

**ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION (ACOT)**  
**U.S. Department of Health and Human Services (HHS)**  
**March 12–13, 2015** □  
**Health Resources and Services Administration (HRSA), Rockville, MD**  
**Meeting Summary**

**Participants**

***Voting Members***

Mark L. Barr, M.D.; Charles Alexander, R.N., M.S.N., M.B.A.; Bryan Becker, M.D.; Sylvia Caley, J.D., M.B.A., R.N.; Bernice Coleman, Ph.D., R.N.; Stephen W. Crawford, M.D.; James D. Eason, M.D.; John Fung, M.D., Ph.D.; David A. Gerber, M.D.; Alexandra K. Glazier, J.D., M.P.H.; Ana Hands, M.D.; Eduardo Lara, B.A., M.H.A.; Arthur Matas, M.D.; Suzanne McDiarmid, M.D.; Jamie Marie Avolio McDonald, M.S.W., L.I.S.W.; Kimberly Molina, M.D. (by phone); Thomas A. Nakagawa, M.D.; Cynthia P. Puryear; Andrew J. Schaefer, Ph.D.

***Designated Federal Official***

Patricia Stroup, M.B.A., M.P.A.

**DAY ONE—MARCH 12, 2015**

**Welcome and Opening Remarks**

***Mark Barr, M.D., Chair, ACOT***

Dr. Barr called the meeting to order at 8:31 a.m. and welcomed the participants. For the many new members of ACOT, he explained that work groups play an important role. He encouraged members to join a work group if they have expertise to contribute and can commit the time required. Dr. Barr described the establishment and role of the ACOT, noting that the Committee advises the HHS Secretary, through HRSA, on all aspects of organ donation, procurement, allocation, and transplantation. Dr. Barr outlined the membership of the Committee and its activities.

At present, ACOT has five active work groups:

- Alignment of Centers for Medicare and Medicaid Services (CMS) Regularity Requirements with Organ Procurement and Transplantation Network (OPTN) and HRSA
- Declining Rates of Donation/Geographical and Other Variations in Organ Distribution
- Research Barriers to Donor Management and Innovation
- Kidney Paired Donation (KPD)
- Brain Death Determination

Work groups may include non-ACOT members. Dr. Barr suggested ACOT members consider others in the field who may be good candidates for a work group.

## **Introduction of All Members and Roll Call**

***Patricia Stroup, M.B.A., M.P.A., HRSA***

Ms. Stroup called the roll, and ACOT members introduced themselves.

## **Program Report, Division of Transplantation (DoT), HRSA**

***Bob Walsh, Director, DoT***

Mr. Walsh introduced his update by noting that there has been little new activity since the ACOT met in January 2015. The OPTN Kidney Allocation System (KAS) went into effect in December 2014, establishing criteria for the use of donated kidneys that rely on more objective aspects than waiting time. Data gathered so far have identified no unintended consequences of the new system.

The OPTN Liver and Intestinal Organ Transplantation Committee is working with the Scientific Registry of Transplant Recipients (SRTR) to examine potential new districts for liver allocation, largely in response to an ACOT recommendation to move toward a more objective allocation system. The OPTN published its concepts and gathered comments through a public forum in September 2014. It is evaluating the input and plans to release another document for public comment in June.

Some years ago, HRSA awarded a fellowship to an expert in logistics, which led to the development of TransNet, a tablet-based application to streamline processes within organ procurement organizations (OPOs). The application is being deployed and has already led to dramatic improvements in workflow and reduced errors.

Building on the success of community partnerships, the HHS Chief Technology Officer has partnered with organizations outside of HHS to fund the Innovator-in-Residence fellowship. The recipient will work closely with communities to identify problems and propose novel solutions. Past and current projects include efforts around patient engagement, home-based health care innovations, and use of geospatial information platforms for health communications.

The Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act became law in November 2013. It allows transplantation of organs procured from HIV-positive individuals to HIV-positive individuals in need. Mr. Walsh said HRSA is working closely with the National Institutes of Health (NIH) to develop research criteria.

The University of Michigan has entered into a cooperative agreement with HRSA to continue operation of the National Living Donor Assistance Center, which reimburses for travel and subsistence expenses related to organ donation. In addition, HRSA established a cooperative agreement with the Lewin Group to conduct the National Goals Study. Mr. Walsh said the national goals set 10 years ago were helpful, because the community rallied around them. The Lewin Group study will help HRSA evaluate progress toward the current goals and provide an overview of all the current activities. The findings will be used to inform future national goals that will aid in achieving the ultimate goal of providing more transplantations for people in need.

Mr. Walsh described HRSA's use of traditional and new media for outreach and education, including, for example, paid advertising in the programs of several professional sports events, which are likely to reach a new audience. He noted that the DoT uses Facebook to reach a large population quickly. The Facebook page includes short videos and graphics that partners can share on their own social media sites. A 5-minute-long video describing the organ donation process was posted on Facebook and YouTube and has been very popular, Mr. Walsh said. Other outreach efforts include a partnership with the retail pharmacy Walgreens, which will print information about organ donation on its prescription receipts.

The DoT is focusing on pediatric organ donation, and during the 2015 Donate Life Month (March), messaging will focus on pediatric donation. The American Academy of Pediatrics has expressed interest in working more closely with the transplant community and will actively promote the message to members and patients' families.

The Workplace Partnership for Life began in 2003 as an effort to promote and educate about organ and tissue donation. Most recently, the program has focused on engaging hospitals, which will push information out to staff and patients.

In closing, Mr. Walsh said HRSA appreciates the participation of all its community partners toward the goal of ensuring more people get the organ transplants they need. At present, about 124,000 people are on the waiting list for an organ transplant.

### ***Discussion***

Dr. Barr asked for more details about the Lewin Group's activities in the National Goals Study. Mr. Walsh said the Lewin Group is working with HRSA to determine all the activities underway and to analyze them to measure their potential impact. The findings will help HRSA set data-based national goals for the near future and inform decision-making about grants, contracts, and activities with the most potential impact. The Lewin Group contract ends in September 2015, and Mr. Walsh expected that deliverables would be available then.

Dr. Barr called the 5-minute video "Organ Donation and Transplantation: How Does It Work?" one of the best educational pieces he has seen in years for children and adults. He asked whether efforts have been made to shorten it and to present it through a national network. The video would be very good for schools, he added. Mr. Walsh said it is challenging to compress the video even further, but there are discussions about disseminating the video more broadly to schools, OPOs, and other organizations.

### **OPTN Update**

***David Klassen, M.D., Chief Medical Officer, United Network for Organ Sharing (UNOS)***

Dr. Klassen gave a brief overview of the process of updating the UNOS OPTN strategic plan. The 2012 plan has six goals:

1. Increase the number of transplants

2. Increase access to transplants
3. Improve survival for patients post-transplant
4. Promote transplant patient safety
5. Promote living donor safety
6. Promote the efficient management of the OPTN

Goals 1–4 have been in place since the inception of the OPTN. Members have contributed opinions about the goals during meetings, and the order of the goals reflects the priorities of the members and the UNOS Board, said Dr. Klassen. The UNOS Policy Oversight Committee ranked patient safety as its number-two priority. When the UNOS Executive Committee met earlier in March, it drafted a proposed strategic plan that revises the goals as follows:

<b>2012 Strategic Plan</b>	<b>2015 Proposed Strategic Plan</b>
1. Increase the number of transplants	Increase the number of transplants
2. Increase access to transplants	Improve equity in access to transplants
3. Improve survival for patients with end stage organ failure	Improve waitlisted patient, living donor, and transplant recipient outcomes
4. Promote transplant patient safety	Promote living donor and transplant recipient safety
5. Promote living donor safety	
6. Promote the efficient management of the OPTN	Promote the efficient management of the OPTN

The proposed plan will be reviewed by members and then by the Board in June 2015. Most of UNOS ongoing projects map to the goals of patient safety and efficient management of the OPTN, suggesting a gap between member priorities and UNOS projects. While UNOS will continue to support projects on patient safety and efficiency, it will also address that gap.

As Mr. Walsh noted, after 10 years of development, the KAS took effect in December, and UNOS is monitoring it weekly. One goal of the new system is to better match the age of the donor and the recipient to foster better longevity of the donated kidney. When the KAS went into effect, the number of donations in which there was a 15-year or more age difference between the donor and recipient dropped dramatically, although it is rising gradually again. The number of non-local donations increased, which was expected because the system aims to increase sharing.

The most dramatic change to date has been the increase in the number of transplants among patients with high calculated panel reactive antibodies (CPRA), which shot up from about 2% to more than 17%. Dr. Klassen posited that the increase may represent a bolus effect. Patients with high CPRAs represent about 9% of the total waiting list, so the percentage may go down over time, he added.

Data show the number of registrations has remained stable. Because the KAS will use the date of dialysis initiation as the registration date, the pressure to register may decline, said

Dr. Klassen. Evaluated by region, the KAS has resulted in an increase in transplants from non-local donors, but there were no big shifts in transplants across defined regions.

Demographic data show the number of transplants among Whites has gone down and those among Blacks have gone up since the KAS was initiated. Dr. Klassen said these findings may be a function of access based on dialysis duration. Transplants also went down in people over age 65 years. There was a decrease in the number of zero mismatches for HLA tissue antigens A, B, and DR. The number of transplants in pediatric patients declined when the KAS went into effect but has quickly rebounded back to historic norms, so initial concerns were not borne out. There has been little change overall in the kidney discard rates.

In June 2014, a UNOS Committee on redesigning liver distribution to reduce geographic disparity published a white paper and collected public comments. That input led to the creation of subcommittees on the metrics of disparity, finance, and logistics and transportation. The subcommittees will develop recommendations and present them to the UNOS Committee and the public in a forum tentatively scheduled for June 22, 2015, in Chicago.

### ***Discussion***

John Fung, M.D., Ph.D., asked whether UNOS intends to make formal recommendations about removing certain organs from the calculation of discards and other measures so that those organs are not counted toward outcome and performance data assessed by CMS. Including such organs in the measures creates a disincentive for centers to use them. Dr. Klassen responded that a subcommittee is discussing whether the current metrics for transplant programs affect decision-making. In addition, there is discussion in other settings about revising metrics to remove disincentives.

David A. Gerber, M.D., asked about the economic impact of the KAS. He said his organization is seeing the cost of travel double for kidney donations. Dr. Klassen agreed that the issue is important and requires additional study. He said UNOS is collecting data and actively evaluating the cost of liver transplantation. In the UNOS Committee's white paper, a model determined that the overall economic impact would be positive, but it did not assess the effects at the center or OPO level.

Dr. Barr asked what aspects of liver redistribution the UNOS Committee is evaluating. Dr. Klassen replied that a group is looking at the appropriate metrics for measuring the impact on the population of multi-organ transplants (e.g., combined liver and kidney transplants).

Dr. Barr asked Dr. Klassen for his thoughts on the dramatic increase in the ability to provide liver transplants for elderly patients that resulted from the liver allocation system. Some elderly patients received very young organs. Dr. Klassen said the UNOS Executive Committee has not discussed the issue of age discrepancy but could do so. He noted that the allocation systems are evolving. Dr. Klassen added that Dr. Barr's example nicely demonstrates how policy changes have a positive impact on patient care.

Dr. Fung said the implementation of the Share 35 liver policy increased access and shortened the waiting time, but there have been reports of inappropriate behaviors, such as passing over some donors to get younger organs. Such behaviors are inappropriate and should be addressed, he said. Dr. Gerber noted that there are regional variations in every system, but there are not yet data from Share 35 after 1 year to evaluate the effects of the policy. Dr. Klassen said there are some data, which UNOS is evaluating now. It appears that the policy is having the intended effects, Dr. Klassen concluded.

**Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) Update**  
**James Berger, M.S., M.T.(A.S.C.P.)S.B.B., Executive Secretary, ACBTSA**

Mr. Berger highlighted two of the recommendations made by the ACBTSA at its November 2014 meeting. Regarding the current policy of permanent blood donation deferral for men who have sex with men (MSM, even once, since 1977), the ACBTSA agreed that the current evidence support changing the policy and that a 1-year deferral would be appropriate. The ACBTSA was also asked to provide insight on enhancing the donor history questionnaire and improving public health education and outreach to blood donors and stakeholders.

Regarding the MSM blood donation deferral policy, the ACBTSA recommended the following to the HHS Secretary:

- Implementation of the recommendations made during the December 2013 ACBTSA meeting, especially those regarding surveillance of transmissible diseases
- Develop and implement a coordinated communication plan regarding a change in the MSM deferral policy focused on all relevant stakeholders

In addition, the ACBTSA recommended the following to the Secretary for all donations:

- Undertake studies to evaluate the effectiveness of the administration of the donor history questionnaire.
- Take steps to improve transparent communication to recipients of the relative risks and benefits of blood, organ, cell, and tissue donation.
- Evaluate and revise the donor education material to improve its uptake, comprehension, and utility to promote accurate disclosures of risk.
- Improve the sensitivity and specificity of the donor selection criteria to identify donors at increased risk of transmissible diseases.

Mr. Berger described the timeline leading to the current MSM deferral policy and the ACBTSA recommendations, including studies about the effectiveness of the donor history questionnaire and the donation and use of contaminated blood products. In December 2014, the Food and Drug Administration (FDA) announced that it would adopt a 1-year deferral policy for MSM blood donors; the draft guidance to support that policy is making its way through HHS clearance now. Also, HHS is setting up a transfusion-transmitted infectious disease monitoring system, as recommended by the ACBTSA.

The ACBTSA also considered several questions related to donor consent and management for hemoglobin S, including notifying donors of testing, informing donors about results, confirmation of results, and obligations to provide counseling and follow-up testing. Mr. Berger said some donors do not wish to know the test results because of the potential impact on insurance premiums. The ACBTSA recommended that the Secretary take steps to ensure the following:

- Donors are informed within the framework of routine consent for donation that their donations may be tested for hemoglobin S and that they will be notified of positive results.
  - Implicitly, donors who do not wish to be tested or notified may decline to donate.
  - Donors who test positive for hemoglobin S or present with a known history of sickle cell trait may be encouraged to donate plasma or apheresis platelets.
- Opportunity is provided for donors to become informed about the significance of sickle cell trait.
- To facilitate donor notification, transfusion services will inform the blood collection establishment in instances where a product is found to be positive for hemoglobin S.
- Given the possibility of false-positive tests for hemoglobin S with certain technologies and in certain donor groups, collection centers should be encouraged to provide information on the specificity of test results (e.g., through confirmatory testing), though this is not a primary responsibility of the blood establishments.
- Additional research and dissemination of the finding of the impact of sickle cell trait to clinicians and the public are performed.

At its upcoming meeting in April, the ACBTSA will focus on improving safety of tissue tracking and traceability. On May 11–12, the HHS Office of the Assistant Secretary for Health, the HHS Office of the Assistant Secretary for Preparedness and Response, and the Department of Defense Medical Research Materiel Command will host a symposium on accessibility and development of tissue products for emergency preparedness. The symposium builds on previous ACBTSA recommendations about the lack of emergency preparedness around tissue. It will raise awareness and bring stakeholders together to encourage dialogue.

### ***Discussion***

Dr. Fung asked whether any other risk factors result in a lifetime ban on blood donation and whether there is a national registry of individuals with conditions that prohibit donation. Mr. Berger responded that some medications and conditions do prohibit donation, but there is no national registry, because each blood collection system operates its own database.

Dr. Barr asked whether there has been any cross-cutting work between the ACBTSA as it focuses on tissue tracking and the TransNet application for organs that Mr. Walsh described. Mr. Berger said some ACBTSA members are also involved in the HRSA

advisory committee that addresses TransNet, and information will be shared at the May symposium. Mr. Walsh added that HRSA staff share information with and among committees, so there is some overlap, but the systems are complex and handled differently because of HRSA staff organization.

Dr. Barr noted that the bar code approach seems to be working well and may offer another area of potential synergy between blood and tissue tracking. He suggested that HRSA consider how resources invested in one area can be leveraged for related projects.

### **Metrics and Data Issues**

#### ***Transplant System Performance Metrics***

*Chris McLaughlin, DoT*

Mr. McLaughlin noted that the next three presentations represent the beginning of a conversation to continue over the next few ACOT meetings about performance measures. The conversation will include a review of the origin of and rationale for current performance measures, how to refine or change metrics, and how to collect data to support measurement. At the next ACOT meeting, discussion will center around the history, use, and refinement of transplant center metrics and potential new metrics.

#### ***OPTN Deceased Donor Potential Study (DDPS)***

*David Klassen, M.D., Chief Medical Officer, UNOS OPTN*

Dr. Klassen provided results of a study proposed by HRSA and conducted by a committee of 52 members representing multiple disciplines and stakeholders. He noted that the number of transplants has remained stable over the past decade (with a slight increase in 2014), and the number of organs recovered from deceased donors has been rising since 1988. The study sought to accurately characterize the size and composition of the potential donor pool and predict changes in donor potential over the next 5–10 years. The findings will provide a foundation for setting national goals and developing policies.

Three major findings emerged from the study:

- Significant donor potential exists. The DDPS estimated 37,000 potential donors per year.
- Most unrealized donor potential resides in the older population (i.e., more than 70% among people 50–75 years old).
- Projected growth of donor potential through 2020 is minimal (i.e., 0.5–1% per year).

Dr. Klassen outlined the methodology of the DDPS and analysis of the results. Two independent subcommittees (OPO and the Caregiver Informant Group [CIG]) used different data sets, different assumptions, and different filtering techniques to estimate the size and characteristics of donor potential. Regression modeling was used to estimate future growth.

