



May 1, 2024

Thomas J. Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education (ACGME) 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Dr. Nasca:

On behalf of the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) thank you for assessing and enhancing the quality of resident and fellow physicians' education. Enclosed is a joint proposal from ASN and AST to request that the ACGME Board of Directors accredit a sub-subspecialty fellowship in adult Transplant Nephrology.

Currently, there are more than 250,000 people with a functioning kidney allograft and approximately 90,000 waitlisted people awaiting kidney transplants, with a growing number added to the kidney transplant waitlist every year. For the vast majority of people living with kidney diseases, a kidney transplant is the best, safest, therapy. It has been estimated that in the US, between 800 and 1,400 adult transplant nephrologists currently provide clinical care to kidney transplant patients at 231 active kidney transplant centers. Formal advanced training in adult transplant nephrology is currently obtained by completing a year of clinical training in one of the 66 US programs that have been accredited as meeting the detailed criteria set forth by the AST via the Transplant Nephrology Fellowship Training Accreditation Program (TNFTAP).

The enclosed application explains why the clinical practice and focus of adult transplant nephrology is distinct from that of general clinical nephrology. The program requirements for transplant nephrology fellowships accredited by TNFTAP and letters of endorsement from nine other organizations in the transplant and kidney communities are also included.

ASN and AST believe that ACGME accreditation will ensure that all transplant nephrology training programs in the United States are uniformly providing the highestquality possible training experience, thus equipping trainees to provide the highestquality possible patient care to people with kidney diseases who have or would benefit from a kidney transplant. Again, thank you for the opportunity to submit this application. To discuss this application, please contact ASN Strategic Policy Advisor to the Executive Vice President Rachel Meyer at <u>rmeyer@asn-online.org</u>.

Sincerely,

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### New Specialty/Subspecialty Proposal Template

Proposals for new specialties/subspecialties must include an official letter from the requesting society or program director association, as well as approval from the corresponding board. Proposals must address items A through H, listed below, per <u>ACGME</u> <u>Policies and Procedures</u>.

### Subject: 12.00 Procedures for Designation of Specialties, Subspecialties, and Subsubspecialties for which Accreditation will be Offered Section: 12.20 Criteria for Designation of a Subspecialty or Sub-Subspecialty for which Accreditation will be offered

The ACGME accredits programs in subspecialties and sub-subspecialties when it can be demonstrated that the clinical care of patients and their safety will be improved through accreditation of education and training in that discipline.

Proposals for designation of a subspecialty or sub-subspecialty for which accreditation will be offered must provide documentation on the professional and scientific status of the new subspecialty or sub-subspecialty, including at minimum, evidence of the following:

# a) the clinical care and safety of patients will be improved through the recognition of the discipline

Kidney transplantation is the treatment of choice for many patients with kidney failure. As compared to either conservative management without any kidney replacement therapy or dialysis, a commonly used kidney replacement therapy option for people with kidney failure, kidney transplantation offers better quality of life and lower mortality.<sup>1,2</sup> Transplantation also substantially reduces longer-term, annual health-care expenditures compared to dialysis. Currently, there are more than 250,000 patients with a functioning kidney allograft and approximately 90,000 waitlisted patients awaiting kidney transplants, with a burgeoning number added to the kidney transplant waitlist every year. It is estimated that there are additionally tens of thousands of patients with advanced kidney diseases currently in referral or still undergoing evaluation for a transplant who are not yet on the waiting list. In 2022, more than 40,000 patients were added to the kidney to the kidney waitlist and more than 25,000 received a kidney transplant.

The Advancing American Kidney Health Initiative (AAKHI), a Presidential Executive Order signed in 2019, aims to double the number of kidney transplants by 2030, creating a need for additional transplant-trained nephrologists to help care for them.<sup>3,4</sup> In 2023, the U.S. Department of Health and Human Services (HHS) announced the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative—made possible by the United States Congress' enactment of the Securing the U.S OPTN Act in 2023—to modernize our nation's transplant system and improve its performance so that more Americans can access a kidney transplant.<sup>5</sup> More recently, OPTN announced a goal of achieving 60,000 "successful, lifesaving deceased donor transplants annually in the U.S. by the end of 2026." That number represents a 58% increase in deceased donor transplants over the next three years.<sup>6</sup> These federal policy initiatives reflect the fact that for the vast majority of patients, a kidney transplant is the best and safest therapy—and increasing the number of patients who benefit

from this treatment will require recognition and growth of the discipline of transplant nephrology by training clinicians to provide the pre-requisite specialized care. Ensuring the highest level of training for transplant nephrologists through the gold standard of Accreditation Council for Graduate Medical Education (ACGME) accreditation is an important step towards this national goal.

The management of kidney transplant patients is complex, as they require special care by nephrologists who have expertise in assessing transplant candidates and candidates for living kidney donation, counseling patients about paired-kidney exchange and ongoing changes in national allocation policy, and ensuring donor and recipient candidates remain transplantready. Transplant nephrologists also work with particularly complex transplant candidates. such as highly immunologically sensitized individuals with high titers of pre-existing anti-Human Leukocyte Antigen (HLA)-antibodies that may make it difficult to find a compatible donor kidney, as well as help patients weigh the benefits and risks of accepting less conventional kidneys, such as from Hepatitis C Virus (HCV)-infected donors. Collectively, these foregoing efforts require that transplant nephrologists understand immunology and organ rejection, have familiarity with peri-operative complications-including transmission of diseases from donors and recurrence of native kidney diseases—and can safely manage the long-term effects of chronic immunosuppression. Immunosuppression and its complications pose substantial medical risks for patients. Transplant nephrologists are uniquely positioned and trained to anticipate, prevent, and potentially manage harmful events in this patient population. This specific expertise has helped to contribute to improved kidney transplant patient outcomes over the past two decades.

The development of this skill set necessitates additional post-subspecialty experience, almost always occurring as formal transplant nephrology sub-subspecialty fellowship training beyond the basic transplant education provided by the general nephrology fellowship. The emergence of xenotransplantation (the transplantation of genetically modified organs from animals into humans) and cell therapy in the not-so-distant future will require even more specialized training.<sup>7</sup>

Transplant nephrology training is distinct from and builds upon training obtained during a general nephrology fellowship, which contains some transplant exposure (two months over the two year fellowship) but is mostly focused on the management of patients with native kidney diseases, patients with acid-base and electrolyte disorders, and patients receiving dialysis. In recognition of this need, both the American Society of Transplantation (AST) and the American Society of Nephrology (ASN) supported and established transplant fellowship criteria, as far back as 1998.

"The transplant nephrologist-patient relationship is the foundation of kidney transplant patient care. Due to the complexity of patient care issues, transplant nephrologists are the only ones that I trust with the nuances of my care. Accreditation for transplant nephrology would further underscore that trust for patients like me." — 19-year post-transplant pre-emptive kidney transplant recipient

### References

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- 3. <u>https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-advancing-american-kidney-health/</u>
- 4. <u>https://aspe.hhs.gov/sites/default/files/private/aspe-files/262056/advancingamericankidneyhealth.pdf</u>
- 5. https://www.hrsa.gov/optn-modernization/march-2023
- 6. <u>https://optn.transplant.hrsa.gov/news/optn-task-force-sets-goal-of-achieving-60-000-</u> <u>transplants-by-2026/</u>
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- b) the existence of a body of scientific medical knowledge underlying the subspecialty or sub-subspecialty that is (i) clinically distinct from other areas in which accreditation is already offered, and (ii); sufficient for educating individuals in a clinical field, and not simply in one or more techniques

The clinical practice and focus of adult transplant nephrology is distinct from that of general clinical Nephrology. Based on extensive literature and sub-subspecialty-specific clinical practice guidelines, transplant nephrology is dedicated to the evaluation of potential kidney, kidney pancreas, pancreas alone, and multi-organ (including kidney) transplant candidates and their subsequent management, both leading up to, and after transplantation. Successful evaluation of potential candidates and maintaining their transplant readiness on the waiting list to optimize the success of transplantation is a key pre-transplant component of transplant nephrology. Evaluation of potential living kidney donors and assessment of potential risk and appropriateness of kidney donation is also an inherent part of transplant nephrology.

In contrast, two-year general nephrology training focuses predominantly on acquisition of expertise in renal physiology and pathophysiology, care for acute and chronic native kidney diseases, and mechanics and delivery of dialysis modalities. Though a two-month exposure (minimum ACGME requirement) to transplant care and the fundamentals of transplant medicine is requisite in general nephrology fellowship, the duration and volume of encounters is insufficient to develop the proficiency necessary for comprehensive practice of kidney transplant medicine. General nephrologists historically have participated in the long-term care of stable, established transplant patients, but even this paradigm is becoming less common as the sophistication of transplant care has evolved.

