

ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION (ACOT)
U.S. Department of Health and Human Services (HHS)
Conference Call * September 4, 2013

Participants:

Voting members: Mark L. Barr, M.D.; Sandy Shih Andrada; Raymond Benza, M.D.; Bernice Coleman, Ph.D., R.N.; Danielle Cornell, R.N., B.S.N., CPTC; 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.; Jamie Marie Avolio McDonald, M.S.W., LISW; Thomas A. Nakagawa, M.D.; Cynthia P. Puryear; Andrew J. Schaefer, Ph.D.

Non-Voting members: Diane H. Corning, Esq.; Matthew J. Kuehnert, M.D.; Laura St. Martin, M.D.

Designated Federal Official: Patricia Stroup, M.B.A., M.P.A.

Welcome and Opening Remarks - Mark Barr, M.D., Chairperson, Advisory Committee on Organ Transplantation (ACOT)

Dr. Barr welcomed the participants and noted that the agenda was very full. The group was going to try to stay on schedule in order to have time for questions and for public comment. He noted that the Advisory Committee on Organ Transplantation (ACOT) Working Groups have benefitted from the active participation by ACOT members and from feedback from transplantation stakeholders, including members of the public. During this meeting, the ACOT's Working Groups and other invited individuals would make presentations.

The first presentation was from the Working Group on Kidney Paired Donation, co-chaired by Dr. Andrew Schaefer and Dr. Dorry Segev.

Working Group Report on Kidney Paired Donation - Andrew Schaefer, Ph.D. & Dorry Segev, M.D., Working Group Co-Chairs

Dr. Schaefer announced that the presentation would review the issue and the Kidney Paired Donation (KPD) Consensus Conference, and they will present a recommendation for the ACOT to consider. Dr. Barr noted that there was enough time on the agenda for this report for the presenters to take their time and for ACOT members to ask any questions they may have.

Dr. Schaefer and Dr. Segev gave an overview of KPD. Dr. Schaefer noted that KPD can be complicated or straightforward; there were lots of flavors and the donations did not have to occur simultaneously. Dr. Schaefer showed slides to illustrate the growth in KPD since 1999, commenting that they are already out-of-date. KPD exceeds 12 percent of U.S. Live Donor Transplants (LDT); a huge number of donations. Moreover, there are a huge number of donations where the donor does not pick the recipient. The situation is less about allocation than about matching, but one has to be careful to be attentive to the donor's wishes, because they lose control in the KPD setting. Hence, it is a key concern, in KPD, that someone other than the donor make the decision about who the recipient is.

There are many questions in the KPD field, including: Are longer chains really better, or do they just attract more media? When does one stop the chain? To whom does the last kidney go? There are questions about shipping, including how to ensure safety and manage logistics with multiple segments. Who should bear the risk of loss or misplacement of the organ? There are also many financial questions. Usually, the donor bills the recipient's insurance, but this is complex with procedures performed at different centers. Another question is who covers donor complications? Who pays for multiple donor and non-direct donation evaluations?

The breadth of questions indicates that the field is not established or set in stone. It demands flexibility and nimbleness in order to adapt to innovations and address financing issues.

With a national chain, the end donors are looking for the same recipient type to continue the chain. This can take longer than expected and the "reneg rate" is high; people definitely drop out of these chains. So, it is an open question of where to stop the chain, and *when to stop it*. Specifically, where does the last kidney go? Does it go to the waiting list of the first donor, or to the waiting list of the last donor? If a center brought a non-directed donor to KPD rather than into the list, were they "owed" a kidney back to their list?

Another issue is who gets priority, and how much? Is it best to prioritize the match within a center? How can the field implement any priorities in the system? Is it better to have programs that run a match immediately, or to wait to let the hard-to-match pairs find matches first rather than wasting them on the easy matches? A lot of work remains to be done to maximize safety in these logistics.

The complexity between centers comes from the payor contracts; payors may be different between the intended recipient and the matched recipient. It is also possible that, even with the same payor, centers may have different contracts with the payor. Different payors may reimburse for different activities, like multiple donor evaluation. This is a complicated situation that touches on pricing and reimbursement.

Further describing this issue, Dr. Segev presented a list of costs associated with KPD:

1. Evaluation of incompatible donors
2. Evaluation of NDD
3. Histocompatibility testing
4. Center-level administration
5. KPD program administration
6. Kidney shipping costs
7. Donor surgeon professional fees
8. Donor complications/follow-up

The KPD financing strategy goals are to:

- Transfer costs from the donor hospital to the recipient hospital
- Eliminate the volume disparity between centers
- Reimburse for donor services by out-of-network providers
- Present consistent/predictable costs for payers
- Remain compliant with the Centers for Medicaid and Medicare Services' (CMS)

regulations

A Standard Acquisition Cost (SAC) strategy has been proposed by some and is attractive to payors. This would resemble the case for deceased donation: A fee for KPD would be defined and agreed on by CMS and other payers. The speakers noted it is not a trivial effort to do this. Each center would be paid the SAC for every KPD transplant it performed, above and beyond the payment received for conventional live donor transplants. The question remains whether the SAC should be national or at the center level; the payors strongly prefer a national level SAC.

The Consensus Conference was held in March 2012 and included the following subjects and leaders: Donor Evaluation: Rodriguez and Serur; Histocompatibility: Reed and Lefell; Geographic Barriers: Segev and Hanto; Financial Issues: Reese and Zavala; Allocation Policies: Gentry and Leichtman; and Implementation: DeMonico and Melcher.

Dr. Segev expressed his thanks for the Conference attendees' hard work in reaching consensus on these issues. He displayed a slide containing the following Consensus Recommendations:

- All potential living donors should be informed about KPD early in the educational process, prior to compatibility testing.
- A centralized information resource for NDDs should be developed by the transplant community. Because of their potential to trigger multiple transplants, all NDDs should be informed about KPD.
- The greatest benefit for candidates can be achieved in a single well-functioning registry that encompasses the successful aspects of currently operating registries.
- A National SAC would best serve KPD given the United States' financial model.
- The designation of a national organization to administer and provide oversight to KPD would best meet the needs of expanding access to Kidney Transplantation in a fair and equitable manner.
- We are impressed by a number of ingenious and resourceful regional and local approaches that have been used.
- However, considering the scope of the national Kidney Transplantation needs, we believe that a national system that maintains the foresight and flexibility to foster innovative approaches to KPD will allow management of one seamless national effort.
- To be successful, a national KPD program would be managed under the auspices of the Health Resources and Services Administration (HRSA). (Irwin et. al., *AJT*, 2012).

Looking at the payor perspective, Dennis Irwin and his colleagues in the payor community published their recommendations in 2012. This paper stated that the designation of a national organization to administer and provide oversight to KPD best meets the needs of expanding access to kidney transplant patients in a fair and equitable manner.

The payors were impressed by the number of resourceful regional and local approaches used in this area; it was an American, business type of landscape with a variety of approaches. But, considering the national scope of kidney transplant needs, payors believe that a national system that maintains foresight and flexibility to foster innovative approaches best allows the management of one seamless, national effort. Further, the payors believe that, to be most successful, a national KPD program should be managed under HRSA.

Creation of a single registry might not be within reach in the short-term. Nonetheless, a single, well-functioning registry, encompassing the current registry's successful aspects, provides the best benefit for all candidates and patients; the financial model would best be served by a national SAC.