Each of the data sets had advantages and drawbacks. The Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) Multiple Cause



Mortality File captures 99% of all deaths and the primary and additional causes of death, but it does not identify co-morbidities or related procedures and does not map to the OPTN. The Agency for Healthcare Research and Quality (AHRQ) Nationwide Inpatient Sample offers a very large sample and allows analysis of rare conditions, but it provides limited demographic data, no laboratory or serologic data, and no measure of organ function. The accuracy of the AHRQ data depends on the accuracy of coding, which changes over time. Finally, the OPTN database provides detailed information about every deceased donor since 1988, including imminent and eligible deaths reported by OPOs. However, the definitions of imminent and eligible deaths were created to measure OPTN performance; they do not capture all potential donors.

The OPO Subcommittee surveyed OPO staff to define relative and absolute exclusion criteria, using the OPTN definition of eligible death. The OPO Subcommittee applied those criteria to the CDC NCHS data. Dr. Klassen cautioned that because some of the criteria are not reflected in the CDC data set, the OPO Subcommittee's findings may overestimate donor potential.

The CIG Subcommittee sought an alternative to the eligible death definition. This group determined that a potential donor should not have a condition that would preclude organ function or pose a risk to the recipient. It sets criteria for eligibility and applied a sensitivity matrix to rank organs according to patient length of stay in the hospital (which correlates with likelihood of donation) and illness severity. The CIG Subcommittee also conducted a separate analysis of the data using the eligible death criteria for comparison.

The CIG Subcommittee applied its filtering strategy to the AHRQ sample. Dr. Klassen pointed out that the last step in that filtering strategy—ranking according to length of stay and severity of illness—yields a range of potential donors depending on the cutoffs selected. For its analysis, the CIG Subcommittee limited the pool of potential donors to those up to age 75 years and with no more than a 14-day length of stay.

Remarkably, given the different data sets and filtering strategies, the two subcommittees reached similar conclusions about the size of the potential data pool: 37,000 according to the OPO Subcommittee, and 38,000 according to the CIG Subcommittee. Dr. Klassen felt the findings suggest some validity. He added that some data were shared across the two groups, such as ventilatory rates, which are a major restriction to donation.

The OPO Subcommittee used data from 2000 to 2010 to estimate deceased donor potential. It found little change during that time in the number of annual deaths, the number of potential donors, or the number of actual donors. A comparison of estimated potential and actual donors according to age also found that both increased slightly from 2000 to 2010 in parallel.

The CIG Subcommittee assessment of actual and potential donors by age illustrated that actual donations begin to decline at age 35 years and then drop substantially, but the potential donor pool increases, so the majority of unrealized potential resides among those ages 50–75 years. Assuming that donor criteria and donation practices remain

constant, both subcommittees projected that the potential donor pool would remain essentially flat through 2020, growing only 0.5–1% per year.

Dr. Klassen said that although the DDPS methodology builds in some overestimation, there is clearly a large potential donor pool. The models assume no changes in practice, but changing demographics and use of new technology for donor management could affect the pool. The number of “imminent death” donors already identified by OPOs approximately doubles the currently identified donor pool, Dr. Klassen added. A similar analysis in Canada reached similar findings.

The DDPS results suggest the need to change system practice goals and policy:

- Specific, attainable, evidence-based performance goals should be set.
- Performance metrics for OPOs should be revised to a) remove disincentives to procurement from less-than-ideal donors, b) identify best practices, and c) explore geographic variations.
- Policy changes and education should be implemented to increase timely and complete donor hospital referrals.
- Transplant center performance metrics should be revised and education provided to centers to reduce risk-averse behavior.
- Multiple interventions should be implemented to maximize results.

Dr. Klassen concluded that many stakeholders have a role to play, including OPOs, the OPTN, transplant programs, HRSA, CMS, third-party payers, and patients.

### ***Discussion***

Suzanne McDiarmid, M.D., pointed out that the data show a 50% gap between the number of potential and actual potential donors for pediatric transplants. Something must be done to improve the consent process among parents. Dr. McDiarmid said she appreciated that the May symposium will focus on raising donor awareness, but she asked what other efforts are proposed. There is high donor potential for the pediatric population, she added. Dr. Klassen responded that donor potential is high across all age groups, but there are not a lot of pediatric patients on the waiting list. Dr. McDiarmid countered that some pediatric patients on the waiting list are dying, which could be prevented with more parental consent and authorization for donation.

Mr. Walsh said the DoT is making a lot of effort to share best practices in the community. In the summer of 2014, a conference on pediatric transplantation sought to address the conversion rate. Mr. Walsh said outreach aims to get families to think about their philosophies around donation before they find themselves in a tragic situation. Any donation is extremely stressful, he said, and making a critical decision about donation without any prior consideration is very hard. The data from the DDPS will help HRSA identify what else can be done to further best practices, community engagement, and education.

In response to Alexandra K. Glazier, J.D., M.P.H., Dr. Klassen said the data presented imply 100% consent; he noted that “potential” and “attainable” are not the same in this case. Mr. Walsh emphasized that “potential” does not mean that a 100%-donor rate could be achieved with more effort. The potential is an overestimate, he noted, but HRSA can apply more filters to get a better sense of the true potential donor rate. Dr. Klassen said he felt that the composition of the potential donor pool is very important, and the fact that there is no projected growth in the pool is especially important.

Ms. Glazier emphasized the importance of aligning incentives and developing an integrated model so that OPOs can ensure an organization is in place to receive organs.

Dr. Gerber asked whether the data provide more granular insight into the types of donations that could be expected from potential donors, such as older donors. Dr. Klassen responded that there are some data but the quality of the information found on death certificates is not ideal.

Thomas A. Nakagawa, M.D., asked whether the model takes into account that the mode of death among those ages 6–18 years is so much different from the rest of the population. Older children are more likely to die as a result of multiple wound trauma, while younger children are more likely to die from isolated head injuries. Therefore, estimated realization rates are lower for younger children, he noted. Dr. Klassen did not think the data looked at realization rates according the cause of death, but he was sure that rates varied dramatically.

A member asked whether the data indicate the proportion of donors who are brain dead, and Dr. Klassen responded they did not.

Charles Alexander, R.N., M.S.N., M.B.A., pointed out that authorization will always play a role in the realization rate. The study provides a snapshot of the current landscape and highlights potential realization. However, the study looks broadly at the system; it does not reveal specific areas to address that could fix the system. Mr. Alexander said that in most European models, increases in transplants and donors are occurring among older people. He said the U.S. system is fundamentally flawed, and efforts must be made to evaluate and fix it.

### ***SRTR—Association of Organ Procurement Organizations (AOPO) Donor Potential Data***

*Jon Snyder, Ph.D., SRTR Contractor*

Dr. Snyder conceptualized the potential donor pool as a series of concentric circles, in which the largest circle is the total number of deaths in a donation service area, the next circle is the number of in-hospital ventilated deaths, and so on down to the innermost circle of donors. Currently, the OPTN and SRTR collect data on the number of deaths in the donation service area, reported deaths, imminent deaths, eligible deaths, and donors; they do not collect data on the number of in-hospital ventilated deaths, so-called potential donors, or authorized donors.

Notably, said Dr. Snyder, there is a hole in the OPTN data stream between the number of deaths reported by a hospital to an OPO and imminent and eligible death referrals. Of the 29,000 reported deaths, only 2% met the imminent or eligible death criteria (ranging from 1% to 6% across 58 OPOs). Of those, 97% are timely referrals, and 36% ultimately become donors. Dr. Snyder said that given the number of imminent and eligible deaths that are also timely referrals, there is potential for doubling the number of actual donors.

Dr. Snyder outlined the current conversion rate published by SRTR to underscore the need to find new measures to assess the potential donor pool. Ultimately, the goal is to measure the number of potential donors from the broadest pool, which includes some donors who fall outside the criteria for imminent and eligible deaths.

To this end, the SRTR and AOPO are conducting a study to understand what data OPOs currently collect about potential donors other than imminent and eligible deaths to estimate the broader potential pool. The results will inform discussion of how such data can be standardized in the future and possibly form the basis for performance metrics.

So far, 36 OPOs have provided data for 2013. Analysis of the ratio of non-donors to donors reveals that OPOs collect and analyze data differently. Some weed out those who meet exclusion criteria before review, while others do not. Dr. Snyder said the analysts looked at the process from the point of referral forward. By going through the records and categorizing each death record, they created a map identifying the factors that prevented donation at each step, from referral to the decision to pursue to the approach to authorization and finally to attempted donation.

The top three reasons for failed conversion all relate to family declination when approached about donation. Some factors, such as medical contraindication or patient arrest, cannot be modified to improve the conversion rate. Dr. Snyder said family declination could—arguably—be amenable to improvement, as could missed approaches. Notably, “list exhausted”—that is, the lack of an identified recipient, could be addressed with a better allocation system. When the number of potentially modifiable cases are calculated, the potential donor pool is about 1.6 times the number of actual donors.

Dr. Snyder cautioned that the study is ongoing, and analysts have not yet assessed the validity of their interpretations or assumptions. They have not yet evaluated the data according to age or race/ethnicity. The findings are preliminary. Dr. Snyder was hopeful that consensus can be reached on how to capture the data. He reiterated that addressing the potentially modifiable reasons for failed conversion could improve the actual donor rate. The findings so far align with other sources of data. The OPO data are self-reported, said Dr. Snyder; one goal is to standardize data collection across OPOs.

### ***Discussion***

Dr. McDiarmid asked whether all personal authorizations for donation are honored. Dr. Snyder said most OPO data identify personal (or first-person) authorization, and those data could be compared with family declination data. He said the findings presented reflect family authorization and not first-person authorization.

Andrew J. Schaefer, Ph.D., said the concentric circles should be modeled in the simulation. Then, analysts could target a specific factor affecting conversion and model how an intervention would affect volume and complexity.

In response to Dr. Barr, Dr. Snyder said there are data on the disposition of organs from most OPOs. Dr. Barr suggested asking OPOs for their estimates of potential yield on the basis of previous data, which would allow for targeting those with the highest yield potential. Dr. Snyder said there are data on age, race/ethnicity, and cause of death, which can be correlated with the reasons for failed conversion.

#### ***OPTN Data Advisory Committee (DAC)***

*Charlie Alexander, R.N., M.S.N., M.B.A., ACOT Member*

Mr. Alexander explained that HRSA requested a committee be established to create a long-term, innovative vision for data use that goes beyond data collection. The DAC is considering ways to provide information the community can use to improve processes. It is also looking at data release practices. Mr. Alexander added that the DAC hopes to tap into available data sets to lighten the burden of data collection and improve data use to further organ transplantation efforts.

The DAC has four projects planned:

- Modify the OPTN/UNOS data release policy, aligning it with the Final Rule and making it more transparent.
- Evaluate current and new data elements for the OPTN database, being mindful of the data burden and ensuring that data requested and collected are used.
- Improve OPO and transplant center metrics and measures to address the current disconnect between the measures and the goals, redefining what constitutes a successful transplant.
- Secure enterprise solutions for the OPTN database by tapping into existing datasets and demonstrating that the database makes a meaningful, positive contribution to measures and metrics.

The current UNOS OPTN data release policy is more restrictive than the Final Rule and inconsistent with the SRTR data release policy. Mr. Alexander believes the DAC can quickly modify the policy to make it more effective; he anticipated that a draft would be available for public comment in August.

The DAC recognizes that requesting new data elements may pose a burden on transplant centers, OPOs, laboratories, and the OPTN, so it hopes to craft an approach that uses data collected from other sources, minimizing data entry. Recommendations will be presented to the Board for consideration.

The DAC requested feedback from OPOs about performance measures. The OPOs believe the current model for measuring organ yield is in line with other performance measures, but Mr. Alexander said the definitions of imminent and eligible death are

highly variable. He believes that some organizations struggle with the current model and there are opportunities to gather better data. However, the current OPO measures are codified in CMS policy, so revision will require changing the regulation, which is very difficult. The DAC may recommend that CMS remove the measurement guidance from the regulation so that measures can be modified as needed to capture data. The DAC formed a subcommittee to reach out to the OPO community to address measures and metrics.

Finally, efforts to secure enterprise solutions for the OPTN database are focused on minimizing burden. The UNOS Information Technology Department has ongoing efforts to automate data transfer between external users and the OPTN database, create a mechanism for collecting and storing data, and facilitate an interface with the database that better meets users' needs.

The DAC includes broad representation. The role of the DAC is to provide leadership so that content experts can address complex questions together. Mr. Alexander anticipated the work of the DAC will take 4 years, and progress and accountability will be assessed periodically. He said the biggest impact will likely be fostering communication, education, and buy-in from the community around improving data. The DAC will reach out to stakeholders to gather input and ensure they understand the process. The communication and delivery of the project are as important as the products, Mr. Alexander concluded.

### ***Discussion***

Dr. Barr asked how the ACOT can help the DAC, noting that the ACOT could make recommendations to the Secretary about changing CMS regulations. Mr. Alexander said he is already seeing a lot of cooperation and alignment over the past few years. He felt that a request from the DAC about regulations may build on previous requests and may not necessarily require a new recommendation.

In response to a participant, Mr. Alexander said that many groups around the country are interested in data issues and performance metrics. He believes that the DAC can build credibility within the community and rely on that to advance its goals.

In conclusion, Mr. McLaughlin said the session aimed to ensure that the ACOT learn about efforts underway. The ACOT may have a role in coordinating the vision that ties all the activities together.

### **Kidney Paired Donation**

#### ***Review of the KPD Work Group Recommendation***

*Andrew Schaefer, Ph.D., and Dorry Segev, M.D., Work Group Co-Chairs*

Speaking by phone, Dr. Segev provided some background information about the current status of KPD, describing four types:

- Straightforward exchange: One individual donates to a specified recipient (or a small group of donors are paired with a small group of recipients).

- Domino (closed chain): The kidney of a non-directed donor goes to someone on the waiting list.
- Non-simultaneous domino (closed chain): Some recipients may have to wait for a kidney, but no one “loses their ticket” in the exchange.
- Non-simultaneous chain (open chain): Non-directed donations go to recipients along a chain, but the open nature means that no one waits too long.

Dr. Segev explained that KPD began in 1999 and took off when the Charlie W. Norwood Living Organ Donation Act of 2008 passed. About 400 transplants involving KPDs occur each year, for a total of more than 4,200 since KPD began. Also since 1999, non-directed donation has taken off, reaching a total of more than 1,300 donations in 2013. In a chain, the first segment is designated as a non-directed donation, while subsequent segments are reported as KPDs. Combined, non-directed donations and KPDs account for 16% of all live-donor transplants, a significant increase since 1999.

The following questions remain unanswered:

- Chains
  - Are longer chains really better, or do they just attract more media? (Media attention is good for encouraging donation.)
  - When do you stop the chain? Is it fair to make a bridge donor wait up to a year?
  - To whom does the last kidney go?
- Matching priorities
  - Should we prioritize better matches, more children, or other considerations?
- Optimization
  - A mathematical framework was created. It is demonstrably better than random selection and widely used, but other approaches are emerging. The batch approach allows a lot of KPDs to collect, while the dynamic approach forces the decision about whether a KPD should occur immediately or be postponed while others are lined up.
- Financial
  - Usually, the donor bills recipient insurance. The situation is complicated when donation and transplant occur at different centers.
  - Who covers donor complications?
  - Who pays for multiple donor or non-directed donor evaluations?

The costs of KPD include evaluation of incompatible and non-directed donors and histocompatibility testing. Centers require administrative staff to organize KPDs and manage KPD programs. Shipping fees (especially air transport) and hospital fees contribute to the costs. The cost of managing donor complications and follow up is also a consideration.

Strategies in place to manage costs include transferring the costs from the donor hospital to the recipient hospital; eliminating the volume disparity between centers (recognizing that the most active centers better manage costs); reimbursing for donor services provided by out-of-network providers; and ensuring consistent, predictable costs to payers. Maintaining compliance with CMS regulations also helps manage costs.

Another strategy is implementation of a standard acquisition charge (SAC) for KPD, as is used with deceased donors. Setting a fee for KPD would be challenging, but once CMS and other payers agreed to the fee, each center would be paid the KPD SAC for each KPD transplant performed, in addition to the costs of the conventional live donor transplant. A national-level SAC would be ideal for payers, but others believe a center-level SAC is appropriate.

A consensus conference in March 2012 recommended the following:

- All potential living donors should be informed about KPD early, before compatibility testing.
- The transplant community should develop a centralized information resource for non-directed donors and inform non-directed donors about KPD.
- A single, well-functioning registry and a national SAC model would best serve the purpose of KPDs.
- A national organization should administer and oversee KPDs, under the auspices of HRSA.

The ACOT's Recommendation 57, unanimously approved by the Committee on September 4, 2013, is available online (<http://www.organdonor.gov/legislation/acotreccs5657.html>).

Dr. Schaefer noted that other questions remain; for example, should the KPD Work Group look at other issues beyond those identified? Dr. Segev noted that the recommendation calls for a paid contractor, as with the AOPO, who would oversee the SAC. Some organizations may not wish to participate, such as those belonging to a consortium that already has effective policies in place. Those organizations could continue their efforts with some oversight by the contractor of policies and practices. Those who participate in the national system would reap the benefits of having a central contracting organization.

### ***HRSA Input on KPD***

*Bob Walsh, Director, DoT*

Mr. Walsh summarized some of the issues HRSA is addressing as it considers its response to the ACOT recommendation and input from the consensus conference and others. Various players are involved in matching donor-recipient pairs to facilitate transplants. The number of single-center programs is growing daily. Multi-center programs may have a transplant center or an outside organization that acts as the coordinator. The UNOS OPTN KPD pilot project began in 2010.

In addition, HRSA is considering the legal framework, taking into account the National Organ Transplantation Act of 1984, the OPTN Final Rule, and the Norwood Act. For example, it is determining whether KPD constitutes directed donation, which is defined in the OPTN Final Rule, or some form of allocation.



There have been developments around KPD since the 2013 ACOT recommendation. For example, the OPTN Board of Directors has recommended that the KPD pilot project become permanent. An OPTN KPD finance work group and others are working with CMS and third-party payers toward a standardized reimbursement model. All KPD transplant centers are required to comply with OPTN policies and evaluation. Some KPD programs facilitating multi-center exchanges are not OPTN members and are not subject to direct OPTN oversight.