Post-transplantation, the management of immunosuppression, and the attendant side effects and risks are the primary focus in transplantation. Immunosuppression management is nuanced and based on the immunological profile of the recipient, the degree of HLA-matching, and the underlying disease of the recipient. Management of side effects of immunosuppression agents requires a detailed understanding of the individual medications, the pharmacology and drug interactions of those agents, as well as the risks of malignancy and infection associated with chronic immunosuppression. The infectious disease risks in the transplant recipient need to take into consideration the donor organ characteristics, the geographic location of the donor and the recipient, the pre-transplant infectious disease serologic status of the recipient, as well as the timing since transplant. Kidney transplant recipients also have unique needs related to COVID-19, including experiencing different immune responses to COVID-19 vaccines than the general population and benefitting from variations in their immunosuppressive drug regimens when affected by COVID-19: these and other COVID-19-related issues are best managed by a transplant nephrologist who can ensure patients are provided with accurate information and appropriate, evidence-based care.<sup>1</sup> In addition, malignancy screening and management in transplant recipients can be a delicate balance between the treatment of a malignancy and the adjustment in immunosuppression that is required to optimize successful treatment of the malignancy and preservation of renal function if possible. Finally, at the 129 US transplant centers certified to perform pancreas transplants (either combined with a kidney or as a pancreas alone), post-transplant medical management primarily falls to transplant nephrologists.

Currently, formal advanced training in adult transplant nephrology is obtained by completing a year of clinical training in a program that has been certified as meeting the detailed criteria set forth by the American Society of Transplantation via the Transplant Nephrology Fellowship Training Accreditation Program (TNFTAP).<sup>2</sup> The requirements set forth by this accrediting body are quite proscriptive and distinct from the training acquired during general nephrology fellowship. The program under which the individual is trained is accredited by the AST Transplant Nephrology Fellowship Training Accreditation Program (TNFTAP; see Appendix 1), but the individual is not. ASN and AST believe there would be great value in having a single accreditation agency (ACGME), as it would be well-positioned to better align the requirements for both general nephrology and transplant nephrology training, which today are proscribed by two separate entities (ACGME and the TNFTAP).

In addition, OPTN rules require that an individual seeking a position as a "primary physician" at an adult kidney transplant center have either completed adult transplant nephrology fellowship training in a fellowship, or otherwise obtained clinical transplant experience or training beyond the ACGME requirement for general nephrology training of two months of exposure to transplantation, as described on pages 87 – 97 of OPTN bylaws.<sup>3,4</sup> Transplant nephrologists who train in ACGME accredited-transplant nephrology training programs would meet these OPTN standards and no changes would be necessary to the OPTN rules.

A primary care physician can provide care to a CKD patient, but a specialist, like a nephrologist, has more knowledge and insight about the specifics of kidney disease. A nephrologist can care for a transplant patient, but a transplant nephrologist has a different skill-set about kidney health, transplantation barriers and the overall health of a newly transplanted patient. — 9-year kidney transplant recipient

References

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- 2. Moe, S. M., et al. The Importance of Transplant Nephrology to a Successful Kidney Transplant Program. Clin J Am Soc Nephrol 17(9):1403-1406.
- 3. https://optn.transplant.hrsa.gov/media/lgbbmahi/optn\_bylaws.pdf

## 4. <u>https://www.acgme.org/globalassets/pfassets/programrequirements/148\_nephrology\_2023</u> .pdf

# c) the existence of a sufficiently large group of physicians who concentrate their practice in the proposed subspecialty or sub-subspecialty

The number of adult transplant nephrologists practicing in the United States is not well documented. It has been estimated that between 800-1,400 currently provide clinical care to kidney transplant patients. This estimate is based on 33% of 4,200 members of the AST self-reporting nephrology to be their primary specialty (personal communication with the AST, January 15, 2020).<sup>1</sup> As of 2021, there were over 250,000 kidney transplant recipients according to the USRDS 2023 annual report with a functioning kidney allograft, and this number continues to grow.<sup>2,3,4</sup> Additionally, there are more than 90,000 candidates awaiting a kidney transplant on the waiting list who require active management to ensure they remain medically acceptable and ready for transplant.<sup>5,10</sup> It is estimated that there are also tens of thousands of patients in the referral and evaluation phases, not yet listed. Thus, it is important that we strive to ensure our workforce is trained to care for this patient population that spans the spectrum of transplant care across 231 active kidney transplant centers in the United States.

Furthermore, transplant nephrologists evaluate pancreas transplant candidates for pancreas transplant alone, pancreas after kidney transplant, or simultaneous kidney and pancreas transplant and provide care to these patients after transplantation. There are approximately 1,000 pancreas transplants performed annually and the prevalent population of patients with a pancreas transplant is around 15,000. Currently, there are approximately 2,800 patients waiting for any form of a pancreas transplant on the waiting list. The proportion of patients with type 2 diabetes on the waiting list is around 22% and many of these are eligible candidates for a kidney and pancreas transplant; these candidates also need a special evaluation process.<sup>9</sup>

Organ transplant candidates and recipients are increasingly older and more medically complex with multiple comorbidities.<sup>6,7</sup> The delivery of kidney transplant care to this expanding population is elaborate and usually involves a multidisciplinary transplant team and care coordination between the transplant and community providers. Central to this care is the transplant nephrologist, a nephrologist subspecialized in the field of kidney transplantation through the completion of a formal transplant nephrology fellowship or by gaining transplant expertise through a focused practice in this area. Transplant nephrologists commonly affiliate with transplant institutes or centers, along with academic appointments in medicine or surgery.

With the growth of the kidney transplant patient population and the increasing complexity of both patients and the landscape of transplant care delivery, most transplant nephrologists now solely engage in the clinical practice of transplant medicine. The clinical care of transplant patients involves not only face-to-face encounters and telephonic counseling of patients, but also non-patient-facing activity, such as reviewing medical records and laboratory testing, answering electronic messages, and providing remote consultation for local providers. In addition, transplant nephrologists may take on various educational or administrative roles as part of an academic institution or a transplant center.

The typical responsibilities of a transplant nephrologist through the phases of kidney transplant care can be divided into three phases: pretransplant, at transplant, and after

transplant. Outlined herein are the responsibilities of the transplant nephrologist during each phase.<sup>1</sup>

In the pretransplant phase, the transplant nephrologist focuses on the evaluation of candidates with advanced CKD (estimated glomerular filtration rate  $\leq 25 \text{ mL/min/1.73 m}^2$ ) or end-stage kidney disease (on chronic dialysis). These patients typically are referred by primary nephrologists to the transplant center for a transplant evaluation. The transplant nephrologist primarily oversees the medical workup to ensure that candidates do not have a contraindication to transplant and that they are medically optimized. The transplant nephrologist is also responsible for counseling candidates on the organ allocation process and individualized pathways to successfully getting transplanted, including the spectrum of both living and deceased donor transplant options.

Ultimately, the decision to approve a candidate for listing at a transplant center falls on a kidney transplant recipient selection committee, of which the transplant nephrologist is a key member. Once approved, a candidate may be registered on the kidney transplant waiting list. Because the health status of candidates on the waiting list may change, the transplant center must be in constant communication with local providers to remain updated. This is particularly relevant for patients that don't have potential live donors as they could wait up to 6-8 years before getting a deceased donor organ offer. The transplant nephrologist plays an important role in performing regular waitlist management visits, reviewing records, requesting additional testing, and determining if candidates remain suitable for transplantation.

During the transplant event review of "organ offers" and the decision to accept or reject a kidney usually falls on the transplant surgeon, with the transplant nephrologist providing guidance when medical expertise is required. Those candidates with an available kidney, whether from a living or deceased donor, then undergo a preoperative medical and surgical evaluation as a "final check" before transplantation.

After transplant, the posttransplant phase can generally be divided into the immediate postoperative period, 90 days to 1 year after transplant, and > 1 year after transplant. During the immediate postoperative period, collaborative care is provided by the transplant surgical and medical teams, which includes perioperative medical care, active titration of immunosuppression, and administration of infective prophylaxis. The transplant nephrologist is primarily responsible for kidney replacement therapy in the setting of delay in the recovery of kidney transplant function. During the early post-transplant period, there are frequent follow-up visits, typically 1-2 times per week, and recipients are monitored closely by the transplant team.

In addition to the management of immunosuppression and infection prophylaxis, the transplant nephrologist also manages electrolyte and acid-base disorders, hypertension, metabolic bone disease, posttransplant diabetes, and cardiovascular complications, if any. Other aspects of care may also include immune monitoring in the form of screening for donor-specific antibodies and performing protocol biopsies and screening or monitoring for infections such as BK virus or cytomegalovirus. Once a recipient is stable, usually occurring 6 months to a year after transplant, and without complications such as acute rejection or an opportunistic infection, the patient can usually transition to stable long-term care delivered by the referring primary nephrologist. Ideally, there is a direct communication or "hand-off" from the transplant team to the primary nephrologist regarding the transition of care after transplant and a

discussion of specific posttransplant issues including the clinical management protocol. The amount of responsibility that a referring primary nephrologist takes on can be highly variable.

The model for delivery of long-term kidney transplant care varies among transplant centers and the communities that they serve – ranging from (1) transplant nephrologist primarily, (2) shared care between transplant nephrologist and referring nephrologist, and (3) referring nephrologist primarily. Anecdotally, the most prevalent is the transplant nephrologist-primary model where transplant nephrologists follow posttransplant recipients long-term and assume primary kidney disease management of the recipient. In this model, the referring nephrologist has a limited role in caring for the recipient unless the recipient becomes acutely ill and requires local care.

