avoid unnecessary expenses. Some tests can be tailored to address donor specific risk factors or for diseases endemic to the donor's country of origin. Early discussions and considerations during the prescreening process may include assessment of donor's blood type (if available),

donor and recipient's interest in KPD, as well as evaluation of recipient's ABO titer in the case of ABO incompatible pairs.

Critical elements include assessing whether the donor candidate will be able to engage in the process, clarifying donor expectations while in U.S., and establishing realistic expectations related to follow-up, complications, ability to return to the United States for medical care, and access to follow-up care in the home country. Donor candidates should be made aware that they will be required to go through further evaluation and testing once at the transplant center that may ultimately conclude that they are not eligible to be a living donor. Proper education of the potential donor candidate and the recipient can mitigate risks of dissatisfaction or blame.

Feasibility of entering and comfort staying in the United States during evaluation, donation, and recovery process should be discussed, including housing, transportation, language/cultural differences and barriers, financial needs, and caregiver support. Costs of evaluation and donation including possible out-of-pocket expenses, and lack of travel grant eligibility (e.g. National Living Donor Assistance Center) should be reviewed.¹⁶ The evaluation team should additionally confirm the presence of an active passport, in preparation to initiate the visitor visa process. The donor candidate's plan and intent to return to their home country after donation should be confirmed. Education should also include mention of living donor priority for DDKT allocation in the United States;¹⁷ however, allocation priority does not include coverage for the costs of returning the United States or the medical cost of transplantation or aftercare, including immunosuppression and other medications.

Pre-screening logistics—Logistics of pre-screening can be complicated: phone screening may be challenging given costs of international calls, time zone differences and language barriers. Online telemedicine may enable some discussions and preliminary interviews, including provision of interpreter support.¹⁸ The evaluation framework should define what interactions the transplant candidate can have on the donor candidate's behalf. In domestic donation, the routine process at most centers is for the potential donor to call to initiate the donor candidate evaluation process – this process helps reduce conflict of interest and offers one indication that the candidate is making the decision to pursue evaluation. However, with international donors, initial contact may be difficult and the transplant candidate or their support person may attempt to be the spokesperson for the international donor, at least at the beginning of the process. Thus, the need to carefully confirm donor autonomy is particularly important. Ultimately, transplant centers will need to communicate directly with the international donor candidate.

Since donor testing completed outside of the United States will almost never be covered by U.S. payers, international donors will need to have access to their own healthcare to complete initial screening. Transplant programs may consider developing a mechanism to cover or provide age appropriate cancer and routine healthcare maintenance screening for international donor candidates to expedite the evaluation process. In addition, programs should consider establishing mechanisms to initiate care and communicate recommendations for problems newly diagnosed during the evaluation or donation prior to the donor returning to their homeland, to help ensure safe follow-up and care.

With permission of the donor candidate, it is advised to speak with the identified support in the country of origin and in the U.S., to help set expectations and confirm plan viability. Some coordination with the recipient may be warranted, as often the donor candidate will be housed with them while in the country. As part of prescreening and education, transplant teams should discuss a tentative timeline for staying in the United States with the donor candidate, allowing sufficient time for completion of evaluation, surgery, and recovery.

Logistics Planning

Recommendation #3: Transplant programs should be proactive in planning for logistical challenges associated with international living donor candidate care.

Develop a plan for overseas coordination of care: Facilitating international donor candidate evaluation requires significant coordination. Establishing a clear process grounded in the transplant program's evaluation guidelines can help to streamline care (Table 3). A process timeline may reflect the following: 1) The initial screening (~1–2+ weeks), 2) Preliminary medical testing and comprehensive psychosocial pre-screen (~1–3+ weeks), 3) Visa application assistance and coordination (~1–6+ months), 4) Scheduling and coordination of the comprehensive evaluation (~1–3+ weeks), 5) Evaluation, surgery and recovery (~3–6 months), 6) Follow-up.

Outline the timeframe of evaluation, surgery and recovery: Expectations regarding the timeframe of evaluation, surgery and postdonation care should be established early and communicated to the international donor candidate, intended recipient, and participating providers. Donor and recipient team collaboration may be essential to coordinate logistical planning.