Given these developments, Mr. Walsh said HRSA would like the community to revisit some issues and provide input on the implications of different approaches. Specifically, Mr. Walsh asked the ACOT to address the following:

- How can the transplant community best approach a balance between innovation and patient safety and outcomes given KPD is an evolving field?
- What are the advantages and disadvantages (and vulnerabilities) of regional KPD systems, single-center KPD systems, or a single national KPD system?

#### *Discussion*

A participant noted that ensuring that a solution for one stakeholder does not create problems for another is the sticking point in the process.

Dr. Fung said his organization is participating in the pilot project, and the issue of donor safety has come up. He called for a national system to avoid creating two parallel tracks—one with regimented follow up and long-term care (for participants in the system) and another without (for non-participants). Living donors should be assured of long-term care and management that follows standards of care, he emphasized.

James D. Eason, M.D., agreed but noted that his organization currently participates in the National Kidney Registry, which works well. All donors are treated the same and receive the same follow up, he said. It is not clear, for example, what would happen to outside registries if one of these systems is pursued. He suggested that the ACOT recommend that all organizations become members of the OPTN.

Dr. Segev offered the following example of the system as he envisions it. The National Kidney Registry, for example, receives a contract from HRSA. If an organization that currently uses the registry wants to continue doing so, then it can. The hope is that other programs would contribute to the national program. Now, UNOS is open to all centers through a sort of OPTN mechanism. The National Kidney Registry figured out how to finance its efforts, and that seems to be working, so it could continue.

Dr. Walsh noted that it is helpful to hear that the Work Group envisions KPD as separate from the OPTN and SRTR and that it would require a separate organ transplant contractor working through HRSA. He asked the ACOT to consider the specifics of a centralized oversight body and to weigh the pros and cons of such an approach. He asked whether organizations would be concerned about a conflict of interest if one national group conducts its own operations and also oversees others.

Arthur Matas, M.D., wondered why KPD donors would be treated any differently from a safety perspective than conventional donors. He added that as long as a national oversight body clearly specifies what will be monitored and provides transparent criteria for acceptable practices, there is no reason that dual systems cannot exist.

Dr. Segev said the Work Group envisioned the oversight body as functioning like the SRTR, which reports to the OPTN. Alternatively, all the organizations could report to HRSA. He said the contractor should not make decisions but rather flag programs for review by HRSA or OPTN.

Dr. Segev agreed that donor safety issues are the same for any live-donor kidney transplant, and they should be addressed by HRSA and the OPTN. He noted that payment for KPD is more complicated than other types of donation. A national SAC would ensure that all donors receive the same follow-up care; it would not provide KPD donors with more benefits.

Dr. Fung called for amending the recommendation to fund appropriate follow up for all living donors. Dr. Barr said the next presentation addresses living donors and would likely raise the question about funding. He said that donor follow-up care and safety are larger issues that should be addressed. Dr. Barr encouraged the ACOT members to provide more detail and guidance to Mr. Walsh and colleagues about Recommendation 57. He asked whether the ACOT should refine the recommendation so that HRSA can act on it.

Mr. Walsh said the recommendation is detailed and complex. He appreciated Dr. Segev's interpretation that independent organizations could continue to operate even if there is a national system. Mr. Walsh said HRSA must work within its authority, funding limits, and regulatory structure to address the recommendation; going forward, the KPD Work Group may be asked to provide expert advice. He noted that ACOT members so far have indicated that any system should maintain balance and allow for innovation, but he called for more input on the pros and cons of a single national KPD system.

Bryan Becker, M.D., pointed to the end-stage renal disease (ESRD) networks, which operate under Federal government contracts and report data uniformly. He said that a network is already in place for KPD, and participating organizations already provide baseline data. Those data could feed into the work of an oversight group, building a framework for performance improvement. Such oversight does not hamper creativity, but it does hold participating organizations to a different level of performance and accountability. In response to Bernice Coleman, Ph.D., R.N., Dr. Becker said that all the ESRD networks feed data into a single repository, which allows assessment of standard practices.

Dr. Gerber agreed that the ESRD networks are a good model. He worried that other approaches could quash innovation. He also raised concerns about an organization that operates a registry taking the role of contractor, because that would require it to take on

an additional administrative burden. He liked the idea of an independent contractor. Dr. Gerber pointed out that organic models emerged for ESRD because no one model fit all the networks.

In response to Dr. Segev, Dr. Gerber elaborated that the recommendation requires a lot more work in gathering and analyzing data. He was concerned that the existing registry groups do not have the capacity to oversee others. Dr. Segev said other have also indicated that a single national contractor that manages the SAC and other administrative aspects should not be in charge of oversight because of the potential conflict of interest and because they may lack the capacity. He suggested providing funding to the OPTN to allow its Membership and Professional Standards Committee to take on some of the oversight role, or another HRSA-designated entity could do so.

Mr. Alexander noted that the infrastructure for peer review, patient safety, surgery standards, and other issues are already in place through the OPTN, so he did not see the need for a separate contractor. Dr. Gerber responded that the OPTN runs a registry and therefore has a conflict of interest in overseeing another registry. He believes there is a compelling case for establishing a firewall between registry operations and oversight of competing organizations.

Mr. Alexander said there is a working allocation system for deceased donors, so he questioned why such a system could not be established for KPD. He also asked why the community would want to have more than one KPD system. Dr. Becker said there are not yet uniform standards around KPD, which increases the potential for disparities. Independent judgment is critical to improving performance, he noted.

Dr. Gerber pointed out that if one of the existing KPD systems were recognized as superior, it would be in widespread use now. The approach is still in the early stages of innovation. Moving to a single center now would shortchange patients, he said. Mr. Walsh acknowledged the concern about quashing innovation. In previous discussions, concerns were raised about how to create a framework for the biggest pool possible.

Dr. Segev said that, ideally, a national contractor would have resources to build a model that would attract most organizations, thus facilitating a transition to a single system. There are some single centers that have established good mechanisms for KPD. Dr. Segev noted that UNOS has its own registry, and any effort to drive the National Kidney Registry out would have a negative effect on patients. He emphasized that the recommendation allows for the competitive, creative spirit that drives single centers.

Stephen W. Crawford, M.D., said local programs tend to choose a system that works best locally; by that logic, it is unlikely that a system would develop that would look at national issues. Dr. Gerber said that transplant centers face the same situation, and coordination is needed. Ms. Glazier argued that, unlike the transplant centers, a KPD system would focus on distribution of resources. The goal is to maintain utility, equity, and transparency, which is difficult without bringing all the players together at some point.

Dr. Segev emphasized that he did not want to place more regulatory burden on KPD but rather create a framework to ensure that KPD is well studied and well used. He favors a national program, but smaller, effective systems could quickly emerge. Dr. Barr asked whether it would be necessary to request more money from Congress to support a KPD system, but Mr. Walsh could not speak to the question. Dr. Segev said it would be reasonable for transplant centers to pay for some of the costs of a KPD system. Other funding could come from SAC arrangements, he said.

Dr. Eason questioned whether organizations that are already part of an effective consortium would be willing to pay another body to provide more oversight, especially when the OPTN already provides some oversight. He said the suggestion on the table could drive up costs. Dr. Segev said centers currently negotiate the costs for every KPD transplant on a case-by-case basis. A central contractor would create a standard method for reimbursement.

Dr. Barr noted that the ACOT members all agree with the spirit of the recommendation and will continue to advise on its implementation, adding expertise as needed. He said the ACOT should come to consensus on the next step. Because the OPTN is the model program for deceased donors, HRSA could provide the OPTN with additional funding to oversee KPD. Dr. Fung agreed that the OPTN is a functional system, and he would prefer it to a separate analytic structure.

#### **Action Item**

Dr. Barr and Ms. Stroup will reach out to ACOT members and other experts who may have insight to contribute about the implementation of Recommendation 57. Dr. Barr encouraged members to let him know if they want to take part in that discussion.

#### **Living Donation**

##### ***Long-Term Kidney Donor Outcomes***

*Arthur Matas, M.D., ACOT Member*

Dr. Matas said that the concern for donor health has been expressed in laws about organ donation, in HRSA guidance, and by the ACOT in recommendations made in 2002, 2005, and 2007. However, there has been no follow up on these calls to study and address the long-term health of donors.

In 2010, HRSA, NIH, and others sponsored a conference on living donor follow up that brought together a wide range of stakeholders. They concluded that systematic collection and reporting of long-term follow-up information on donors is needed to ensure fully informed consent for future potential donors, to improve evaluation and provide reliable counseling for potential donors, and to identify problems in time for effective intervention. The conference yielded recommendations for data collection:

- Complete data should be collected in the following circumstances:
  - Perioperative complications at 3 months

- Long-term cardiovascular disease or ESRD mortality
- Long-term follow up on predefined endpoints for disease-related and psychosocial disabilities
- For certain subgroups, intermediate-term outcomes should be assessed for specified donor characteristics and donation characteristics. Within those subgroups, certain medical, psychosocial, and socioeconomic outcomes should be assessed.

Dr. Matas explained the importance of better understanding long-term outcomes. Removal of one kidney is associated with a 20–30% decrease in renal function. In the general population, a mild decrease in renal function is associated with increased risk of cardiovascular disease or mortality and renal failure. It is possible that nephrectomy increases those risks among donors.

Past studies are hampered by short duration, as transplants from living donors is a relatively new phenomenon; the small number of living donor transplants that occurred in the early years of transplantation; the wide age range of donors; and the difficulty of identifying a control group.

Historically, living donors have been compared with the general population. Until 2013, studies have consistently found no difference in mortality between donors and healthy control subjects. Kidney failure and precursors of ESRD occur at the same rate in both populations. The risk for type-2 diabetes also appears to be the same. Women who become pregnant after donation and their children do well, except for the increased risk of gestational diabetes and preeclampsia associated with pregnancy.

Recent studies have compared donors with a selected population of healthy controls rather than the general population, reasoning that donors are selected from among the healthy population. Compared with normal, healthy controls, donors have an increased risk of mortality (all causes), cardiovascular mortality, and ESRD. The two groups begin to show differences in mortality at about 15 years in to the follow up.

A closer look at nine donors in one study who developed ESRD (out of 1,901 donor subjects) revealed that all were first-degree relatives. The median time from donation to ESRD was 18 years, and the relative risk of ESRD was 11.4 compared with non-donors.

A study of ESRD in a much larger set of U.S. donors and controls found the risk of kidney diseases was 10 times higher among donors, even though the absolute rate of disease was still small. For donors in this study, the lifetime risk of ESRD was better than that of the general population.

Dr. Matas said both studies concluded that the absolute risk of disease following donation is low and living donation should still be promoted. However, these studies are the first to show increased risk for living donors. The methodology of both studies has been criticized.

Dr. Matas said the most important finding in both studies was that the risk of ESRD for donors is higher among those who are related to the recipient, although the causes of ESRD in these donors were not always hereditary. Because kidney disease usually starts in middle age, a) normal young donors are at higher long-term risk than normal older donors and b) those with low normal glomerular filtration rates (GFR) are at risk for ESRD when kidney disease starts. Dr. Matas called for a long-term study in the United States to determine whether donation increases the risk of kidney disease.

Studies of psychosocial outcomes have all compared donors with the general population, not with selected healthy controls. In general, donors fare better than the general population, although there are some reports of decreased quality of life, usually related to complications of the donation or to the short survival time of the recipient. Donors have a lower rate of depression than the general population, but some report depression that they relate to the donation.

Many donors complain about the financial burden associated with donation, including donors with insurance and those who are employed. A survey of donors found that many covered expenses by using their savings, grant funding, loans from family, fundraisers, and even bank loans. Dr. Matas stressed that the transplant community must address the financial burden on donors.

Almost all of the research is limited by small numbers, and there are few data on donors who are not Caucasian or who fall into the recently expanded criteria for donation (older donors, obese donors, donors with hypertension). Both the government and the transplant community agree on the need for more long-term research.

Dr. Matas called for the following:

- Ongoing, extended follow up of medical and psychosocial outcomes among current donor populations, with appropriate controls, to clearly define the risks associated with donation
- Long-term studies of medical and psychosocial outcomes in certain subgroups to clearly define the risks associated with donation
- A system to evaluate and care for donors who develop medical or psychosocial problems related to donation
- A system that ensures that donation is not a financial burden

### ***Considerations for Long-Term Study and Care of Living Donors***

*Bryan Becker, M.D., ACOT Member*

Dr. Becker explained that the demographics of the U.S. population are changing, and so will those of future donors, but most long-term data come from Caucasians. Moreover, the prevalence of obesity and diabetes are both increasing rapidly in the United States, so the transplant community needs to address new issues of potential donor assessment, selection, and follow up that have not been part of the process to date.

Data indicate that the donation procedure is safe and few significant complications occur in the in first 2 years after donation. But chronic conditions and other events can take

their toll in the face of reduced kidney mass. The existing data may not be reliable for answering future questions.

Dr. Becker pointed out that State legislation on living donors varies, and follow up has not been defined in a uniform way even with existing resources. As Dr. Matas said, the ACOT has recommended long-term follow up numerous times. The transplant community does a good job with the immediate process, from education of potential donors to low complication rates associated with donation procedures. Dr. Becker asked whether the “back end”—that is, long-term follow up—should be as intensive as the front end, and, if so, how that should happen.

Other relevant issues to address include the lack of a standardized approach to follow up beyond the basic requirements, the lack of engagement with donors to reform the health care system, and the failure to look to donors as potential sources of important information about patient satisfaction and value. Dr. Becker said the transplant community should continue education efforts but also begin managing long-term donor relationships.

Dr. Becker pointed out that money is an obstacle to more and better data collection. He noted that about 5,200 people were living donors in 2014, and the health care system does not focus intensely on any other condition that affects so few people. He emphasized that although the numbers are small, living donors are an important and vulnerable population. New technology and social media offer cost-effective opportunities to reach donors that did not exist even 5 years ago. Dr. Becker concluded that the transplant community stands at a critical juncture in which it must decide whether and how to engage living donors.

### ***Discussion***

Dr. Fung asked who is accountable for ensuring long-term donor follow up. He noted that organizations like the American Kidney Foundation can make recommendations for minimal follow up, but he asked how the ACOT could translate its recommendations into a mandate. Dr. Matas responded that the real barrier is cost. Many donors do not have insurance and so do not get follow-up tests. He called for some mechanism to ensure that donors are evaluated at least every couple of years in a local center, so they do not have to travel far.

Dr. Gerber said it is incumbent on all those in the transplant community to look after donors, but in reality, the amount of follow up depends on location, and connecting donors with follow up can be hard. Even in the general health care system, compliance is about 50%. Dr. Gerber said efforts must be taken to make follow up easier on donors. The economic impact of donation is like a glacier, he said, in that it is much larger than it appears. Consideration must be given to the indirect and later costs, such as the cost of gas for travel to a center for follow-up testing 2 years after a donation, which offers no immediate benefit to the donor, such as preventive care.

Cynthia P. Puryear said that as a donor, she found the data alarming. She said she took a month off of work to donate at her own expense, and she had one follow-up visit 10 days after donation. Ms. Puryear reported that she has had no contact from the transplant center since then (7 years ago). She called for a bridge that provides some assurance to donors of some sort of follow up. Donors should not have to bear their burden alone. Ms. Puryear said she did not have an answer but urged continued efforts to address the problem.

Dr. Gerber and Dr. Matas both cited models in other countries that cover some costs for donors, such as lost wages and child care, but even those do not include long-term follow up. Dr. Matas said that even when problems are identified, there are no good mechanisms for accepting that the problems are related to donation and addressing them.

Dr. Barr said it is important to expand the minimum long-term follow up to at least 5–10 years, when complications might realistically be expected to appear. Despite the fact that only about 5,000 people donate per year, those people are extraordinary, he said, so long-term follow up is the right thing to do. The logistics and financing, however, are problematic. Creative approaches, such as better use of electronic data and virtual electronic medical records, are encouraging. The Bone Marrow Registry is an example of a very detailed database, but it is very expensive to maintain, said Dr. Barr.

Dr. Barr said the public comments to the ACOT indicate strong feelings around this issue. Because there is pressure on HRSA to push harder for donation, it is necessary to find a balance. He asked what the ACOT can do. Mr. Walsh acknowledged that the ACOT has weighed in, and he said that HRSA is very interested in having more and better long-term data. Mr. Walsh said his perception of the day's discussion is that the ACOT agrees with the conference recommendations described by Dr. Matas, but he asked for additional specifics about the types of data that should be collected. Dr. Matas clarified that the conference recommendations called for complete, comprehensive data on a small number of endpoints (not a representative sample).

Dr. Crawford stated that he was playing the devil's advocate when he asked whether the results of long-term data would have an economic impact on transplant centers in the long run. He pointed out that donors would be unlikely to change their minds on the basis of long-term data. He questioned how much money the transplant community was willing to spend to get those data. Dr. Matas responded that it is the duty of the transplant community to collect data for the informed consent of future donors. Currently, donors are told that donation is safe, which is generally true, but the transplant community must prove that it is true. Long-term data are needed, for example, to counsel young donors. Dr. Matas agreed that long-term follow up is expensive and doing it well is even more costly.

Ms. Glazier noted that as efforts are underway to increase the number of living donors, the community is obligated to be honest. Dr. Barr emphasized that for the sake of truly informed consent, more information is needed on more donors, such as those of non-Caucasian race/ethnicity, and the risk factors they may face.



Dr. Coleman said that data are key to building trust. Subsequently, the return on investment in long-term follow up comes from increasing the whole donor pool. The ability to present long-term data from donors who are still alive would have a huge return on investment, she said.

Dr. Becker said one financial argument could be the long-term savings of transplant over dialysis. Dr. Crawford pointed out that private payers do not cover dialysis after 6 months; the costs are picked up by Medicare. He said that to convince private payers to cover more costs for living donors, he needed an argument that addresses the bottom line, clearly stating why it is important to fund long-term follow up.