Additional aspects of care related to kidney transplantation include:

- Evaluation, counseling, and care of living kidney donor candidates.
- Management of infections and malignancies in the context of transplant immunosuppression management requires careful coordination of care with the infectious diseases and oncology teams. Providing longitudinal care as comanagement during the treatment and follow-up phases of these disease processes is vital to achieving favorable outcomes.
- Providing guidance on vaccination, including COVID-19 vaccination
- Continued management of cardiovascular and metabolic complications (such as diabetes) in conjunction with cardiovascular teams is essential, given that these complications are highly prevalent in the transplant recipients and major risk factors for mortality and morbidity.
- Post-transplant metabolic bone disease and fractures, due to chronic immunosuppression (e.g. corticosteroids) and pre-existing CKD and/or dialysisrelated disturbances in bone-mineral metabolism. Coordination of care and follow-up along with orthopedics and endocrinology become an integral part of the care of the transplant recipients.
- Women's health considerations, such as contraception, planned pregnancy and delivery, are life events that transplant nephrologists provide medical guidance for, often in coordination with the obstetrics and gynecology teams, to ensure mother and baby can get through pregnancy as safely as possible.
- Terminal illness and end-of-life decisions often fall to the transplant nephrologist, reflecting the long-standing relationships that patients form with their transplant providers. High-quality decisions require coordination of care in tandem with the palliative care teams.
- Given the aging nature of the eligible transplant population, transplantation in the context of the greater comorbidity burden in this population as well as special considerations associated with immunosuppression management in the elderly requires additional skill sets unique to the transplant nephrologist in the management of long-term post-transplant care in this vulnerable population.
- Care of patients with a pancreas transplant, for which all of the preceding aspects of care must be considered.
- Care of non-kidney solid organ transplant recipients with acute kidney injury or chronic kidney disease. Chronic kidney disease occurs in at least half of all non-kidney organ recipients as a result of underlying comorbidities or drug nephrotoxicity. Depending on center and local practice, these responsibilities may fall on either the transplant nephrologist, the primary nephrologist, or both.

"As a transplant recipient who is grateful to be living with the precious life-saving gift of a kidney, it must be protected at all costs, and that includes having a well-trained transplant nephrologist manage my post-transplant care." — 17-year post-transplant kidney transplant recipient

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# d) the existence of national medical societies with a principal interest in the proposed subspecialty or sub-subspecialty

ASN and AST have a principal interest in the sub-subspecialty of adult transplant nephrology and recognize that kidney transplantation is the best form of kidney replacement therapy for the majority of individuals with kidney failure. Both societies recognize the need for trained transplant nephrologists.

The sub-subspecialty integrates knowledge and skills that are common to all of organ transplantation. This includes comprehension and insight into organ allocation policy, an understanding of, and ability to control the alloimmune response, diagnosis, and treatment of

rejection, preventing and managing immunosuppression-related side effects (e.g. infections, malignancies and metabolic complications) and awareness of potential drug-drug interactions. Additionally, the sub-subspecialty requires knowledge and skills specific of general nephrology, including but not limited to assessment of kidney function and acute kidney injury, diagnosis and treatment of recurrent diseases assessment of dialysis need and ability to provide it, recognition of a failing allograft and its comorbidities, and to assess eligibility of potential kidney transplant candidates and living kidney donors.

As an illustration of ASN's recognition of the importance of transplant nephrology as a separate area of expertise, ASN's annual meeting (ASN Kidney Week) has a designated Transplant Nephrology Track. The ASN Kidney Week sessions that focus on transplant nephrology are developed by transplant nephrologists, reflecting their specialized knowledge in transplant. Furthermore, as part of the annual ASN Kidney Week pre-meeting, ASN and AST offer a day-long course on kidney transplantation targeted to the non-transplant nephrologist. The rationale behind the day-long course is that the transplant material covered during the meeting is unique to the transplant field and not well understood or known by nephrologists who have not done additional training in transplant nephrology, with the goal of enabling general nephrologists to not only provide basic care to transplant recipients but also to recognize when referral to transplant nephrology is most appropriate. Of note, this one-day course is not a substitute for fellowship training focused on transplant nephrology and immunology.

At the annual AST meeting, the American Transplant Congress, sessions are identified that are of interest to transplant nephrologists, as clinical presentation and management differ between transplant nephrology, transplant hepatology, transplant pulmonary, and transplant cardiology.

The American Journal of Transplantation, the official journal of the American Society of Transplantation, is widely read by and of interest to transplant nephrologists and not general nephrologists, as the topics are geared towards transplant nephrologists and transplant surgeons. The American Society of Nephrology's journals, *JASN*, *CJASN*, and *Kidney 360*, primarily focus on topics of interest to general nephrologists and researchers in general nephrology, containing some articles focused on topics of interest to the transplant nephrologist.

In addition to annual in-person offerings at the society meetings, both ASN and AST provide webinars and other educational opportunities focused on transplant nephrology and immunology. Historically, AST and ASN have collaborated in accrediting non-ACGME-recognized transplant nephrology fellowship programs. Since 2012, AST has been responsible for this effort.

# The transplant nephrologists who seek innovative solutions that meet the needs of individualized patient-centered care have saved my life. — Four-time kidney transplant recipient

In contemplating application for ACGME accreditation for transplant nephrology, ASN and AST—both jointly and independently—have weighed the pros and cons of the pursuit of ACGME accreditation for the future of the sub-subspecialty, recognizing certain tradeoffs exist in both directions. Frequently discussed potential concerns that may arise from the pursuit of

ACGME accreditation for transplant nephrology are discussed throughout this application, designated under **bold**, **underlined** section headers.

### Potential Concern: Add to burden for transplant nephrology training program directors.

ASN and AST recognize there is a concern that an official ACGME accredited subsubspecialty means that transplant nephrology training program directors (TPDs) will have to comply with the documentation and compliance-related requirements ACGME holds programs accountable to, which are likely more stringent and extensive than the present transplant nephrology program documentation and compliance-related requirements. However, ASN and AST also note that the majority of transplant nephrology training programs will *already* have to comply with ACGME requirements given that the majority of transplant nephrology training programs have J-1 visa holders. Effective July 1, 2023, institutions that maintain training programs that do not have ACGME accreditation or ABIM certification (including transplant nephrology) that sponsor J-1 visa holders must meet ACGME Non-Standard Training (NST) Program Requirements.

The NST documentation and compliance-related requirements are close to identical to those for formally accredited ACGME sub-subspecialties (such as conducting initial and formative assessments of ACGME milestones in the closest related ACGME-accredited subspecialty, and meeting ACGME requirements related to curriculum and clinical and educational hours).<sup>1, 2</sup> Accordingly, the increased burden for transplant nephrology programs that sponsor J-1 visa holders (which are the majority of transplant nephrology training programs) if ACGME bestowed accreditation would be minimal. For some institutions that are more used to oversight of accredited programs than of programs designated as NST, ACGME accreditation for transplant nephrology might reduce the burden.

As described elsewhere, formal ACGME accreditation of transplant nephrology as a subsubspecialty would potentially confer other benefits not available to NST programs (despite a similar administrative and program requirement burden). Transplant nephrology fellowships that sponsor fellows with J-1 visas would still have to follow the ACGME requirements, and ASN and AST plan to support TPDs in meeting those requirements to the greatest extent possible (whether formal ACGME accreditation is bestowed, or whether transplant nephrology training programs that have J-1 visa holders continue to apply for NST recognition). Both societies are committed to supporting TPDs in making the transition to ACGME accreditation (or continued NST program status) and stand ready to invest both societies' resources in delivering on that commitment.

ASN and AST also recognize that one of the benefits of ACGME accreditation is eligibility for transplant nephrology training programs to become eligible for Medicare GME funding to support training slots, the costs of which have to date been unfunded by the federal government and instead borne by institutions. and/or Nephrology Divisions (and potentially creating a disincentive to support these slots). The potential availability of Medicare GME funding would help to mitigate the cost of some of these additional responsibilities. Not only would the 0.2 Full Time Employee (FTE) protected time ACMGE mandates for TPDs help offset additional burden associated with ACGME accreditation, but the funding made possible by ACGME accreditation could create a more favorable funding opportunity for institutions to support transplant nephrology training programs than at present.

### References

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- 2. https://www.acgme.org/programs-and-institutions/institutions/non-standard-training-nst-recognition/
- e) the regular presence in academic units and health care organizations of educational programs, research activities, and clinical services such that the subspecialty or sub-subspecialty is broadly available nationally

There are an estimated 800 to 1,400 adult transplant nephrologists working at 231 active kidney transplant centers across the US and US territories (Figure 1).<sup>1</sup> This relatively small pool of transplant nephrologists plays a critical role in the success of kidney transplant programs as they provide and coordinate clinical care to over 250,000 kidney recipients currently living with a functioning graft and approximately 90,000 patients on the kidney transplant waiting lists in addition to tens of thousands of patients being evaluated for listing.  $_{2,3,4}$ 

Over 80% of transplant nephrologists work at large academic institutions, where they are actively involved in teaching students, residents, and fellows; many are also engaged in research activities<sup>5</sup>. There are currently 66 AST-accredited transplant nephrology fellowship programs in the US (Figure 2) that train fellows. Graduates of this fellowship training are then eligible to be medical directors/primary physicians of OPTN -approved kidney transplant programs<sup>6</sup>. A majority of transplant nephrologists are also active members of ASN and AST and regularly participate in the annual meetings of these two societies. Transplant nephrologists currently serve on the Board of Directors (AST) and Council (ASN) of both these societies.