Dr. Schaefer presented the ACOT Working Group recommendation, noting that it is very much aligned with the Consensus Conference recommendations. Dr. Schaefer read the recommendation and the list of Working Group members:

Kidney Paired Donation (KPD) plays an emerging role in the United States, now comprising more than 10% of live donor kidney transplants. The current decentralized organization of KPD programs is not optimal in terms of equity of access, broad participation by centers and patients, donor safety, and transparency. Providing a nationally accessible KPD system with incentives to participation in this system rather than in smaller, decentralized programs would improve equity of access and facilitate participation by centers and patients. Implementation of a standardized reimbursement model (such as a standard acquisition charge) would improve donor safety by ensuring medical care for donors, in addition to providing an equitable framework for reimbursement of KPD transplants. Evaluation of all KPD programs by a centralized group would improve transparency.

To address these issues, the ACOT recommends that the Secretary identify a national KPD 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; (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.

Discussion

Dr. Barr noted that this was a lot of information and could be hard to follow, but the issue is very important due to the sheer number of cases. The ACOT felt that it deserved a Working Group and a specific recommendation. Dr. Segev added that the recommendation is a mouthful but the Working Group had many discussions about it. Dr. Segev expressed his appreciation to the Working Group members for their input and for making the recommendation.

Dr. Barr said that the plan is to finalize the language and vote on the recommendation at this meeting so it can be sent to the Secretary. He said that the language has been looked at by Ms. Levine and vetted by multiple HRSA staff members. Dr. Barr asked if any ACOT members had questions.

Dr. Fung asked Dr. Segev to explain how the United Network for Organ Sharing's (UNOS)

current financing program works and is compatible with the proposal for the new KPD program to be added to its contract. Dr. Segev said that, broadly, UNOS has an active KPD matching program that uses published optimization techniques, and has thought these issues through. The vision is for a contract, like the Organ Procurement and Transplantation Network (OPTN) or Scientific Registry of Transplant Recipients (SRTR) contract. If UNOS wants to apply for the contract, it could; others, like the National Kidney Registry or the Alliance for Paired Donation, could also apply. The key thing is for the contractor to be able to identify best practices and work quickly because KPD cannot tolerate slowness. As noted, the SAC reimbursement would be available to centers that fully participate in the system, creating a carrot and a stick at the same time. The stick is that, even if a center does not fully participate in this system, it still is subject to oversight by the system. The carrot is that, a fully participating center would have access to the SAC. Centers could still function outside of the system, but the recommendation rewards participation in the system.

Dr. Gerber asked how the mandate would go forward without a lot of separate universes existing. Dr. Segev responded by presenting a scenario in which a group got the contract as described, and most centers participate because, by doing so, they got the SAC. In this model, it is not a big deal if a center does not participate for whatever reason; that center would only exchange within its own center so it does not need the SAC. Or, if UNOS got the contract and the National Kidney Registry, just to use a hypothetical example, had a different way reimburse and negotiate a standard rate with payors and wants to be outside the national contractor, there would still be oversight by the national contractor. It would function in a parallel universe without the SAC.

Dr. Segev continued that, at the end of the day, the SAC seems like a carrot but is really a stick: payors would deal with the national SAC and it would be hard to negotiate outside of that. Participation in the national SAC is expected to draw most centers in the country to the national contractor rather remaining outside the system. The goal is, however, to keep it in America and give people the opportunity to do things as they saw fit; if they were clever enough to negotiate the contract, more power to them.

Dr. Gerber thanked Dr. Segev for that helpful explanation. He asked, from an oversight standpoint, what entity would conduct oversight of the center's participation. Right now, he continued, UNOS is at one place, CMS is at another place, and this is a potential third player. Dr. Segev responded that the vision is for the entity that held the contract to do the KPD-specific oversight. He presented an example of the matching strategies: If a non-contractor works with several centers and there is a feeling of unfairness in terms of the matching (i.e., racial or geographic bias, or bias toward particular centers), then the centers would be subject to oversight by the contractor.

Dr. Segev continued with an example: If there was a national program and everybody was happy except for Hopkins (for example), which did not want to participate and figured out a way to do things that were good for it — but the oversight system said that one of its choices disenfranchised African-Americans or other patients, because none were getting matched or getting the opportunity to participate in the national program — the national contractor would have responsibility for that oversight. Those centers would be accountable to HRSA.

Dr. Eason said that he applauds this work, but has questions. For example, he asked if the SAC

has been compared to the costs to participate in some of the commercially available KPD programs. A lot of centers have paid into those programs and it is unclear how this proposal would impact them. Dr. Segev responded that this is a great question and that the SAC has not been worked out yet. One goal would be for the national contractor to work it out with payors. The SAC would be levied on payors, not on centers; the program would be free for centers so they would not have to pay up-front (or, in some cases, per transplant) as they do currently. The goal is for all of the costs of running KPD to be covered either by HRSA, the payors, or some combination of the two, and not land on the centers.

Dr. Barr asked if Stephen Crawford wanted to comment, since he is one of the few people on the call who really understand all of the details of the proposal. Dr. Crawford described himself as the medical director for transplant for CIGNA, and said that he deals exclusively with transplants. He is also a co-author of the Irwin paper. Dr. Crawford said that he did not have much to add, other than his support for the recommendation. Paying for KPD is a real issue and a stumbling block that prevented people from being involved in it. A clear, national system that allowed everyone to participate is critical to expanding access. The situation is confusing, with multiple patients, recipients, and payors. It is essential to figure out how to pay for KPD, or the number will not expand; a national SAC would largely take care of the issues of payment.

Dr. Fung asked HRSA staff to comment on standardizing fees for deceased donors and non-renal organs. Organ procurement organizations (OPOs) have a wide variety of charges, so standardizing fees for extra-renals might reduce transplantation fees.

Dr. Barr commented, saying that is a separate question and off-topic from KPD. It is important, and people raised the issue before, and experts have opinions on it. Dr. Barr said he was going to table the question for the New Business section, and return to the recommendation on the table. If ACOT members want, a new Working Group could be formed to look at that issue. Mr. Walsh agreed it was tangential and that the group could talk about it later; he asked the ACOT not to get into it today.

Dr. Barr asked if there were any additional comments from ACOT members or HRSA staff. Hearing none, the members voted on the recommendation. The vote was unanimously in favor of the recommendation among ACOT members present on the call. (Ms. Jones and Mr. Lara were not on the call.)

RECOMMENDATION

Kidney paired donation (KPD) plays an emerging role in the United States, now comprising more than 10% of live donor kidney transplants. The current decentralized organization of KPD programs is not optimal in terms of equity of access, broad participation by centers and patients, donor safety, and transparency. Providing a nationally accessible KPD system with incentives to participation in this system rather than in smaller, decentralized programs would improve equity of access and facilitate participation by centers and patients. Implementation of a standardized reimbursement model (such as a standard acquisition charge) would improve donor safety by ensuring medical care for donors, in addition to providing an equitable framework for reimbursement of KPD transplants. Evaluation of all KPD programs by a centralized

group would improve transparency.

To address these issues, we recommend that the Secretary identify a national KPD 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; (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.

Dr. Barr thanked the Working Group and Dr. Segev for their efforts, noting that it is a huge accomplishment to get this done; Dr. Barr appreciated everyone's hard work on this.

Program Report - Bob Walsh, Director, Division of Transplantation, HRSA

Mr. Walsh said that there is a lot of exciting work and new activities going on at the Division of Transplantation (DoT) right now; some of which would be the subject of presentations later in the afternoon. Many of his comments set up the afternoon's discussions.

