



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

December 9, 2019

Katherine H. Goodrich, MD
Director of the Center for Clinical Standards and Quality (CCSQ)
CMS Chief Medical Officer
Centers for Medicare and Medicaid Services
900 23rd Street, NW
Washington, DC 20037

Dear Dr. Goodrich:

As President of the American Society of Transplant Surgeons (ASTS), I am following up on our recent Transplant Learning Collaborative conference call. ASTS looks forward to actively participating in the Collaborative, and we encourage the agency to view us as a partner in achieving the Collaborative's objectives. As a first step in the process, ASTS is pleased to have the opportunity to respond to the four questions that we received from you relating to the Learning Collaborative.

Preliminarily, however, we would like to emphasize our strong recommendation that CMS expand the scope of the Transplant Learning Collaborative to encompass living donor kidney transplantation. We firmly believe that expansion of living donor transplantation has the greatest potential to achieve the largest increase in kidney transplant availability over the short term, with the best clinical results and the most significant potential cost savings. Living donor transplantation has a number of significant clinical and cost advantages over deceased donor transplantation (see Attachment A). Available data clearly indicates substantial variation in the effectiveness of Transplant Centers' living donor programs. Looking at the top 15 centers by volume of kidney transplants performed, there is a great variation in the utilization of living kidney donors. Among the largest transplant centers in volume, living kidney donation can account for as much as 65% of their transplants or as little as 19% of their transplant volumes. The national data highlight the fact that much could be learned from high performing living donor kidney transplant centers and much could be gained by widespread dissemination of best practices related to living donation.

While much can be gained by disseminating best practices through the Learning Collaborative, meaningful improvement in the use of organs at risk of discard will require important systemic changes as well—some of which fall within the jurisdiction of CMS and some of which fall within the jurisdiction of the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) in their capacity as Health Services and Resources Administration (HRSA) contractors. Increased utilization of “less desirable kidneys” at risk for discard has been a high priority for the transplant community for a long time.

President

Lloyd E. Ratner, MD, MPH
Columbia University

President-Elect

Marwan S. Abouljoud, MD, CPE, MMM
Henry Ford Transplant Institute

Secretary

A. Osama Gaber, MD
Houston Methodist Hospital

Treasurer

William C. Chapman, MD
Washington University

Immediate Past President

Dixon B. Kaufman, MD, PhD
University of Wisconsin

Past President

Jean C. Emond, MD
Columbia University Medical Center

Councilors-at-Large

Talia B. Baker, MD
Jonathan P. Fryer, MD
Alan I. Reed, MD, MBA
Michael J. Englesbe, MD
Julie K. Heimbach, MD
Debra L. Sudan, MD
Matthew Cooper, MD
Ryutaro Hirose, MD
Kenneth Washburn, MD
Georgeine Smith, MS, MHS, PA-C

Executive Director

Daniel D. Garrett, CAE
daniel.garrett@asts.org

National Office

1401 S. Clark St.
Suite 1120
Arlington, VA 22202
703-414-7870
asts@asts.org
ASTS.org

American Transplant Congress

May 30 – June 3, 2020
Philadelphia, Pennsylvania

Challenges for success include but are not limited to:

- Better identification of which of these kidneys will provide reliable short and long term benefit,
- Mechanisms to remove financial disincentives for utilization of these kidneys,
- Policy to remove outcome disincentives to utilization of these kidneys,
- Identification of which recipients may benefit most from utilization of these kidneys, and
- Development of a system that rapidly places these kidneys to recipients to limit cold ischemia time.

All of these objectives could be addressed through the establishment of a demonstration program that specifically focuses on increasing the clinically appropriate use of organs at risk of discard, as described in response to Question 3, below.

Four Questions

With respect to the four questions posed by CMS related to the Learning Collaborative, we offer the following thoughts and recommendations:

1. What is ASTS already doing to address the problems and opportunities described? Do you know of any high performers with data from your work?

ASTS engages in multiple educational efforts to increase transplantation, improve waitlist management, improve organ procurement, and decrease discard rates (see Attachment B). In addition, over the past several years, ASTS' advocacy efforts with CMS and other agencies have focused on increasing the availability of transplantation as a treatment option for those with CKD (including ESRD). In fact, ASTS submitted to the CMS Innovation Center (CMMI) a comprehensive proposal for a demonstration program specifically focused on increasing transplant rates in demonstration areas through the creation of broad "Transplant Cooperatives" structured to include the local OPO as well as area transplant center(s), nephrologists, donor hospitals, and others (see Attachment C). We would be pleased to provide an overview of this concept to the HHS officials involved in the Learning Collaborative.

In addition, we have long supported the elimination or significant modification of CMS recertification requirements, OPTN membership criteria, and SRTR star ratings, to remove or substantially modify one-year outcomes requirements, which have been shown to disincentivize the use of organs at risk of discard. In this regard, we applaud CMS' elimination of one-year outcomes requirements as a condition of Medicare recertification of Transplant Centers, and we are continuing to pursue similar changes in OPTN and SRTR processes. Unless and until SRTR and OPTN outcomes requirements are eliminated or modified, we believe that it is unlikely that the removal of CMS one year outcomes requirements will have the desired impact on Transplant Centers' willingness to utilize organs at risk of discard.

Our work thus far has not focused on the identification of "high performers" that successfully utilize organs at risk of discard; however, since our call with CMS we have given considerable thought to the methodology that should be used to identify "high performers" in this area. In this regard, it is critical that the methodology ultimately used to identify "high performers" give adequate consideration not only to a center's use of organs at risk of discard but also to the clinical outcomes. Promoting utilization of these organs indiscriminately without regard to clinical outcomes could do a significant disservice to our patients.

With this in mind, we would recommend that the process set forth at Attachment D be used to identify “high performers.”

We would be pleased to work closely with CMS and with the SRTR to assist in the identification of high performers and to help confirm that the processes utilized by these programs warrant dissemination through the Learning Collaborative.

2. What are your thoughts on the most credible data sources to use in identifying high performers?

As noted by CMS, there are numerous sources of data that may be useful in identifying “high performers,” including, but not limited to, data compiled by the SRTR, OPTN, OPOs, USRDS, CMS, involved professional societies and individual researchers. In fact, in light of the plethora of data, the greater challenge is to articulate clearly the specific criteria that characterize “high performers,” and to then focus on a small subset of metrics that may be relevant, as described at Attachment D.

