

LIVING KIDNEY DONATION STAKEHOLDER MEETING

September 3rd, 2015

1:00-4:00 PM

Stakeholders Attending:

1. American Society of Transplantation
2. American Society of Transplant Surgeons
3. Coalition to Promote Living Kidney Donation
4. Donate Life America
5. National Kidney Foundation

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Minutes

This stakeholder meeting was convened to discuss what goals living donor transplant policy should pursue and how best to pursue them.

Prior to the meeting, all stakeholders had come to the consensus that: (1) HRSA ought to allow for grants to support educating the public, patients, and their families about living donor transplantation; and (2) that this collaboration between our stakeholder groups and HRSA on living donation issues should be ongoing. The main topics discussed at the meeting were:

- **Education and Awareness:** All attendees agreed on the need to prioritize improving education and awareness about living donation for the public, patients and their families. Home visits, donor champion programs, peer mentoring, and broad public awareness campaigns were discussed as attractive programs. HRSA cannot disclose what projects will be eligible for future grant programs but expressed enthusiasm about living donor education efforts.
- **Donor Follow-Up:** There was consensus in the group that follow-up care and study of living donors needed to be improved. HRSA has included in the new SRTR contract a feasibility study for a living donor registry. The challenge of persuading donors to return to transplant centers was emphasized. Two complementary solutions were suggested: first to make HIPAA authorizations for long-term follow-up information from PCPs to transplant centers part of the donor intake process; second, to provide research stipends to donors each year they participate in follow-up study and care. The American Society of Transplantation, WaitList Zero, and American Association of Kidney Patients (AAKP) expressed support for the stipend approach, with AAKP making the

point that it was especially important to ensure that any such stipends did not operate as an incentive and were consistent with federal practice and guidelines.

- **Increasing Living Donation:** Some stakeholders (the National Kidney Foundation, Donate Life America, and the Coalition to Promote Living Donation) maintained that increasing living donation should be a priority for national transplant policy (with the NKF focused on achieving these gains through education). The American Society of Transplantation indicated that it did not feel comfortable advocating for this position because of the conflict of interest of promoting a surgery that would benefit its members. One HRSA staffer indicated that HRSA's role was to support the transplant community's decision-making and to facilitate donation and transplantation.
- **Further Collaboration:** All attendees agreed that a public clearinghouse listing living donation projects would be a valuable next step from the meeting. A Living Donation Breakthrough Collaborative was discussed that would collect data and disseminate and standardize best practices. The need for measurable goals was emphasized. The American Society of Transplant Surgeons indicated they were putting together a task force to increase access to organ donation led by Dr. Dorry Segev. The idea of future in-person stakeholder meetings on this topic was deemed attractive, and a Living Donation Working Group was proposed.

**Appendix A
Meeting Agenda**

Time	Discussion Item
1:00 PM	Introductions and Opening Remarks
1:45 PM	Living Donation Landscape and Policy Challenges
1:45 PM	<p style="text-align: center;">Donor Safety, Psychosocial Health, and Follow-Up</p> <p><i>Summary of recent safety and psychosocial health data about donation. What donor and recipient qualification standards exist in the field? What questions remain? What follow-up study would be useful?</i></p>
2:10 PM	<p style="text-align: center;">Transplant Education of Patients, Donors, and the Public</p> <p><i>What knowledge gaps exist for the public, patients, and their families? What education methodologies have been tried recently and with what results?</i></p>
2:35 -2:50 PM	BREAK
2:50 PM	Living Donation Policy Approaches
2:50PM	<p style="text-align: right;">HRSA Policy</p> <ul style="list-style-type: none"> – <i>What goals should living donation transplant policy have and how can those goals be achieved?</i> – <i>What data could be collected to inform living donation policy?</i> – <i>Should living donation projects be eligible for HRSA grant funding?</i> – <i>How many years of patient follow-up should be required?</i>
3:30 PM	<p style="text-align: right;">Expanding Patient Education</p> <ul style="list-style-type: none"> – <i>What do Stakeholder groups propose as an actionable step to improve patient education?</i>
3:50 PM	<p>Next Steps and Concluding Remarks</p> <ul style="list-style-type: none"> – <i>Plan for ongoing collaboration on living donation issues</i>
4:00 PM	Adjourn