Visa and letters of support: The majority of potential international donors will require a nonimmigrant visa (for temporary stay), and will need to apply for a visa through their local U.S. embassy or consulate generally located within their country of permanent residence. This can be a lengthy, expensive and challenging process, taking up to 6 months or more. It is important to be aware of the time involved in a visa application, and to encourage prescreened donor candidates to apply for a visa as early as possible.

Transplant centers may educate their donor candidates on the visa application process and the content most embassies require from visa applicants. Applicants commonly will be required to obtain a valid passport, apply online, schedule a visa interview, pay fees, gather documents, and appear for an in-person visa interview. The consular or embassy officer will often require demonstration of a reason for the visit, length of stay, evidence of funds to cover personal expenses, and clear intent to return to the country of origin (including social and/or economic ties). Applications are sometimes denied; multiple applications are costly and time consuming. The donor candidate should be advised to keep the transplant program abreast of the visa application status.

The transplant program may provide a letter to support the candidate's visa application, which can help document the intent of the visit and urgency of the request. The applicant

can submit this supportive documentation to the Consulate General or Embassy. Suggested content for a visa support letter is summarized in Table 4.

Schedule the evaluation and surgery: Upon obtaining a visa, the transplant program assists the international donor candidate in scheduling the full evaluation at the transplant center. The donor candidate will likely require familial support, including transportation and accompaniment to the appointments. Additionally, use of interpreters should be coordinated for the visits and teams should prepare for longer visits. Once in country, the process for the donor candidate will likely require continued momentum, as most visas are time-limited to 3–6 months. Close coordination between the donor candidate and the transplant center is necessary to schedule all required tests, consults, and ultimately surgery in a timely yet safe fashion. While in most cases when the donor candidate is approved, donation surgery occurs during the same U.S. visit as the evaluation, the candidate should be advised on the possible need for a return trip (e.g. if surgery is delayed based on donor or recipient candidate medical necessity, or in the context of KPD).

Postdonation follow-up: The transplant team may reach out to providers in home country to coordinate postdonation care and follow-up, and should verify contact numbers.

Comprehensive Evaluation

Recommendation #4: Upon successful entry to the United States, the donor candidate should complete a comprehensive evaluation based on the program evaluation guidelines with special emphasis on psychosocial, socioeconomic, ethical, and financial considerations.—The evaluation of the international living donor candidate will resemble the transplant program’s standard,^{19,20} with several tailored considerations. Education pertaining to pre-, peri-, and postdonation care and patient responsibilities should be provided in the donor candidate’s native language, and when possible, culturally competent.²¹ It is important to use a professional interpreter (independent of the family and recipient candidate), and account for additional time when scheduling the evaluation, consultations and tests.

Special emphasis should be given to family systems and dynamics, and assessment for the presence of coercion, undue pressure or financial motivation.^{12,22} Socioeconomic stability should be assessed, including review of patient’s lifestyle, occupation, confirmation of gainful employment and/or financial support from family. Potential financial implications of living donation, including impacts both within their country of origin and during stay in the United States, should be evaluated. Feasibility of prolonged stay in the United States during the evaluation and recovery process should be again discussed, including housing, transportation, linguistic/cultural barriers, financial aspects, and caregiver support.

A consultation with a transplant infectious disease specialist may be warranted to ensure proper screening for endemic infections in the potential donors’ country of origin. The psychosocial evaluation should focus on motivation, adequate emotional and concrete supports while staying in the United States, and understanding of the risks and benefits of donation, including the specific implications of being a non-U.S. resident for access

to care after donation. Transplant programs should develop strategies to protect against commercialism and coercion, especially among unrelated foreign donors.²³

Despite extensive pre-screening and preliminary medical testing, the international donor candidate may ultimately be declined as a donor. It is important to provide sufficient education and support to both the donor candidate and the family during this time, as all have invested a significant amount of time, energy and resources into the evaluation, and for continued protection of the donor as they often are dependent upon the recipient while in the United States. In addition, assurances about the option of confidential donation withdrawal should be explained carefully, as confidentiality practices may differ markedly in the donor's home country.