3. What offers and requests do you have for CMS as related to these goals of increasing the number of beneficiaries who receive kidney transplants from deceased organ donors?

CMS should be applauded for spearheading important initiatives focused on increasing the availability of kidney transplantation as a treatment option for those with late stage CKD and ESRD. ASTS very much appreciates the actions that CMS has taken to further this goal, including eliminating outcome requirements as a condition of recertification, by launching new and innovative demonstration programs that include a specific incentive for increased transplantation, and by focusing attention on improving OPO metrics.

We believe that the effectiveness of these initiatives could be significantly enhanced by closer collaboration with the transplant community and initiatives aimed at removing regulatory and financial barriers to increased transplantation. The Demonstration Project proposal submitted by ASTS to CMMI (Attachment C) addresses both regulatory and financial obstacles to increasing the number of kidney transplants performed, and we urge reconsideration of this proposal. Additional ideas to increase the number of beneficiaries receiving deceased donor kidney transplants include the following:

a) Increase inpatient payment for renal transplantation of increased risk recipients and of organs at risk of discard.

As described in Attachment E, there has been a change in the landscape of both deceased kidney donors and kidney recipients. Both the absolute numbers of older patients on dialysis and/or on the transplant waiting list, as well as the percentage of the wait-list composed of those older candidates, have increased dramatically. This demographic trend, in conjunction with increasing prevalence of older and/or marginal organ donors, is partially responsible for high rates of kidney discards. These issues also create significant financial concerns for Transplant Centers and negatively impact patient care as patients may stay on dialysis longer.

Currently, patients who are listed for transplant are given an Estimated Post Transplant Survival Score (EPTS), which takes into account the patient's age, diabetes status, time on dialysis, and history of previous transplant. A higher EPTS score denotes a patient at higher risk for post-transplant complications. At the current time, over 25% of the current kidney transplant waiting list is > 65 years of age, and the average EPTS score for the national wait-list is increasing. There is a direct correlation between incremental hospital costs and higher EPTS patients, and Medicare payments do not sufficiently compensate for these additional costs.¹ Consequently, transplanting Medicare recipients with a high EPTS may create a financial barrier to transplantation for such potential recipients.

In addition, organs from donors are ranked using a Kidney Donor Profile Index (KDPI) score, taking into account 11 different donor variables. Higher KDPI (>85%) kidneys have higher rates of failure, delayed graft function, infections, re-hospitalization rates, and use of kidney pumps, all of which increase the cost of the transplant episode and of post-transplant care. In a 10 year retrospective analysis, it was noted that transplant center incremental costs were increased with organs from donors with diabetes (\$3370), hypertension (\$665), or donation after cardiac death (\$6182), with no corresponding increase in payments for transplanting these organs. Under these circumstances and considering that the national average payment rate for kidney transplant admissions is less than \$20,000, transplant centers that undertake these more costly procedures run the risk of considerable financial loss.

At this stage, there is only a single Diagnosis Related Group (DRG) for kidney transplants. CMS could use a stepped approach based on donor KDPI and possibly recipient EPTS to decrease the financial disincentives for programs to transplant higher risk recipients and to use higher risk kidneys, by providing an "add-on" payment for the performance of kidney transplants that make use of organs at risk of discard and/or those that are performed for defined at-risk recipients. We believe that such a program would help decrease discard rates of high KDPI and high CIT (cold ischemic time) kidneys that are likely to have DGF (delayed graft function) and associated higher inpatient hospital costs but adequate long-term outcomes — especially if combined with the exclusion of these cases from the OPTN's outcomes requirements and from SRTR five star ratings.

A demonstration project along these lines could serve a number of important research objectives in addition to addressing the financial obstacles to increased use of organs at risk of discard. The recipient candidates that may benefit most from utilization of these kidneys have not been well studied. It is expected that kidneys from less desirable donors will improve and lengthen life compared with dialysis but their longevity will likely be shorter compared with kidneys from other donors. Clearly, candidates at the top of the waiting list (or the top of the high KDPI waiting list) who have accumulated significant allocation points may likely derive more benefit from the "next offer" from a more desirable donor. Indeed, the candidates that may benefit most are likely not at the top of the list but may in fact be at the bottom of the list! These candidates are not in line for a "next offer" and face many years of waiting in many parts of the country.

Development of a mechanism to identify characteristics of candidates who are listed but are unlikely to be transplanted (i.e., they are removed from the list or die on the list) would be

¹ See sources cited at Attachment E.

valuable. If these types of candidates could be identified as likely to benefit from utilization of these kidneys and the criteria for identifying these candidates were standardized, then it may be possible to improve the use of the current system, which includes mechanisms for obtaining separate consent of recipients poorly tolerant of wait-time for receipt of high KDPI kidneys, or to establish an alternative allocation system for these kidneys and recipients.

We note that such a demonstration program would be relatively straightforward to design and implement. Adequate data sources exist to define the characteristics of organs at risk of discard and/or at-risk recipients that generally do not receive transplants, and ASTS would be pleased to work with CMS to identify those transplant admissions that would qualify for an add-on payment. CMS has already placed a \$15,000 value on increased transplantation in the context of the Kidney Care First (KCF) and Comprehensive Kidney Care Contract (CKCC) models, since this is the amount of the Transplant Bonus payable under these demonstrations.² And since CMS already provides “add on” payments for new technology used in connection with particular DRGs, there is an administrative mechanism in place to provide add-on payment. We believe a targeted program aimed at alleviating the current financial disincentives to the use of organs at risk of discard has the potential to significantly increase the availability of kidney transplantation, especially for older potential recipients. Such a program would likely decrease discard rates, increase the overall number of transplants performed, and specifically improve access for high EPTS patients.

b) Make sure that vigorously and systematically incentivizing transplantation is baked into any dialysis/ESRD pay for performance initiative.