The first thing he reported was the very significant development that the Secretary published a *Federal Register* notice to change the definition of "organ" to include vascularized composite allografts (VCAs) for the purposes of activities under the OPTN contract. (There is going to be a presentation on this during the afternoon sessions.) Also, the OPTN Board of Directors passed the new kidney allocation policy at its June meeting, with the intent to enhance post-transplant survival benefit and increase the utilization of donated kidneys and transplant access for biologically disadvantaged candidates. This change should happen in 2014.

In July 2013, the Department of Health and Human Services (HHS) agreed to terms on the OPTN contract with UNOS, which allowed for option years to continue the contract through September 2018. The contract included an optional task to incorporate VCAs as an organ in regular OPTN operations.

Also in collaboration with the OPTN, DoT and HRSA have been engaged in the electronic tracking and transport program. As part of an HHS-wide Entrepreneurs Fellowship, DoT hired an external expert to help address organ packaging, labeling, and tracking and reduce errors in that process. Working through a modification to the OPTN contract, OPTN did a great deal of work in the last year, including conducting a failure mode and effects analysis to identify weaknesses in the process. OPTN developed a prototype application to help facilitate and streamline the organ procurement process; this is currently being field-tested.

HRSA provided additional funding to develop an evidence-based approach to optimize geographic distribution to get the ideal maps for new regions for liver allocation as a first stage. Dr. Segev is deeply involved in developing optimization models and the OPTN is discussing the

variables necessary to optimize the allocation for all organ types. The SRTR has developed the first of the maps and is working with the OPTN Committee. This would be further developed in the next stage of the SRTR contract.

Another DoT activity is the promotion of best practices in organ procurement and transplantation, funded by HRSA through a cooperative agreement with the Alliance. In the third year of this three-year cooperative agreement, the Alliance engages in a strategic process to help the community continue to promote best practices in organ procurement and transplantation. DoT is involved with discussions to optimize that strategic plan. A number of on-going activities are funded through the Communities of Practice, including monthly webinars that have been positively received and are growing each month. This includes the National Pediatric Donations Summit, which Dr. Gerber will describe later this afternoon.

In the public education branch, DoT is soliciting applications for two grant programs focused on increasing organ donation. They have been posted and will accept applications through Fall, 2013. In response to recommendations received directly from the Secretary to look more deeply at encouraging and promoting higher rates of pediatric organ donation, both grant programs include a focus on that particular area. DoT is seeking best practices and good ideas from the community about how to best achieve the maximum number of organ donors and make the best use of organs procured.

DoT also directly promotes enrollment in state donor registries in order to increase organ donation and number of transplants. This effort includes the hospital campaign, by which hospitals and state hospital associations promote state donor enrollment. There are a number of partners in this effort, including 10 national association partners, almost all of the OPOs, and about half of the state hospital associations. So far, DoT has managed to document more than 200,000 new registrations.

Another interesting new campaign coming out of the public and professional education branch is a new public service advertisement (PSA) campaign focusing on the concept of “made possible by.” These PSAs focus on how the transplant recipients’ added life was “made possible by” organ donation. These powerful PSAs have been picked up on a number of radio and TV spots and reached nearly 30 million individuals; the goal is to spark the viewers’ interest in donation.

In recognition of the changing world and increasing use of electronic media, DoT also focuses on social media to get information about organ donation. DoT is developing a number of strategies for targeted advertising and graphics to share on Facebook. Mr. Walsh showed some of the eye-catching graphics, which were designed to draw attention and inspire people to “like” and share them. To date, a projected 1.5 million people have seen the graphics, which have been shared 22,000 times. Because DoT recognized that most people consume information electronically and “on the go,” it developed a mobile version of the *organdonor.gov* website that is accessible through mobile devices.

DoT has also actively promoted the 50-plus Campaign, which educates older individuals that they are not excluded from becoming donors.

Mr. Walsh noted that DoT is very proud of a new video about the donation process that was

released last month. It has been very well-received and garnered positive feedback. The video uses friendly graphics and non-threatening messaging to explain the transplant system and correct myths about organ donation. Mr. Walsh said that he has shared the video with his children (aged five and eight), and that they could actually understand this information. Mr. Walsh showed the video to the participants.

Discussion

Dr. Barr said that the video is very impressive. Dr. Barr thought that, while the video is a bit long to use as a PSA, it would be useful to attach something like it to the Super Bowl or another huge event, so more people could see it. A shorter version that flowed as well as this version would be great. Members of Congress should see it to help them understand issues around immunosuppressive drug coverage; that bill was still held up.

Dr. Fung asked about the sequester's impact HRSA and its grants. Mr. Walsh responded that all Federal programs have taken a hit; DoT has tried to be good stewards and spread the cuts out across the programs. The promotion grants are important and being maintained, but other grant areas are getting pinched. Dr. Barr added that there is not enough money for the CIOPS grants, for example. Mr. Walsh confirmed that those were not being funded currently, due to the sequester.

OPTN Update - Brian Shepard, Acting Chief Executive Officer, UNOS

Mr. Shepard presented an update on UNOS' activities since the last ACOT meeting. Several high-profile allocation issues are likely to consume most of his presentation time, but Mr. Shepard said that he also wants to provide an update on the OPTN pilot program, quality measurement changes, new things in the OPTN contract, and upcoming activities.

The first major issue is the long-awaited changes to the kidney allocation policy, approved at the Board of Directors' June 2013 meeting. The new kidney policy replaces the existing policy definitions of "standard" and "expanded criteria" with a Kidney Donor Profile Index (KDPI). The KDPI classified kidney offers by the length of time the organ is likely to continue to function once transplanted, based on a formulaic description of the donor kidney's quality. This index is already in use in order for professionals to familiarize themselves with it. The feedback to UNOS is that it provides a much more accurate distinction between what was previously defined as "standard" and "expanded-criteria" donors (ECD).

The policy also includes a formula to estimate the number of years each specific candidate on the waiting list is likely to benefit from kidney transplant: the "estimated post-transplant survival." The 20 percent of kidney offers with the longest estimated function would be offered first to the 20 percent of candidates estimated to have the longest time benefit. This is expected to create significant benefits in terms of overall life years for recipients. It should also reduce the recipients' need for future/repeat transplants and allow more transplants to occur among candidates waiting for their first opportunity.

Among the remaining 80 percent of candidates, the process is much the same as the current system — unless the donor receives additional parity based on other considerations. The

changes are intended to increase utilization and minimize differences in local transplant waiting times. Primarily, this is an allocation policy, not a distribution policy and the Kidney Committee recognizes that; it understands that distribution is the next step.

As in the current system, the KPDI policy would continue to award higher parity based on candidate's waiting time. However, waiting time would be calculated from the date the person first had a specific glomerular filtration rate (GFR) score or began dialysis (or other renal replacement therapy), even if that date preceded his or her transplant listing. There is an opportunity to post-date the patient's need for a kidney transplant, which will address access issues when dialysis patients do not get to transplant care quickly. The policy also establishes a sliding scale for candidates: those with few opportunities for compatible transplant receive higher parities than those with more moderate levels.

The policy also eliminates paybacks and variances. The KDPI has been displayed and made available for professionals to start getting used to it. The next phase of programming is to allow some necessary data collection (like dialysis days and diabetes status), to occur early in 2014. By the end of 2014, the new kidney allocation policy should be programmed and operational.