Appendix B List of Attendees

HRSA Attendees

Jim Bowman, Medical Director, Division of Transplantation
Cheryl Dammons, Associate Administrator, Healthcare Systems Bureau
Mary Ganikos, Chief, Division of Transplantation Education Branch
Mesmin Germain, Project Officer for the National Living Donor Assistance Center
John Mallos, Senior Advisor, Healthcare Systems Bureau
Chris McLaughlin, Chief, Division of Transplantation Organ Transplant Branch
Robert Walsh, Director, Division of Transplantation

Stakeholder Attendees

Bill Applegate currently serves as the Senior Vice President of Government Relations Health Care Association Practice at Bryan Cave LLP and the AST's Director of Government Relations. Mr. Applegate has represented the AST since 1998. As the Society's federal lobbyist, Mr. Applegate connects AST leadership with key congressional, regulatory, and executive branch decision-makers to support issues relevant to transplantation.

James Allan is a thoracic surgeon and current president of the AST. Dr. Allan is on the active clinical staff in Thoracic Surgery at Massachusetts General Hospital. He is the current Co-Director of the Cardiothoracic Transplantation Lab at Massachusetts General Hospital's Transplantation Biology Research Center, and is a NIH-funded investigator in the area of lung transplantation. His current efforts focus on developing strategies to promote the long-term acceptance of transplanted organs without the need for immunosuppression

James Alcorn is the Director of Policy at the United Network for Organ Sharing (UNOS). There he manage a team of policy analysts that staff the 19 Committees (including the Living Donor Committee) and around 350 Committee members. These staff and Committees are the rule making arm of the OPTN.

Paul Conway is the President of the American Association of Kidney Patients. Prior to being elected AAKP President, Mr. Conway served as the Vice President and Chair of the Public Policy Committee for AAKP. He serves on the Polycystic Kidney Disease Foundation (PKDF) national board and is a member of the Kidney Health Initiative (KHI). He is a kidney transplant recipient who has managed his kidney disease for 34 years. Mr. Conway has an expansive career in public service, including service under three governors and four U.S. presidents. His federal posts have included Chief of Staff of the U.S. Department of Labor and as an agency Chief of Staff at the U.S. Department of Homeland Security.

Matthew Cooper is a Professor of Surgery and the Director of Kidney and Pancreas Transplantation at the Medstar Georgetown Transplant Institute. He is a member of the NKF National Board of Directors. He has served as the chairman of the United Network of Organ Sharing's (UNOS) Living Donor Committee and on UNOS' Board of Directors, as well as the Board of the American Foundation for Donation and Transplantation.

David Fleming is the President and CEO of Donate Life America.

Tom Foster is a member of the Board of Directors for the Alliance for Paired Donation. He is also President of Fosven Management in Perrysburg OH. Tom and his wife Laurie have run businesses in the outdoor sporting goods field for the last 30 years. In 2012, Tom received a living kidney transplant from a brother at the University of Toledo Medical Center.

Laurie Foster is a member of Alliance for Paired Donation's Board of Directors and became interested in the APD through the first-hand experience of living with a spouse with ESRD. She has worked with her husband Tom for 30 years, operating businesses in the outdoor sporting goods field.

Rodger Goodacre is a member of the Transplant Recipients International Organization Board of Directors and co-Chair of its Public Policy Committee. Prior to retirement, he spent 40 years with the federal government largely in the health care area in the administration and management of the Medicare and Medicaid programs. He received a liver transplant in 1998.

Richard Knight is a transplant recipient and previous hemodialysis patient from Lanham, MD. He is the VP of Corporate Relations for Aercrete Advantage, LLC in Waldorf, MD and a member of the Mid Atlantic Renal Coalition, Baltimore Washington Corridor Chamber, American Kidney Fund – Mid Atlantic Advisory Council and Bowie State University – School of Business Board of Advisors.

Kim Gifford, MBA, is the Executive Director/CEO of the American Society of Transplant Surgeons (ASTS) and its affiliated Foundation. Ms. Gifford is also the project manager for the National Living Donor Assistance Center (NLDAC).