Dr. Barr said Ms. Purser's experience alone should make the case for better long-term follow up. Mr. Walsh expressed shock that Ms. Puryear was never contacted. Dr. Gerber said he believes more transplant centers are held accountable now, at least for short-term follow up, then they were when Ms. Puryear donated 7 years ago. A participant said the requirement to track donors for 2 years just went into effect.

Dr. Barr asked that HRSA provide more guidance on what the ACOT can do. Mr. Walsh said HRSA is reviewing the ACOT's recommendations and recognizes the importance of the issue. Today's discussion reassures him that HRSA has not overlooked some important aspect of the issue, he said. Dr. Barr reiterated that the changing population demographics and recent studies indicating possible risks of donation underscore the need for long-term follow up. It is now up to HRSA to implement the recommendations of the ACOT and others.

#### **Action Item**

Dr. Barr asked HRSA to consider whether the ACOT should establish a living donor work group.

#### **Brain Death Determination: Review and Reconsideration of Recommendation 56 Thomas A. Nakagawa, M.D., ACOT Member, and Alexandra K. Glazier, J.D., M.P.H., ACOT Member**

Ms. Glazier reminded the group that in 2011, the ACOT recommended standardization of neurologic death using existing national adult and pediatric guidelines given inconsistent practices and the lack of a national registry. The full recommendation is available online (<http://www.organdonor.gov/legislation/acotrecs5657.html>). Ms. Glazier pointed to a recent high-profile legal case about how to manage a patient following brain death (*Winkfield v. Children's Hospital Oakland et al.*, also known as the McMath case).

Ms. Glazier said death is defined by State law. Every State has enacted the Uniform Death Determination Act, which defines death, but questions remain about how death is diagnosed. Definitions seek to balance the need for certainty with some flexibility for accepted medical practice, which changes over time. Ms. Glazier summarized some of the legal issues involved and highlighted some of the ramifications of the McMath case.

The potential consequences of requiring hospitals to continue to provide support of a body that has been declared legally dead include inappropriate use of medical resources (when donation is not planned), emotional conflicts for families and providers, and fewer recovered organs for donation. Ms. Glazier and Dr. Nakagawa asked the ACOT to consider whether Recommendation 56 should be amended or revised to address when medical therapy should cease once a patient is declared dead and organ donation is not planned. Ms. Glazier noted that revising the recommendation could be seen as a conflict of interest, in which case other organizations could address the issue.

### *Discussion*

In response to Dr. Barr, Mr. Walsh said HRSA is proceeding cautiously because of the sensitive nature of the issues under consideration, and he does not yet have a response to the ACOT regarding Recommendation 56. Ms. Glazier said that inconsistency in clinical practices affects the ability to increase the availability of organs for donation. Dr. Nakagawa pointed out that cases of brain death in the United States are declining, perhaps because fewer adults suffer from stroke and because more patients are withdrawn from medical treatment before brain death occurs.

Ms. Glazier said the ACOT may be the only Federal advisory committee addressing brain death determination, and Dr. Barr said that the ACOT has a mechanism for reaching the HHS Secretary, unlike other organizations. Ms. Glazier emphasized that the unresolved question revolves around hospitals' obligations following a declaration of death, which she thought would have to be addressed by a mandate from CMS.

In response to Dr. Coleman, Ms. Glazier acknowledged that she was not sure that implementation of the ACOT's Recommendation 57 would have prevented the McMath case from going to court, but if hospitals have a policy in place, they may be able to avoid such escalation. Dr. Coleman said enforcement of hospital protocols and CMS guidelines is unclear. Dr. Nakagawa said that at the least, hospitals should be aware of potential issues and should have policies in place on determination of death.

Questions arose about which entities have the authority to address this issue. Ms. Glazier said CMS likely can have a major impact, but she agreed that the American Medical Association and The Joint Commission have strong influence on providers and hospitals. Emily Levine of the HHS Office of General Counsel confirmed that the ACOT can always reword its recommendation.

Dr. McDiarmid believed that the ACOT has a conflict of interest and that what happens after death is declared is beyond the scope of the ACOT. She suggested other groups that advise on hospital policy should address the issue. Mr. Walsh said that amending the recommendation by adding the phrase "medical therapy should cease once a patient is declared dead and organ donation is not planned" is significantly different from recommending that the Secretary encourage hospitals to follow consistent guidelines.

Ms. Glazier said that the proposed phrase addresses organ donation and therefore connects directly with the role of the ACOT. However, she recognized the potential

conflict of interest. Ms. Levine noted that the ACOT charter allows the group to advise on a broad range of topics, and it is up to the ACOT to decide whether the proposed addition goes beyond its scope. She added that the Presidential Commission for the Study of Bioethical Issues may be in a position to address the topic.

Sylvia Caley, J.D., M.B.A., R.N., said the biggest problem she sees around brain death determination is ineffective communication. Dr. Coleman added that such problems arise in all hospitals, not just those serving indigent populations. Ms. Caley called for better communication, especially in hospitals with more vulnerable patients. Dr. Nakagawa agreed, but noted that some do not accept any declaration of death until the heart stops, even if brain death is declared.

Dr. Barr posited that Recommendation 56 could be amended and circulated to the ACOT members for review and a vote, but there was no motion in support of such action.

## DAY TWO—MARCH 13, 2015

### **Overview of the Office of Human Research Protections (OHRP)**

#### *Irene Stith-Coleman, Ph.D., OHRP*

Dr. Stith-Coleman described the mission and organization of the OHRP, which provides leadership in protecting the rights, welfare, and well-being of subjects involved in research conducted or supported by HHS. The OHRP offers guidance and educational programs and materials; it also maintains regulatory oversight. The OHRP has four components:

- The Office of the Director provides training for institutions involved in international research and includes the Secretary's Advisory Committee on Human Research.
- The Division of Compliance Oversight evaluates written, substantive indications of non-compliance with HHS regulations, which typically involves investigation or on-site evaluation. The OHRP determines whether regulatory actions are needed to protect human subjects.
- The Division of Education and Development provides guidance, education, and resources to institutions and individuals and participates in professional and academic conferences. It also offers quality improvement consultations to institutions.
- The Division of Policy and Assurances prepares policies, guidance, and interpretation of regulatory requirements, disseminating information to the research community. It coordinates efforts among the 15 agencies and departments that have signed on to the Common Rule (the Federal Policy for the Protection of Human Subjects). It also administers the Federalwide Assurance process and institutional review board (IRB) registration.

### *Discussion*

Dr. Barr said that working with the OHRP may be helpful in developing protocols to improve the quality and quantity of donated organs. Ms. Glazier asked how the OHRP selects topics to address with guidance. Dr. Stith-Coleman said new guidance can result from suggestions of the Secretary's Advisory Committee or from questions posed to the OHRP from various sources. She noted that the FDA has human subjects protections regulations almost identical to those of the OHRP, and the two agencies often coordinate, sometime providing parallel or joint guidance. In response to Ms. Glazier, Dr. Stith-Coleman said a recommendation from the ACOT on human subjects research would come to the OHRP for consideration and possible guidance development.

#### **Action Items**

Dr. Barr said the ACOT staff will determine whether the Donor Management Research Work Group should engage with the OHRP directly or indirectly.

Dr. Barr will talk with Dr. Laura St. Martin, the FDA liaison to the ACOT, about working with the FDA regarding human subjects protection issues.

#### **Donor Intervention Research Work Group**

##### ***David Gerber, M.D., Work Group Co-Chair***

Dr. Gerber explained that the Work Group grew out of the Donor Management and Research Work Group to address how to procure more organs from deceased donors. Currently, the number of ideal donors is insufficient, and more organs are coming as a result of donation after cardiac death (DCD) and from marginal and expanded criteria donors (ECDs). Dr. Gerber said the quality and quantity of organs for transplant must improve, because inferior organ quality is associated with morbidity and mortality for recipients.

To increase the number of organs available, efforts should focus on mitigating waiting list candidates' morbidity and mortality. To improve the quality, efforts should mitigate recipient morbidity and mortality.

The Work Group seeks to address some of the scientific, ethical, logistic, and regulatory obstacles to improving organ quality and quantity, taking into account the concerns of all the stakeholder groups. At present, no infrastructure exists to support effective donor intervention studies. The magnitude and complexity of the challenges require guidelines and processes to facilitate safe, effective clinical trials in deceased donors, and those guidelines and processes should be applicable to all U.S. institutions.

The Work Group is focusing on identifying key elements of protocol and oversight, how to share information, donor authorization for research, ethical considerations, risks to recipients, recipient consent, and follow up. It has identified some existing mechanisms to facilitate research.

There is a strong need for guidance to support the initiation and growth of donor research activities. Some efforts are underway by other organizations (e.g., the Institute of Medicine has funding for a planning meeting on the topic). The Work Group has mapped

out the steps of a potential protocol, linking them to supportive resources. For the protocol, the Work Group aims to flesh out, for example, the process for review of scientific merit and how to ensure appropriate oversight, including human research protections. Dr. Gerber said questions remain about defining and stratifying the risks of research; whether risks vary by organ or approach; and whether research would affect allocation. Collecting data, monitoring safety, and communicating safety concerns in real time are also important issues to be addressed.

Other topics discussed by the Work Group include whether to seek authorization under the Uniform Anatomical Gift Act (UAGA) for the dual purposes of transplant and research, how to define OPO standards for review and participation, and donor hospital considerations. Regarding transplant, the Work Group has addressed the need for a framework to quantify risk, communication strategies to ensure the receiving team has important information about the protocol, and informed consent of the recipient.

### ***Discussion***

Ms. Glazier said deceased donors are not considered human subjects under the Common Rule, but the UAGA does have standards. She said the ACOT can help by examining how best to navigate existing rules and what can be improved to facilitate more clinical trials. More clarification is needed around existing regulations, such as when a recipient is considered a human subject. In the short-term, said Ms. Glazier, the ACOT could request more guidance about existing regulations.

Another option, Ms. Glazier continued, is to develop a different pathway for donor research under the existing regulations, just as emergency medicine has done. Such an approach could include getting pre-consent on the basis of risk stratification, so that recipients agree in advance to accept an organ that has been subject to an intervention.

Mr. Alexander said the risk stratification strategy makes sense. Some ethical issues of informed consent remain, he said. For example, there may be instances in which a recipient who refuses to give consent, even for a low-risk study, has limited access to organs. Ms. Glazier said the Work Group concluded that consent and access must be balanced against the need to advance the science in the field. At present, recipients are aware that they may have less access to an organ if they are unwilling to accept one from an ECD.

Dr. Gerber pointed out that the research would target a pool of donors that does not exist now, so access may not be affected. Mr. Alexander felt that point should be emphasized, and Dr. Gerber agreed that efforts to develop guidance for DCD research should not affect existing research activities. Ms. Glazier said there must be a commitment from the field around the vital need for research to increase the quality of available organs.

Dr. Gerber noted the need for a national, transparent model with the same requirements of participation for all. Mr. Alexander agreed that, given the new allocation policy, regional models would not be feasible. Dr. Barr stressed the need to get buy-in from OPOs and transplant centers. Under current regulations, there is no leeway to conduct

research, even on low-risk interventions that raise no objections. Guidance and protocols must also specify how to set up higher-risk intervention studies that do not have a significant impact on the donor pool or allocation. On the flipside, said a participant, the current standard of care may not be helpful to recipients.

In response to Dr. Eason, Ms. Glazier said the Work Group is focusing on research in which death is declared so that the donor is not considered a human subject. Dr. Barr said there is growing research on ex vivo perfusion, and ex vivo lung perfusion may be approved by the FDA soon.

Dr. Matas reminded the ACOT of the concerns raised earlier in the meeting about how center-specific reporting requirements affect innovation. Dr. Gerber said that as new research protocols emerge, the transplant community will have to educate potential recipients about risks and address numerous other factors.

Ms. Glazier suggested that, as a first step, the ACOT should ask the OHRP to clarify existing guidance. Dr. Barr believed the Work Group could reach out to OHRP without a formal ACOT recommendation.

**Action Item**

The Donor Intervention Research Work Group will work with the OHRP to clarify existing guidance.

**HOPE Act: Follow Up and Discussion of Criteria, HHS/NIH Update**

*Jonah Odum, M.B.A., M.D., Ph.D.*

Dr. Odum said the HOPE Act allows the transplant of organs from HIV-positive donors to HIV-positive recipients. The HHS Secretary directed NIH to develop guidance on implementation of the law and criteria to enable research to move forward. The National Institute of Allergy and Infectious Diseases (NIAID), HRSA, the CDC, the FDA, and the professional community have been in discussions. The NIAID Work Group has developed criteria that are in the clearance process now and will be published in the *Federal Register* for public review.

The evidence base for developing the criteria is slim, said Dr. Odum. A few centers in South Africa have transplanted organs from HIV-positive donors to HIV-positive recipients. Recent data from South Africa demonstrated very good outcomes with kidney transplantation in this setting when compared with the general population. The rate of rejection in these data is much lower than that seen in the U.S. population of HIV-positive organ recipients, said Dr. Odum.

The NIAID Work Group determined that the use of antiretroviral and immunosuppressive drugs is complicated, so the best place to begin research is in centers that already have experience transplanting HIV-negative organs to HIV-positive recipients. In the United States, centers only have such experience with liver and kidney transplantation. Research criteria address the following categories:

- Donor eligibility
- Recipient eligibility
- Transplant program qualifications
- OPO responsibilities
- Prevention of inadvertent HIV transmission
- Outcome measures: waiting list, donor organs (deceased and living), living donors (post donation), and transplant recipients

Dr. Odum said the NIAID Work Group felt that living donors should be included in the research criteria, but the transplant community is divided. He asked for guidance from the ACOT on donor issues. South African researchers did not use living donors in their study, but they do have substantial experience with kidney transplants from living donors.

The criteria for recipient eligibility are similar to those in the South African study and require laboratory evidence that the recipient does not have AIDS. The criteria for transplant program qualifications emphasize experience and expertise. The Work Group struggled to define experience, said Dr. Odum, finally agreeing that evidence of at least five HIV-negative-to-HIV-positive transplants over 4 years provided sufficient evidence. A local IRB must serve as the final arbiter of experience for a trial.

The OPO responsibilities relate to consent, standard operating procedures, and handling infected tissues or organs. Preventing inadvertent HIV transmission is a key concern, so the criteria spell out requirements. The outcome measures are those the Work Group felt constituted the minimum data set needed to enable the Secretary to evaluate programs after 2 years. Dr. Odum described some of the specifics of the proposed outcome measures. Monitoring the rejection rate is particularly important given the high rate of rejection of HIV-negative-to-HIV-positive transplants in the United States.

Dr. Odum said there was considerable debate within the Work Group on several topics, and he welcomed ACOT input on them:

- Are pre-implant biopsies useful or necessary? The South African research team conducted biopsies and found evidence that could signal accelerated loss of kidney function. In the United States, mandating biopsies is a contentious issue, and questions arise about who would conduct them, manage the results, and archive the findings.
- Should living donors be included? Many transplant nephrologists believe living donors should be excluded. Other Work Group members said the matter would be addressed by the courts if the research criteria do not.
- How should the Secretary gather the data needed to conduct the 2-year evaluation mandated by the HOPE Act?

### ***Discussion***

Dr. Odum clarified that the NIAID Work Group included representatives from the National Institute of Diabetes and Digestive and Kidney Diseases, the CDC, the FDA, AIDS and infectious disease experts, and transplant experts. As the Work Group reached

consensus, it presented its proposals at professional meetings to gather more input from the community.

Dr. Fung said the South African experience did not shed light on the evolution of matching genotypes between donors and recipients. If pre-implant biopsies are mandated, it would be important to understand whether there are genotype differences between donors and recipients that require attention. The long-term implications of genotype differences should be better understood.

Dr. Odum said the underlying concern relates to transplanting a different strain of disease. Transplant physicians only have 3 days to evaluate a deceased donor; assays for genotyping are difficult to do and take 3 weeks or more. Setting national criteria for genotyping is problematic given the long window needed. Dr. Odum worried that if the criteria are too detailed, research would not go forward.

In response to Dr. Fung, Dr. Odum said that the NIH is interested in funding this research. Once the criteria are finalized, it will be up to the transplant community to propose research projects. Responding to a participant, Dr. Odum said there is some experience with pediatric patients, but only with HIV-negative-to-HIV-positive transplants.

Dr. Odum asked Dr. Matas for his thoughts on living donors. Dr. Matas said he had concerns about whether the operative risk of donation would be higher for HIV-positive donors and whether there are long-term impacts of donation on HIV. He was not sure whether experts can predict the rate of ESRD in HIV-positive vs. HIV-negative patients, regardless of donation. He pointed out that there is increased risk of ESRD among certain groups, such as African Americans, and those at higher risk should be studied. However, Dr. Matas said, he was leery about donations from people who are already at high risk, and he did not think such donations would significantly affect the availability of organs.

Dr. Klassen, a transplant nephrologist, said he did not believe that living donation is warranted because of the potential for renal disease and the lack of good data that the benefits outweigh the risks. Dr. Barr said more research is critical to answer these questions; he proposed research go forward in stages—first addressing long-term outcomes among the current population of living donors, and later looking at HIV-positive living donors.

Dr. Odum said he was intrigued by the presentation addressing the implications of donor research on transplant recipients. The NIAID Work Group debated the potential effects of access to HIV-positive organs on those HIV-positive people on the waiting list. The Work Group also questioned whether transplant centers that accept HIV-positive organs would have more or less access to organs in general.

Dr. Gerber stated that centers must be able to exclude these transplant cases from their outcomes reporting, because they require risk-taking and innovation. Dr. Barr said risk adjustment is a concern in all transplant settings, even in routine cases. Dr. Gerber added that transparency is vital to ensure that bad studies are terminated.



