Overview of the Advisory Committee on Organ Transplantation

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Mark L. Barr, M.D.
Chair, Advisory Committee on Organ Transplantation

Authority and Charter for the Committee

- Established under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000)
- Initially chartered September 1, 2000
- Renewed every 2 years -- most recently in August 2014
- Up to 3 meetings each fiscal year (typically 2)
- Advises the Secretary, acting through HRSA Administrator, on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines

Subject Areas as Outlined in the Charter

- Federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation
- Review significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable
- Provide expert input to the Secretary on the latest advances in the science of transplantation...and, additional medical, public health, patient safety... relevant to transplantation

Committee Membership

- Up to 25 members to include expertise in:
  - transplantation medicine and surgery
  - organ donation
  - health care public policy
  - critical care medicine
  - other relevant physician and non-physician health professionals
  - law and bioethics and other relevant professions
  - transplant candidates/recipients, living organ donors and family members of deceased and living donors
- 6 Federal ex-officio, non-voting members from: NIH, CDC, FDA, CMS, AHRQ, ACBTSA

Alignment of CMS Regulatory Requirements with the OPTN

- ACOT has met 24 times since first meeting in 2001. This is the 25th meeting.
- 57 recommendations – most related to improving safety of living organ donation and efforts to increase the number of donor organs made available for transplantation – other relate to improvement of organ allocation policies and transplant/organ procurement system
- Most recent meeting held on January 27, 2015
- Recommendations 56 & 57 sent to Secretary Sebelius in September 2013

ACOT Recommendations 56 & 57

- **Recommendation 56:** The ACOT recommends To standardize brain death testing for children and adults
- **Recommendation 57:** *The ACOT recommends that the Secretary identify a national KDP contractor responsible for implementing a nationally accessible KPD system, identifying optimal matching strategies, and encouraging participation by all transplant centers. The Contractor would also be responsible for (1) administering a standardized reimbursement model for KPD costs, donor workups, and post-donation medical care that would be available to centers fully participating in the system;*

ACOT Recommendation 57 (continued)

- *(2) evaluation of KPD programs and transplant centers that choose to perform KPD outside of the national registry; (3) balancing the needs of current and future patients; (4) striving towards equity in patient access to kidneys; (5) ensuring quality through frequent and critical assessment of equity and efficacy; and (6) recommending process and/or policy changes as appropriate.*

Current Areas of Interest

- Working Groups Formed to address five major issues:
  - Alignment of CMS Regulatory Requirements with the OPTN – Address impact of CMS conditions of participation for transplant hospitals on organ donation and utilization of donor organs
  - Declining Rates of Donation/Geographical and Other Variations in Organ Distribution – Address declining rates in organ donation and geographic distribution of donor organs

Current Areas of Interests (continued)

- Research Barriers to Donor Management and Innovation
- Kidney Paired Donation
- OPTN Alignment

Areas of Interest of ACOT Workgroups

- Kidney Paired Donation Workgroup
  - Kidney Paired Donation (KPD) is a rapidly growing transplant modality in the United States, currently representing 10% of living donor transplants and performed at the majority of centers that perform living donor kidney transplants
  - Many KPDs involve matching between transplant centers, often across large geographic regions, and often involving air transport of living donor organs
  - Administration of KPD currently rests with approximately 15 competing programs, several of which consider themselves "national", most of which compete for participation and matches

Areas of Interest of ACOT Workgroups (continued)

- Kidney Paired Donation Workgroup
  - KPD has grown beyond a single center or regional issue into a national one in need of oversight, quality assurance, and sensitivity to disparities
  - The ACOT KPD Work Group is evaluating how KPD should be administered, financed, and regulated (and by whom), and how the algorithms for assigning living donor matches should be treated in the context of the principles and priorities of organ allocation

Areas of Interest of ACOT Workgroups (continued)

- Research Barriers to Donor Management and Innovation Workgroup
  - Innovation and research in deceased donor management and treatment has the potential to substantially increase both the quantity and quality of organs available for transplantation and thus mitigate waitlist mortality and improve post-transplant outcomes
  - Despite the potential clinical applicability of diverse interventional strategies affecting physiologic and immunologic consequences of brain death as well as ischemia / reperfusion injury, such innovative research is severely hampered by ethical, logistical, and regulatory barriers at multiple levels of a complex process

Areas of Interest of New ACOT Workgroups (continued)

- Research Barriers to Donor Management and Innovation Workgroup
  - The Research Barriers to Donor Management and Innovation workgroup will focus on how to best facilitate a coordinated effort among overlapping entities and agencies, to permit safe and optimal design of clinical trials in deceased donors

Alignment of CMS Regulatory Requirements with the OPTN

- Flattening of rate of growth in the number of organs procured and utilized for transplant roughly contemporaneous with CMS issuance of conditions of participating for transplant programs and conditions of coverage for organ procurement organizations
- Risk-adjusted metrics used by CMS to evaluate transplant program performance appears to have resulted in reduced utilization of donor organs
- Transplant program outcome metrics developed by the OPTN as a quality improvement tool are being used by CMS to certify/decertify transplant programs

Questions?