Thomas Kelly is Board President and Co-Founder of WaitList Zero. He is completing his PhD in Political Science at UC-Berkeley with a research focus on lobbying. He became a kidney donor in 2014.

Mark Lukaszewski serves as Policy Associate for the American Society for Nephrology.

Jennifer Martin is the Vice President for Constituent Services at the National Kidney Foundation (NKF), overseeing NKF's programs and services for kidney patients, organ donors and those at risk for kidney disease.

Libby McDannell serves as the Executive Vice President of the AST. Ms. McDannell is responsible for overseeing all of the AST's activities including budgeting, financial management, membership recruitment and retention, conferences and exhibits, corporate sponsorship and new program development. Prior to her promotion to Executive Vice President, she served as the Society's Executive Director.

Josh Morrison is Secretary of the Coalition to Promote Living Kidney Donation and Executive Director of WaitList Zero, which he founded after working as General Counsel

at the Alliance for Paired Donation. He is an attorney graduating with honors from Harvard Law School, where he was an editor of the Harvard Law Review. He became a kidney donor in 2011.

Ken Newell is a kidney and pancreas transplant surgeon and immediate past president of the AST. Dr. Newell established the unrelated paired donor kidney exchange program at Emory University hospital in 2007 and served as director of the living donor kidney transplant program until stepping down in 2014 so he could spend more time tending to his national responsibilities with the AST.

Peggy Tighe is Counsel in the public policy and government relations group of Power, Pyles, Sutter & Verville PC and advises the American Society of Transplant Surgeons on public policy strategies. Prior to joining the Powers firm, Ms. Tighe served as lead lobbyist for the American Medical Association and, most recently, served health system, provider, and patient clients at Strategic Health Care, a health care consulting firm. She is a former President of Women in Government Relations, a non-partisan government relations association in the Washington metropolitan area.

Troy Zimmerman is Vice President for Government Relations at NKF and has been with the Foundation for 18 years. He is NKF's primary contact to Congress on chronic kidney disease, dialysis and organ transplantation issues and he assists with the Foundation's federal agency efforts.

Appendix C

Coalition to Promote Living Kidney Donation Statement of Principles

We come together to support policies to increase the annual rate of living kidney donation by five thousand transplants within five years.

Our Principles. Our Coalition believes:

1. Deceased donation alone can never end the deadly kidney shortage, and any policy that takes that shortage as given is morally unacceptable.
2. Living donation is a noble choice that is not right for everyone, but donors themselves can benefit from the better health of their loved ones and the psychic gains to donation. Since studies show the vast majority of living donors do not regret donating, federal policy should presume donation to be a positive choice worth promoting.
3. Informed consent must be maintained for every kidney transplant. Any effort to coerce or pressure someone into donating is unacceptable.
4. Improvements are always possible, but the current transplant system does an excellent job of ensuring informed consent for the thousands of living donors who give each year.
5. Government programs to increase living donation should not and will not impinge on the ability of transplant centers to ensure informed consent and guarantee the absence of coercion.

Our Policies. Our Coalition will achieve the following:

- Donors should never be worse off for having donated. Government should: (1) guarantee the reimbursement of donor lost wages, (2) provide health insurance coverage to alleviate risks of donation, and (3) devote appropriate resources to ensure long-term donor follow-up.
- Transplant awareness and education should be increased for the public, patients, and their families. All patients and patient families should receive specialized and comprehensive transplant education before they go on dialysis (when possible) and immediately thereafter (when necessary). Access to paired kidney donation should be universal.

Our HRSA Campaign: We ask that the Health Resources and Services Administration:

1. Publicly support the goal of increasing living kidney donation;
2. Allow grant funding, including that pursuant to 42 U.S. Code §274f-1(b), to go to projects intended to increase living kidney donation;
3. Allocate such funds in rough parity between living and deceased donation projects;
4. Include metrics and goals related to the increase of living donation on HRSA's FY 2016 Annual Performance Report; and
5. Sponsor a Living Donation Breakthrough Collaborative to disseminate transplant center best practices and ensure that living donation goals are met.

Members of the Coalition may have different views as to the advisability of financial incentives for living donation, but the Coalition believes there are many ways the federal government can increase living donation that do not raise the controversy of incentives, and our campaign is not intended to promote the adoption of incentives.