The other major allocation issue is pediatric. In June 2013, the national media started covering the story of an 11-year-old Philadelphia girl awaiting a lung transplant. The child's condition was worsening and she had not been transplanted, so her mother began to make public appeals on her behalf. The parents filed a lawsuit asking the HHS Secretary to change the allocation process and the division of donors and candidates under age 12 into a separate pool from those aged 12 and older.

A Federal court judge in Philadelphia granted a temporary restraining order, the first such judicial intervention in the order of listed candidates. The OPTN Executive Committee met and determined that there should be a process to allow centers to list young candidates for adolescent and adult lung offers. Since the policy change went into effect in June, the Lung Review Board (LRB) has approved six patients. As of yesterday, three had been removed from the waiting list due to transplant. One received two transplants from the waiting list that the candidate would not otherwise have been eligible for; two received a transplant from the original waiting list registration. These did not result from the policy change.

The new pathway of appeal for the LRB created by the Executive Committee is going to expire in July 2014. In the meantime, the Committee is considering data to determine whether extremely young patients are at a disadvantage compared to other patients. It is also considering whether age is an appropriate descriptor of the differences in children's physical status at different developmental stages, or whether other indicators might work better.

Discussion

Dr. Gerber asked how KPDI is being integrated into the SRTR data set. He added that there is a new report from January or July of 2014 and they are still trying to learn it. Mr. Shepard said that he would look into that and email the ACOT members with an update.

Dr. Fung asked whether retroactive designation disadvantaged minority groups whose members

might present for the first time with end-stage renal failure. He asked how estimates about when the patients first went into renal failure would be made for those with late access to medical care. Mr. Shepard said that people have to have a measured GFR; while there are access issues, the data suggests there is an intervening level of access where people get dialysis but not transplant information, and are not getting on the wait list. The proposal is intended to balance that and is expected to benefit minority populations.

Ms. Glazier noted that she is the chair of the UNOS Ethics Committee; she expressed concern about access issues being affected by center turndown practices, which vary significantly across the country. Her Committee is going to look at the data on turndown rates and discuss considerations related to access and transparency.

Dr. Barr said it is appropriate to note that both the Thoracic Committee and the Ethics Committee prefer a more deliberative process for considering whether changes need to be made to pediatric lung allocations. The Executive Committee ultimately decided that it is damaging to avoid a conclusion in the Philadelphia hearing, and moved forward with an interim policy while those discussions were on-going. It is a matter of heated debate and two committees were inclined to take a more studied approach; there was not 100 percent agreement.

Dr. Barr expressed his personal view that there should be an appeals process in the OPTN; the fact that it did not exist before was an oversight. There was no huge policy change – just the change to have an appeals process, which currently exists for every other age group. This would have already been built into the system had it been thought of before. What the Executive Committee did was exactly the correct thing to do, independent of the media storm, he believed.

Mr. Shepard returned to his presentation with an update on the KPD pilot program. So far in 2013, there had been 33 transfers. Mr. Shepard expressed the hope that the program was now at the tipping point and critical mass where these programs appear to take off. A few things were different: The OPTN now runs matches more often (once a week) and is getting fewer declines. It was going to start to manually implement the use of bridge donors this week, which should increase the success rate. Opening for bridge donors is expected to be completed early in 2014.

The OPTN contract calls for the Board of Directors and HRSA to review the pilot program and determine next steps, and assess if it should be fully integrated as part of the OPTN. That review is going to occur over the next two board meetings; there will be something from the Board of Directors by the June 2014 Board meeting (i.e., a recommendation on whether to make this a permanent part of the OPTN). The one significant difference between the existing OPTN pilot program's goals and ACOT's discussion is that the OPTN program is not currently involved with finance issues. The recommendation's other goals (i.e., finding appropriate matches and protecting patient safety) were goals of the existing OPTN program, but the financial issue is a notable difference between the pilot program and the ACOT recommendation.

In terms of quality measurement issues, MPSC (Membership Professional Standards Committee of the OPTN) is starting to use the new OPO metrics and five have been flagged and under review and to develop criteria for handling flags. It is still in the early stages for the metrics' use and the Committee is trying to learn lessons about applying them in a way most helpful to improving OPO performance. New methods for the flags are going to be proposed and would be

open for public comment on September 6th. The proposal was based on a Bayesian model and should improve accuracy in flagging and reduce the number of false flags. While this was an important step in improving accuracy, a flag remains the first indicator of the need to review. The Board and leadership are discussing how to avoid creating unintended consequences for the reuse of some of the same numbers that may not mean the same things in every context. The flag is not a bright-line indicator of a good vs. bad program or OPO; it is simply a directional sign to show the Committee where to focus a review.

The Department of Evaluation and Quality, UNOS, (DEQ) is also looking at its site survey process. The new process triggers prompt reviews as needed, in order to focus on those in need of the most help and spend less time on those needing less help. Triggers might include policy violation, safety incidents, performance flagging, or some combination. CMS also seemed to be thinking about similar strategic items. The work will be guided by an *ad hoc* OPTN Committee to set the triggering criteria.

OPTN is happy to continue to serve the community through the extended contract. The contract includes a few additions to the OPTN responsibility, including: Incorporation of VCA (there is going to be a presentation on this during the afternoon), and creation of a Data Advisory Committee (DAC) to evaluate how OPTN uses data, why data are collected, how data could be used better, etc. This role might sound familiar because it was originally envisioned as the Policy Oversight Committee's role. That Committee has evolved into strategic planning for the OPTN as a whole, so the new DAC is intended to ensure that data issues continue to be addressed.

The new contract also includes the electronic tracking and transport project described earlier. An *ad hoc* committee is working to develop a process and application that would allow an OPO to print labels in the field and reduce transcription errors. A trial version is being field-tested at five OPOs now, and HRSA is discussing the next generation for broader release.

The ACOT has had a long history of interest in issues associated with geography. The OPTN is working on possible changes to the geographic distribution of organs; this is going to be discussed at the Liver Committee later in September. The other committees are actively engaged in determining variables that represent equality, fairness, and equity among the regions; then the variables would be used to make maps to accomplish that goal.

Finally, in a conference call in August 2013, after the new contract extension was signed, the Board of Directors approved a new budget with significant new investment in Information Technology (IT) capabilities. This new investment should provide resources to deliver changes in a timely manner. The goal is to ensure that decisions being made by the transplant community through the OPTN policy are implemented and available to serve both members and the patients they serve as quickly as possible. This new IT investment is a significant step forward that should facilitate robust and speedy delivery system for new policies going forward.

Discussion

Dr. Barr thanked Mr. Shepard for the presentation.

Dr. Eason asked, with regard to geographic distribution and policies, if there is a timetable for changing it for liver and addressing it in kidney. He asked if the ACOT could do anything to expedite this. The response was that the Liver Committee is meeting on September 23, 2013, which would be a significant event in this process. Changes have to go through public comment process, so even the first iteration was going to be widely discussed and take time to hash out. There might be a proposal out in the Spring or Fall of 2014, depending on how it goes.

Dr. Kuehnert asked about the electronic tracking project, which seemed like a very interesting initiative to reduce errors. He noted that coding organs is a global issue and asked if the project has a component that allows tissues to be coded in the same way organs are. And, was there an alignment with tissues, since both were often recovered from same donor? The response was that this was really an IT project to deliver an application that OPOs could use in the field to create labels quickly and accurately. HRSA is certainly aware of, and has discussed, the advantages of a national database or international ID number for donors. Nothing is going to preclude the adoption of a system like that. Mr. McLaughlin concurred that the project addresses organs but could be expanded in a future world and regulatory scheme.