Kidney diseases and kidney failure disproportionately affect underrepresented minority and socioeconomically disadvantaged communities--and both populations face lower rates of access to waitlisting and kidney transplantation than other populations. By ensuring broad nationwide adoption of uniformly rigorous transplant nephrology training, ASN and AST hope to secure better access to the expertise of transplant nephrologists and the care they provide for those communities.



## Potential Concern: No Benefit to J-1 Visa Holders

Similar to general nephrology—the gateway fellowship program to transplant nephrology—transplant nephrology benefits disproportionately from the contributions of international medical graduates (IMGs). More than 65% of the U.S Nephrology fellows were IMGs in 2021, a percentage higher than in any other ACGME-accredited specialty.<sup>7</sup>

Most transplant nephrology fellowship applicants are IMGs who need either J-1 or H-1B visas during their transplant training. Starting July 1, 2023, ACGME-accredited institutions wishing to host J-1 physicians in NST programs have been required to obtain ACGME NST\*<sup>1</sup> recognition<sup>8</sup>, without which they won't be able to accept transplant fellows on J-1 visas. Obtaining this recognition process involves a substantial application process that would not be required if ACGME accreditation for transplant nephrology were secured, thereby maintaining access to training programs for the majority of applicants and consequently securing the transplant nephrology workforce pipeline.<sup>9</sup> Importantly, programs that receive ACGME recognition as NST programs must also comply with ACGME NST program requirements on an ongoing basis (requirements that are close to identical of those for formally accredited ACGME sub-subspecialties).

In sum, ACGME accreditation for transplant nephrology would obviate the need for each transplant nephrology training program to obtain NST recognition from ACGME to sponsor J-1 visa holders, ensuring that every transplant nephrology training program can continue to benefit from the contributions of J-1 visa holders, while also creating potential benefits for the program not otherwise available (such as eligibility for GME funding).

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<sup>&</sup>lt;sup>1\*</sup> "Non-standard training (NST) programs are advanced clinical subspecialty disciplines or paths for which Accreditation Council for Graduate Medical Education (ACGME) accreditation and/or American Board of Medical Specialties (ABMS) Member Board certification is unavailable. On 7/1/2023, oversight of NST programs (for example: Transplant Nephrology, Transplant Infectious Disease, etc.) was shifted to ACGME. However, ACGME will confer NST recognition to sponsoring institutions with NST programs and not upon individual NST subspecialities. If the NST programs or specialties at ACGME-accredited are now required to comply with the same requirements as for those of ACGME accredited programs with regards to trainees' clinical and educational hours, annual assessment, opportunity to raise concerns and provide feedback, etc., it is logical for transplant nephrology to transition from NST status to ACGME accreditation if accreditation is pursued." [Singh N, Anand P, Gaurav G, et al. Should Transplant Nephrology pursue recognition from the Accreditation Council for Graduate Medical Education (ACGME)? CJASN Feb. 2024 DOI: 10.2215/CJN.0000000000000441] [ECFMG Sponsorship Types. Non-Standard Training. Available at: https://www.ecfmg.org/evsp/applying-types.html. Accessed on 7/20/2023.]

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# f) a projected number of programs sufficient to ensure that ACGME accreditation is an effective method for quality evaluation, including current and projected numbers for each participating specialty if the subspecialty is multidisciplinary

In 1998, AST and ASN established the adult transplant nephrology fellowship training criteria, outlining infrastructure requirements for institutions to establish a fellowship program. In 2014, the TNFTAP was launched and currently accredits institutions in the United States and Canada that have developed programs to provide specialty transplant nephrology training.<sup>1, 2</sup> A list of programs is available on the TNFTAP website.<sup>1</sup>

Most transplant nephrology fellowship positions are one-year clinical fellowships. Based on data from TNFTAP, the number of accredited training programs has substantially grown, increasing from 16 in the academic year 1998-1999 when TNFTAP was launched, to 71 in the academic year 2022-2023 (Figure 3). Of these 71 programs, 66 are in the United States. Most programs offer one position per academic year, with a few programs offering two positions. The number of fellows who have received transplant nephrology fellowship training rose from four in 1998-1999 to 76 in 2021-2022 (Figure 3). In 2022-2023, there were 63 fellows who trained in 55 programs. There have been a total of 1,105 transplant nephrology fellows trained from 1998 to the present.

ACGME accreditation may result in more individuals seeking transplant nephrology fellowship training and the establishment of additional transplant nephrology fellowship programs, particularly in academic institutions associated with the 231 kidney transplant centers in the US.<sup>3</sup> There are several reasons ASN and AST believe that transplant nephrology will be stronger as a result of ACGME accreditation including: <sup>3</sup>

- Improved recognition of transplant nephrology as a distinct medical sub-subspecialty.
- Enhanced quality and uniformity in transplant training due to emphasis on competencybased medical education articulated through sub-subspecialty specific milestones.
- Easing of state licensure requirements for exceptional pathway fellows. Exceptional pathway fellows are IMGs who entered Nephrology without a prior US internal medicine residency. In order to qualify for licensure in most states, 3 years of ACGME training is required, hence exceptional pathway fellows who graduate from standard 2-

year general nephrology fellowships currently do not meet state licensing requirements. ACGME accreditation of transplant nephrology fellowship programs will allow graduated transplant nephrology fellows who previously received internal medicine residency abroad but completed 2 years of general nephrology fellowship in the US to meet state licensure requirements.

• The possibility of obtaining Centers for Medicare and Medicaid Services (CMS) designation: ACGME accreditation is required to obtain CMS Provider Enrollment, Chain, and Ownership System (PECOS) designation for any specialty, and CMS reimbursement rates for medical services are often tied to specialty designations. The American Medical Association (AMA)'s Relative Value Scale Update Committee gives recommendations to the CMS regarding the creation of new current procedural terminology code and relative value units associated with the services and procedures specific to a specialty.

Currently, transplant nephrology does not meet criteria for CMS designation as a specialty, hence transplant nephrologists bill using generic E/M codes that are not specific to transplant nephrology. ACGME accreditation will allow the specialty to be AMA-recognized and CMS-recognized, thus providing the opportunity to negotiate with AMA and CMS the creation of specific current procedural terminology codes with higher relative value units for transplant nephrology. This will help capture the many hours of nonbillable work and the complex and value-based care that transplant nephrologists provide. Moreover, it will allow CMS to separately identify transplant nephrologists from general nephrologists allowing billing for new patient visits among patients already seen by general nephrologists from general nephrologists in the same practice. Finally, CMS' ability to distinguish transplant nephrologists from general nephrologists allowing billing based care delivery models and Centers for Medicare and Medicaid (CMMI) care models as it will allow for identification of transplant nephrologists and their contributions to patient care.

In addition, ACGME accreditation can support growth in transplant nephrology fellowship programs/positions as it will remove current disincentives for programs to offer positions to trainees on a J-1 visa (e.g. to obtain NST recognition from ACGME) and may help support funding of transplant fellows through graduate medical education funds.<sup>3</sup> As discussed previously, the ability to offer positions to trainees on a J-1 visa without obtaining individual program NST recognition is highly relevant because more than 65% of all matched nephrology fellows (and thus potential transplant nephrology fellow candidates) in the last few years are IMGs.<sup>4,5</sup> There is a clear need for growth in transplant nephrology training, and IMGs play an important role in the transplant nephrology workforce.

The number of patients who have received kidney transplants has increased considerably over the last decade (Figure 4), and, similarly, the number of prevalent kidney transplant recipients has increased substantially with 251,988 patients at the end of 2021 (USRDS 2023 ADR), an increase of 38.9% since 2010 (Figure 4).<sup>6,7</sup> In addition to kidney transplant recipients, there are approximately 90,000 patients on the kidney transplant waiting list (approximately 75,000 of whom are receiving maintenance dialysis) (Figure 4) who generally require multiple years of longitudinal waiting list management by transplant nephrologists to ensure they remain suitable transplant candidates, and there are tens of thousands of additional patients who are either in the referral or evaluation phases of their kidney transplant journey but not yet on the waiting list, or who have been declined as transplant candidates after their initial evaluation.<sup>6,7</sup>

In addition to managing kidney transplant candidates and recipients, transplant nephrologists also provide long-term transplant care for simultaneous pancreas/kidney and pancreas-alone transplant recipients. There are approximately 1,000 simultaneous pancreas/kidney (SPK) and pancreas-alone transplants (PAT) performed annually in the US (Figure 5)<sup>6</sup> and there are currently 1,994 patients waiting for an SPK and 841 patients waiting for a PAT.<sup>6</sup> In addition to managing transplant recipients and candidates, transplant nephrologists are responsible for counseling and evaluating thousands of potential living kidney donors each year and help fulfill the transplant center responsibility for post-donation follow-up. In 2023, 6,293 living donors donated a kidney in the US. Based on the estimate that 1 in every 6-8 donor candidates ultimately donate, this translates into approximately an additional 31,000-44,000 individuals who were evaluated as potential kidney donors. Finally, recent advances in xenotransplantation have brought the field closer to real-world implementation in the likely not-so-distant future. This will require even more specialized training and a greater demand for transplant nephrologists due to increased access to organs.