Postdonation Care and Follow-Up

Recommendation #5: The transplant program should outline a postdonation follow-up care plan and document the donor candidate's willingness and ability to comply with follow-up.—A plan for follow-up care in the donor's country of origin should be identified in anticipation that the donor may not be able to gain re-entry return to the United States for postdonation follow-up monitoring or care. Clearly, follow-up plans will have different implications for international donors from countries with well-established universal healthcare than for international donors from countries with rudimentary (if any) healthcare access. The transplant program should outline recommendations for long-term care to support the health and well-being of the donor, and should serve as a resource to address questions from primary care physicians after the donor's return to their country of origin.^{19 24} A plan should be developed to address both medical and psychosocial postdonation concerns.

From a program perspective, it is worth noting that OPTN policy-compliant donor follow-up was substantially lower for international living donors at 6, 12, and 24 months postdonation (2015 cohort: 45%, 33%, 36%, compared to 76%, 71%, 70% for domestic living kidney donors, $P < 0.001$).¹¹ Transplant programs, especially small volume programs, should be aware of the possible adverse impact of accepting international donors on the program's follow-up performance metrics.²⁵

Additional Considerations: Kidney Paired Donation

Recommendation #6: Being identified as an international donor candidate should not be a universal exclusion to participation in KPD, although we acknowledge barriers.—Review of national registry data by the authors demonstrates there were 46 international donors who participated in KPD from 2012-May 2018. While a precedent for including an international donor in KPD has been established, multiple challenges and considerations exist in enrolling an international donor into KPD. A primary concern relates to the of travel from the country of current residence to the United States when a potential match is identified, not only due to issues of travel time but also difficulties obtaining quick permission to reenter the country and costs. The lack of travel assistance from programs like the U.S. National Living Donor Assistance Center (NLDAC) as well as visa-related travel limitation make participation in KPD challenging. Internal swaps

compared to registry-based KPD participation may be easier to manage, but also carry similar burdens. In highly sensitized recipients where there is a need for preliminary HLA cross-matching, combined with short half-life for frozen/preserved donor cells, obtaining fresh blood samples in a timely manner poses unique challenges. We recommend that programs evaluate each case individually for feasibility and logistical considerations, and not automatically disqualify a potential pair with an international donor from participating in KPD.

The Global Kidney Exchange (GKE) proposed by Rees et al. raises a novel possibility of enrolling the combination of an ESKD patient from a developing country along with their willing living donor candidate to exchange with an incompatible pair in the United States, and deploying the funds saved by the expedited transplant of a U.S. ESKD patient to create the opportunity to transplant the economically disadvantaged international pair by paying for their travel, transplantation, immunosuppression and follow-up.^{26,27} Limitations and concerns related to this strategy includes the legality of GKE given each nation's unique transplantation laws, as well as concern for exploitation risk.²⁸ For example, in the U.S. NOTA explicitly prohibits the exchange of organs for "valuable consideration"; participation in standard KPD and coverage of travel for living donation have been deemed to be compliant with NOTA, but the GKE model includes coverage of additional expenses. The altruistic nature of exchange perhaps may be permitted both under the NOTA and Norwood Act, but requires careful deliberation.

Transplant program staffing and resource considerations

In our experience, the care of international donors is resource intensive. Anecdotally, these donor candidates may take twice to five times the amount of staff time as a local donor candidate. We posit international donor care may be a specialty area in which not all transplant programs will actively engage; those with many immigrant patients will probably field more inquiries from international donor candidates and thus find it worthwhile to develop protocols and guidelines. Centers with few or no international donors may also find such protocols helpful, or may choose to refer the occasional international donor inquiry to a center with protocols in place.

Recommendations for Future Research and Advocacy

Future work to improve the care of international living donor candidates may include defining and quantifying the resources required to conduct these evaluations, and assessing the feasibility and impact of establishing connections to foreign medical facilities for more efficient and direct care (Figure 2). Optimal relationships should begin in the prescreening stage and continue throughout postdonation recovery, in accordance with standard OPTN mandates. Developing strategies to support compliance with postdonation follow-up, including innovative approaches to care, such as telemedicine, web conferencing, text or other platforms, should be explored through research and advocacy. Future work should also explore strategies for optimizing the logistics related to participation of an international donor and U.S. recipient in KPD.