Dr. Barr asked about feedback since Share 35 went into effect. Mr. Shepard said that the feedback is currently just anecdotal. The Liver Committee is doing a thorough data review but the data do not have to be submitted until up to 60 days post-transplant, so it is not possible to provide a data-driven answer right now. The Liver Committee knows that it has to monitor it, however.

Public Health Service (PHS) Guideline on Transmission of HIV through Organ Transplantation - Matthew Kuehnert, M.D., CDC

Dr. Kuehnert said that the key point is that the new Public Health Service (PHS) guideline — “Guideline for Reducing HIV, HBV, and HCV Transmission through Organ Transplantation” is intended to reduce the transmission of Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) through organ transplantation. This guideline was updated from 1994 to improve safety and availability by: Assessing donors for risk; assessing recipients for transmitted infections; and recommending a study of the recommendations’ impact, including ways to improve availability.

The Guideline is published and is available at Public Health Reports. It focuses on organs and blood vessels used for transplantation. It was developed over five years by the PHS using an evidenced-based process and expert input — including input from HHS, HRSA, the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Centers for Disease Control and Prevention (CDC) led the technical part of the process with input from external partners, both subject matter experts and organizational representatives.

There were five phases to the process:

1. Organize the Technical Advisors for Guideline Development
2. Conduct a Preliminary Literature Search in Support of Questions for Systematic Review
3. Develop Questions for Systematic Review and Analytic Framework
4. Produce an evidence report (also available online)
5. Develop the Guideline

The following five key topics resulted in 10 key questions for consideration in the guidelines:

1. Risk of disease transmission through solid organ transplantation;
2. Potential risks and benefits of transplantation of solid organs from infected donors;
3. Methods to mitigate the potential risks of transplantation of solid organs from infected donors;
4. Potential risks and benefits of interventions to mitigate transmission of transmissible diseases; and
5. Approaches as to how recipients can be informed about the risk of disease transmission and be evaluated for possible exposure post-transplantation.

The Guidelines contain 12 criteria for donor risk factor assessment; 34 recommendations; and 20 recommendations for further study that could be answered from evidence in the literature. The recommendations are neither regulation nor required by policy, and their conversion into policy is something for other entities to consider over time.

Dr. Kuehnert summarized the recommendation topics:

- Risk Factors for Recent HIV, HBV or HCV Infection
- Risk Assessment (Screening) of Living and Deceased Donors
- Testing of Living and Deceased Donors
- Informed Consent Discussion with Transplant Candidates
- Testing of Recipients Pre- and Post-transplant
- Collection and/or Storage of Donor and Recipient Specimens
- Tracking and Reporting of HIV, HBV and HCV

The recommendations for future study include the need to evaluate the risk-benefit of transplanting organs from HIV-infected donors into HIV-infected transplant candidates and a review of legislative action needed to allow the recovery of HIV-positive organs. Another issue is the danger of under-utilization of Hepatitis C-positive or HIV-positive organs. It is important for people to understand the risks and factors in under-utilization that result from misunderstanding the risk. While the recommendations speak for themselves, there is a need for education on what the results mean in terms of offering organs, ensuring informed consent, and acceptance of the organ.

In terms of the frontiers of reducing transplant-transmitted disease and improving outcomes, there are some guidelines nationally and internationally for management of patients who receive organs from donors known to be infected with Hepatitis B or Hepatitis C. These could be better delineated to help people better understand the risks and benefits. If the law about transplantation of infected organs changes, then the guidelines would also have to change.

Other policies are being implemented for other infectious diseases and emerging pathogens (i.e., West Nile). There are clusters of transplant-transmitted diseases that cause meningo-encephalitis. A second case of rabies brought this issue to the forefront and prompted the CDC to look again at the 14 clusters that have occurred since 2002 (including West Nile Virus, Lymphocytic Choriomeningitis, Rabies, and the free-living ameba *Balamuthia mandrillaris*).

The common themes include, first, that many of these donors did not appear to have evidence of

an infection at the time of their death (death was frequently attributed to intracranial hemorrhage). Second, some donors had evidence of encephalitis, and could have included an abnormal lumbar puncture, but the clinicians who cared for the donor did not make the diagnosis. Third, recipients were often spread out nationwide; without an active surveillance system, it is hard to link donor and recipient infections in a timely manner allowing any sort of therapeutic or preventive intervention. Finally, there is very high mortality among recipients even with therapeutic interventions (some of which were quite dramatic, including removing the transplanted kidney).

The plan is to convene a transplant-transmitted encephalitis group to address this issue and get input from other agencies and external stakeholders. There is a need to raise awareness about infectious encephalitis among potential organ donors and to assess the possibility of a standard evaluation tool for potential infectious encephalitis. There is also a need for a definition of “encephalitis,” and assessment of questions or laboratory testing to be recommended. What criteria could be used to assess donors for whom one should proceed with extreme caution, if there were known infectious encephalitis? What specific informed consent can be made for recipients, as with the increased risk for HIV and Hepatitis?

In summary, the 2013 PHS Guideline has been published with new recommendations on donor screening, recipient testing, informed consent, and disease reporting for OPOs and transplant centers. Targeted studies are needed to study the impact of transplant-transmitted disease and efforts for prevention, and to look at improving availability (such as use of HIV-positive donors). HIV and hepatitis were not the only (and were not the largest) infectious disease threats to poor outcome in transplant recipients, and these other pathogens also needed consideration.

Discussion

Dr. Barr asked if there is anything the ACOT could do to help. He said that he assumed the Disease Transmission Advisory Committee is involved; Dr. Kuehnert confirmed this and added that it is up to others to determine what should be converted into policy. The ACOT could monitor that process. The CDC has started to prepare a crosswalk between the new guidelines, OPTN policy, the old guidelines, and CMS’ standards and interpretive guidance. Dr. Kuehnert said that he is leaving it to the ACOT to see where it could best engage in the process.

Dr. Barr added that the ACOT might not need to insert itself here, but asked Dr. Kuehnert to let him know if the ACOT needs to do anything. As with KPD, the ACOT is in a position to bring parties to the table for discussion, although that does not seem to be needed here. The ACOT is open to help and has certainly been interested in ensuring alignment between CMS and the OPTN. If some of the guideline’s content were integrated into policy (vs. just staying as educational recommendations), it would be very important for the OPTN and CMS to be exactly on the same page and have a unified message.

Mr. Alexander suggested that it would be beneficial to include an OPO member on the encephalitic work group to discuss feasibility around what testing can and should be done. Dr. Kuehnert agreed that was a good suggestion.

Recommendation 55 Working Group Report - Danielle Cornell, R.N., B.S.N., CPTC

Ms. Cornell noted that the Working Group finished its work about a year ago at the August 2012 ACOT meeting, when Recommendation 55 was unanimously voted in. The recommendation pointed out that CMS' performance metrics for OPOs and transplant centers were misaligned and lacked effectiveness. When published, they might have been the best solution, but a lot has been learned since then.

Ms. Cornell provided an example about the questionable integrity of the data, much of which is self-reported. Some definitions were outdated, such as "extended criteria" or "donor ECD," which describes kidneys rather than transplants. The ACOT Working Group is concerned that the performance metrics may cause transplant centers and OPOs not to pursue marginal donors and transplants because doing so could hurt their data, which was not the intention.