The kidney transplant population is expected to continue to increase in the future, especially in light of federal policy changes such as the aforementioned Executive Order on Advancing American Kidney Health (issued in July 2019) and the Securing the US Organ Procurement and Transplantation Network Act (passed by Congress in September 2023), both of which aim to dramatically increase kidney transplantation in the US.<sup>8,9</sup> In the coming years, as the population of kidney transplant patients continues to increase, there will be a continued need for transplant nephrology training programs that can equip trainees with the expertise to provide the necessary transplant-related care for this growing patient population.





# Figure 5: Trends in Simultaneous Kidney and Pancreas Transplant and Pancreas Transplant Alone

"Transplant nephrologists are necessary and need the work they do changes and saves life. Transplant nephrology is a specialty that deserves recognition. This letter is to not only explain the significance they have had in my life but to also amplify the importance they have in healthcare. More people than ever need kidney transplants, and now is the time to ensure that those who are in need receive the care they deserve. — 9-year postkidney transplant recipient

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# g) the duration of the subspecialty or sub-subspecialty program is at least one year beyond education in the primary (core) specialty

The standard adult transplant nephrology fellowship is a one-year clinical fellowship, designed for nephrologists who have successfully completed a standard ACGME-accredited (or foreign equivalent for Canadian programs) Nephrology fellowship. TNFTAP accredits transplant centers that have developed programs to provide specialty transplant nephrology training. The number of accredited transplant nephrology training programs and the number of graduating transplant nephrology fellows have grown steadily over the past 10-15 years. In 2008, there were 50 accredited transplant nephrology training programs that graduated only 29 fellows.<sup>1</sup> There are currently 66 accredited programs in the USA located in geographically diverse regions nationwide. The list of TNFTAP accredited transplant nephrology fellowship programs is available on the TNFTAP website.<sup>2</sup>

## Potential Concern: Decrease Number of Applicants to General Nephrology

ASN and AST are aware of, and have considered at length, a concern raised within the kidney and transplant nephrology communities that pursuit of ACGME accreditation of transplant nephrology could potentially have a detrimental effect on fellowship applications to pursue training in general nephrology. At present, trainees wishing to pursue a third year of training to specialize in transplant nephrology must first successfully complete the two-year general nephrology training program, a structure ASN and AST envision will remain in place should ACGME accreditation be awarded. Bestowing that third year of transplant nephrology with the recognition associated with ACGME accreditation should, therefore, not have any effect on the number of trainees who elect to enter general nephrology.

Moreover, in recent years, considerable attention has been given to the fact that general nephrology training programs have not filled their available fellowship slots.<sup>3</sup> In turn, the highly visible absence of filled slots contributes to the widespread perception that nephrology is not a desirable career path to pursue. Interestingly, literature suggest that nephrology likely over-expanded the number of slots and that the specialty is in need of "right-sizing."<sup>4</sup> If transplant nephrology were to receive ACGME accreditation, nephrology divisions could use their discretion to allocate a certain number of annual GME-funded training slots to third-year transplant nephrology training for committed trainees, rather than ending up with unfilled general nephrology slots in addition to having to absorb the cost of transplant nephrology training slots through divisional revenue. This shift would allow many divisions of nephrology to capture more of the available GME funding than at present—and, by filling more of the total slots allocated to nephrology (general nephrology plus transplant nephrology combined), increase the global fill rate and help showcase nephrology (and transplant nephrology) as a more competitive and desirable subspecialty (and sub-subspecialty).

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## h) the educational program is primarily clinical

The educational program in adult transplant nephrology is primarily a clinical training program. A minimum of six months of training must be performed in inpatient clinical service. This typically involves collaborating with the multidisciplinary inpatient team (transplant surgeons/trainees, advanced practice providers, social work, pharmacy) in caring for recipients during the index admission for transplant, as well as readmissions for transplant-related complications. The transplant nephrology fellow must be involved for the duration of their fellowship training as the primary transplant provider in the longitudinal care of at least 30 newly transplanted kidney recipients.

Besides vacation time, the remaining training period is designated for outpatient clinical activity, including but not limited to observing deceased organ procurement and the transplant surgical procedure (and live donor nephrectomy), evaluation and waiting list management of kidney transplant candidates, evaluation, counseling and management of live kidney donors, gaining experience in tissue typing through spending time in the HLA laboratory, as well as exposure to kidney transplant pathology. Since transplant nephrologists are also the primary transplant clinicians who provide long-term care to pancreas transplant recipients, transplant fellows at centers that perform pancreas transplants are expected to acquire expertise in this area during their training. Transplant nephrology fellows who train at hospitals where non-kidney transplants (e.g., heart, lung, liver) are performed, manage kidney disease in these organ recipients as well. Opportunities exist for additional pursuits during the training, for example, taking electives in pediatric transplantation or transplant infectious diseases, educational conferences, and/or kidney transplant-related scholarship.

## Potential Concern: Increased Exam Burden for Transplant Nephrologists

Often, a certification exam of some form follows the completion of a clinically focused educational program as the next step in a trainee's journey. At present, trainees who complete a third year of training in transplant nephrology following their two years of general nephrology complete the ABIM Nephrology Board exam and continue to recertify through ABIM's general nephrology pathways. ASN and AST are aware of, and understand why, apprehension exists in the transplant nephrology community regarding a new third exam or additional Maintenance of Certification (MOC) requirements in addition to internal medicine and general nephrology.

ASN and AST are especially eager to ensure that ACGME certification of transplant nephrology does not result in the unintended consequence of additional exam (and financial) burden for transplant nephrologists. ASN and AST have identified a spectrum of options that could potentially address concerns regarding additional exam burden as well as create opportunities for transplant nephrologists to demonstrate their excellence in their chosen field. While ACGME accreditation and ABIM certification are separate processes, ASN and AST wish to demonstrate that thought has been dedicated to both processes. Should ACGME grant transplant nephrology ACGME accreditation, ASN and AST are committed to working closely with the transplant nephrology community to determine the most appropriate approach to initial and ongoing certification, and to engaging with ABIM and other stakeholders to consider all potential options to mitigating additional exam burden, including maintaining the current approach to initial certification in general nephrology, NEDIM-2/certification, practice profiles, and/or focused practice.<sup>1, 2, 3, 4</sup>

# I commend the transplant nephrologists who devote their lives to continuously learning and expanding their knowledge to find solutions to my problems. — Four-time kidney transplant recipient

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## Contact for questions and proposal submission

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Submit the proposal and any supporting documentation by email to <u>Jessalynn Watanabe</u>.

Upon receipt of a proposal for the designation of a new subspecialty or sub-subspecialty, the proposal will be posted on the ACGME website for a 45-day period of public comment.

If the subspecialty is multidisciplinary, the ACGME Board will designate the Review Committees that will review programs in the subspecialty based on the projected numbers of programs by specialty and in accordance with Section 14.10 of the ACGME Manual of Policies and Procedures. For participating specialties not expected to reach the threshold of five programs within five years, programs must apply for accreditation to one of the designated Review Committees. If at any time in the future, there are five or more programs from a participating specialty that is not a designated Review Committee, that specialty Review Committee may be newly designated to review programs in that subspecialty.

# Appendix 1. AST Transplant Nephrology Fellowship Training Accreditation Program Recommended Educational Curriculum

Available at: https://txnephaccreditation.org/fellowship-program-details

## **Fellowship Program Details**

The AST Transplant Nephrology Fellowship Training Accreditation Program (the "Program") *accredits institutions* that have developed programs to provide specialty transplant nephrology training:

- The goal of the program is to provide a basis for the standardization of transplant training and a method of uniform documentation of education for those who wish to lead transplant nephrology programs.
- As a result of the Program's approval by the United Network for Organ Sharing (UNOS), graduates of accredited transplant nephrology fellowship programs are qualified to head UNOS approved transplant nephrology programs.
- Graduates of individual fellowship programs are not directly certified by the TNFTAP. Fellows who graduate are certified by the Program from which they graduated.

The standard transplant nephrology fellowship is a one-year clinical fellowship, designed for nephrologists who have successfully completed a standard ACGME (or foreign equivalent for Canadian programs) nephrology fellowship, post-completion of an Internal Medicine Residency Program in the US, Canada or equivalent abroad. In order for foreign candidates to qualify for IM/Nephrology ABIM Certification, the candidate must complete a US (or foreign equivalent for Canadian programs) ACGME-Accredited Internal Medicine Program or serve under the supervision of an ABIM-certified faculty at a US academic institution for a minimum of three years in order to sit for the ABIM boards. Training under the standard fellowship is to be completed within 12 continuous months.