Dr. Odum asked Ajay Israni, M.D., of SRTR to comment on evaluation of centers. Dr. Israni said the community has been clear about the need for risk stratification, and the DAC is looking at risk factors. If risk data are gathered, they could be incorporated into modeling and assessed.

Dr. Barr said collaboration between centers, CMS, SRTR, OPTN, and others would be needed. Mr. McLaughlin clarified that the OPTN would determine how to flag HIV transplant research for monitoring, the SRTR would report on it, and HRSA would exercise authority over it. He said HRSA could opt to separate some data from regular patient outcomes. Dr. Barr said other requests to exempt some cases from outcomes evaluation have fallen on deaf ears; the message has not reached SRTR. Mr. McLaughlin pointed out that research conducted under the HOPE Act would be treated differently than other OPTN activities (as would donor research protocols, Dr. Barr added).

Mr. McLaughlin said OPTN would need to determine how to collect research data, which it does not do now. Dr. Barr noted that the endpoints described in the proposed criteria are more granular than the data typically collected by the OPTN. Mr. Walsh observed that the HOPE Act states that HIV-positive transplantation will go forward under a research protocol for now and that the OPTN has a role in evaluation in collaboration with the Secretary. In addition, said Mr. Walsh, there is discussion about multi-center collaborations to coordinate such transplants.

Dr. Klassen did not believe that the OPTN has the capacity to collect research data now. Dr. Gerber added that research protocols deviate from standard practice, but it is important to gather and share data. Dr. Odum said that if NIH funds the research, it would require investigators to have a mechanism for collecting and reviewing data, and it would provide some oversight. He wondered how the community would learn about studies funded by other organizations.

Dr. Matas said the discussion was mixing two separate points: the mechanisms for data collection on the one hand and the need to exclude research data from center-specific reporting on the other. Dr. Gerber said the ACOT could make recommendations to the Secretary about how research activities are reviewed, whether donor- or recipient-related, and that recommendation could guide the OPTN.

Ms. Levine said that under the HOPE Act, all HIV-positive-to-HIV-positive transplants must be conducted under NIH research criteria until the Secretary reviews the scientific data with the OPTN and determines otherwise. She asked how to collect the data the Secretary needs to make that determination. Dr. Odum agreed that the NIH would like guidance from the ACOT on this question.

#### **Action Item**

Dr. Barr will oversee the creation of an ACOT Work Group to advise NIH on the criteria for HIV-positive-to-HIV-positive transplant criteria. Dr. Odum will

identify members of the NIAID Work Group who can serve as liaisons to the new ACOT Work Group.

**Preliminary Results of CMS Mitigating Factors Reviews and Systems Improvement Focused Reviews of CMS Requirement for Quality Assessment and Performance Improvement (FQAPI) Systems in Solid Organ Transplant Programs**  
*Thomas Hamilton, CMS*

Mr. Hamilton explained that when transplants were first covered, CMS set thresholds for transplant patient survival rates and later adopted the SRTR and OPTN approaches to harmonize data collection. With the first CMS Conditions of Participation in 2007, programs had to have program and management structures consistent with appropriate, effective care and demonstrate the ability to gather and apply performance improvement data.

Comparing the CMS and OPTN outcome measures, Mr. Hamilton noted that programs are not in violation unless they fail to meet all three of CMS' minimum measures for graft and patient survival. A program may be flagged for review, but it would not receive a conditional-level citation unless the same substandard performance persists in subsequent SRTR reports. Mr. Hamilton said CMS aims to position its outcome measures in a way that backs up the OPTN peer review process. He said CMS is working with HRSA and the SRTR to track the differences in the outcome criteria and will decide whether to adopt new criteria. He noted that CMS cannot change its standard until a body of evidence supports such a change.

In adopting its regulations, CMS considered how it could best back up the OPTN and how to reinforce the tradition of continuous quality improvement (CQI) in the transplant community. In the Conditions of Participation, CMS included the FQAPI to reinforce CQI. They also build in the mitigating factors approval process for citations and include a systems improvement agreement process that gives programs more time to implement changes.

Backing up the OPTN are CMS' patient and graft survival outcome measures. At any given time, 8–11% of programs have a single SRTR report that raises a flag. Only about 3–5% have two of five SRTR reports showing statistically significant outcomes that raise flags and thus merit a condition-level citation. Once a program is flagged, CMS assumes that the OPTN peer review process kicks in, and the program addresses the issue. By building in this tolerance, Mr. Hamilton said, CMS can focus on persistent outliers.

The mitigating factors approval process allows CMS to consider, for example, the effects of natural disaster on program outcomes. The process allows programs 210 days to recognize substandard performance, assess the root causes, design and implement an intervention, and demonstrate improvement. In some cases, an SRTR report will show improvement midway, and the mitigating factors process is ended.

The most important mitigating factor is evidence of a program addressing its own problem successfully, said Mr. Hamilton. The regulation has been amended to state

explicitly that documented performance improvement constitutes grounds for CMS to grant approval based on mitigating factors if all criteria are met. The systems improvement agreement process is also spelled out clearly in the regulations.

Mr. Hamilton pointed out that CMS recognizes innovation as a mitigating factor. That is, if the effects of an innovative service skew the overall results, it may be appropriate to separate those effects before evaluating the outcomes the general patient population.

The regulation explicitly recognizes innovation as grounds for mitigating factor approval, but there is still no formal process for doing so, said Mr. Hamilton. He said the ACOT may wish to advise on setting up a process. Mr. Hamilton recommended that a third party, outside of the transplant center, endorses an innovative model, acts as an arbiter, and identifies the individuals who would be affected and whose data should be pulled out. If there were some mechanism to identify innovative practices and separate data in advance, transplant centers could avoid being cited in the first place. Risk adjustment models are needed to support such an approach.

To obtain mitigating factors approval, a program must demonstrate substantial improvements that address the root cause(s) of the problem. It must show that performance improvement plans have been implemented and institutionalized and that they are sustainable. Finally, it must provide evidence of improved outcome that support a finding of current compliance.

Almost all programs cited apply for mitigating factors approval, and many meet the criteria outright. Some implement changes but are unable to provide outcomes data; such programs usually enter into a systems improvement agreement with CMS, which allows an additional 12 months for data collection provided the program agrees to a performance improvement regimen. Some programs achieve compliance before the 210-day deadline and so no longer require approval. A few programs withdraw from CMS program participation rather than face termination.

The most important element of a system improvement agreement is on-site evaluation. Such agreements are established only when the circumstances seem promising for improvement and strong institutional support is evident.

The FQAPI is an important aspect of regulation that ensures that hospitals have internal capacity to monitor their performance and improve outcomes, said Mr. Hamilton. Ideally, the FQAPI infrastructure integrates lessons learned from best practices, process improvement, and innovation, codifying them into standard practices. Mr. Hamilton outlined the major aspects of the FQAPI, which embody the principles of CQI (e.g., performance measurement, analysis, implementation of changes, and follow-through).

Mr. Hamilton provided examples of ways in which programs have applied data analysis to better understand their outcomes and improve performance. In one case, for example, the hospital believed its poor outcomes resulted from their use of organs from ECDs. Data analysis showed the same poor outcomes applied to recipients of organs from

standard donors, and the program went on to identify and fix system and practice flaws affecting outcomes.

In another case, five of nine recent deaths were related to non-compliance. Closer evaluation revealed the program offered little preparation or education to recipients. Better root cause analysis might have identified problems earlier.

Mr. Hamilton observed that every hospital evaluated with persistent substandard outcomes had staffing issues, and improving performance involved stronger staffing with support from hospital leadership. Improving the use of electronic health records is also very helpful, especially in large organizations, to identify transplant recipients who return for care and to notify the transplant program.

Performance can be enhanced by using multi-disciplinary teams. For example, coordinating and training intensive care nurses about transplant issues is key to improving performance. Similarly, transplant programs tend to rely on one group of specialists to care for their patients but those specialists may not have specific training in transplant care. Identifying a subset of specialists, providing them with targeted training, and adjusting schedules to ensure that one of those specialists is available benefits transplant programs.

In another case reviewed by CMS, a program attributed its substandard outcomes to a population with a large number of African Americans and high rates of cardiovascular disease. While the characterization of the population was accurate, review also showed that the hospital did little testing or intervention before transplant, and no transplant specialists were involved in clearance. By adopting more interventions up front, the program improved rapidly.

One program attributed its failure to improve despite reform efforts to a single, poor surgeon. Analysis revealed that the surgeon was not significantly worse than peers; in fact, even the best surgeon had poor outcomes at 1 year. By addressing underlying factors, the program succeeded in bringing its outcomes up to national averages.

Mr. Hamilton said CMS analyzes its own efforts to assess effectiveness. Evidence suggests that programs that receive mitigating factors approval continue to perform similar to those that have never been cited for substandard outcomes. Programs that required system improvement agreements appear to improve and do better over time. Mr. Hamilton cautioned that these data are preliminary.

Mr. Hamilton described several national trends, noting that sustained improvement in 1-year survival rates likely reflect continuous learning and improvement efforts of transplant programs. He said CMS may be helping poorly performing programs improve, but the national averages are getting better, so transplant programs should be proud. He concluded that CMS aims to promote synergy and avoid duplicating efforts; he hoped that all regulatory and oversight bodies would work together to reinforce each other's efforts to improve care for recipients.

### *Discussion*

Dr. Eason said transplant centers are improving, and that explains some of the better outcomes. However, some are becoming more selective, excluding risky patients to avoid being flagged on center-specific reports. He asked whether CMS applies similar requirements to OPOs, which should be improving their donor management, informed consent, and other processes. Mr. Hamilton said he has heard anecdotally about the impact of risk aversion, but he has not seen good studies demonstrating it. He wondered whether other programs pick up the slack when one becomes more selective; he noted that the number of transplants overall has not gone down and still correlates highly with the number of organs recovered. Mr. Hamilton said a new national strategy to improve organ availability may be needed.

Regarding innovative practices, Mr. Hamilton said he hoped CMS could work with the ACOT, the OPTN, and others to promote innovation—for example, designating a program to test the use of organs that are now discarded.

Dr. Matas pointed out that donations have not increased over the past decade. He believes programs are reluctant to conduct trials for several reasons. Even before CMS cites a program, poor outcomes related to innovative practices can lead to a program losing its center-of-excellence designation, which means losing money. Mr. Hamilton responded that CMS has the capacity to work with programs upfront to support demonstration projects, such as drug testing, and separate out trial participants' outcomes from those of other patients. However, he acknowledged that doing so would not address concerns of private payers.

Dr. Matas said private payers have a lot of influence on the field. Getting private payers to agree to work upfront with programs to support innovative trials is essential to short- and long-term outcomes, he said. Dr. Gerber said much work needs to be done to simplify reporting around innovative research. The FQAPI results in a good end-product, but programs need to become much more efficient about reporting. Dr. Gerber said centers would be responsive to working with CMS on minimizing the burden of data collection and reporting.

Mr. Hamilton said CMS reevaluates its reporting requirements frequently to ensure it is collecting valuable data. Regarding OPOs, he said OPOs undergo registration once every 4 years, while other programs have continuous, ongoing review. There is no “redemption” process in place for OPOs that perform poorly. Mr. Hamilton called on the transplant community to recommend better ways to harmonize metrics across OPOs and transplant centers, saying that CMS is a willing partner.

Dr. Barr said conversations between HRSA and CMS should include representatives from OPOs who can provide feedback. The ACOT could facilitate such conversations, which could lead to formal changes. Dr. Barr noted that because of allocation changes, multi-organ transplants do not get counted, which has encouraged a huge increase in re-

transplants or transplants of more than one organ at once. He hoped that attention would be given to how CMS and private payers address that issue.

Dr. Fung said incentives should be established to encourage better OPO performance. Now, all the onus for performance improvement falls on the transplant centers. Dr. Barr said the ACOT may be able to create a work group to address that topic.

### **Vascularized Composite Allografts (VCAs)**

#### ***Suzanne McDiarmid, M.D., ACOT Member***

Dr. McDiarmid gave an overview of the emerging field of hand and face transplants, or VCAs. In the United States, 28 such procedures have occurred to date in 11 programs. Recent military conflicts highlighted the need; a number of veterans are eligible, and Dr. McDiarmid expected the Department of Defense will be a strong partner in the field. She called VCA life-altering.

The new American Society of Reconstructive Transplantation partnered with the AOPO and the American Society of Transplant Surgeons (ASTS) to request oversight of VCA under the OPTN. In 2013, HHS defined VCAs as organs and requested that a committee define policies for VCAs under the OPTN by July 2014. The VCA Transplantation Committee quickly proposed revisions to the UNOS OPTN Board to revise existing policies to include VCAs. Because of the extremely short deadline, the policies were approved by the Board and implemented for a finite time (through June 2015). Public comments will be gathered and presented to the Board, which will revise the policies as needed.

The proposal to the Board defined VCAs, established membership requirements for VCA transplant programs, created a VCA allocation system, and developed donor authorization procedures. It also outlined exemptions from certain bylaws and policies not applicable to VCAs. Dr. McDiarmid described each of these aspects of the proposal in more detail. She noted that in some cases, living donors can provide, for example, abdominal wall segments for use in scalp or breast reconstruction. The HHS Secretary allowed living donation under the definition of VCAs.

The allocation process is relatively simple, because there are not enough data to support the utility of more complex testing and assessment. Separate, specific, written donor authorization is required for VCA donation, and the policy is consistent with UAGA and State laws. Among other requirements, members must identify what kind of VCAs they plan to conduct.

The VCA Transplantation Committee also addressed data collection and submission requirements for VCAs. A proposal was put out for public comment in fall 2014. It directs the OPTN to collect and disseminate data on VCAs in the United States. The proposal will be presented to the Board in June 2015. The Committee is also working on proposals around membership requirements (e.g., education, training, and certification requirements for surgeons) similar to those for solid organ transplant programs.

The Committee also seeks to raise awareness and educate stakeholders about the potential for living donor VCAs, a topic which sparked interest quickly among public commenters. It is developing a guidance document and resources that mirror those for living donors in general. Dr. McDiarmid said it must be clear to the public that the same ethical principles apply to living donors of VCAs, that donor safety is paramount, and that the risk-benefit ratio changes when a transplant is not considered life-saving. Finally, the Committee is also working on improving the allocation process and better defining graft failure.

### **Discussion**

Dr. Barr thanked Dr. McDiarmid and the Committee for their efforts. He noted that an ACOT recommendation to the Secretary helped make the new VCA policy a reality. He asked how allocation would be affected when a patient has multiple needs, e.g., both a face and hand. Dr. McDiarmid responded that the number of transplants now is so small that it would be premature to craft policies that are very specific. The few programs considering face and hand transplants have reached agreements with OPOs, which has been effective. There have been no efforts yet to prioritize transplants.

Dr. Barr asked whether rapid advances in prosthetics affect the VCA field. Dr. McDiarmid said the evolution in technology has been astounding, but the decision is a very personal one. Some recipients feel the best prosthesis will never be as good as a sensate hand. Dr. McDiarmid added that transplant programs take very seriously the risk of immunosuppression, which can be fatal, and work to educate candidates about that risk.

### **Public Comment**

**Josh Morrison**, Executive Director of Waitlist Zero and a transplant recipient, read a letter to HRSA signed by more than 400 living kidney donors.<sup>1</sup> The signatories supported efforts to increase living donations in an effort to eliminate the waiting list. They said they did not make the decision to donate lightly and accepted that no surgery is without risk. They were glad to donate, as are most living donors. Fewer than one in 20 donors regret their decision, and the signatories sympathized with those who did. However, the long-term risks of donation are manageable, while the impact of donation on the recipient is striking. Only increasing the number of living kidney donors will address the lack of organs available for transplant. Education and promotion of living donation can only improve informed consent. The signatories called for better education of the public, expanded access to donation, expanded follow up, provision of health insurance for donors, and reimbursement of donor expenses. Some recipients may need additional transplants, and many people are in need of transplants now. Donation may not be the right choice for everyone, but the signatories were glad about their choice to donate and hoped more people would do so (see Appendix A and Appendix B).

**Harvey Mysel** of the recently founded Coalition to Promote Living Donation, founder of the Living Kidney Donors Network, and a two-time kidney transplant recipient, said the Coalition is eager to include OPOs, transplant centers, and other non-profit organizations. He noted that the number of transplants from living kidney donors in 2014 was at its

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<sup>1</sup> The letter was not provided to HRSA. The contents of the letter are paraphrased here.

lowest since 2000. In eight of the past 10 years, living donations decreased from the previous year. These numbers should raise a red flag. In 2000, 35,000 people with ESRD were awaiting a kidney transplant. Today, that number is 100,000. Clearly, policies are needed to improve living donation. Major changes are positive and possible. The Coalition believes that living donations could be increased through comprehensive education of the public, universal access to donation, and better treatment of donors (who currently bear the cost of travel and other expenses). Better follow up and study of donors should be a realistic goal. Two years of follow up is not nearly enough. Donors should get health insurance to alleviate their risks and avoid future gaps in care. Treating donors better will save dollars. Promoting donation does not apply coercion; the best method is through better education. The best encouragement for living donation is reducing the medical and financial burden on donors. Living kidney donation is not the best choice for all, but it is an admirable one with tremendous potential consequences for the United States and the public. The government should support living kidney donation wholeheartedly.

**Sigrid Frye Revere**, President of the Center for Ethical Solutions, said she speaks not as an advocate of living kidney donation but rather an advocate for living kidney donors. She said she tried to donate her kidney to a friend and cleared the medical and psychological screening but was refused for socioeconomic reasons, and her friend died. Ms. Revere presented a TED talk on her experience, which inspired the creation of two new organizations. One is Stop Organ Trafficking Now, which aims to influence how living donors are treated. Stop Organ Trafficking Now created a politically feasible proposal, modeled after initiatives in Australia, Israel, and Ireland that compensate donors for lost wages and living expenses. This proposal draws on those models and includes other ideas to protect living kidney donors. The proposal would save Medicare money, requires limited startup costs, requires limited bureaucratic changes, and requires no appropriations. Ms. Revere provided a background document for the ACOT's consideration (see Appendix C).