The Working Group pulled the data: Between 1988 and 2006, the U.S. deceased donor volumes went from 4000 to 8000; for the last six years, however, they have remained at 8000 and on pace for that number again in 2013. There is a lot of stagnant donation and transplantation volume, yet the waiting list continued to grow and is at nearly 130,000. One could fill up Soldiers' Field in Chicago to its maximum capacity and it could not hold all of the people on the national transplant waiting list. Ms. Cornell expressed the belief that change is needed so that regulations to measure OPO and transplant center performance do not compromise the mission to increase donation and make organs available for transplant.

Recommendation 55 asked the Secretary to direct CMS and HRSA to conduct a comprehensive review of regulatory and other requirements, and to promulgate changes that unify their mutual goals. The ACOT recommended that this review be completed within one year and action be taken within two years. Today, Ms. Diane Corning from CMS, an *ex-officio* ACOT member, is going to report on CMS' proposal; Mr. McLaughlin was also present on the call.

CMS Notice of Proposed Rule-Making (NPRM) - Diane Corning, CMS - Ex Officio Member, ACOT

CMS has a proposed rule out for comment that includes modifications to the current outcome requirements. Right now, all OPOs must meet all three of the outcome measures under the Conditions of Coverage or risk de-certification. CMS has found that most OPOs meet all three measures; many OPOs are missing one and still do all right in terms of performance. CMS believes the measures are too stringent; its new proposal was for OPOs to meet two out of the three measures.

CMS also solicited comments on all of the current outcome measures and feedback on any potential, empirically based outcome measures for future use. CMS specifically asked for comments on the new yield measure. Ms. Corning reiterated that she wants everyone to know about the comment period, which closes on Friday at 5:00 pm. The beginning of the rule included a description about how to submit comments and the relevant page numbers in the 200-page proposed rule were pages 43671 to 43672; the actual regulatory changes were on pages 43706 to 43707.

Since the proposed rule came out, CMS has been asked if there would be any other proposed

changes. Ms. Corning said that she could not comment on anything else CMS might do in terms of rule-making but that the agency was currently reviewing all of the OPO conditions for coverage. Ms. Cornell asked if CMS could describe any of the comments it has received thus far, but Ms. Corning replied that none had been submitted yet.

Mr. Alexander said that AOPO has identified some opportunities for comment that it hopes CMS would consider. He thought it would be best for the ACOT to wait for the final rule and comment on that. There were a lot of flawed measures that need to be tightened up. Ms. Cornell agreed that many people believed the measures were flawed. She added that going from three to two was a good short-term fix, but was not a viable long-term solution.

Ms. Glazier said that part of Recommendation 55 was not addressed by CMS' current proposal. A decrease from three to two measures does not address the issues that the ACOT has identified: Specifically, that the measures are flawed and misaligned with other incentives. She asked what CMS' longer-term strategy is to address this problem. Ms. Corning said that CMS is reviewing all OPO requirements, as well as comments on the measures, and is going to seriously consider them. She asked that comments be submitted on outcome measures as well as proposed and future outcome measures and said that people can comment on other things if they want.

Ms. Cornell asked if action on this would have to come further down the line. The response was that CMS could not comment on other requirements; the agency is looking at this and is aware of the concerns and is going to seriously consider the comments it receives.

Crosswalk – OPTN/CMS - Chris McLaughlin– Chief of Organ Transplantation Branch, DoT

Mr. McLaughlin said that he is going to provide an update on some of the activities HRSA, OPTN, and CMS are working on to improve the harmonization of compliance activities. The OPTN-CMS transplant center compliance crosswalk resulted from long-term discussions between CMS and HRSA and concerns over the perceived misalignment and overlap between OPO bylaws and policies and the transplant center Conditions.

The crosswalk effort is not intended to be a regulatory review of CMS' Conditions of Participation, policies, or bylaws. It is intended to identify areas where misalignment exists and identify areas where coordination could be improved between CMS and the OPTN. While this effort predated the ACOT recommendation, it grew out of the same concerns.

The crosswalk was completed about a year ago. Since then, OPTN and CMS have continued working to modify policies and processes and to interpret guidance to address the identified issues. OPTN and compliance staff talk regularly about changes being implemented and how they affected the other group's work. There were also regular conversations between HRSA and CMS. For example, the recent OPTN bylaws change when programs were inactive for prolonged periods of time led to changes in the evaluation plan. OPTN and CMS staff have discussed implementation of these changes prior to their effective dates and how they need to be reflected in CMS guidance.

One of the things being developed is compliance-monitoring map of all of the routinely monitored policies and their associated monitoring plans. This would enable OPTN to develop

consistency among site surveyors and greater transparency for members. This mapping would identify any area of monitoring and consistency with CMS, so OPTN could adjust monitoring plans to avoid conflicts or situations that cause confusion and frustration.

Discussions between CMS and HRSA are occurring to ensure better coordination for transplant surveys. The crosswalk shows there is an alignment between OPTN policy on living donation and donor requirements for CMS. Preliminary planning and discussions have occurred about having OPTN surveyors join CMS' living donor survey teams, or be part of CMS teams to identify similarities and differences in approaches to surveys related to living donor programs. This would also help identify particular areas of content expertise that may be coming through in one survey or the other. The OPTN is considering the integration of the (currently separate) living donor program surveys into the overall transplant centers' survey. This is going to be discussed in the review of the overall survey process during the next few months.

Although the transplant center compliance crosswalk is intended to be an internal tool for HRSA, OPTN, and CMS' use, it became clear it would be useful for the community and for centers to understand their compliance requirements. The document is updated at least twice annually to reflect changes in requirements and processes. Finally, as CMS geared up for a potential new round of OPO certification surveys next year, it is working to address concerns of alignment with OPO compliance and regulatory activities. CMS asked for the involvement of surveyors and surveyor training and was discussing the possibility of developing a similar requirement and survey crosswalk to help inform the upcoming CMS surveys and on-going OPTN surveys.

Discussion

Dr. Fung asked how many OPOs have been de-certified, adding that it seems that there were a number of inefficient OPOs; transplant centers appeared to be held to a higher level of accountability than the OPOs. The response was that there have been no de-certifications under the current regulations. Dr. Eason added that it was frustrating, on the transplant side, that the OPOs largely self-report their data. The same checks and balances do not appear to exist for them as on the center side.

Ms. Glazier said that she believes the OPO community would agree that self-reported data were less than ideal; the OPOs have raised this issue with CMS repeatedly that self-reported data are not verified. In terms of being consistent with the transplant center regulations, however, OPOs note that CMS does not currently have discretion under the OPO regulations, unlike with transplant center regulations. The OPOs' regulations are more stringent than transplant centers' regulations.

Dr. Fung commented that, since some centers, but no OPOs, have been de-certified, he wondered if the requirements are not stringent enough. It could be that there is an inability to get good metrics. He noted that, in his area, there is an OPO that has not given a single donation after cardiac death organ (DCD) to the pool, while others achieved 20 percent; this was frustrating.

Mr. McLaughlin said that this is the first complete cycle for which there were complete metrics to meet in order to retain certification. He suspected that, as the cycle concluded, some OPOs would be at high risk of de-certification. The measures have not previously been in place to have

a complete cycle. The OPO Directors wanted better measures for assessing performance. DCD should be part of it, along with other metrics to look at OPOs and Donation Service Area (DSA) performance. The OPOs are not resistant to the point being made.