Transplant Nephrology Fellowship Programs are expected to develop an educational curriculum for the transplant nephrology fellows. The content and implementation of the curriculum are an essential part of the program evaluation during the initial accreditation and re-accreditation processes. The lecture content and timing of educational activities will be specifically developed by each program but at a minimum should expose each transplant nephrology fellow to current practices or advanced learning in the following areas:

I. Treatment Options for Patients with Advanced Chronic Kidney Disease

- II. Transplant Immunology
- III. Histocompatibility and Immune Monitoring
- IV. Immunosuppressive Medications and Protocols for Kidney Transplantation
- V. Kidney Allocation/Organ Quality
- VI. Living Donor Kidney Transplantation and Exchange Donor Options
- VII. Evaluation of Kidney Transplant Candidates
- VIII. Kidney Transplant Operation and Surgical Complications
- IX. Early and Late Complications of Kidney Transplantation
- X. Infections in Kidney Transplantation
- XI. Diagnostic Imaging and Biopsy Technique
- XII. Pathology of Kidney Transplantation and Rejection
- XIII. Transplantation Options for Patients with Diabetes
- XIV. Transplantation Options for Patients with Liver Disease

XV. Kidney Transplantation in Context of Other Solid Organ Transplantation

XVI. Special Issues in Pediatric Transplantation

XVII. Psycho-Social and Financial Aspects of Transplantation

XVIII. Psychiatric Aspects of Kidney Transplantation

XIX. National Organ Transplant Act and Ethics

XX. Business and Administrative Aspects of Kidney Transplantation Programs

## **Recommended Applicant Timeline**

The TNFTAP recommends the following timeline for transplant nephrology fellowship applicants and training programs:

- \*May 1 August 31: Inquiries and application filing
- July 1 October 31: Fellow candidate interviews
- October 1 December 31: Decision

\*Calendar year prior to start of training.

## **Eligibility Criteria**

Each of the following criteria must be continuously satisfied by an accredited transplant nephrology fellowship training program:

- 1. The transplant nephrology fellowship program must be UNOS approved as a renal transplant program. Notwithstanding the preceding sentence, transplant nephrology fellowship programs that are not UNOS approved will be evaluated by the Program on a case-by-case basis.
- 2. The transplant fellowship program director must be a transplant nephrologist who would be eligible for membership in the American Society of Transplantation. The AST Transplant Nephrology Fellowship Training Accreditation Program, LLC defines a transplant nephrologist as:
  - Someone who has completed a transplant nephrology fellowship program at a program accredited by the AST Transplant Nephrology Fellowship Training Accreditation Program, LLC, or
  - Someone who meets the qualifications to be a UNOS primary kidney transplant physician
- 3. The transplant nephrology fellowship program must have a full-time faculty member or members capable of teaching a curriculum with a broad base of knowledge in transplant medicine, including the outlined transplant topics noted above. More specifically, the curriculum must include: training and experience in end-stage renal disease management; training in the selection of appropriate transplant recipients and donors; experience in the immediate and long term care of both living and deceased donor transplant recipients, as well as the appropriate management of the living donor; and training in the performance of renal transplant biopsies. Additionally, there must be an emphasis on the management of immunosuppressive agents and the evaluation of renal transplant dysfunction.
- 4. Combined surgical and medical rounds should be conducted on a regular basis. The didactic section of the transplant nephrology fellowship program should follow the list of outlined transplant topics noted above. It is strongly recommended that transplant nephrology fellows participate in other educational opportunities, such as the AST/ASN Transplant Nephrology Core Curriculum, and the AST "T3: Timely Topics in Transplantation" webinar series. These and other educational activities are available on the AST website, www.myAST.org.
- 5. Each transplant nephrology fellowship program must perform a sufficient number of kidney transplants to allow for adequate training. The minimum requirement is 50 kidney transplants per year for the training of one transplant nephrology fellow. If a program

wishes to train a second transplant nephrology fellow, then an additional 30 kidney transplants must be performed per year. Therefore, programs that train two transplant nephrology fellows must perform a minimum of 80 kidney transplants per year. Each transplant nephrology fellow must be primarily responsible for 30 inpatient renal transplant recipients and 30 outpatient recipients (the inpatient and outpatient encounters may involve the same patients). Outpatient follow-up must be continuous for a minimum of at least three months after transplantation.

- 6. A minimum of six months of training must be performed in inpatient clinical service in order to allow the transplant nephrology fellow's involvement in the care of at least 30 new transplant patients. The remaining training period should be designed to provide training and experience in tissue typing, experience on another organ transplant service, and exposure to transplant pathology. The transplant nephrology fellow should also be involved in activities that provide experience in transplant related scholarship. Examples of this include, but are not limited to, performing research, writing up case reports, and drafting reviews or chapters.
- 7. The transplant nephrology fellowship program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period in both deceased donor as well as living donor transplant recipients. The transplant nephrology fellow must primarily manage the transplant recipient's medical care including, but not limited to, hypertension, diabetes, and dialytic problems. Transplant nephrology fellows must also serve as primary members of the transplant team and participate in making decisions about immunosuppression.
- 8. The transplant nephrology fellowship program must provide training in the indications for, the performance of, and the interpretation of, renal transplant biopsies. Each transplant nephrology fellow must perform a minimum of 10 renal transplant biopsies during the training period. Documentation of the completion of these biopsies is required. Furthermore, the transplant nephrology fellowship program must provide didactic pathological experience with the transplant nephrology fellow reviewing renal transplant biopsies under the supervision of certified professional.
- 9. It is encouraged that the transplant nephrology fellow gain experience in the evaluation and management of pancreas transplantation. Pancreas experience documentation and certification requirements should be addressed directly with UNOS.
- 10. The transplant nephrology fellowship program must provide training and experience in an accredited histocompatibility/tissue typing laboratory and training and experience in the procedures and activities of an organ procurement organization.
- 11. Each transplant nephrology fellow must observe at least 3 renal transplants, at least one of which is a living donor transplant and one a deceased donor transplant. Each transplant nephrology fellow must also observe at least 3 organ recovery procedures, at least one of which is from a deceased donor and one from a living donor.
- 12. Each transplant nephrology fellow must obtain experience evaluating 25 potential kidney transplant recipients, and 10 potential living donors, as well as participate in selection committee meetings.
- 13. If a transplant nephrology fellowship training program cannot provide any aspect of the required elements, such as experience in living or deceased donor transplantation or tissue typing, the program can make arrangements with another accredited transplant nephrology fellowship training program to have the transplant nephrology fellow(s) receive training in that element at that program. In general, the amount time spent by a transplant nephrology fellow with an outside transplant nephrology fellowship training program should not exceed 3 months.
- 14. There are two set pathways for transplant nephrology fellowship programs to follow:

- A standard one-year transplant nephrology fellowship, which is designed for nephrologists who have successfully completed a standard ACGME (or foreign equivalent for Canadian programs) nephrology fellowship. Training under the standard fellowship is to be completed within 12 continuous months.
- An alternative pathway designed for nephrology fellows who have a more in depth academic interest in transplantation and wish to pursue active research related to transplantation over the span of a two or three year training period.
- 15. Transplant nephrology fellows who wish to pursue the alternative pathway must currently be enrolled in an ACGME approved (or foreign equivalent programs) nephrology fellowship program at an accredited center. Transplant nephrology fellows must have already completed the clinical rotations for their general nephrology fellowship program. The alternative pathway does not require fellows to be board-eligible or board-certified at the initiation of the transplant nephrology fellowship if the fellow is concurrently enrolled in an ACGME-certified (or foreign equivalent programs) standard nephrology fellowship with the following expectations:
  - The transplant nephrology fellowship program is accredited by the AST Transplant Nephrology Fellowship training Accreditation Program, LLC.
  - All clinical training that is counted towards the transplant nephrology fellowship training is done in addition to the standard renal fellowship clinical requirements. This must be documented by the transplant nephrology fellowship training program director who will certify that the transplant nephrology fellow has completed all requirements for both fellowship programs.
  - Research performed during this training should be relevant to the field of transplantation.
  - In order to be considered qualified to head UNOS-approved renal transplant programs, the transplant nephrology fellow must be board-certified in nephrology by the American Board of Internal Medicine (ABIM), or the foreign equivalent, by the end of the training.
- 16. Transplant nephrology fellows who wish to partake in the alternative pathway are required to complete all of the eligibility criteria outlined above, but the requirements are to be spread out over two or three years, while the transplant nephrology fellow pursues active research related to transplantation. In addition to the requirements for the standard one-year renal transplant fellowship:
  - The inpatient experience is to be two or three months per academic year (or calendar year), totaling a minimum of 6 months. This flexibility is designed to allow fellows on grants requiring protected time to fulfill both research and clinical obligations.
  - The outpatient exposure is to be increased compared with the standard one-year program. It must include a primary responsibility for the longitudinal follow-up and care of at least 30 transplant patients in the outpatient clinic for a minimum of 3 continuous months each year for a minimum of 2 training years. The transplant nephrology fellow is expected to participate in transplant related conferences throughout the training period.
- 17. Interruption of the fellowship training may be allowed in situations specified in the leave policy of the training institution. Any leave period that exceeds vacation allotment will require the continuous extension of the fellowship by a duration equal to the interruption. The period of interruption can not exceed 12 months.
- 18. Documentation that the transplant nephrology fellow has successfully completed the prerequisite number of 30 in-patient and 30 outpatient recipient management experiences; 3 surgical observations; 3 procurement observations; 10 renal transplant biopsies; 25 recipient evaluations, and 10 living donor evaluations must be kept.