Ms. Revere said her TED talk also inspired creation of the American Living Organ Donor Fund (ALODF), the only public charity she knew of that advocates and provides services to all types of donors and only to donors. Most organizations serve both donors and recipients. Ms. Revere provided the ACOT with ALODF's informational pamphlet. Its website offers information about individual State laws and regulations affecting donors. The ALODF also sponsors a private online support group via Facebook for donors and those considering donation. The ALODF implemented a network of volunteers and mentors to help with some expenses and other services, such as transportation. It created a fund for living donors. Currently, donors can get some financial assistance from the National Living Donor Assistance Center for transportation to a transplant center, but they often feel abandoned after their donation. Ms. Revere said the ALODF's pilot project has made 34 transplants possible, but 50 more people are waiting for help. She believed the experience of ALODF could inform future efforts that the ACOT may want to pursue.



Finally, Ms. Revere said her TED talk was about solving the kidney shortage. Taking better care of living kidney donors will result in more donors. While she said increasing the number of donors is not her priority, the approach she offers is an ethical way to do so.

The comments of **Rebecca Hays** of the American Society of Transplantation can be found in Appendix D. The comments of **Richard Formica, M.D.**, of the American Society of Transplantation can be found in Appendix E.

Written comments were also submitted by **Peter Stock, M.D., Ph.D.**, president of ASTS (see Appendix F), and **Christine Wright** (see Appendix G). "An Open Letter to HHS Secretary Burwell on Ethically Increasing Organ Donation," published online in *Transplantation Direct* on March 6, 2015, is in Appendix H.

**Gene Ridolfi**, executive director of the Washington University in St. Louis and Barnes-Jewish Hospital Transplant Center, addressed the impact of KPD on transplant centers. He and his colleagues support KPD, but the resources required are significant. His center often invests dedicated resources for KPD, but much time is spent on coordinating events that never result in transplant. Mr. Ridolfi called for focusing on advancing process efficiencies of KPD to ensure greater success of KPD and less time invested in events that do not move forward.

#### **New Business**

Dr. Fung suggested the ACOT recommend a cost-benefit analysis of the use of belatacept for kidney transplantation involving ECDs. Dr. Fung will submit a proposal for consideration by HRSA and FDA to conduct a long-term cost-benefit analysis.

Dr. Matas suggested that the ACOT establish work groups to address long-term follow up of living donors and the conflict between innovation and the need to ensure good center-specific results (which affect reimbursement).

#### **Action Item**

Dr. Barr agreed that the ACOT should consider creating a work group to address long-term follow up of living donors.

#### **Adjournment**

Dr. Barr encouraged members to email him with ideas about new work groups or if they would like to participate in an existing work group. Planning for the next ACOT meeting is underway. Dr. Barr adjourned the meeting at 12:40 p.m.

## Appendix A

WaitList Zero  
666 5<sup>th</sup> Avenue  
New York, NY, 10103

Mark Barr  
Chairman  
Advisory Committee on Transplantation  
5600 Fishers Lane  
Rockville, MD 20857

Dr. Barr,

The number of transplants from living kidney donors in 2014 was the lowest on record since 1999, fifteen years ago. That year, about 35,000 ESRD patients were waiting for a transplant. Today more than 100,000 are. Clearly, policies to revitalize living kidney donation are needed.

The past decade of deceased donation policy shows that major positive changes are possible. The number of eligible deceased donors has decreased from 12,000 annually in 2002 to 9,000 today, yet even amidst that challenging environment, sustained effort to increase deceased donation has yielded exemplary results. Since the creation of the Organ Donation Breakthrough Collaborative in 2003, the amount of deceased donor kidney transplants has risen by more than 3,000. In that time, the conversion rate of eligible deceased donors to actual donors has risen from about 50% to over 75%, achieving the Collaborative's publicly stated goals. A similar breakthrough is needed for living donation.

That is why we have come together to form the Coalition to Promote Living Kidney Donation. We believe sincerely in fighting to increase deceased donation, but on its own deceased donation will never be enough to end the shortage. It is only by promoting living donation that we can provide hope to all of the patients on the waitlist as well as the tens of thousands more who suffer from ESRD, are medically suitable for transplantation, but never even make it onto the list.

Promoting living kidney donation means making it easy for patients to ask for a transplant and easy and attractive for people to donate. That requires supporting patients through comprehensive transplant education for them, their families and the public. It requires universal access to paired kidney donation.

It also means ensuring the best possible treatment for donors. Currently donors are left to bear the cost of their own lost wages, travel, childcare, and other expenses related to donation. That needs to change. Better follow-up care and study of donors needs to be ensured in a way that is realistic about donors own schedules and the

Appendix A (continued)

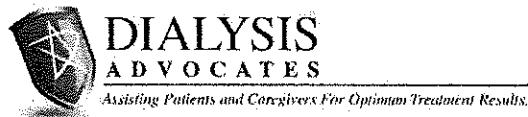
demands on their time. Donors should be provided health insurance to alleviate risks of donation and to avoid gaps in coverage.

Treating donors and patients better will increase transplant and thus save American lives and taxpayer dollars. But promoting donation does not imply coercion or exploitation. Quite the opposite. The best way of maintaining and strengthening informed consent is through excellent patient education. The best way of ensuring donors do not regret donation is reducing its financial and medical burden.

Living kidney donation is not the right decision for every American, nor even for most, but it is admirable and an act of public service. It is a choice with tremendously positive consequences for the American public, and it is one the U.S. government should support wholeheartedly.

Sincerely,

The Coalition to Promote Living Kidney Donation



**WAITLIST ZERO**

## Appendix B

WaitList Zero  
666 5<sup>th</sup> Avenue  
New York, NY, 10103

Mary K. Wakefield, PhD, RN  
Administrator  
Health Resources and Services Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Living Kidney Donors in Support of Donation

We the undersigned kidney donors support efforts to increase living kidney donation.

We did not make our choice to donate lightly. With the help of transplant professionals, we carefully weighed the risks and rewards. The medical professionals we worked with never pressured us to donate. Quite the opposite— they worked hard and in good faith to educate us to make our own informed choice. We are grateful for their support.

We are glad we chose to donate, as are most donors. No surgery is without risk or potential disappointment, but studies have repeatedly found that fewer than one in 20 donors regret their decision. Our hearts go out to those who regret donating: More must be done to reduce their number. Nevertheless, theirs is not the normal donor experience.

The long-term risks of kidney donation are real but manageable:

- a three in 10,000 chance of dying during surgery;
- an increase to a 1% lifetime risk of kidney failure (the general population has a 3% risk but kidney donors start off healthier); and
- for female donors, a 6% increase in the risk of preeclampsia during pregnancy.

Donation neither reduces life expectancy nor prevents donors from living normal, healthy lives.

The positive impact of the recipient dwarfs the expected cost to the donor. A living donor kidney lasts an average of fourteen years. By contrast, the five-year survival rate of dialysis is about the same as brain cancer. The impact of a transplant is so striking that recipients often look noticeably healthier as soon as they emerge from surgery.

Appendix B (continued)

Thousands of Americans die each year because of the kidney transplant shortage. Increases in deceased donation can never be sufficient to meet this need. It is only by increasing living kidney donation that we can save these patients.

Education and promotion among potential living donors can only improve informed consent. We support policies to:

- Better educate the public, patients, and their families about transplant;
- Expand access to paired kidney donation;
- Expand follow-up study and care; and
- Reduce the costs of donation by reimbursing donor lost wages and travel expenses and by providing health insurance to donors.

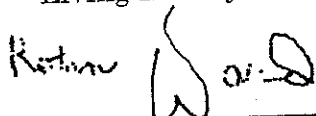
Each of these measures would support transplant and increase donation without reducing our system's strong current commitment to informed consent.

The very patients to whom we donated may need another transplant in the future. More than a hundred thousand patients just like them need a transplant today. Donation is not the right choice for everyone or, indeed, for most people. But we are glad of the choice we made, and we hope it is one that more Americans will be able to make in the future.

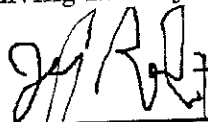
Signed,



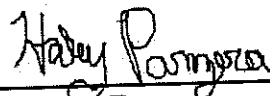
Marie Speicher  
Living Kidney Donor



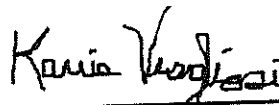
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Living Kidney Donor



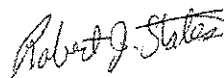
Jeremy Roman  
Living Kidney Donor



Haley Panzera  
Living Kidney Donor



Karrie Viscogliosi  
Living Kidney Donor



Robert States  
Living Kidney Donor

Appendix B (continued)

*Crystal Hazlett*

Crystal Hazlett  
Living Kidney Donor

*Christi Perez*

Christine Perez  
Living Kidney Donor

*Barbara Wolf*

Barbara Wolf  
Living Kidney Donor

*Anne Crew*

Anne Crew  
Living Kidney Donor

*Jeffery Smith*

Jeffery Smith  
Living Kidney Donor

*Debbie Glover*

Debbie Glover  
Living Kidney Donor

*Lauren Stark*

Lauren Stark  
Living Kidney Donor

*Gabriel Bennett*

Gabriel Bennett  
Living Kidney Donor

*Marcy Gorrell*

Marcy Gorrell  
Living Kidney Donor

*Anne Mannette Wright*

Anne Mannette Wright  
Living Kidney Donor

*Tiffany LeRoux*

Tiffany LeRoux  
Living Kidney Donor

*Philecia McCain*

Philecia McCain  
Living Kidney Donor

*Jubel Caldwell*

Jubel Caldwell  
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*Wayne Trznadel*

Wayne Trznadel  
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*Diane Brockington*

Diane Brockington  
Living Kidney Donor

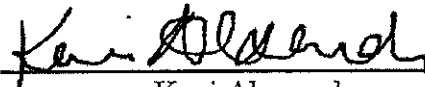
*Lita Tomas*

Lita Tomas  
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Appendix B (continued)



Wende Shurin  
Living Kidney Donor



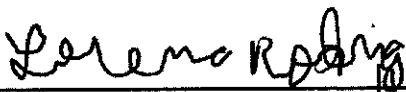
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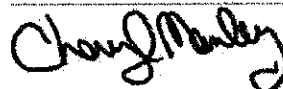
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Jenna Bromberg  
Living Kidney Donor



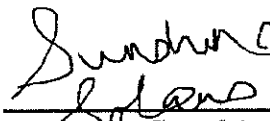
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Cheryl Manley  
Living Kidney Donor



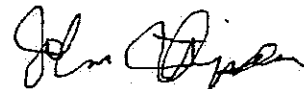
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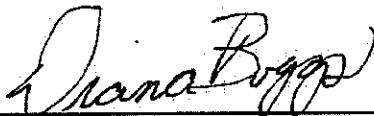
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Erica Castaneda  
Living Kidney Donor



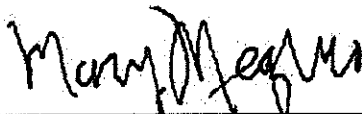
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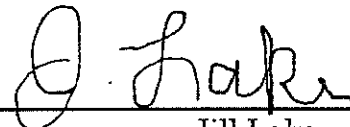
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LaDonna Strowbridge  
Living Kidney Donor



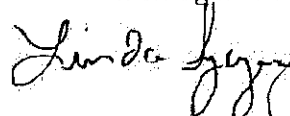
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Jill Laker  
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Carole Moore  
Living Kidney Donor



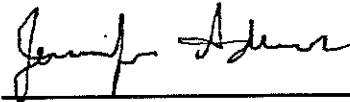
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Appendix B (continued)



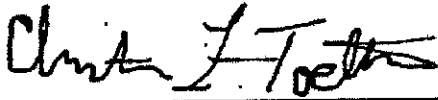
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Anne Hotz  
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Jennifer Adams  
Living Kidney Donor



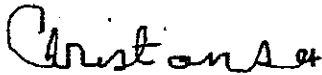
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Christina Toedtemeier  
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Wendie Levy  
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Karen Christiansen  
Living Kidney Donor



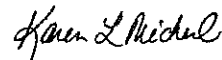
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Lorie Triantos  
Living Kidney Donor



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Karen Michul  
Living Kidney Donor



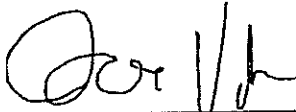
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Kayle Seitz  
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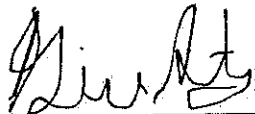
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Joe Vohs  
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Sara Toffoli  
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Gina Stravinsky  
Living Kidney Donor



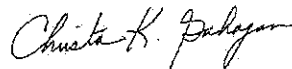
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Cathy Schroeder  
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Lisa McKeown  
Living Kidney Donor

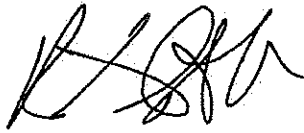


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Christa Gahagan  
Living Kidney Donor



Appendix B (continued)



Robert Rosser  
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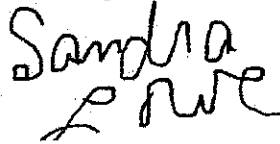
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Living Kidney Donor



Tom Chaklos  
Living Kidney Donor



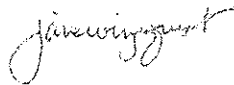
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Sandra Lowe  
Living Kidney Donor



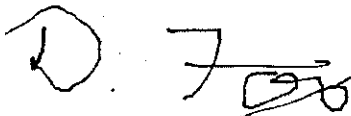
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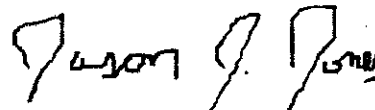
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Gina Ormond  
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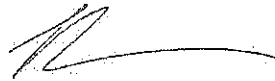
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Jason Jones  
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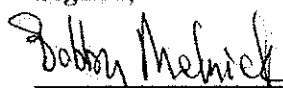
Lawrence Mitchell  
Living Kidney Donor



Eric Parrie  
Living Kidney Donor



Kristine Speckmann  
Living Kidney Donor



Bobby Melnick  
Living Kidney Donor

Appendix B (continued)

*Kim McFarlane*

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Kim McFarlane  
Living Kidney Donor

*Robert Ireland*

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Robert Ireland  
Living Kidney Donor

*Patricia Shapiro*

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Patricia Shapiro  
Living Kidney Donor

*Anne Patnode*

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Anne Patnode  
Living Kidney Donor

*Marivel Magallanes*

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Marivel Magallanes  
Living Kidney Donor

*Doni Todd*

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Doni Todd  
Living Kidney Donor

*Glenn Mary Colby*

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Glenn Mary Colby  
Living Kidney Donor

*Matthew Zuckerman*

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Matthew Zuckerman  
Living Kidney Donor

*John Bedard*

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John Bedard  
Living Kidney Donor

*John Hodges*

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John Hodges  
Living Kidney Donor

*Christina Steenbergen*

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Christina Steenbergen  
Living Kidney Donor

*Lynn Bolduc*

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Lynn Bolduc  
Living Kidney Donor

*Diane Ortenzio-Cooling*

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Diane Ortenzio-Cooling  
Living Kidney Donor

*Corky Parmet*

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Corky Parmet  
Living Kidney Donor

Appendix B (continued)

*Lisa Mccrea*

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Lisa Mccrea  
Living Kidney Donor

*Amy Morris*

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Amy Morris  
Living Kidney Donor

*Patricia Thomas*

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Patricia Thomas  
Living Kidney Donor

*Nicole Harris*

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Nicole Harris  
Living Kidney Donor

*Robyn Couch*

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Robyn Couch  
Living Kidney Donor

*Linda Case*

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Linda Case  
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*Douglas Asofsky*

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Douglas Asofsky  
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*Joy Downes*

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Joy Downes  
Living Kidney Donor

*Tanya Mallach*

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Tanya Mallach  
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*Allante Mitchell*

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Allante Mitchell  
Living Kidney Donor

*Donna Smith*

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Donna Smith  
Living Kidney Donor

*Danielle Jewell*

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Danielle Jewell  
Living Kidney Donor

*Hannah Mulligan*

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Hannah Mulligan  
Living Kidney Donor

*Judith Peck*

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Judith Peck  
Living Kidney Donor

Appendix B (continued)

*Julie Navin*

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Julie Navin  
Living Kidney Donor

*Namrata Patil*

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Namrata Patil  
Living Kidney Donor

*Karen VanWhy*

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Karen VanWhy  
Living Kidney Donor

*Monica Arce*

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Monica Arce  
Living Kidney Donor

*Geri Emma*

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Geri Emma  
Living Kidney Donor

*Lisa Buentello*

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Lisa Buentello  
Living Kidney Donor

*Christine Clinkenbeard*

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Christine Clinkenbeard  
Living Kidney Donor

*Teresa Kosse*

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Teresa Kosse  
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*Patti Norton*

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Patti Norton  
Living Kidney Donor

*Shanna Baker*

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Shanna Baker  
Living Kidney Donor

*Linda Snead*

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Linda Snead  
Living Kidney Donor

*Joelle Fleurimont*

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Joelle Fleurimont  
Living Kidney Donor

*Yvonne Alexander*

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Yvonne Alexander  
Living Kidney Donor

*Candy Campbell*

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Candy Campbell  
Living Kidney Donor

Appendix B (continued)

*Emily Milleville*

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Emily Milleville  
Living Kidney Donor

*Kathleen Romeyn*

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Kathleen Romeyn  
Living Kidney Donor

*Eryn Lunceford*

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Eryn Lunceford  
Living Kidney Donor

*Ivanna Lomeli-Perez*

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Ivanna Lomeli-Perez  
Living Kidney Donor

*Tiffany Ayers*

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Tiffany Ayers  
Living Kidney Donor