ASTS submitted extensive comments on the proposed KCF and the CKCC models. While we applaud CMS for addressing the need to increase the availability of kidney transplantation as a treatment option for ESRD and certain other CKD patients, for the reasons set forth in that prior correspondence we believe that these efforts are unlikely to significantly “move the needle” toward increased access to deceased donor kidney transplantation. For this reason, we urge CMS to include the changes described in the ASTS correspondence on this issue when new applicants are sought in 2020 or 2021.

c) Consider allowing OPOs to add exceptional charges on top of the kidney SAC. For example, allowing OPOs to claim special or extraordinary transportation fees or perhaps machine pulsatile perfusion utilization employed in the placing of organs at risk of discard may be helpful in decreasing organ wastage.

d) Incentivize the Use of Dual High KDPI/ECD kidneys and pediatric en-bloc kidneys. CMS currently does not incentivize the utilization of dual high KDPI/ECD kidneys or pediatric en-bloc kidneys. These transplants involve significantly higher costs, such as longer operative times, with all the attendant costs those impose, the use of more disposable equipment, longer average hospital lengths of stay and higher rates of early postoperative complications. If centers received a Transplant Bonus, along the lines discussed above for the performance of these procedures, we believe it likely that more of these transplants would be performed. In addition, current Medicare payment policy does not incentive OPOs

² The Professional and Global Direct Contracting Models do require that at least 20% of the Transplant Bonus be payable to a transplant “provider” but the transplant provider for these purposes need not necessarily be the Transplant Center that performs the transplant. For example, the “transplant provider” for the purposes of these models may be an individual physician or surgeon (including a transplant nephrologist) or an OPO.

to place dual high KDPI/ECD kidneys. If both kidneys are transplanted into one recipient, the OPO only receives one SAC fee. Policy clarification regarding dual renal transplantation and financial incentives for OPOs to place these organs may also be helpful in increasing the number of transplants performed.

e) **Address access to kidney transplantation under Medicare Advantage (MA) Plans.** At this time, ESRD-eligible Medicare beneficiaries are only eligible to enroll in Special Needs MA Plans. Beginning in 2021, however, ESRD-eligible Medicare beneficiaries will be able to enroll in MA Plans for the first time. We urge CMS to focus on whether, and to what extent, the enrollment of ESRD-eligible Medicare beneficiaries in MA Plans will impact access to transplantation. MA plans add layers of administrative work to transplant centers by insisting on pre-certification of every procedure needed before and after transplant and by creating formularies that restrict post-transplant rejection therapy. In addition, MA Plans deprive transplant centers from a portion of the payment they receive as part of their part A cost report, which can have a significant negative impact on patient access to transplantation. MA Plans generally pay dialysis facilities at significantly higher rates than Medicare Fee-for-Service, and for this reason, dialysis facilities will have a clear financial incentive to encourage ESRD-eligible Medicare beneficiaries to enroll in MA Plans and to keep them on dialysis as opposed to referring them for transplantation. Under these circumstances, we strongly encourage CMS to proactively address transplant access under MA before 2021.

4. Who else should we be reaching out to as we prepare for this initiative?

We urge CMS to include patient groups in this initiative, such as the National Kidney Foundation and the American Association of Kidney Patients (AAKP).

ASTS appreciates the opportunity to partner with CMS to achieve the goals of the Collaborative and we look forward to hearing from you on next steps.

Sincerely,



Lloyd E. Ratner, MD, MPH, FACS
President, American Society of Transplant Surgeons

Cc:

Dennis Wagner, Director of the Quality Improvement & Innovation Group (QIIG) in CCSQ
David Wright, Director of the Quality and Safety Oversight Group (QSOG) in CCSQ
Renee Dupee, Director of the Division of Program, Management, Communications & Evaluation in QIIG
& Executive Champion of the Kidney Transplant Initiative
Jade Perdue, Director of the Division of Quality Improvement Innovations Model Testing in QIIG
Lisa Plummer, Nurse Consultant in QIIG & Team Champion for the Kidney Transplant Initiative

Attachment A

The Advantages of Living Donor Transplantation

ASTS strongly believes that the Transplant Learning Collaborative should include expansion of living donor transplantation as a primary objective. Given the marked difference in utilization of living donor kidney transplantation across transplant centers in the United States, we believe there is a real opportunity for sharing of best practices. Dissemination and adoption of these best practices could significantly increase the number of living donor transplants performed nationwide. Looking at the top 15 centers by volume of kidney transplantations performed, there is a tremendous variation in the utilization of living kidney donors. For example, the largest kidney transplant program in 2018 performed just 19% of their 433 kidney transplants using living donors (81), compared with more than 65% of 245 total transplants performed at another transplant center. The program in the country with the highest utilization of living kidney donors performed 198 living kidney donors out of a total 327 kidneys in 2018, performing 150 more living donor kidneys than a nearby program, which performed just 57 living donors out of 278 total kidney transplants.

The primary benefits of LDKT (living donor kidney transplant) over DDKT (deceased donor kidney transplant) are:

1. LDKTx leads to a higher rate of preemptive KTx. Avoiding dialysis saves money (approximately \$125,000 in the year leading up the transplant), avoids unnecessary dialysis access procedures with those attendant costs and morbidities, and of course eliminates the annual cost incurred once a patient begins dialysis. Preemptive KTx also is associated with better outcomes, which magnifies the cost savings associated with renal transplantation relative to maintenance dialysis.
2. LDKTx has a better graft survival than DDKTx. This is according to SRTR data. Several likely reasons for this including avoiding long dialysis time which has been shown to decrease post-transplant survival, as well as reduced injury to the grafts during organ recovery, and better graft selection.
3. Lower wait-list mortality.
4. Allows for kidney paired donation. This improves the likelihood of transplantation for patients with anti-HLA antibodies and ABO blood-group incompatible donors.
5. A LDKTx really allows two people to be transplanted—the person receiving the LDKTx and the person without a living donor who will now get the deceased donor kidney that would have been given to the person who instead found a living donor. Currently a little less than 1/3 of kidney transplants are from living donors. If none of those occurred then the wait list would be overwhelmed. In contrast, even a slight increase in living donation could have an enormous impact on the deceased donor waiting list.
6. Lower rates of delayed graft function. This reduces post-transplant cost and hospital length of stay. More importantly, decreased DGF rates are independent predictors of improved allograft survival and decreased likelihood of acute rejection.
7. Allows for medical optimization of patients for transplant since the timing of transplant can be predicted and controlled. This includes several categories such as older patients who might need cardiac workups and patients on anticoagulants who would require blood thinners.
8. Better HLA matches may be possible. In the best case scenario, an HLA-identical sibling can be found. This has the best immunologic graft survival—better than even 0-ABDR mismatched deceased donors.

9. Perhaps most importantly, longer graft survival provided by LDKT will result in a reduced need for re-transplantation as fewer recipients return to the wait-list.