Documentation should, at a minimum, be in the form of a log that contains the signature of the transplant physician present. This documentation must be kept by the transplant nephrology fellowship program and the transplant nephrology fellow.

- 19. Each transplant nephrology fellow is required to complete an evaluation form at 6 months and at the completion of the 12-month fellowship. The evaluations are to be submitted on a form prescribed by the Program. Transplant nephrology fellows who pursue the alternative pathway are required to complete evaluation forms every 6 months until completion of the transplant nephrology fellowship. Each transplant nephrology fellowship program director will be responsible for ensuring that the transplant nephrology fellow receives and completes the appropriate forms. Upon receipt, the forms will be reviewed for adequacy and compliance with the requirements contained herein.
- 20. The transplant nephrology fellowship program director must provide a letter and a certificate of completion to each transplant nephrology fellow upon successful fellowship completion. The letter must state that the transplant nephrology fellow has met all of the above criteria and is capable of being certified as a UNOS transplant physician if the training occurred at a UNOS approved transplant program. A copy of this letter and certificate, along with a written statement validating the transplant nephrology fellow's participation in the required didactic sessions and patient management experiences, must be sent to the Transplant Nephrology Fellowship Training Accreditation Program, LLC office for inclusion in the transplant nephrology fellowship program's file.



April 15, 2024

Ms. Jessalynn Watanabe Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Ms. Watanabe,

The American Kidney Fund (AKF) is pleased to offer our endorsement for the joint American Society of Nephrology (ASN) and American Society of Transplantation (AST) application for a new kidney transplant subspecialty.

AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, to support people wherever they are in their fight against kidney disease — from prevention through post-transplant living.

AKF knows all too well how important the kidney transplant specialty is to the community we serve. Our charitable assistance programs assist more than 1,600 patients each year to receive a life-saving kidney transplant and transplant equity is a key focus of our Kidney Health for All campaign. Our hope is that providing additional training and accreditation to these physicians will increase access to the most effective treatment for those in end-stage kidney disease.

Sincerely,

Dans Q. Auta

LaVarne A. Burton President and CEO



April 24, 2024

Thomas Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Dr. Nasca:

Please accept this letter of support from the American Society of Transplant Surgeons (ASTS) for the joint proposal from the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) for approval for an Accreditation Council for Graduate Medical Education (ACGME) accredited subsubspecialty fellowship in transplant nephrology.

ASTS is the leading organization of the surgeons, physicians and scientists who have pioneered and continue to advance the field of transplantation. Our members have taken the field from experimental trials to highly precise and advanced therapies that offer a growing number of men, women, and children a new chance at a longer, healthier life. ASTS members have a responsibility to bring their institutions at the forefront of transplantation surgery, medicine, and research in the United States. The ASTS has over 2000 members who specialize in abdominal and thoracic organ transplantation.

ASTS is committed to defining and promoting training and the career-long education of transplant surgeons. The primary avenue by which ASTS defines and promotes training is through its Accreditation of Abdominal Transplant Surgery Fellowship Training Programs and has been accrediting program to train fellows since the early 80's. The ASTS established the Transplant Accreditation & Certification Council, LLC (TACC) in 2017 and the TACC is now the accrediting body for Abdominal Transplant Surgery Fellowship Training Programs.

Transplant nephrology is a sub-subspecialty of nephrology. Kidney transplantation is the treatment of choice for most patients with kidney failure, and numerous federal government efforts are underway to increase patients' access to kidney transplantation. Transplant nephrologists typically lead the management of patients before and after transplant, with responsibilities that include evaluation and waitlisting of appropriate patients referred for transplantation, ensuring that patients remain transplant-ready while on the waiting list, conducting living donor evaluation, and providing short- and long-term management of the allograft, encompassing immunosuppressive therapy and attendant complications.<sup>1</sup>

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Since 1998, transplant nephrology training programs have been accredited by AST, and the total number has reached 66 in the United States. As the sub-subspecialty has matured and the need for highly skilled transplant nephrologists continues to grow, ASTS concurs with ASN and AST that transplant nephrology would benefit from the coordination and rigor in training conferred by ACGME accreditation. Ultimately, this shift will ensure more kidney transplant candidates and recipients will be served by the highest quality transplant nephrologists possible nationwide.

Overall, ASTS supports the rationale laid out in the ASN-AST application to ACGME and encourages ACGME to approve transplant nephrology as a new sub-subspecialty. We appreciate the opportunity to have our perspective considered in your deliberations and is available to answer any questions you may have regarding our support for this application.

Sincerely,

Ogener A. Pompet

Elizabeth Pomfret, MD, PhD President

<sup>1</sup> The Importance of Transplant Nephrology to a Successful Kidney Transplant Program. Moe SM et al. CJASN 17: 1403–1406, 2022. doi: https://doi.org/10.2215/CJN.02000222



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IDSA Headquarters

4040 Wilson Boulevard Suite 300 Arlington, VA 22203 TEL: (703) 299-0200 EMAL: Info@idsociety.org WEBSITE: www.idsociety.org April 24, 2024

Thomas Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Dr. Nasca:

Please accept this letter of endorsement from the Infectious Diseases Society of America (IDSA) for the proposal from the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) for approval for an Accreditation Council for Graduate Medical Education (ACGME) accredited sub-subspecialty fellowship in transplant nephrology.

IDSA is a community of over 13,000 physicians, scientists and public health experts who specialize in infectious diseases. Our mission is to bring together the curiosity, compassion and knowledge of our members to strengthen the field of infectious diseases, advance science and advocate for health equity. IDSA members include practicing clinicians who provide direct patient care, scientists and researchers in the academic setting, public health officials, hospital epidemiologists, and infectious diseases specialists working in many other settings.

We were pleased to have the opportunity to review ASN and AST's draft application and provide feedback. IDSA notes that the ACGME accreditation ASN and AST are pursuing is congruent with similarly accredited solid organ transplant training pathways, such as transplant hepatology for liver transplantation and advanced heart failure and transplant cardiology for heart transplantation. As documented in the application, the practice of transplant nephrology is becoming increasingly complex, and demand for specialized transplant care is expected to grow. IDSA agrees with ASN and AST that transplant nephrology would benefit from the coordination and rigor in training conferred by ACGME accreditation.

IDSA hopes that ACGME accreditation for transplant nephrology will mean more kidney transplant candidates and recipients are receiving care from transplant nephrologists who received the highest-quality training possible nationwide. Given that disadvantaged communities are particularly affected by kidney failure, ensuring that as many of them as possible can benefit from rigorously trained transplant nephrologists is an important goal.

Overall, IDSA supports ASN and AST's application to ACGME and encourages ACGME to approve transplant nephrology as a new sub-subspecialty. If you have any questions about IDSA's support, please don't hesitate to contact IDSA's CEO, Chris Busky, at cbusky@idsociety.org.

Sincerely,

Aluniton

Steven Schmitt, MD, FIDSA IDSA President



19/04/2024

Thomas Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Dr. Nasca:

Please accept this letter of support for the joint proposal from the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) for approval for an Accreditation Council for Graduate Medical Education (ACGME) accredited sub-subspecialty fellowship in transplant nephrology.

The International Pancreas and Islet Transplant Association (IPITA) is devoted to developing cures for diabetes through replacement or regeneration of insulin-producing beta cells. One indication for beta cell replacement is when kidney failure associated with type 1 diabetes is treated with a simultaneous kidney-pancreas transplant. Furthermore nephrologists frequently are involved in islet transplant programs to manage immunosuppression.

Transplant nephrology is a sub-subspecialty of nephrology. Kidney transplantation is the treatment of choice for most patients with kidney failure, and numerous federal government efforts are underway to increase patients' access to kidney transplantation. Transplant nephrologists typically lead the management of patients before and after transplant, with responsibilities that include evaluation and waitlisting of appropriate patients referred for transplantation, ensuring that patients remain transplant-ready while on the waiting list, conducting living donor evaluation, and providing short- and long-term management of the allograft, encompassing immunosuppressive therapy and attendant complications.<sup>i</sup>

Since 1998, transplant nephrology training programs have been accredited by AST, and the total number has reached 66 in the United States. As the sub-subspecialty has matured and the need for highly skilled transplant nephrologists continues to grow, IPITA concurs with ASN and AST that transplant nephrology would benefit from the coordination and rigor in training conferred by ACGME accreditation. Ultimately, this shift will ensure more kidney transplant candidates and recipients will be served by the highest quality transplant nephrologists possible nationwide.

Overall, IPITA supports the rationale laid out in the ASN-AST application to ACGME and encourages ACGME to approve transplant nephrology as a new sub-subspecialty. IPITA appreciates the opportunity to have our perspective considered in your deliberations and stands ready to answer any questions you may have regarding our support for this application. Sincerely.

Amesliklan

Thomas Kay

<sup>&</sup>lt;sup>i</sup> The Importance of Transplant Nephrology to a Successful Kidney Transplant Program. Moe SM et al. CJASN 17: 1403– 1406, 2022. doi: https://doi.org/10.2215/CJN.02000222



Friday, April 26

Thomas Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Dr. Nasca:

Please accept this letter of endorsement for the proposal from the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) for an Accreditation Council for Graduate Medical Education (ACGME) accredited sub-subspecialty fellowship in transplant nephrology.