It can be challenging for potential donor candidates from certain countries to gain access to a visa for travel to the United States. Advocacy for the creation of a visa category specific to international donor candidates may help facilitate travel for donation. A tailored category may allow for closer support (financial, logistical, and/or language) while in the country, and enhance the ability to study and report on travel for living donation. Additionally, a specific international donor visa may address the need for greater flexibility to extend the stay or accommodate return visits as needed.

Costs associated with international donor evaluation and care in the country of origin are not currently covered, before or after donation. Future work should explore creating organizations or collaborating with pre-existing ones to assist with funding donation-related care. An example of a cost specific to the care of international donors is shipping services to send samples such as donor blood cells to the United States. Further, international donors who unfortunately develop ESKD may incur in substantial expenses if attempting to return to the United States to receive DDKT allocation priority. Therefore, mechanisms to facilitate, offset the cost and assure posttransplant care should be explored.

Summary

The evaluation of international living donor candidates is a resource-intensive process that raises key considerations for assessment of motivation, communication, logistics, and follow-up. Establishing transplant program guidelines, and allocating staff and training resources can improve efficiency and quality of care of this process. Ongoing research and advocacy efforts related to removing barriers and disincentives while optimizing the care of this unique group of living donors should be prioritized.

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Abbreviations:

AST LDCOP	American Society for Transplantation Live Donor Community of Practice
DDKT	deceased donor kidney transplantation
ESRD	end-stage renal disease
KPD	Kidney Paired Donation
LDKT	living donor kidney transplantation
NLDAC	National Living Donor Assistance Center
NOTA	National Organ Transplant Act
OPTN/UNOS	Organ Procurement and Transplantation Network/ United Network for Organ Sharing

PCP primary care provider

REFERENCES

1. U. S. Renal Data System. USRDS 2015 Annual Data Report: End-stage Renal Disease (ESRD) in the United States. Ch 7: Transplantation. Available at: https://www.usrds.org/2016/view/v2_07.aspx (Accessed: July 2, 2017). Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2016.
2. Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. *Am J Transplant* 2018.
3. Schnitzler MA, Skeans MA, Axelrod DA, et al. OPTN/SRTR 2016 Annual Data Report: Economics. *Am J Transplant* 2018;18 Suppl 1:464–503. [PubMed: 29292607]
4. OPTN (Organ Procurement and Transplantation Network)/UNOS (United Network for Organ Sharing). National Data Reports, Transplants by Donor Type, Latest Data <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/> (Access date: May 6, 2019).
5. Hart A, Smith JM, Skeans MA, et al. OPTN/SRTR 2017 Annual Data Report: Kidney. *Am J Transplant* 2019;19 Suppl 2:19–123. [PubMed: 30811893]
6. Al Ammary F, Bowring MG, Massie AB, et al. The changing landscape of live kidney donation in the United States from 2005 to 2017. *Am J Transplant* 2019.
7. Lentine KL, Mandelbrot D. Addressing Disparities in Living Donor Kidney Transplantation: A Call to Action. *Clin J Am Soc Nephrol* 2018;13:1909–11. [PubMed: 30429153]
8. Lentine KL, Mandelbrot D. Moving from Intuition to Data: Building the Evidence to Support and Increase Living Donor Kidney Transplantation. *Clin J Am Soc Nephrol* 2017;12:1383–5. [PubMed: 28818848]
9. Purnell TS, Luo X, Cooper LA, et al. Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014. *JAMA* 2018;319:49–61. [PubMed: 29297077]
10. LaPointe Rudow D, Hays R, Baliga P, et al. Consensus conference on best practices in live kidney donation: recommendations to optimize education, access, and care. *Am J Transplant* 2015;15:914–22. [PubMed: 25648884]
11. Al Ammary F, Thomas AG, Massie AB, et al. The landscape of international living kidney donation in the United States. *Am J Transplant* 2019.
12. Ambagtsheer F, de Jong J, Brammer WM, Weimar W. On Patients Who Purchase Organ Transplants Abroad. *Am J Transplant* 2016;16:2800–15. [PubMed: 26932422]
13. Danovitch GM, Chapman J, Capron AM, et al. Organ trafficking and transplant tourism: the role of global professional ethical standards—the 2008 Declaration of Istanbul. *Transplantation* 2013;95:1306–12. [PubMed: 23644753]
14. Lentine K, Henderson M, Rasmussen S, et al. Care of International Living Kidney Donor Candidates In The U.S.: A Survey Of Contemporary Experience, Practice & Challenges. *Am J Transplant* 2019;(ATC Abstract Issue).
15. Hartsock JA, Helft PR. International Travel for Living Donor Kidney Donation: A Proposal for Focused Screening of Vulnerable Groups. *Transplantation* 2019.
16. Tietjen A, Hays R, McNatt G, et al. Billing for Living Kidney Donor Care: Balancing Cost Recovery, Regulatory Compliance, and Minimized Donor Burden. *Curr Transpl Rep* 2019;(ePub).
17. OPTN (Organ Procurement and Transplantation Network)/UNOS (United Network for Organ Sharing). OPTN Policies, Policy 8: Allocation of Kidneys. <http://optn.transplant.hrsa.gov/governance/policies/> (Accessed: May 6, 2019).
18. Mitchell M, Kan L. Digital Technology and the Future of Health Systems. *Health Syst Reform* 2019:1–8.
19. Lentine KL, Kasiske BL, Levey AS, et al. KDIGO Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors. *Transplantation* 2017;101:S1–S109.