Dr. Eason commented that OPOs are rewarded for a good conversion rate or a good consent rate, but their number of donors per million are low. While donors per million is no longer a metric, he feels there should be some expectation of number of donors for a given population size. Mr. McLaughlin said that this was the sort of comment CMS sought; Ms. Corning agreed that this sort of comments should be submitted to CMS.

Dr. Barr asked Mr. McLaughlin whether the crosswalk has addressed the concerns expressed in ACOT's Recommendation 55 and its timeline. At the August 2012 meeting, the ACOT members had wordsmithed the recommendation to ensure that feedback occurred within a set period of time. Mr. McLaughlin said that the attempt to harmonize efforts was on-going; the crosswalk was one way to try to accomplish that. He encouraged the ACOT Working Group to continue to monitor this situation to see if more needed to be done. Activities are on-going between HRSA, CMS, and the OPTN in order to try to improve areas where there is perceived or real misalignment. By the next ACOT meeting, he believes there will be more products or changes from these efforts.

Mr. McLaughlin asked if there is a new Working Group addressing this. Dr. Barr said there was no Working Group currently and that he wants to ensure everyone gets what they need, and that the ACOT is giving the correct feedback to help. Ms. Cornell expressed her frustration that the recommendation has not actually been followed: It directed CMS and the OPTN to work with members of the donation community on these issues. She expressed the need for someone at an OPO to participate in these talks, such as an ACOT member who is also part of an OPO. The Working Group raised the issue but is not the one to fix the situation.

Dr. Barr asked Ms. Stroup to send the ACOT Working Group members the additional feedback and materials received from Dan Schwartz's group, and to set up a conference call during this quarter to discuss these issues. He felt the need to keep moving on the agenda, but thanked members for volunteering. Ms. Cornell clarified that the original Working Group was actually very large; she asked that the reconstituted Working Group be comprised just of ACOT members to address these issues first. Dr. Barr agreed to this.

Report on the Publication of Article / Determination of Death – James Bernat, M.D.

Dr. Bernat's slides were located and put on the screen and ACOT website. He reported that this presentation was the latest in a series of updates on the paper entitled "Circulatory Death Determination in Uncontrolled Organ Donors." Three ACOT members participated in the panel and are co-authors on the paper. He thanked Dr. Wall, who was on the panel and indicated that he will give the counterpoint position.

The paper was published in the *Annals of Emergency Medicine* in 2013; it was submitted in February, accepted in May, published online in May, and the print publication is pending. One letter to the editor had been received already and is going to be published with a response.

The group's charge was restricted to making recommendations on the criteria for death determination of uncontrolled donors, not to recommend directions for uncontrolled donation or whether it was desirable or feasible. Some members of the panel wanted to expand that charge but he, as chair, resisted these efforts.

The panel concluded that it required showing permanent or irreversible cessation of function for donor death to be confirmed. Once optimal cardiopulmonary resuscitation (CPR) efforts failed, it was necessary to wait seven minutes for any auto-resuscitation that might occur (based on reported cases of auto-resuscitation following CPR). The panel recommended ruling out post-mortem organ support technologies that re-established systemic circulation of warm oxygenated blood. The panel was not crazy about balloon use due to a number of panelists' perception that it was contrived and could be viewed as trying to achieve a desired end regarding the patient's death. This was certainly not the intent, but the only way to avoid it was not to use the balloon. Circulation organ support technologies such as *ex vivo* extracorporeal perfusion (ECMO) would be acceptable, because they cannot produce any reanimation or perfusion of the brain.

The paper included a table showing the conceptual timeline with six events (Time 1 through Time 6), starting with cessation of systemic circulation and ending with destruction of the brain. Time 3, the moment when circulation ceases permanently, was divided into two categories: Controlled with no CPR, and with CPR.

Opposing Views - Letter to the Editor - Stephen Wall, M.D., New York University

Dr. Wall said that he would briefly explain the methods of the panel and how they differed from modern, social reform theory. While the panel was charged solely with death determination, he is also going to discuss the policy implications from the panel's work.

Modern social reform theory stated that an ideal situation is when one has a three-way partnership; in this case, one that included government officials, community members, and subject experts. Dr. Wall stated that he was a consultant to the panel but was not allowed to be on it due to a conflict of interest. Yet, in modern social reform theory, one would expect to have transplant experts and health economists on the panel. Also, the panel was unable to achieve consensus; two people refused to sign on.

As far as the context, there were different nuances when one talked about donation after neurologic or brain death. Uncontrolled donation attempted to resuscitate a patient who had undergone unexpected cardiac arrest. The study panel was focused on people who had a cardiac arrest outside a hospital; Dr. Wall is going to focus on that population.

He asked the participants to imagine a situation in which someone had a cardiac arrest and responders tried resuscitation for 30 minutes (at minimum), then the person was pronounced dead. Soon after, there was a discussion with an authorized party, which would take 5 to 20 minutes. That was a natural hands-off period. After that, one would initiate a preservation method, and continue it for enough time to allow an authorized party to be approached for a donation decision (or, if the patient was on the registry, he or she could be preserved for donation at that time). In controlled donation, the difference is that patients are terminally ill and there is a discussion about donation prior to termination of life support. There is an explicit understanding

there would be no methods used to resuscitate the patient after death occurs.

In Europe, there is an understanding that death is based on an absence of electro-cardiac activity; a more heart-based view, while the United States' culture is circulatory-based. As far as the post-mortem preservation measures, it is clear that manual chest compressions and chest compression devices do not provide perfusion pressure sufficient to bring back brain function. It is far below normal physiologic range. With ECMO, using a balloon is the nuance between active versus passive decisions.

In terms of the panel, it really could only be considered an uncontrolled donation; the implication is that only lungs would be available using uncontrolled donation. It is acceptable for kidneys but the CMS guidelines right now are such that the thresholds are in a range that make transplant centers fear using them. It is not appropriate for livers, given the evidence. If one looked at the data about potential uncontrolled donation, 34 percent of all donations would actually be available if this pool could be used.

New York is currently planning a long program. The speaker advocated for a flexible policy in order to account for evolving medical innovations and both controlled and uncontrolled donations.

Discussion

Dr. Barr asked what the ACOT's role is in this area and noted that the ACOT had been represented in this group. If there were future initiatives, the group could certainly discuss them, but that would probably be more appropriate for HRSA than the ACOT.

Ms. Stroup agreed; this effort had started as a HRSA initiative and the ACOT was asked to follow up and hold the expert panel meeting. Now that this has occurred and the paper published, nothing further was planned. Anything further would be a HRSA activity.

Vascularized Composite Allografts (VCA) Update – James Bowman - DoT

Mr. Bowman stated that he is presenting remarks prepared by Mr. Shepard. In the *Federal Register* notice published on July 3 2013, HHS announced that vascular composite allografts (VCAs) would be added to the definition of organs covered by Federal regulation under the OPTN final rule and the National Organ Transplant Act (NOTA). This will be effective on July 3, 2014, a year after publication in the *Federal Register*.

The announcement establishes criteria for body parts to qualify as VCAs and makes future transplants subject to the requirements of the OPTN final rule (i.e., transplant program designation, data submission, compliance with applicable OPTN policies and bylaws). The ruling follows consideration of public comments on the December 2011 notice of proposed rulemaking in the *Federal Register*.

The OPTN President appointed Dr. Susan McDiarmid to chair the OPTN's Vascular Composite Allografts Committee. Dr. McDiarmid is the Medical Director of the University of California at Los Angeles (UCLA) hand transplant program. Potential committee members were being

reviewed; the Committee was going to start off as an *ad hoc* OPTN committee because this provided the most flexibility to get the right experts at the table and create a regionally representative committee.