*Kevin Travers*

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Kevin Travers  
Living Kidney Donor

*Diane Manning Lomax*

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Diane Manning Lomax  
Living Kidney Donor

*Teresa Navickas*

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Teresa Navickas  
Living Kidney Donor

*Melissa Bratt*

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Melissa Bratt  
Living Kidney Donor

*Camilla Spicer*

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Camilla Spicer  
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*Taren Talmage*

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Taren Talmage  
Living Kidney Donor

*Cynthia Allery*

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Cynthia Allery  
Living Kidney Donor

*Erika Decoteau*

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Erika Decoteau  
Living Kidney Donor

*Jessica Lauer*

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Jessica Lauer  
Living Kidney Donor

Appendix B (continued)

*William Fralix*

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William Fralix  
Living Kidney Donor

*Kathy Geisler*

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Kathy Geisler  
Living Kidney Donor

*Jason Seales*

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Jason Seales  
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*Vikz Laz*

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Vikz Laz  
Living Kidney Donor

*Elizabeth Williams*

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Elizabeth Williams  
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*Julie Oberhand*

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Julie Oberhand  
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*Ann Marie Mones*

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Ann Marie Mones  
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*Erin Sochocky*

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Erin Sochocky  
Living Kidney Donor

*Angelina Nappier*

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Angelina Nappier  
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*Samuel Silsby*

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Samuel Silsby  
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*Anne Campbell*

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Anne Campbell  
Living Kidney Donor

*Cara Yesawich*

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Cara Yesawich  
Living Kidney Donor

*Dale Hanlon*

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Dale Hanlon  
Living Kidney Donor

*Elizabeth Joyce*

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Elizabeth Joyce  
Living Kidney Donor

Appendix B (continued)

*Kerry Palmer*

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Kerry Palmer  
Living Kidney Donor

*Kendal McDonald*

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Kendal McDonald  
Living Kidney Donor

*Betty Springer*

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Betty Springer  
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*Lisa Branting*

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Lisa Branting  
Living Kidney Donor

*Marcela Speert*

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Marcela Speert  
Living Kidney Donor

*Lori Hennings*

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Lori Hennings  
Living Kidney Donor

*Ashley Hoyng*

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Ashley Hoyng  
Living Kidney Donor

*Phillip Butler*

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Phillip Butler  
Living Kidney Donor

*Shelly Atkinson*

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Shelly Atkinson  
Living Kidney Donor

*Michelle deCelle*

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Michelle deCelle  
Living Kidney Donor

*Arta Ward*

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Arta Ward  
Living Kidney Donor

*Kristie Lemmon*

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Kristie Lemmon  
Living Kidney Donor

*Ashley Try*

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Ashley Try  
Living Kidney Donor

*Dolores Golden*

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Dolores Golden  
Living Kidney Donor

Appendix B (continued)

*Susan Hill*

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Susan Hill  
Living Kidney Donor

*KC Ward*

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KC Ward  
Living Kidney Donor

*Jason Nothdurft*

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Jason Nothdurft  
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*Angie Sayer*

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Angie Sayer  
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*Larry Miller*

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*Nancy Couch*

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*Toni Krebbs*

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*Roopal Shah*

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*Kaila Luu-kwan*

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*Rebecca Hovland*

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*Joe Knotts*

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*David Margentino*

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*Barbara Cohen*

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*Stacy Prochnow*

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Stacy Prochnow  
Living Kidney Donor



Appendix B (continued)

*Teresa Kieffer*

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Teresa Kieffer  
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*Laura Robb*

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Laura Robb  
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*Kelly Fischer*

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Kelly Fischer  
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*Breann Fagan*

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*Mary Brooks*

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*Mark Smith*

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*Barry Benecke*

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*Alex Franges*

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*Kimberly Hill*

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*Teressa Eppright*

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*Brian Carter*

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*Annalisa Ciccotto*

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*Sheketa Daniels*

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*Bob Watkins*

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Living Kidney Donor

Appendix B (continued)

*Willie Green*

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Willie Green  
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*Larry Knight*

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*Kathy Kreiter*

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*Chuck Johnson*

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*Leta Raquel-Lee*

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*Donna Pehrson*

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*Melissa Carrera*

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*Tatiana Erosa*

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*Richard Chisholm*

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*Jeremy Balthis*

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*Rori Block*

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*Stephanie Ledesma*

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*Amy Ford*

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*Vanessa Freeman*

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*Brigitte Dysart*

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Living Kidney Donor

*Alicia Rodriguez*

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*Edan McPherson*

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*Alexander Berger*

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*Michelle Thomas*

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*Alfredo Fernandez*

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*Beth Lake*

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*Daniel Harding*

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*Ted Garding*

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*Kimberly Smith*

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*Susan Gianstefani*

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*Charles VanCleaf*

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*Shantel Magner*

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*Gloria Trevino*

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*Debbie Steinfort*

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*Erik Mason*

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*JoAnne Thorn*

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*Amy Sevier*

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*Kirk Stark*

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*Maureen Boncey*

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*Lauri Boardman*

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*Stephen Schumacher*

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*James Spraggins*

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*Roxanne Mills*

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*Jennifer Hope*

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*Suzanne Robinson*

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Appendix B (continued)

*Daniel Scheer*

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*Karen Webb*

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*Laurie Braverman*

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*Donna Waldron Gillispie*

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*Dan F. Morrissey*

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*Bernadette Morrissey*

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*Vickie Napier*

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*Brenda Hanson*

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*Isabel Dossantos*

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*Maryrose Bargmann*

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*David Smith*

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*Erika Fedorowski*

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*Susan Wedel*

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*Carrie McLain*

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*Scott Clouder*

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Scott Clouder  
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Appendix B (continued)

*Nicole Stromath*

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*Margaret Devinney*

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*Rebecca Nolan*

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*Sharon Wentz*

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*Angela Leone-Hess*

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*Judy Kent*

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*Ann Lundeen*

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*AJ Fawver*

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*Elizabeth McMahon*

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*Karel Zaleski*

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*Rachel Goemaere*

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*Kathy Panozzo*

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*Joe Rumney*

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*Stacey Gregory*

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*Ryan Davies*

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*Laleise Curtiss*

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*Jim Kintz*

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Jim Kintz  
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*Angelica Padilla*

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*Paula Kok*

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*Carol Setten*

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*Eunice Meadoux*

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*Mary Ehlert*

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*Heidi Coleman*

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*Sherri Barber*

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*Kari Robbins*

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*Kristi Noone*

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*Curtis Williams*

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*Richard Daniels*

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*Becky McKinney*

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*Jessica Brown*

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*Stephanie Grant*

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*Gerard Hilbig*

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*Ronald Tyer*

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*Erica Liepmann*

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*Shanna Baker*

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*John Duff*

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*Edan McPherson*

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*Kim McFarlane*

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*Kelly Gatlin*

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*Willie Green*

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Willie Green  
Living Kidney Donor

Appendix B (continued)

*Crissi Flippen*

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Crissi Flippen  
Living Kidney Donor

*Lani Young*

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Lani Young  
Living Kidney Donor

*Dallas Morales*

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Dallas Morales  
Living Kidney Donor

*Lisa Schonfeld*

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Jennifer Naraki  
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*John Duff*

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*Teresa Hudson*

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*Jennifer Hope*

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*Suzanne Robinson*

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Suzanne Robinson  
Living Kidney Donor

Appendix B (continued)

*Gary Ross Reynolds*

Gary Ross-Reynolds  
Living Kidney Donor

*K.M. Sanner*

Kathleen M. Sanner  
Living Kidney Donor

*Stan W. Wilkison*

Stan Wilkison  
Living Kidney Donor

*Michael Griffen*

Michael Griffen  
Living Kidney Donor

*Jeff Friedrich*

Jeff Friedrich  
Living Kidney Donor

*Paul Mikolaycik*

Paul Mikolaycik  
Living Kidney Donor

*Christine O'Brien*

Christine O'Brien  
Living Kidney Donor

*John Duberg*

John Duberg  
Living Kidney Donor

*RaNae Vodder*

RaNae Vodder  
Living Kidney Donor

*Rachel Bloomer*

Rachel Bloomer  
Living Kidney Donor

*Patrice J. Hudson*

Patrice Hudson  
Living Kidney Donor

*James Chittock*

James Chittock  
Living Kidney Donor

*Meredith Hagan*

Meredith Hagan  
Living Kidney Donor

*Jody A. Welsh*

Jody Welsh  
Living Kidney Donor

*Kathy Madison*

Kathy Madison  
Living Kidney Donor

*Jennifer Dorrance*

Jennifer Dorrance  
Living Kidney Donor

Appendix B (continued)

*Josh Morrison*

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Joshua Morrison  
Living Kidney Donor

*Thomas Kelly*

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Thomas Kelly  
Living Kidney Donor

## Appendix C

# The SOTN Proposal In Simplest Terms

- **Increase penalties for organ brokering at home and abroad.**
- **Follow original intent of NOTA and have Medicare help patients in greatest medical need first and according to UNOS current wait list criteria by:**
  - (a) **paying expenses of donors willing to give to top match in their region, and**
  - (b) **paying the Organ Procurement Organizations (OPOs), which currently match deceased donor organs with recipients, to arrange living matches as well.**
- **Allow 501(c)(3) public charities (and recipients themselves) to cover all donation related expenses – The same expenses that currently can be deducted from state income taxes at the state level. Charities can help any donor, not just those giving to front of the list.**
- **Create living donor registry that puts donor AND one relative to the front of the list at any time donor chooses.**

### **First Things First**

#### **Remove Barriers to Living Donation**

**Please sign our Petition at [www.StopOrganTraffickingNow.org](http://www.StopOrganTraffickingNow.org)**

(The SOTN Act would apply to all living donors, including bone marrow and liver donors, but for simplicity, we use living kidney donation as the example throughout this document.)

The Problem: There is a huge organ shortage. Over 100,000 of the 120,000 Americans waiting for transplants need kidneys. Americans resort to purchasing organs on the black market because not enough organs are available at home. Note: A third of all kidney transplants currently done in the United States are through living donation. Even if every American agreed to be a deceased donor there would not be nearly enough cadaver organs to fill the need. There are millions of potential living donors in the United States.

The Solution: Make more living donor organs available at home and increase the penalties for illegal transplant tourism. Removing barriers does not mean creating incentives; it means making donation financially possible for those who otherwise can't donate. Removing barriers to donation alone could reduce the U.S. organ waiting list by as much as 30% in five years.

#### The SOTN Proposal:

- 1) Increase the criminal penalties associated with the brokering of / or sale of organs for transplant. This will help stem the tide of Americans seeking organs illegally abroad. This will work best if at the same time it becomes easier for Americans to find living organ donors at home.
- 2) Remove the financial disincentives that hinder living donation by establishing a federal benefit to help donors cover the non-medical expenses inherent in any living organ donation. The federal benefit established by this legislation should only apply to Americans willing to donate to people

## Appendix C (continued)

at the top of the waiting list in their own transplant region. If patients make it to the top of the transplant waiting-list, it is pretty clear they have exhausted all other options for getting an organ. No one wants to wait longer than absolutely necessary because the longer patients are on the list, the more the chance that they will develop health problems that disqualify them from getting a transplant. Also, Medicare saves the most money by removing those at the top of the waiting list because those are the patients who are at the highest risk of developing debilitating illnesses that cost Medicare more than providing a transplant.

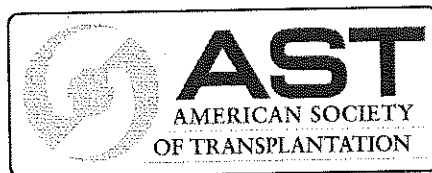
This could be done with a federally issued debit card. A debit card is currently the procedure used by the National Living Donor Assistance Center to pay donors expenses. The problem with NLDAC is that it helps the poorest of the poor – those who can show both they and their recipients earn no more than 300% above the poverty line. The National Organ Transplant Act (NOTA) was passed to create a system to help those in greatest medical need regardless of income. The SOTN proposal goes back to the original intent of NOTA. Also note that according to the U.S. Census Bureau, only the top 8% of US earners have enough in discretionary funds in a month to pay the average of \$5,000 in out-of-pocket expenses donors pay to donate. Twenty percent of Americans have no savings at all. This means 92% of Americans have to either spend their savings or go into debt to donate. NLDAC only helps the poorest of these Americans and it does so at a financial cost. The SOTN proposal is set up to help more Americans and at a savings to Medicare.

Consider as an example: Medicare now pays Organ Procurement Organizations (OPOs) approximately \$50,000 to retrieve and deliver a kidney. It currently pays OPOs \$0 to include living organ donors in its matching system. If Medicare paid OPOs \$20,000 to test and list information for living organ donors, Medicare could pay living organ donors' out-of-pocket nonmedical expenses up to \$10,000. Then, Medicare would save \$20,000 for every organ transplant done with a living donor rather than a cadaveric organ. Adjustments would have to be made in the calculation to account for hospital costs for living organ donor, but transplants done with cadaveric organs tend to be more expensive anyway because it is harder to get the organ started, they have a higher failure rate than living donor organs, and they last a shorter time than organs from living donors. This is just a hypothetical example. The \$50,000 comes from the 2013 book *The Global Organ Shortage* by economists Beard, Kaserman, and Osterkamp.

- 3) Allow charitable organizations to provide non-medical assistance to donors without fear of violating the National Organ Transplant Act (NOTA). The federal benefit would only go to donors willing to give to someone at the top of the waiting list, but charities could help any donor, for example, a linchpin donor for a chain (domino or paired) donation or someone who wants to donate to a family member or friend before that person even goes on dialysis.
- 4) Create a living donor registry that allows living donors to move themselves, and/or one relative, to the front of the transplant waiting list in their region should they at some later date need an organ themselves or for a relative. This provision removes a non-financial disincentive for donation. Some people say they can't donate to a friend or more distant relative because they fear a closer relative may need an organ some day. This eliminates the need to "save" ones organ in case someone very close needs one in the future.

**Please note that Stop Organ Trafficking Now!'s proposal removes the DISincentives that exist in the current U.S. living organ donation system. It does not create financial incentives to tempt people to donate. It is our contention that the financial burdens of donation and the fear that a donated kidney might be needed later hinder many Americans from becoming living donors. Our proposed legislation will remove those disincentives and thus increase the number of kidneys available for Americans who need them. And, as a welcomed additional consequence reduce the number of Americans resorting to illegal organ purchases on the black market.**

## Appendix D



### **“Improving Human Life by Advancing the Field of Transplantation”**

#### **Living Donor Consensus Conference**

On behalf of the American Society of Transplantation and the AST Live Donor Community of Practice (LDCOP), we commend ACOT for prioritizing discussion of living organ donor care. We write to affirm support of ACOT recommendation 49 to establish methods to track living donor outcomes and facilitate past living donors’ access to care. In addition, we wish to offer background on a recent consensus conference that may shed further light on opportunities to improve education, access, and care for those considering living donation.

The AST LDCOP is a group of clinicians with expertise in living donation formed in 2012. Its mission is to advocate, support and advance knowledge to improve the education and care of the live organ donor. The LDCOP initiated a consensus conference, held June 5-6, 2014, to identify best practices and knowledge gaps pertaining to live donor kidney transplantation and living kidney donation. The meeting aimed to identify:

- Approaches to improve access to donation and live donor kidney transplantation
- Optimal strategies for educating potential living donors about the currently known long-term and short-term risks and benefits of live kidney donation
- Efficiency improvements for living donor evaluation processes
- Ways to reduce and remove financial and systemic barriers to live donation

The consensus conference participants made recommendations for education of clinicians, donors and recipients, improvements in clinical practice, standards for transplant programs, public policy recommendations, and research priorities. These recommendations have been published in the American Journal of Transplantation and an executive summary is enclosed. We also have been working on an extensive dissemination plan to educate key stakeholders about the recommendations and implement change.

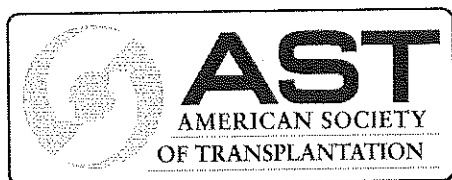
Moving forward, we are eager to continue dialogue with all ESRD stakeholders—including past living donors and those with ESRD—on these important issues. Again, thank you to the leadership and members of ACOT for this opportunity to provide public comment on the importance of living donation.

**Presented By:** Rebecca Hays, MSW

*On behalf of the AST Board of Directors and AST Live Donor Community of Practice*



## Appendix E



### **"Improving Human Life by Advancing the Field of Transplantation"**

#### **AST – ACOT open letter**

The American Society of Transplantation is an organization of transplant professionals; physicians, surgeons, scientists, pharmacists, social workers, and others whose mission is to improve the lives of people with organ failure.

It is accepted that living donor kidney transplantation saves lives, often providing the very best possible outcome for the recipient. As advancements in the surgical technique have reduced the operative and perioperative risks to an absolute minimum, more family members, friends and acquaintances have come forward to help their loved ones. The AST believes that the cornerstone of safe living donor kidney transplantation is the education of donor and recipient about the risks and benefits of living donor kidney transplantation. Additionally, the AST is concerned there is inadequate education about living donor kidney transplantation and this lack of education creates a barrier in access to living donor kidney transplantation for individuals in disadvantaged socio-economic classes and more remote parts of the country. Finally, the AST believes it is the responsibility of the transplant community and the governmental agencies overseeing transplantation to work to eliminate barriers in access to living donor transplantation for all members of society regardless of income, education or place of residence.