20. OPTN (Organ Procurement and Transplantation Network)/UNOS (United Network for Organ Sharing). OPTN Policies, Policy 14: Living Donation. <http://optn.transplant.hrsa.gov/governance/policies/> (Accessed: May 6, 2019).
21. Gordon EJ, Lee J, Kang RH, et al. A complex culturally targeted intervention to reduce Hispanic disparities in living kidney donor transplantation: an effectiveness-implementation hybrid study protocol. *BMC Health Serv Res* 2018;18:368. [PubMed: 29769080]
22. Martin DE, Van Assche K, Dominguez-Gil B, et al. Prevention of Transnational Transplant-Related Crimes-What More Can be Done? *Transplantation* 2016;100:1776–84. [PubMed: 26528771]
23. Martin DE, Van Assche K, Dominguez-Gil B, et al. A new edition of the Declaration of Istanbul: updated guidance to combat organ trafficking and transplant tourism worldwide. *Kidney international* 2019;95:757–9. [PubMed: 30904066]
24. Cheng XS, Glasscock RJ, Lentine KL, Chertow GM, Tan JC. Donation, Not Disease! A Multiple-Hit Hypothesis on Development of Post-Donation Kidney Disease. *Curr Transplant Rep* 2017;4:320–6. [PubMed: 29201600]
25. OPTN (Organ Procurement and Transplantation Network)/UNOS (United Network for Organ Sharing). OPTN Policies, Policy 18: Data Submission Requirements. <http://optn.transplant.hrsa.gov/governance/policies/> (Accessed: May 6, 2019).
26. Brunner R, Fumo D, Rees MA. Novel Approaches to Expanding Benefits from Living Kidney Donor Chains. *Curr Transpl Rep* 2017;4:67–74.
27. Bozek DN, Dunn TB, Kuhr CS, et al. Complete Chain of the First Global Kidney Exchange Transplant and 3-yr Follow-up. *Eur Urol Focus* 2018;4:190–7. [PubMed: 30145113]
28. Delmonico FL, Ascher NL. Opposition to irresponsible global kidney exchange. *Am J Transplant* 2017;17:2745–6. [PubMed: 28834177]



Figure 1. Programmatic considerations for the care of international living donors and donor candidates.