In summary, increasing the number of living donors is an essential component of reducing the number of patients waiting for kidney transplant, and it would lead to overall improved graft survival, improved quality of life, and decreased costs in the entire system. Thus, we urge you to expand the proposed collaborative to include best practices in both living and deceased kidney donor utilization.

Attachment B

ASTS Educational Programs & Activities

Background

The American Society of Transplant Surgeons (ASTS) was founded in 1974; today it comprises over 1800 solid organ transplant surgeons, physicians, scientists, pharmacists, advanced transplant providers, and allied health professionals dedicated to advancing surgical care in transplantation.

The ASTS is the leadership organization of the surgeons, physicians, and scientists who have pioneered and continue to advance the frontiers of life-sustaining organ transplantation. The ASTS has taken the field from experimental trials to highly developed treatment modalities that increasingly offer a growing number of men, women and children a new chance at an ever longer and healthier life.

The ASTS Foundation was established in 2002 to provide for additional programs that support the mission and to ensure the future of the ASTS.

ASTS Mission

ASTS advances the art and science of transplant surgery through patient care, research, education and advocacy.

ASTS Vision

Saving and improving lives with transplantation.

Programs & Activities:

Patient Care Programs

To create a network of resources that are ethical, safe, timely, and effective for learning and dissemination of knowledge focused on optimal patient care.

National Living Donor Assistance Program (NLDAC)

Many people would like to donate an organ to a family member or friend but would have trouble paying for related expenses—like transportation, lodging, and food—that are not covered by insurance. The costs of the process can be a burden for donors and recipients; for some, these costs might make living organ donation impossible. The National Living Donor Assistance Center exists to provide access to transplantation for those who want to donate but face financial barriers to doing so.

The program is administered by the Division of Transplantation (DoT), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), United States Health and Human Services (HHS) through a cooperative agreement with the University of Arizona (UA) and the American Society of Transplant Surgeons (ASTS).

Our mission is to reduce the financial disincentives to living organ donation. To this end, we operate a nationwide system that provides reimbursement of travel and subsistence expenses to people being evaluated for and/or undergoing living organ donation. Priority is given to those who could not otherwise afford to donate.

Organ Donation

The ASTS is actively engaged in ethical issues including development of guidelines for donation after cardiac death (DCD) organ recovery, development of guidelines for procuring surgeons, development of resource documents professionals and for patients, and removal of financial disincentives for living organ donors.

Educational Programs:

Transplant Accreditation & Certification Council

The Transplant Accreditation & Certification Council (TACC) serves the public and healthcare community by promoting excellence and professionalism through education, accreditation, and certification.

Academic Universe & Online Curriculum

The Academic Universe is the cornerstone for educational initiatives within ASTS. Housing an expansive curriculum online surgical log, the Academic Universe is an outstanding online educational resource for fellows, advanced transplant providers, and established surgeons. The academic universe brings the information right to the learner's fingertips; users are able to learn from the leaders in the field of transplantation without leaving the comfort of their own location. ASTS has championed the advancement of education within the field of transplantation and the results are a testament to the Society's commitment to its mission of providing career-long education and professional development.

The National Transplant Surgery Curriculum for fellows defines the key areas of knowledge necessary for mastery of the field of transplantation surgery. In addition to our National Curriculum, the Resident Curriculum is also available to surgical residents who need additional resources during their transplant rotation. Both curricula offer learning modules that address major points within the designated transplant material which allow the learners to develop an organized, detailed, and comprehensive understanding of the area. Each module has a narrated presentation on a specific topic and is accompanied by written summaries, suggested readings, and a self-assessment to gauge learning. The curriculum provides an educational guide for trainees and serves as a dynamic reference for all ASTS members.

Fellowship Training

Currently, 65 institutions in the United States and Canada can proudly boast ASTS accreditation for training transplant fellows in abdominal organ transplantation. As the leading Society advancing surgical

care in transplantation, the American Society of Transplant Surgeons (ASTS) and Transplant Accreditation & Certification Council (TACC) are committed to defining and promoting training and the career-long education of transplant surgeons. The primary avenue by which TACC defines and promotes training is through accreditation of abdominal transplant surgery fellowship training programs and is the only provider of this service to the transplant community.

Fellowship Training Program Accreditation provides validation that a training program meets prescribed high standards and is a seal of approval formally recognized by the United Network for Organ Sharing (UNOS), Organ Procurement and Transplantation Network (OPTN) and others. Accredited training programs serve as the primary pathway for transplant surgeon designation and associated privileges. Regulatory bodies, third-party payers, and academic transplant centers increasingly view completion of an accredited training program as an important qualification.

The objective of a transplant surgery fellowship training program is to develop proficiency in the surgical and medical management of patients with end-stage organ diseases amenable to transplantation. Candidates for such training must have satisfactorily completed a residency which satisfies the educational requirements for certification by the American Board of Surgery or the American Board of Urology or foreign equivalency.

Clinical fellowships are 24 months in duration and designed to provide fellows with adequate exposure to transplant methodology, surgical procedures and pre- and post-operative patient care and management. These intense requisites produce top-notch surgeons with the combined experience and in-depth education to truly advance the field.

Educational Meetings and Symposia

ASTS believes that an educated and strong community is important in achieving this goal. The meetings and symposia that ASTS offers throughout the year strive to present the most up-to-date and most relevant issues before the transplant community to equip them with the most up to date skills in the field. These events also provide networking opportunities for members of the global transplant community.

All education initiatives are developed in strict compliance with the guidelines, policies, and criteria of the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. In 2009, the Society received the highest level of accreditation, "Accreditation with Commendation," as a provider of continuing medical education for physicians awarded by the ACCME. Accreditation with Commendation is awarded to providers that demonstrate exemplary compliance in all 22 criteria. This decision was based on the ACCME's review of ASTS' self-study report, evidence of performance-in-practice and for demonstrating that the Society provides a learning environment for transplant surgeons in support of physician learning and change that is a part of a system for quality improvement. This acknowledgement demonstrates the Society's purpose and aligns with our mission, which is to deliver best in class professional education that is evidence-based, focused on the improvement in quality care, and is designed to address the specific scopes of practice and professional practice gaps of transplant professionals.