The growing disparity between the number of patients in need of transplantation and availability of transplantable organs has increased interest in living kidney donation. This increased interest has resulted in individuals coming forward to be evaluated for kidney donation who do not fit the classical definition of a kidney donor. The term used to describe this type of donor is "the medically complex donor". Such individuals may have pre-hypertension or overt hypertension, early glucose intolerance or mild obesity. While a paternalistic approach to evaluating these donors would be to decline them out of hand, it is becoming recognized that their opinions should be accounted for in the donor evaluation process. After all these individuals love and care for their potential recipient with the same intensity as a "medically perfect donor" and have a right to assume risk to help someone they care about. However it is here that the AST is concerned. There exists an incomplete understanding of live donor outcomes and by allowing the medically complex donor to donate without the necessary information to evaluate the risk, we may be in breach of our fiduciary responsibility to them. Despite the long history of living organ donation, the information regarding medical and psychosocial consequences is lacking. Moreover, the information that does exist, while helpful, reflects only short-term outcomes which are not relevant for a donor who will live out a lifetime and wishes to understand the long-term implications and risks associated with their decision to donate. The AST recognizes that clinical experience informs us that living donation is fundamentally safe in both the short and long term and therefore does not believe that the current deficiency in understanding the long term outcomes of kidney donation should limit the existing practice. However the AST strongly believes that the best way to honor these

## Appendix E (continued)

remarkable individuals as well as continue to improve transplantation is to begin to study the question of long-term donor outcomes now.

The AST wishes to emphasize the following concerns and provide recommendations to address them.

- **There is an incomplete understanding of live kidney donor outcomes.** Despite the long history of living kidney donation, there is incomplete information regarding medical and psychosocial consequences. This limits the ability to counsel potential donors. Short-term follow-up is mandated by the OPTN at the center level, though many centers struggle with providing accurate data on all donors. Longer-term data is even more difficult to generate. At the current time, there is no widely available mechanism to fund donor follow up and data analysis.

AST endorses:

1. Developing approaches to obtain meaningful, long-term outcomes data that can be used to properly inform and educate potential living kidney donors about the risks of donation.
  2. That the above referenced outcome data be collected in a manner so that it can be used to educate a donor about their unique risk based upon their individual health characteristics.
  3. Targeted efforts by the OPTN and other interested parties to define parameters most likely to inform the living donor process, then collecting and analyzing data in a cost effective manner that does not pose undue burden on transplant centers or donors.
- **There are educational deficiencies about that availability and benefits of living kidney donation.** While there is a growing awareness of the benefits of living donation, there are regions of the country where the rate of living donation lags. While there may be justified reasons for this, the AST is concerned that there is also a lack of educational materials available to patients to assist them in the process of seeking referral for transplantation and understanding the option of living donor transplantation.

AST endorses:

1. Partnering with the Health Resources and Service Administration and other interested parties to develop and disseminate educational materials about the option of, the means to obtain, the associated risks and potential benefits of living kidney donation.
  2. Fully transparent education of the potential living donor regarding known risks and benefits of donor testing, surgery, and long-term outcomes.
- **There is no guarantee living kidney donors will have health insurance when it is needed.** Insurance coverage for the living kidney donor can become problematic in both the short- and long-term. The cost of the surgical procedure and the care following the surgery are generally covered by the recipient's insurance, but only for a defined, and relatively brief, period of time. More importantly, because data about health outcomes that reflects a time frame relevant to the healthy kidney donor is lacking, ensuring the availability of health insurance when the kidney donor is likely to need it provide an important safety net. The

## Appendix E (continued)

AST believe ensuring the well-being of the living kidney donor is both a moral imperative and an acknowledgment of what the donor has done for the recipient and society as a whole.

The AST endorses:

1. Advocacy for access of living donors to health insurance.
2. Exploration of provision of insurance coverage for donors (such as Medicare eligibility) to assure protection from financial expenses that might arise as a consequence of donation.

The **American Society of Transplantation** believes that by addressing the issues outlined above, both the process and outcome of living organ donation in the United States can be improved. Furthermore, the AST believes that living kidney donation can be advanced in an ethical fashion with the necessary protection for potential living donors via the following additional measures:

- Educational programs to increase public awareness of the benefits of organ donation.
- Professional education programs addressing living donor issues and utilization.
- Promotion of kidney paired donation.
- Public recognition of organ donors and their families through Honors/Donor medals.

**Presented By:** Richard Formica, MD  
*On behalf of the AST Board of Directors*

## Appendix F



American Society of Transplant Surgeons

March 13, 2015

Mark Barr, MD  
Chair, Advisory Committee on Organ Transplantation  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Barr:

On behalf of the Executive Committee of the American Society of Transplant Surgeons (ASTS), I want to commend the Advisory Committee on Organ Transplantation (ACOT) for its work to enhance organ donation, ensure the system is grounded in the best available medical science, assure the public that the system is as effective and equitable as possible, and increase public confidence in the integrity and effectiveness of the transplantation system. ASTS and its members share these goals and are dedicated to saving and improving lives through transplantation.

Over the last 13 years, ACOT has made 56 recommendations to the HHS Secretary, many of which have influenced significant and positive changes within the transplant community. Yet despite these constructive recommendations and the efforts of many, the number of people waiting for an organ transplant continues to grow, the number of donated organs has remained relatively stable, and the rate of living donor kidney transplantation has fallen. As ACOT considers how to invest its time and energy over the coming year, we encourage you to prioritize the issues of living donor best practices, organ donation research, and transplant system performance metrics. ASTS believes that your work in these key areas supports the over-arching goals of ACOT and demonstrates leadership on key issues that best serve donors, transplant candidates, transplant recipients, and society as a whole.

### Living Donor Best Practices

Over the last 10 years, ACOT recommendations 42, 44, 45, and 49 (Appendix A) have all addressed issues related to living organ donors. Furthermore, the 2006 IOM report, *Organ Donation: Opportunities for Action*, made specific recommendations regarding living donation, including the creation of registries to study the short and long-term medical and other outcomes of living donation. We know that living donors not only have a potential medical risk, but many also face financial risks. ASTS has long been an advocate for living donors, as evidenced by our role in the creation and operation of the National Living Donor Assistance Center.

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## Appendix F (continued)

Additionally, ASTS has participated in six consensus conferences on living donor issues since 2000. Of note, in September 2010 the Living Kidney Donor Follow-up: State-of-the-Art and Future Directions conference was convened to review the limitations of existing data on outcomes; assess and define the need for long-term follow-up; identify potential system requirements, infrastructure, and costs of long-term follow-up; and explore options for development and funding of data collection in the United States. The conference concluded that enhancing knowledge of donor outcomes will require access to health care facilities and financial resources to pay for medical and laboratory assessments. Whereas the United States is unique in that there are donors who still lack health coverage, this presents significant hurdles to long-term outcomes studies. ASTS strongly supports meaningful follow-up and outcomes studies and would welcome the opportunity to partner with ACOT, HRSA, CMS, OPTN, and the broader transplant community to develop a formal approach to long-term outcomes studies.

### **Organ Donation Research**

Logistical and regulatory barriers inhibit the clinical science of sustaining, preserving, and rehabilitating and/or optimizing organs for donation in deceased donors through donor intervention research. The issues are multifaceted, and despite two national conferences, pathways toward a solution remain undefined. ASTS has engaged in discussions with the Institute of Medicine (IOM) regarding these complexities. As an independent organization, the IOM has a demonstrated record of providing unbiased and authoritative advice to decision makers and the public. We are pleased to report that the Arnold Foundation has committed funds toward a stakeholder meeting to finalize the scope and statement of task for an IOM study. Our goal is to facilitate a pathway to examine the gaps, barriers, and opportunities for clinical research in deceased donors that aims to increase the quality and quantity of donated organs. We urge ACOT to prioritize the efforts of the workgroup to complement these efforts and provide much needed input into the array of ethical, policy, regulatory, and logistical issues that currently obstruct innovate research designed to increase the quality and quantity of organs from deceased donors.

### **Transplant System Performance Metrics**

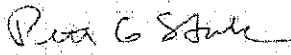
ACOT recommendations 52 and 55 (Appendix A) addressed the regulatory inconsistencies between OPTN and CMS policies. ASTS was encouraged by the initial steps taken after recommendation 55, but our initial enthusiasm has waned due to lack of apparent progress since then. ASTS strongly supports performance evaluation and consequences for programs that under-perform but believes that OPTN and CMS should unify and harmonize program evaluation processes to the extent possible. In past communications to HRSA, CMS, and others, ASTS has outlined numerous approaches that could alleviate the inconsistencies and avoid duplicate functions. HRSA and CMS have established policy regarding participation in the OPTN or participation within CMS payment programs. There are numerous examples of minor and major inconsistencies in these policies, and ASTS has repeatedly asked for harmonization of apparently conflicting policies. Furthermore, the performance metrics for OPOs and transplant centers should be re-aligned to support the collective goal of transplanting more organs, and survey processes could be better coordinated, with an appropriate division of responsibility. It is our perception that increasingly strict performance metrics have resulted in risk-averse behavior and avoidance of using lesser quality, but suitable, organs. We would encourage SRTR re-evaluation of the risk stratification flagging mechanisms to diminish the underutilization of existing organs. We urge ACOT to continue to

## Appendix F (continued)

push to resolve the misalignments, which in their current form waste scarce governmental and institutional resources.

In conclusion, ASTS recognizes that the issues facing the field of transplantation are numerous and diverse. ACOT plays an important role in prioritizing issues for the Secretary and effecting positive change. As you look forward, ASTS urges ACOT to prioritize the issues of living donor best practices, organ donation research, and transplant system performance metrics and would be pleased to work with you on all of these initiatives.

Sincerely yours,



Peter G. Stock, MD, PhD  
President

Presented by: Kimberly A. Gifford, MBA, ASTS Executive Director  
On behalf of the Executive Committee of the American Society of Transplant Surgeons

## Appendix F (continued)

### Appendix A: Previous ACOT Recommendations

**Recommendation 42:** ACOT recommends to the Secretary that the OPTN be asked to expeditiously consider all issues associated with the development of a registry for matching living donors and recipients, paying particular attention to informed consent and the monitoring of long-term outcomes of the donors.

**Recommendation 44:** ACOT recommends to the Secretary that he promote collaboration between the transplant community and the insurance industry to adopt standards of coverage for living organ donors specifically relating to future adverse events (e.g., hernia repair, biliary tract reconstruction) resulting from the donation.

**Recommendation 45:** ACOT recommends to the Secretary that he take action intended to provide Medicare eligibility for any living donor who loses insurability as a result of disability on the basis of previous organ donation.

**Recommendation 49:** ACOT recommends that the Secretary take actions to ensure that data on the general health status of living donors are collected on a nationwide basis by a centralized entity. The ACOT recommends that such data be collected, at a minimum, on an annual basis for a period of 10 years post-donation. The ACOT further recommends that the transplant program that performed a donor's transplant be principally responsible for the data submissions or ensure that another institution providing ongoing medical care to, or follow up on, the donor collect and submit such data.

**Recommendation 52:** The ACOT recommends that the Secretary encourage HRSA and CMS to resolve the regulatory inconsistencies between CMS and OPTN policies.

**Recommendation 55:** The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and TC representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs. The ACOT recommends that this review be completed within one year and that action be taken within two years.

## Appendix G

### Comments of Christine Wright

The following is from OPTN's Board of Directors, June 2003\*:

*"The Board directed UNOS to develop the methodology for providing living donors with the information sent to the central registry on their behalf.*

*The Board directed UNOS to develop a standardized educational tool to be provided to all potential living donors and recipients."*

*"The Board recommended several measures involving the long term follow up of living donors including the transplant center's responsibility for follow-up data submission for the first year after living donation, and the central registry/UNOS will collect follow-up data, either from the center or the donor, from years two through nine; the long-term follow-up of living donors undertaken by a central registry used to conduct research projects using sampled data; a unified registry approach; funding for the long-term follow-up registry; and informing donors prior to the surgery that data will be collected after donation."*

Nearly 12 years has passed.

- Living donors still cannot access information submitted to OPTN on their behalf.
- There is no "standardized educational tool" for potential living donors (a checklist is not a "tool").
- 60 years after the first living kidney donor transplant, we do not even have one year of comprehensive data.
- No data exists at all after two years post-donation.
- No funding for a living donor registry (Despite ODRIA granting authority for the creation of one in 2004).

Living kidney donors are unable to access the Medicare coverage given to them in the 1972 End-Stage Renal Disease Benefit, but Revere-Fry and her ilk would like the federal government to assume the travel, lost wages and childcare costs for potential living donors. Such consideration is given to no other patient population, including veterans of our armed forces. Such a request is highly inappropriate, and creates a dangerously slippery slope.

Meanwhile, three young men who refer to their organization as WaitlistZero have presented ACOT with a petition encouraging the federal government to promote living donation. Yet the statistics used in their missive are erroneous and misleading. This does not reflect positively on the informed consent process of every living donor who signed.



## Appendix G (continued)

Living donors are patients, and we deserve the same protections and respect given to those struggling with end-stage renal disease. The overwhelming push by the transplant centers, transplant-related organizations, and OPTN, to increase living donor transplants does nothing to keep living donors safe.

12 years ago, the Board of Directors set a direction; why has so little been accomplished since then?

\*See Page 7:

[http://optn.transplant.hrsa.gov/SharedContentDocuments/Executive\\_Summary\\_June\\_2003.pdf](http://optn.transplant.hrsa.gov/SharedContentDocuments/Executive_Summary_June_2003.pdf)

## OPEN

# An Open Letter to HHS Secretary Burwell on Ethically Increasing Organ Donation

Hon. Sylvia Mathews Burwell  
Secretary of Health and Human Services  
Washington, DC

Dear Madame Secretary:

In 1984, Congress passed the National Organ Transplant Act (NOTA). That statute not only established the Organ Procurement and Transplantation Network but also enshrined in law a principle that had guided the development of organ transplantation worldwide over the previous 30 years: organs from living and deceased donors are precious gifts, and should not be bought and sold as market commodities.

## Remove the Obstacles to Donation

The growing demand for transplants currently exceeds the supply of donated organs. In the previous decade, a collaborative effort among the Department of Health and Human Services, organ procurement organizations, physicians, and community groups produced a 25% increase in the number of deceased donor organs. Yet, over the course of the past ten years in the United States, the number of kidney transplants (which account for more than two thirds of all transplants) made possible by living donors has declined by approximately by a thousand.

One major reason for this decline is that living donors in the United States incur on average more than U.S. \$6000 in out-of-pocket costs. Potential donors may not be able to afford these expenses and may either be unaware of, or not meet the strict requirements for, programs that cover some but not all of donors' financial costs and losses.

If the United States wants to increase organ donation, we should begin by removing these financial disincentives. We are aware that some people have recently called on the President and Congress to repeal, or at least suspend, NOTA's prohibition on paying organ donors. However, when it looked at "Ways to Reduce the Kidney Shortage" (September 2, 2014), the *New York Times* rightly concluded that "there are lots of reforms that could be made without resorting to paying for kidneys."

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## Appoint a New Task Force on Organ Donation and Transplantation

Thirty years ago, NOTA instructed your predecessor to establish a Task Force on Transplantation to address the then current issues and to recommend rules for the ethical procurement and distribution of organs. That body was charged to prepare "an assessment of public and private efforts to procure human organs for transplantation and an identification of factors that diminish the number of organs available for transplantation." That task now needs to be revisited for organ donation and transplantation.

We know that these disincentives include a range of financial burdens, such as the costs of travel and lodging for medical evaluation and surgery, lost wages, and the expense of hiring a replacement to provide services to one's own dependents during the period of organ removal and recuperation. Concerns over safety also arise and can be addressed by life-long follow-up for all living donors, with guaranteed provision of any donation-related medical care not fully covered by donors' own health insurance. Likewise, donors' families should be protected by the provision of insurance to cover disability or death that results from having been a donor. Discrimination against donors seeking to purchase their own insurance has been reported and must be outlawed.

HHS could charge your Task Force to develop pilot programs to test out means of removing the financial and other obstacles to organ donation. The objective should be to ensure that being an organ donor is a financially neutral act—one that neither enriches living donors or the families of deceased donors nor burdens them with costs they would not otherwise face. The task force can also address inefficiencies in current living donor programs and promulgate best practices.

Covering these costs will actually save Medicare and private insurers' money because kidney transplantation is not only better for patients than long-term dialysis but costs much less. Increasing the number of kidneys donated each year means more transplants and less spending on end-stage renal disease. Another way to lower spending and reduce the number of patients needing transplants would be to correct an anomaly of current regulations under which the antirejection drugs that recipients need to keep their transplanted kidney working are only covered for 3 years. When that funding ends, those who are unable to afford the immunosuppressive medications may lose their transplant and end up back on dialysis, hoping for another transplant.

### Financial Incentives for Donation Would Violate Global Standards and Will Not Work

These are all matters that need urgent attention from a new Task Force. And they are all steps that would enjoy widespread support and would not contravene the law's prohibition on giving "valuable consideration" in exchange for an organ. In contrast, those who propose to begin pilot studies to provide financial benefits to incentivize organ donation are asking that you directly contravene principles against financially rewarding donors that were adopted, with strong American support, by the World Health Organization in 1991 and renewed in 2010.<sup>1</sup>

The World Health Organization drew on decades of global experience which shows that paying for organs inevitably exploits the poor. Configuring financial benefits for donors, such as funds for college education or retirement, would not change the laws of economics, which apply in the United States just as in any other country. The people who are activated by such benefits would simply be engaging in a financial transaction, trading the commodity they have (a kidney) for a commodity they need (such as education, retirement funds, or perhaps something more immediate, such as a mortgage payment).

Given this experience, United Nations bodies and the Council of Europe (by legally binding instruments aimed at stopping organ trafficking) and medical professionals (such as in the Declaration of Istanbul) have consistently opposed financial incentives for organ donation, while encouraging the removal of disincentives.<sup>2,3</sup> Global experience has also shown that paid donation replaces unpaid organ donation rather than supplementing it.

We urge HHS to convene a Task Force on organ donation and transplantation that will develop new ways to increase voluntary, unpaid organ donation, through means such as removing the financial burdens that deter donors rather than by adopting measures that will inevitably lead to human organs being treated as commodities, both in the United States and around the world.

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