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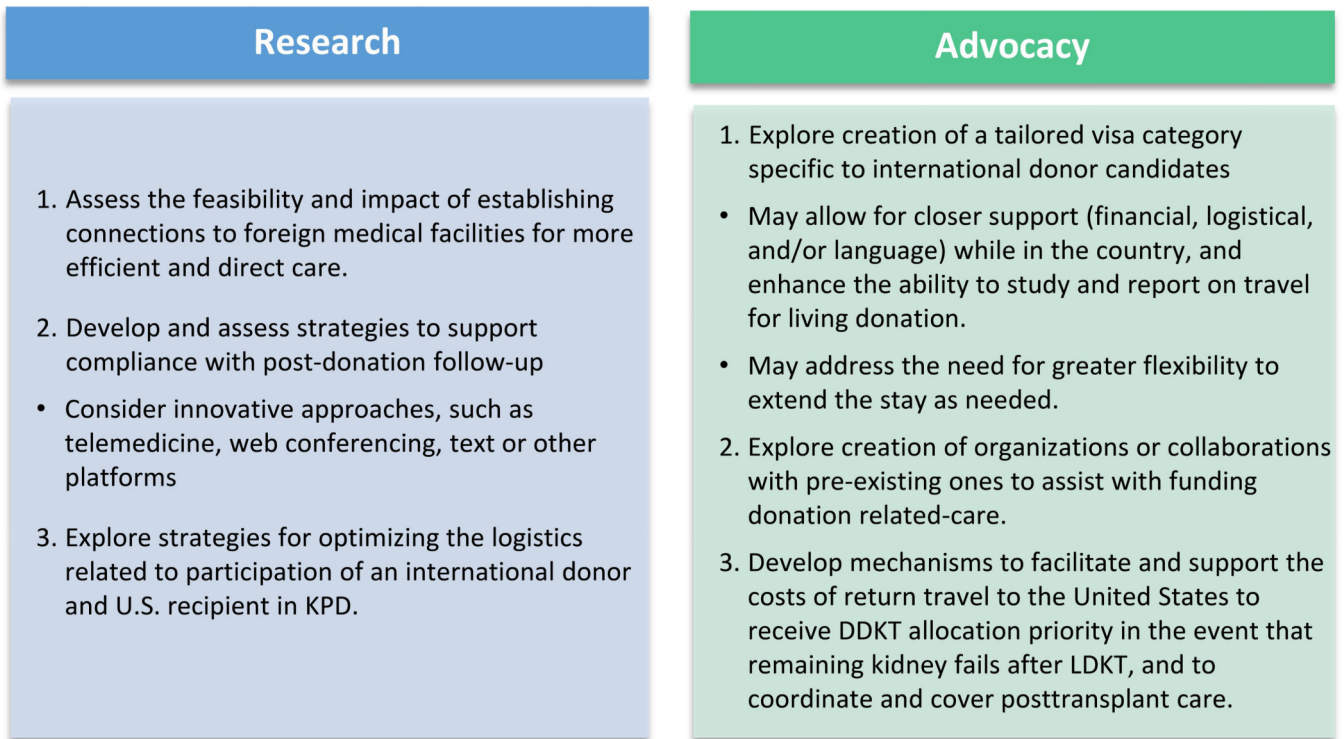


Figure 2.
Research and advocacy recommendations to advance the care of international living donors.

Table 1.

Unique challenges and considerations in evaluation and care of international living donors

Challenge/ Consideration	Description	Recommended Approaches
Risk of exploitation/ inducement	<ul style="list-style-type: none"> Power and resource differentials between international donor candidates and US recipients are common. Donor candidates may have limited resources, limited access to medical care, & may be at risk of pursuing donation in the hopes of remuneration or migration opportunities. 	<ul style="list-style-type: none"> Conduct early assessment of relationship between donor and recipient, and of donor motivation and autonomy. Consider a center-specific guideline defining required types/ duration of relationship between donor and recipient.
Communication barriers	<ul style="list-style-type: none"> Costs of international calling, time zone differences, limited access to email, & linguistic/literacy barriers make the donation process challenging Despite the ease, the intended recipient cannot be relied upon to be the only communication conduit due to risks of conflict of interest. 	<ul style="list-style-type: none"> Provide written education via email or mail if calling is impossible; materials should be translated into preferred languages. Request medical records and be prepared to have these translated.
Logistics barriers	<ul style="list-style-type: none"> Travel and lodging are expensive. Acquiring a Visa for donation-related travel may be difficult, costly and time-consuming. The unpredictability of KPD may be particularly challenging. 	<ul style="list-style-type: none"> Complete as much screening/ evaluation as possible prior to US travel. Provide standard documentation about Visa application process in the context of living donation. Consider a program-specific policy addressing the feasibility of KPD for international donors.
Donor follow-up barriers	<ul style="list-style-type: none"> International donors are unlikely to be able to receive follow-up care at a U.S. center. Access to medical care in their home country, may or may not be available or include access to specialty services (such as nephrology). 	<ul style="list-style-type: none"> Conduct early assessment of donor candidate access to care. In addition to verbal report, request medical records as available and complete pre-screening in their home setting (serving the dual purpose of demonstrating access & ascertaining current health status). Educate early in the process about follow-up requirements. Identify a plan for both routine follow-up and access to care in the case of complications.