- American Transplant Congress

The American Transplant Congress (ATC) is a joint scientific meeting of the American Society of Transplant Surgeons and the American Society of Transplantation designed for physicians, surgeons, scientists, nurses, organ procurement personnel, pharmacists, allied health professionals, advanced transplant providers, researchers and coordinators who are interested in the clinical and research aspects of solid organ and tissue transplantation. This meeting has become the premier event in the field of transplantation with over 4,500 attendees from all areas of transplantation science and medicine. Each year, the program is developed to encourage the exchange of new scientific and clinical information and support an interchange of opinions regarding care and management issues, as well as socio-economic, ethical, and regulatory issues relevant to organ and tissue transplantation.

- Annual Fellows Symposium

ASTS hosts an annual Surgical Fellows Symposium in which second-year transplant fellows in ASTS accredited fellowship training programs come together to gain focused knowledge in areas that have been identified as underemphasized in many clinical training programs. Through a series of interactive lectures and case studies, the program offers educational content which focuses on cited gaps in fellowship training, including histocompatibility, immune function and immunosuppression, technical procurement pitfalls, transplant candidate evaluation, organ allocation, practical aspects of donor and recipient pairing, long-term patient management, lifelong transplant surgeon education and professionalism. The Symposium is a great networking opportunity for emerging members of the transplant community to connect with established leaders in the field.

- Hands-on Workshops

In concert with the ASTS' mission to advance the art and science of transplant surgery through patient care, research, education, and advocacy, ASTS education focuses on the lifelong learning commitments of healthcare professionals practicing in the field of surgical transplantation. As demonstrated through previous activities, education is an important tool in improving transplant outcomes. Fully informed healthcare professionals can act more effectively to care for their patients, themselves, and their loved ones. ASTS is committed to developing evidence-based educational programs to meet the learners' educational needs to enhance competence and performance and ultimately improve patient care. To address the needs of their specific expertise, the Laparoscopic Donor Nephrectomy and Comprehensive Donation after Circulatory Death Workshop were developed to focus on skills-based learning that promotes changes in competence and performance to ultimately improve patient outcomes in two key areas, laparoscopic donor nephrectomy and donation after circulatory death.

The workshops incorporate new techniques with learners' previous experience by linking didactic lectures, interactive case-based discussions, and hands-on cadaver labs. An experienced slate of faculty share their experiences, engage learners through in-depth discussions, and provide feedback during the surgical skills lab. Faculty members are selected based on their status as a key opinion leader or their expert level in the field. The resulting discussions and questions posed by audience members allow for a

directed yet open forum of communication. In addition, due to the small size of the course, more personalized education is achieved through direct feedback, leading to practice-ready actions.

- Leadership Development Program

The ASTS Leadership Development Program provides surgical and administrative leadership with essential business skills necessary to successfully lead transplant centers within an increasingly complex financial and regulatory environment. ASTS partnered with the Kellogg School of Management at Northwestern University to design a highly customized executive management course exclusively for the field of transplantation. Key components of the program include an exposure to necessary business practices, leadership skills, and an overview of the legal and regulatory aspects of transplantation. Topics include finance, accounting, negotiating productive agreements, transplant center quality metrics, team leadership, and institutional relationships.

- State of the Art Winter Symposium

ASTS offers an annual topic-driven State of the Art Winter Symposium that focuses on the most recent advances in the field of transplantation and offers a wealth of new information that refreshes and hones the highly specialized technical training of members of the global transplant community. The conference provides a forum for information exchange so participants can examine innovative techniques and disciplines in transplant surgery while expanding their knowledge of new scientific and clinical information. In addition, the Symposium provides practice-based learning of new aspects regarding the care and management of both transplant donors and recipients in order to improve patient outcomes and facilitates an area for the interchange of ideas regarding controversies in the practice of common transplant surgical techniques that improves knowledge and positively affects outcomes.

- Transplant Financial Bootcamps

The ASTS Financial Bootcamps were designed by and in response to a recurring request from attendees of the popular ASTS Leadership Development Program (LDP). Many LDP attendees requested a deep dive into the financial aspects of a managing successful kidney and liver transplant programs.

Attachment C

Care Coordination to Increase Transplantation Demonstration Project

This outlines a proposed demonstration project structured to increase transplantation for Medicare patients with kidney disease, by providing financial incentives and regulatory relief to transplant centers, dialysis facilities, Organ Procurement Organizations (OPOs,) community hospitals, nephrologists and others to increase transplantation rates in the area covered by the demonstration project.

Background

It is undisputed that kidney transplantation is the best treatment option for appropriately selected Medicare patients with ESRD and potentially for Medicare patients with kidney disease short of ESRD (hereafter, "Demonstration-eligible patients"). It is also undisputed that kidney transplantation is the most cost-effective treatment for such patients. However, under today's Medicare program, dialysis is the usual treatment for these patients, and transplantation is the exception. Transplantation should be the first line treatment, with dialysis available for those patients for whom transplantation is contraindicated and those for whom a suitable organ is unavailable.

Misaligned Incentives to Transplant

The Medicare program includes a number of financial and regulatory disincentives for providers to maximize the use of transplantation as the treatment of first choice for Demonstration-eligible patients. On the financial side, dialysis facilities and associated nephrologists have a strong financial incentive to maintain patients on dialysis as long as possible. OPOs, which are paid by Medicare on a cost basis, have little financial incentive to increase the supply of viable organs. Non-transplant hospitals—a potential source of additional organ donors—have no financial incentive to ensure that OPOs are fully and effectively informed in a timely manner of potential organ donors.

Regulatory Rules, Existing Demonstration, & Legislative Challenges

Current Medicare regulations do not encourage, and in some ways actually discourage activities that would lead to an increased number of transplants being performed. OPO conditions of participation dissuade OPOs from retrieving kidneys from kidney-only donors. Transplant Center conditions of participation impose outcomes requirements that dissuade centers from accepting "marginal" organs for transplantation. Dialysis facilities are required to counsel patients on the availability and benefits of transplantation but often fail to do so (or fail to do so effectively). Nephrologists' quality measures currently do not address referrals for transplantation evaluation and there is only one recently added dialysis facility quality measure that does so. And reimbursement to potential living donors for the costs associated with donation is limited by concerns over NOTA prohibitions.

The ESRD CEC demonstration program currently underway encourages dialysis facilities to maintain relatively healthy patients on dialysis rather than referring appropriate patients for transplant evaluation, since shared savings would cease in the event of transplantation. While we understand that an expansion of the CEC Demonstration Program is under consideration, it does not appear that this

significant error in the architecture of the CEC, which will potentially limit patient access to transplantation with all the attendant disadvantages for patients and system costs has been resolved.

