



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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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 innovative 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

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,

A handwritten signature in cursive script that reads "Peter G. Stock".

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 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.