The International Society for Heart and Lung Transplantation (ISHLT) is an international and multidisciplinary professional society representing more than 3,000 members of the broad health care delivery teams engaged in the management of patients with end stage heart or lung disease.

Transplant nephrology plays a critical role in the context of a multidisciplinary society for heart and lung transplantation due to its focus on managing the complex renal issues that often arise in patients before, during, and after transplantation.

Given the high incidence of renal dysfunction and failure in recipients of heart and lung transplants — often as a consequence of the transplantation process itself or the required long-term use of immunosuppressive medications, as well as the increase in combined heart-lung-kidney transplant — there is a compelling need for specialized nephrological care within these transplant programs.

Developing additional accredited sub-subspecialty fellowships in transplant nephrology would enhance patient outcomes by ensuring dedicated expertise in the management of kidney health, an integral component of comprehensive transplant patient care. This specialization ensures that nephrological considerations are seamlessly integrated into the multidisciplinary approach necessary for optimizing the long-term success and overall health of transplant recipients.

In sum, ISLHT supports ASN and AST's proposal to establish an ACGME accredited sub-subspecialty fellowship in transplant nephrology. Please contact me at greg.schultz@ishlt.org (312) 224-0013 with any questions regarding ISHLT's endorsement.

Sincerely,

Greg Schultz, CAE

Chief Executive Officer International Society for Heart and Lung Transplantation



30 E. 33<sup>rd</sup> Street New York, NY 10016 212.889.2210

April 19, 2024

Jessalyn Watanabe Administrative Manager Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Re: Letter of Support

Dear Ms. Watanabe,

The National Kidney Foundation (NKF) supports the proposal by the American Society of Nephrology (ASN) and the American Transplant Society (AST) for an accredited Transplant Nephrology Fellowship Training Program.

Representing the 37 million adults in America with kidney disease, including the more than 90,000 awaiting a kidney transplant, the National Kidney Foundation believes that there is a significant need for greater transplant education in the field of nephrology. Individuals with kidney failure often feel uninformed or underinformed about transplant as a treatment option, are unpreprared to navigate the transplant evaluation and waitlisting process, or – if they are fortunate to receive a kidney transplant – feel undersupported with their post-transplant needs (e.g., immunosuppressive medication management).

Accrediting transplant nephrology as a sub-specialty would elevate the field of transplant nephrology, create more rigor and standardization in transplant nephrology training, and assure that clinicians have the knowledge, skills, and training necessary to assure quality transplant care, patient safety, and outcomes . The management of donated organs, a precious life-saving resource, is a complex task that necessitates meticulous clinical knowledge to maintain the health of a transplanted organ and its recipient. Action by the Accreditation Council for Graduate Medical Education (ACGME) to implement improved educational training will not only benefit the field of nephrology but will enhance the quality of care for patients.

NKF appreciates the opportunity to advocate for this endeavor. If you have any questions, please contact Morgan Reid, Director of Transplant Policy and Strategy, at <u>Morgan.Reid@kidney.org</u>.

Sincerely,

Kevin Longino CEO and Transplant Patient

Mon

Sylvia E. Rosas MD, MSCE President



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EXECUTIVE DIRECTOR Adonia Calhoun Groom, CAE, CMP Rockville, Maryland April 24, 2024

Thomas Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Re: Proposal for ACGME Accreditation of a Sub-subspecialty Fellowship in Transplant Nephrology.

Dear Dr. Nasca:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. For fifty years, RPA has been the national representative for physicians engaged in the study and management of patients with kidney disease.

RPA is writing to express our support for the joint proposal from the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) for approval of an Accreditation Council for Graduate Medical Education (ACGME) accredited sub-subspecialty fellowship in transplant nephrology. Recent years have seen an appropriately intensified commitment on behalf of federal policymakers to increase kidney transplant rates in the U.S., and this underscores the need for a suitably trained workforce specifically for kidney transplant patients. Transplant nephrologists provide management services to kidney patients leading up to the transplant procedure and in post-transplant care, including but not limited to counseling on the waitlist process, living donor evaluation, medication management, allograft management pre- and post-procedure, and addressing complications if they arise.

Accordingly, RPA concurs with ASN and AST that transplant nephrology would benefit from the coordination and rigor in training conferred by ACGME accreditation. RPA believes that an accredited sub-subspecialty fellowship in transplant nephrology will facilitate the availability of more kidney transplants and that persons receiving kidney transplants will be optimally served by the highest quality transplant nephrologists possible nationwide.

# For these reasons, we urge ACGME to adopt the proposal from ASN and AST to create an accredited sub-subspecialty fellowship in transplant nephrology.

RPA welcomes the opportunity to work with ACGME in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to ACGME in its future work on issues related to accreditation in kidney disease care. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at <u>rblaser@renalmd.org</u>.

Sincerely,

Kalland

Keith Bellovich, DO RPA President

CC: Adonia Calhoun Groom, CAE, CMP, RPA Executive Director



Service to those affected by chronic kidney disease

April 24, 2024

To: Whom It May Concern,

I founded Renal Support Network (RSN) in 1993 to empower people who have kidney disease to become knowledgeable about their illness, proactive in their care, hopeful about their future and make friendships that last a lifetime. I was diagnosed at age 2 and since then have spent 13 years on dialysis and now doing well with my 4<sup>th</sup> transplant.

RSN supports the standardized ACGME Accreditation Task Force (ACGME) as we believe that ACGME accredited training will greatly benefit patients by providing the highest quality transplant care.

Our focus is on ensuring that future transplant nephrologists adopt a holistic approach towards their patients, recognizing them as individuals with lives outside the clinic. We aim to promote collaborative care planning that takes into consideration the specific goals and needs of each patient through effective communication.

Transplantation is a life-saving procedures that demand intricate interpersonal care. We want our physicians to have extensive training, advanced knowledge of innovative approaches for patient-centered care, and empathetic communication skills. Patients don't care how much you know until they know how much you care.

RSN hopeful, life-enriching programs help people who have kidney disease, whether they are in the early stages of the disease, are on dialysis or have received a transplant.

Please feel to reach out if you should have any questions.

Sincerely,

More Hutrud

Lori Hartwell President & Founder

An illness is too demanding when you don't have hope!

Tuesday, April 23

Thomas Nasca, MD, MACP President and Chief Executive Officer Accreditation Council for Graduate Medical Education 401 North Michigan Avenue, Suite 2000 Chicago, IL 60611

Dear Dr. Nasca:

Transplant Recipients International Organization (TRIO) appreciated the opportunity to consider the proposal from the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) regarding Accreditation Council for Graduate Medical Education (ACGME) accreditation for transplant nephrology. TRIO is committed to providing support for our members and the entire transplant community and to being a voice for transplantation.

On behalf of TRIO, we wholeheartedly support the concept that transplant nephrology requires its own additional training and education in the field of nephrology. In general, TRIO completely agrees with the concepts outlined in ASN and AST's application document and supports the proposal for ACGME accreditation.

As responders for TRIO, it is certainly important to acknowledge that we are not medical practitioners or clinicians. However, we wish to point out the TRIO leadership's collective decades-long journey with kidney transplantation, beginning for me with my spouse's simultaneous kidney-pancreas transplant in June 1999. Kidney transplantation care now needs to focus on not just the pre- and 1-year post transplant care but now on patients who are 10, 20, and even 30 years post-transplant. The kidney transplant population is living longer, and post-transplant medical care management changes with this longevity.

We have remained in the care of a single transplant nephrologist throughout not only the pretransplant evaluation, but also the entire post-transplant journey. We recognize that this is easier to do in a large urban transplant center complex; it has made post-transplant success much easier from a travel and lodging point of view.

In our experience, our transplant nephrologist has served not only as the "kidney care doctor"; he has also been at the center of all medical care management. This includes directing us to specialists versed in transplantation for cardiovascular management, endocrinology, gynecology, eye treatment, gastroenterology, immunology, and any other medical specialty where the specialist's knowledge of transplantation has been vital for the co-ordination of care. This has been especially true concerning prescription drugs, where knowledge of the interactions of drugs with the continued day-to-day use of immunosuppression has been absolutely vital to the long-term success, in my case, of the kidney-pancreas transplant of 25 years. Every specialist doctor has participated in consultations with our transplant

nephrologists to ensure prescription drug safety and success. Long-term success in transplantation means that medicine is NOT practiced as if the patient's care is divided into silos.

In addition, kidney transplantation is often combined as one component of a multi-organ transplant. Kidney-heart, kidney-liver, kidney-lung are becoming more and more a part of transplant programs, far beyond kidney alone, or even kidney-pancreas. This facet of transplantation makes care management even more complex and requires clinicians with more in-depth understanding of kidney care.

Therefore, when it comes time to establish ACGME transplant nephrology training program requirements, we would emphasize that they recognize that success comes from a team approach to the practice. This approach is more than justified by the increased longevity of the patient population. The successful practice of transplant nephrology is not just about the kidney.

Thank you for your consideration of TRIO's perspective and support for this application. I can be reached at irajay2004@gmail.com.

Sincerely,

Ira J. Copperman Vice-President TRIO