The Demonstration Concept

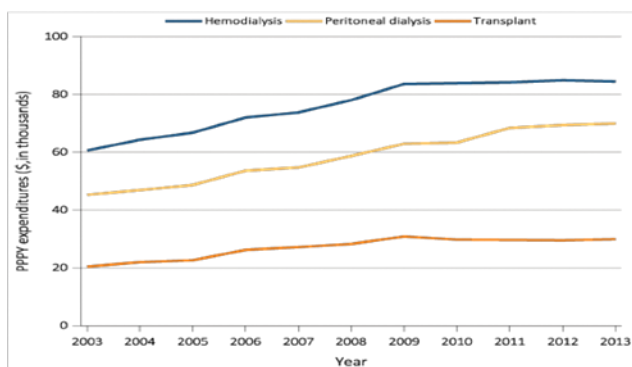
Goals increase transplantation for Medicare patients with kidney disease, by providing financial incentives and regulatory relief to transplant centers, dialysis facilities, OPOs, community hospitals, nephrologists and others to increase transplantation rates in the area covered by the demonstration project.

Changing the Paradigm of Dialysis & Transplantation

The patient cost of transplantation, over a short period of time, is far less than dialysis; patient life expectancy for transplantation is far longer than dialysis; savings to the Medicare program would increase if transplant were advanced more methodically.

- The United States Renal Data System (USRDS) 2015 Report notes that total Medicare expenditures per person/per year for hemodialysis patients is \$84,550; for those on peritoneal dialysis, \$69,919; and for renal transplantation, \$29,9201 (approximately \$34,795/year including estimated Part D expenses).
- The average expected duration of the benefit of therapy after renal transplantation is twice that of hemodialysis: Life expectancy for hemodialysis is 5.7 years with nearly universal mortality, and, for renal transplantation 12 years (“graft survival”) with 25% mortality.
- Thus, total Medicare savings for each patient who is transplanted rather than being maintained on hemodialysis is estimated at \$283,603 over the average 5.7 lifespan on hemodialysis, based on USRDS data. And, based on the cost trends for dialysis and transplantation, it appears that the savings are likely to grow over time.
- Additional published data also suggests that considerable cost savings would result from increasing transplantation for clinically appropriate patients.

Total Medicare ESRD expenditures per person/per year, by modality



Changing Financial Incentives, Removing Disincentives

Instead of continuing to allow the misalignment of incentives and perpetuating disincentives to transplant, all providers involved in the care of Demonstration-eligible patients should receive a financial incentive to increase transplantation of clinically appropriate patients, using a shared savings (and potentially shared losses) incentive system similar to that used under the ACO program and various Centers for Medicare and Medicaid Innovation Center (CMMI) demonstration programs.

Demonstration Parameters

The demonstration would provide financial incentives and regulatory relief to address the issues noted above.

Financial Incentives

- A target number of transplants for the demonstration area would be determined using USRDS data, based on historical transplant rates and taking into consideration “imported” and “exported” organ volumes.
- Participants in the demonstration program (consisting of transplant center(s), dialysis facilities, the OPO, physicians, and community hospitals) would be paid their fee-for-service rates under whatever Medicare payment system ordinarily applies.
- For each additional Medicare ESRD patient transplanted over the target, savings equal to some percentage of the average difference between the cost of transplantation and the cost of dialysis would be paid into a separate segregated account established by the demonstration participants and managed by a third-party trustee.
- Payments would continue for the average 5.7-year lifespan of patients undergoing dialysis, unless the transplanted patient dies, requires dialysis, or requires re-transplantation. (Separate shared savings calculations could be made for Medicare patients who have renal disease and who are clinically appropriate for pre-emptive transplantation but who are not yet on dialysis.)
- Funds paid into the separate segregated fund are distributed by the trustee among demonstration participants based on an agreement among the participating providers and approved by CMS prior to inception of the demonstration project.
- Phase II of the program might include an option under which the program participants could share the losses in the event that transplants do not meet the target.

Regulatory Relief

In addition to the financial incentives described above, demonstration participants could be entitled to a waiver of certain otherwise applicable Medicare rules. For example, CMMI may consider the following:

- Waive or liberalize the OPTN and SRTR outcomes measures applicable to participating transplant centers, so long as outcomes equal or exceed outcomes of dialysis or some other negotiated benchmark.

- Allow the National Living Donor Assistance Center (NLDAC) to reimburse lost wages for living donors who meet established financial criteria.
- Waive OPO cost reporting principles to enable program participants to establish an OAC for organs for paired kidney donation.
- Enable transplant centers to count as an “in house donor” of any donor who was declared deceased and consent with authorized in its facility. These donors can then be cared for in a more cost-effective organ recovery center that are now being established by OPOs, without adversely impacting transplant center revenue while simultaneously decreasing the cost of transplantation and potential increasing organ recovery.
- Enable program participants to pay for immunosuppressive coverage beyond 36 months.
- Provide that participation in the demonstration program constitutes a Clinical Practice Improvement Activity and could include a measure relating to nephrologist referrals for transplantation evaluation as a quality measure under MIPS. (It is unclear that the demonstration project would qualify as an “Advanced Alternative Payment Model” without additional risk-bearing features.)