Table 2.

Recommendations for a systematic approach to the evaluation and care of international living kidney donors, grounded in development and implementation of programmatic guidelines.

<p>1. Program Guideline Development</p> <ul style="list-style-type: none"> • Transplant programs should develop guidelines for the evaluation and selection of international living donors that promote patient understanding, consistency, accountability and safety. • The guidelines should address: <ul style="list-style-type: none"> • Ethical considerations • Eligibility criteria • State/county specific considerations • Screening questions • Assistance with Travel Visa • Communication process between team, potential donor and transplant candidate • Costs of donor work-up covered under recipient’s insurance • Plan of care to address medical issues identified during the evaluation process • Education • Follow-up care
<p>2. Pre-screening</p> <ul style="list-style-type: none"> • Staff: In addition to the Living Donor Coordinator, programs may choose to involve social workers, ILDAs, psychologists / psychiatrists, and/or ethicists at this stage. • Content: <ul style="list-style-type: none"> • Review of donor candidate’s medical (including blood type if available), surgical, psychosocial, and family history to evaluate for program’s exclusionary criteria • Evaluate donor candidate’s relationship to the intended recipient • Assess for: <ul style="list-style-type: none"> • Presence of coercion, undue pressure or financial motivations • Complexity of family systems and dynamics • Evidence of prior altruistic behavior • Communication Issues: <ul style="list-style-type: none"> • Availability of reliable communication options • Availability of qualified interpreters • Time differences • Feasibility of entering and staying in US during evaluation process • Comprehension of costs of evaluation and donation <ul style="list-style-type: none"> • Overview of possible out-of-pocket expenses • Lack of U.S. government-supplied supportive resource eligibility (NLDAC) given foreign status • Gainful employment and/or support from family • Plan and intent to return home • Additional consideration during screening: <ul style="list-style-type: none"> • Evaluation of recipient’s ABO type and titer if applicable • Donor/Recipient interest in KPD
<p>3. Logistics Planning (see Table 3)</p> <ul style="list-style-type: none"> • Develop a plan for overseas coordination of care • Visa letter of support • Outline the timeframe of evaluation, surgery and recovery <ul style="list-style-type: none"> • Clarify donor expectations while in U.S. and readiness for the challenges of being abroad in a foreign country • Establish realistic expectations related to post-operative follow-up, complications, ability to return to US for medical care, and ESKD care outside of U.S. <ul style="list-style-type: none"> • Schedule the evaluation
<p>4. Comprehensive Evaluation</p> <ul style="list-style-type: none"> • Initial evaluation at center largely does not differ from local candidates, but warrants emphasis on the following elements: <ul style="list-style-type: none"> • Psychosocial / Socioeconomic / Motivation / Financial • Given lack of insurance in U.S., some routine medical tests (PAP, colonoscopy) may require coverage/support
<p>5. Postdonation Care and Follow-Up</p> <ul style="list-style-type: none"> • Assess patient commitment to participate in donation-related follow-up and general healthcare maintenance • Develop plans for: <ul style="list-style-type: none"> • Obtaining medical care and follow-up in place of residence • Addressing post donation psychosocial concerns • Managing communication challenges
<p>Additional Consideration for Donors in Kidney Paired Donation Programs:</p> <ul style="list-style-type: none"> • Strength of donor/recipient relationship • Possibility of donor fatigue (potentially more prolonged process)

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- Bridge donor
- Travel Visa extension / Renewal
- Availability and affordability of extended stay in U.S.
- Risks unique to kidney paired donation
 - Donor may donate but recipient may not receive an organ
 - Importance of trust in the U.S. medical/transplant system

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Logistics planning for the international donor candidate evaluation and related timeframes.