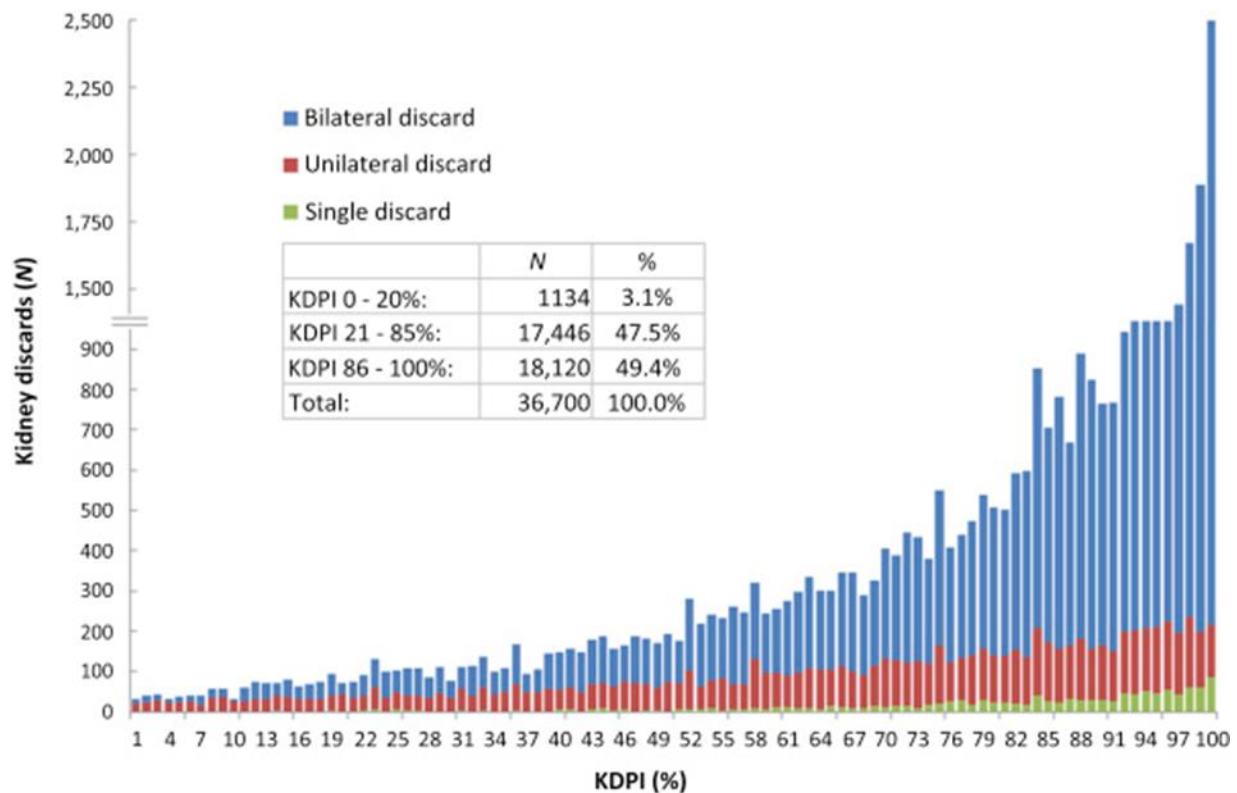
Conclusion

The proposed demonstration project has the potential to achieve considerable savings for the Medicare program while substantially improving the care for ESRD patients and other Medicare patients with renal conditions for which transplantation is clinically appropriate. By aligning incentives and encouraging care coordination, the demonstration program has the potential to significantly increase the availability of transplantation for Medicare patients for whom transplantation is the best and most cost-effective treatment option.

Attachment D

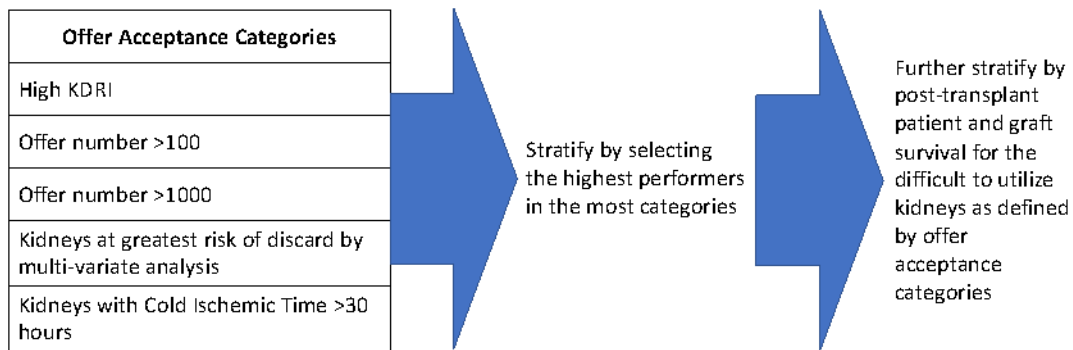
A Process for Identification of “High Performers”

There are multiple reasons why kidneys from deceased donors are not utilized, both due to them being discarded or not procured. While much focus has been on the utilization of high KDPI (defined as KDPI >85%) (e.g., UNOS COIIN Project), greater than 50% of discarded kidneys are from donors with KDPI <86% (see graph and table below). And, the reasons that many of these kidneys are not utilized are multi-factorial or poorly documented. Additionally, decisions to utilize a kidney or not are often colored by logistical considerations (i.e., cold ischemic time), donor co-morbid conditions, histologic findings, performance on mechanical perfusion devices, donor renal dysfunction, anatomical injuries or anomalies, and the appropriate pairing of donor organ and patient. Thus, identification of high performers cannot rely upon a single data element such as utilization of high KDPI donor organs.



However, there are several readily available data elements that can be utilized. There are also additional data that should be generated to help identify the high performers.

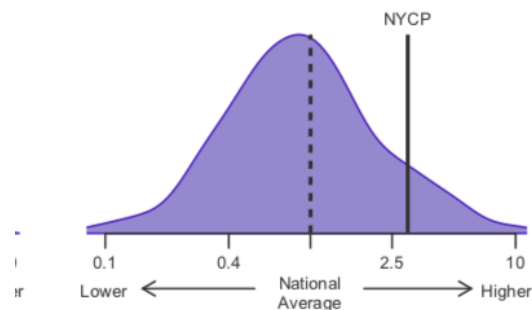
The ASTS recommends identifying the highest performers in each of the below offer acceptance categories, selecting those that are high performers in the most categories, and then further segregating them by post-transplant outcomes for the kidneys that are at high risk for non-utilization. We believe that to identify best practices, it is not sufficient to identify the high performers in terms of usage of these difficult organs. Rather, we need to identify the high users that yield the best outcomes.



Offer Acceptance Categories

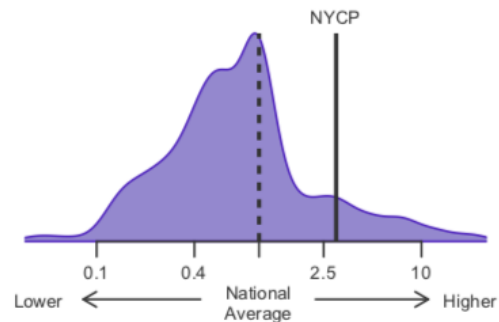
- High KDRI** – Offer acceptance for kidneys from high KDRI donors is calculated by the SRTR and provided in the Program Specific Reports and presented in the format below. KDRI (Kidney Donor Risk Index) is the number generated from donor multivariate analysis that correlates with post-transplant graft survival. Thus, high KDRI denotes likely worse graft survival than lower KDRI organs. KDPI is a percentile ranking based on KDRI.

Figure B10. Offer acceptance: High-KDRI



- **Offer Number >100** – Offer acceptance for kidneys that are transplanted into patients that are >100 on the national allocation sequence, i.e., that these kidneys have been turned down for the first 100 patients or more on the waiting list. This captures some of the intangible or unquantified elements that can result in kidney discard. This data is calculated by the SRTR and provided in the Program Specific Reports and presented in the format below.

Figure B11. Offer acceptance: Offer number > 100



- **Offer Number >1,000** – This captures more of the intangible or unquantified elements that can result in kidney discard. This data is not calculated by the SRTR or provided in the Program Specific Reports. Going out to sequence >1,000 on the allocation match run will likely eliminate programs in single center organ procurement organizations (OPOs) that have the flexibility to select the most appropriate patient for the kidney in question. Additionally, presumably, these are likely to be the most difficult kidneys to place.
- **Kidneys at High Risk for Discard Based on Multivariate Analysis of Donor Factors** – A multivariate analysis of donor demographic, laboratory, geographic, and histologic factors should be performed to determine those factors that place kidneys at highest risk for discard. Then centers can be ranked for usage of those kidneys with the highest risk for discard.
- **Kidneys with Cold Ischemic Times >30 Hours** – Frequently, cold ischemic time is a surrogate for undesirability of a kidney. If the kidney is not accepted for use locally, the additional time that it takes to successfully allocate, place, transport, and transplant a kidney is reflected in extended cold ischemic time. Again, this parameter will reflect donor or organ specific factors that may not be quantifiable based on other data.

Stratification of the Highest Performing Centers

There will be much overlap in the kidneys that fall into the above five groups of Offer Acceptance Categories. The top 10% of centers in each category should be identified. Those centers can then be stratified by ranking how many of the five Offer Acceptance Categories the center falls into the top 10% of usage. Then those centers can be further stratified based on post-transplant outcomes for kidneys that have been defined as difficult to place in the five offer acceptance categories.

We believe that this approach will serve to successfully identify those centers that are truly most successfully utilizing the kidneys with the greatest likelihood of discard or non-use.

Attachment E

The Need for Risk Adjusted Inpatient Payment for Kidney Transplants

At the current time, over 25% of the current kidney transplant waiting list is > 65 years of age. Alongside this, comorbidities among these patients have also increased. Currently, patients who are listed for transplant are given an Estimated Post Transplant Survival (EPTS) score, which takes into account the patient's age, diabetes status, time on dialysis, and history of previous transplant. A higher EPTS score denotes a patient at higher risk for post-transplant complications. Previous studies have shown that there is a direct correlation between incremental costs and higher EPTS patients, and that Medicare payments do not sufficiently compensate for these additional costs (1). Consequently, transplanting Medicare recipients with a high EPTS may create a financial barrier to transplantation for such potential recipients.

Organs from donors are similarly ranked with a Kidney Donor Profile Index (KDPI) score, taking into account 11 different donor variables. Higher KDPI (>85%) kidneys have higher rates of failure, delayed graft function, infections, re-hospitalization rates, and use of kidney pumps, all of which increase the cost of the transplant. In a 10 year retrospective analysis, it was noted that transplant center incremental costs were increased with organs from donors with diabetes (\$3370), hypertension (\$665), or donation after cardiac death (\$6182), with no corresponding increase in payments for transplanting these organs. And yet, the use of such organs shows an increased patient survival of 29%, and costs of 12.2% less per Quality of Life Years (QALY) compared to dialysis (2,3). The use of such organs at risk of discard has been associated with net financial loss for transplant programs (4). Thus, while there is an overall societal benefit in the use of organs at risk of discard, the increased costs and regulatory pressures are borne by the transplant center alone.

Yet another sequelae from the high kidney discard rates in the United States has been the increasing cost of procuring kidneys. Beginning at 5.1% in the 1980s, the current kidney discard rate is around 18%-19%. Much of this change has happened due to the declining quality in the donor pool (2). The costs of procuring kidneys for transplant by the Organ Procurement Organizations (OPOs) are passed on to the transplant centers in the form of their Organ Acquisition Costs (OACs). This is typically averaged out for the costs for all the kidneys procured. Hence, as more kidneys get discarded, the costs related to pursuing these organs is spread out over the total costs of organ procurement. It has been demonstrated that the costs of procuring deceased donor kidneys has increased over the years, in direct correlation to the number of kidney discards (5). Incentivizing use of such organs may reduce discards and reduce organ procurement costs.

Thus, the costs of transplantation are increasing, due to an increasing number of high risk recipients and high risk donors. These changes in clinical characteristics result in incremental costs. The use of riskier organs and acceptance of riskier recipients for transplant may be cost prohibitive for many transplant centers, resulting in higher kidney discard rates and more patients remaining on dialysis.

It is widely recognized that transplantation improves outcomes and reduces costs long term, even with such risky donor organs and recipients. In fact, use of higher risk (high KDPI) organs has been shown to maximize benefit for older (>50 years) recipients with longer waiting times (6). Yet, the immediate increased costs of such transplants are solely upon the transplant center. Transplant centers are reimbursed for a single Diagnosis Related Group (DRG), which does not adequately account for donor or recipient factors. Liver and heart transplants are currently subject to the CMS Hierarchal Condition Codes (HCC) for additional DRG weighting. There is no such provision for kidney transplants. We would suggest that such a risk-adjusted payment model be considered to incentivize the use and reduce the discard of marginal kidneys.

References:

1. [Axelrod D, et al. AJT 2017; 17:377-389](#)
2. [Sharma N, et al. Curr Opin Organ Transplant 2019, 24:92-96](#)
3. [Axelrod D, et al. AJT 2018;18:1168-1176](#)
4. [Englesbe MJ, et al. AJT 2008;8\(3\):586-592](#)
5. [Held PJ, et al. AJT doi:10.1111/AJT.15669](#)
6. [Massie AB, et al. AJT 2014;14\(10\): 2310-2316](#)