Table 3.

Phase	Estimated Timeframe	Considerations
The Initial Screening	1-3+ weeks	<ul style="list-style-type: none"> • Communication may initially be with the recipient/family • Accessible and reliable communication methods • Time zone differences • Language/cultural barriers • Early discussions around blood type/ABO
Preliminary Medical Testing and Comprehensive Psychosocial Prescreen	1-6+ weeks	<ul style="list-style-type: none"> • International donor educational packet and information instructions regarding next steps/required tests sent – if by mail this can be expensive and timely • Donor candidate often pays fee, has to travel far from home to undergo a physical and/or required medical testing • Language barriers, records may not be in English – if sent by mail can be expensive and timely
Visa Application Assistance and Coordination	1-6+ months	<ul style="list-style-type: none"> • Donor team recommends initiation of visa application process • Donor candidate may need to obtain a passport – this can be expensive and timely • Visa application process often requires travel outside of home town and can take weeks to months to be scheduled for final in-person interview • Donor candidate may be declined and require reapplying • Donor team may be asked to speak with Embassy/Consulate office directly • The donor candidate updates transplant program on visa application status and outcome.
Scheduling the Comprehensive Evaluation	1-3+ weeks	<ul style="list-style-type: none"> • Coordination for donor to make long-term arrangements to leave home and travel to United States • Donor candidate will likely require familial support throughout the evaluation process (transportation, accompaniment to the appointments)
Evaluation, Surgery, Postdonation	3-6 months	<ul style="list-style-type: none"> • Most visas are valid for 3-6 months • Close coordination between the donor candidate and the transplant center in order to schedule all required tests, consults, and surgery
Follow-Up	2 years for OPTN mandate	<ul style="list-style-type: none"> • Timing of coordination to obtain required follow-up testing • Coordination with home country/medical facility • Beyond the 2-year OPTN follow-up mandate, lifelong primary care-based follow-up should be encouraged, with the transplant center as a resource for questions and recommendations

Table 4.

Visitor/Travel Visa Resources, Categories and Requirements

U.S. DEPARTMENT OF STATE – BUREAU OF CONSULAR AFFAIRS RESOURCES:	
<ul style="list-style-type: none"> • Visa Wizard, a tool which assists foreign citizens in pursuit of a travel to the United States: https://travel.state.gov/content/travel/en/us-visas/visa-information-resources/wizard.html • Detailed Overview of the Travel/Visitor Visa requirements: https://travel.state.gov/content/travel/en/us-visas/tourism-visit/visitor.html 	
VISA CATEGORY	
<ul style="list-style-type: none"> • Nonimmigrant Visas - For temporary travel to the United States • Immigrant Visas - For permanent residency in the United States 	
COMMON LIVING DONOR VISA TYPE:	REQUIREMENTS FOR APPLICATION:
B-2: Visitor Visa (Tourism) – Medical Treatment	<ul style="list-style-type: none"> • Online Visa application • Schedule an Interview • Payment of non-refundable visa application fee • Documents: <ul style="list-style-type: none"> • Passport • Nonimmigrant Visa application • Application free payment receipt • Photo • Additional documents may be requested, including: <ul style="list-style-type: none"> • Evidence of the purpose of the trip (i.e. Living Donation) • Intent to depart the United States after trip. • • Ability to pay all costs of the trip, including medical and living expenses while in the United States.
VISA SUPPORT LETTER: SUGGESTED CONTENT	
<ul style="list-style-type: none"> • Donor candidate’s legal name and contact information • Recipient’s legal name and the nature of the donor/recipient relationship • Purpose of the visitor visa request, including the length of stay, and timeframe of the evaluation, surgery and recovery • Financial arrangements for the donor candidate evaluation and donation, including affordability of travel, medical and living expenses in the United States • If available, an explanation of blood type compatibility with the recipient • If a caregiver companion is required, the letter should include the identified caregiver’s name, date of birth, and reason why he/she is encouraged to accompany the donor candidate during the evaluation and donation process. • Recommended postdonation follow-up 	