The Committee is going to include members from VCA programs, traditional organ programs, and VCA-specific physicians and surgeons. It has three immediate tasks to accomplish before the regulation takes effect:

1. Identification of the specific organs to be covered.
2. OPTN membership criteria for specific VCA programs such as hand, face, etc.
3. Requirement for VCA-specific donation authorization.

Current VCA programs are associated with relatively large academic hospitals with solid organ transplant programs, so the OPTN did not expect membership criteria to be controversial. It did not expect the explicit second donor authorization to be controversial, either, since all of the OPOs currently engage in this practice already. The OPTN and UNOS clarified that the current first-person authorization does not mean something different would happen when the regulation takes effect in 2014. Completing these three tasks by July 3, 2014, was likely to require a special public comment cycle in the Spring with approval by the Board of Directors at its June 2014 meeting.

The next task is to consider allocation policy. This could begin as soon as the Committee puts the first pieces out for comment. It did not have to wait until July 2014 to begin discussion. The demand was low enough that the OPTN could take a deliberative approach to policies and get the basic framework in place to initiate the process. The start-up funds necessary to cover the cost of integrating the VCA processes were provided under an option in the current OPTN contract.

Discussion

Dr. Barr thanked Dr. Bowman for making the presentation. Dr. McDiarmid is an incoming ACOT member, providing the ACOT with direct feedback in this area. He suggested that she could present at the ACOT's next meeting about the newly formed *ad hoc* committee (which will probably eventually become the standing committee). VCA is going to be a bigger specialty in terms of future volume.

SRTR Update – Bertram Kasiske, M.D., SRTR Director

Dr. Kasiske said he would take questions after giving a brief update on SRTR that focused on three hot topics:

- Cumulative Sum (CUSUM) quality assurance tool
- Update on the delay in releasing Program Specific Reports (PSR)
- Adopting PSR Bayesian methods

SRTR is up and running with CUSUMs, which are sometimes referred to as “control charts.” The first release was in July and there have been three releases of CUSUMs for kidney, heart, liver, and lung transplant programs. These were (and will continue to be) released monthly and placed on programs' secure websites. There are separate CUSUM charts for living and deceased donor recipients as well as for adults and pediatric recipients. There are charts for one-year graft

survival and one-year patient survival. Historical records are maintained to provide SRTR with access to all of the archived CUSUMs.

Dr. Kasiske displayed examples of the CUSUMs. Each CUSUM covered 36 months over a three-year interval, advancing every month and dropping the oldest month. A program could go online and select and focus on time periods; sliders enabled one to move up and down the CUSUM chart.

Dr. Kasiske showed an example of a one-sided CUSUM chart, which has a threshold based on each program's daily-expected hazard rates and 95 percent of the percentile (the maximum value within each chart of that center's CUSUM). It gives a threshold of concern when the program exceeds an outcome that is unusual. This does not mean the center would get flagged, necessarily, because the CUSUM is not the same as a PSR flagging. But, it is an indication that things are going amiss when the line exceeded the threshold. The notation to the right was the caveat stemming from the lack of the Master File deaths in these CUSUM charts. Dr. Kasiske showed an example of a one-sided CUSUM that invoked the trigger by crossing the threshold line, as well as an example of a two-sided CUSUM that could go up or down.

Along with the CUSUM charts, SRTR provides a table of all the data that go into the CUSUM. This is an HTML data table with all the co-variances and models; centers could cut and paste them if they wanted to play with their data. The CUSUMs are provided as Quality Improvement tools, and came out of popular demand generated at the PSR conference. They are only available at the SRTR secure website and are not designed to identify programs for review by the OPTN, specifically the MPSC or CMS. They are not being provided to the general public, either.

But, as SRTR suspected would happen, private insurance providers and/or companies have asked programs to provide CUSUMs (most recently, this happened with Optimum Health). This is currently a topic of much discussion and debate among transplant programs. CUSUMs are not designed to be an evaluation source; rather, they were structured to look at a program's outcomes over time. They do not compare one program to another, or rate or rank programs.

Discussion

Dr. Barr asked if there has been any contact between the SRTR and OPTUM related to the SRTR's concerns about that use of the CUSUMs. It would be important to know if they were getting feedback from SRTR. The response was that SRTR said it was not going to provide them and did not think insurance providers should use them. Otherwise, they have not had any discussions or been in contact with insurance providers.

Dr. Gerber said that he felt that others would mandate and/or request the CUSUM reports. SRTR knew it was going to have to look at this going forward, but Dr. Gerber wondered if it had received any preliminary feedback or if this discussion had started at the SRTR level. Dr. Kasiske said that SRTR did not support this idea; CUSUMs are not designed to rank or compare one program to another. Every CUSUM is based on the individual record; they simply identify a potential problem within a specific program so that it can be addressed.

Dr. Crawford commented that, while he has not spoken to Dennis about how he is using the

CUSUM, he could address the fact that CIGNA has used it on a case-specific basis. In the absence of the SRTR data, programs said they are doing much better and should be included in CIGNA's network. The payor asked the programs to provide evidence of improvement; that evidence would include the CUSUM reports. CUSUMs were only sought for very specific cases to confirm a program's assertion of its current performance. Dr. Crawford expressed the idea that transplant candidates could use the data to help them choose an appropriate facility for listing. Releasing the CUSUM to the public could help people make the best-informed choices.

Dr. Kasiske reiterated that the comparison made was *within* the program. One could have the best results in the world with a program with an increasing CUSUM line for a period of time, which might then decline again. It could not be looked at in isolation. The SRTR was writing a paper about the need for education about the CUSUM's meaning and use. While Dr. Kasiske supported transparency and patients' access to data, the CUSUMs required a lot of interpretation, education, and understanding of the context.

Dr. Kasiske returned to his presentation. The second hot issue is the program-specific report delay. This delay stemmed from the fact that SRTR supplemented the OPTN's data with death records supplied by the publicly available Social Security Administration Death Master File (SSADMF). These deaths were used in post-transplant outcomes and post-listing mortality assessments. In November 2011, the SSA restricted access to certain records in the file, reducing the deaths available to the SRTR by about 33 percent. As a result of this incomplete death ascertainment and its impact on the accuracy of PSRs, HRSA instructed SRTR to halt production of the PSRs until other data sources could be identified for patient status information.

The proposed solution is for the OPTN to use other sources as supplements. Information in some of these sources has to be confirmed before it could be incorporated in the OPTN database. The OPTN contractor is piloting a new process for verifying the current status (i.e., living or dead) of some transplant candidates and recipients. The OPTN contractor is going to contact the appropriate transplant programs by email and provide them with an Excel spreadsheet containing relevant information for each patient. All verified patient status information is going to be incorporated into the OPTN database and used by the OPTN and SRTR for data analyses and reporting (including for the program-specific reports).

The hope is to do three program-specific reports at the same time in the next upcoming cycle. That would include the January 2013, July 2013, and January 2014 cycles. This would enable an extended review time for programs to review their data, because they would be looking at data from the three-time cohorts (December 2nd through January 31st). After correcting their data, SRTR would go in and do the models and release them to the secure site. All three of these cohorts and program-specific reports would be released around March 20th. Thereafter, SRTR would be on cycle; it would produce a program-specific report in July 2014 and would continue to be on cycle.

Discussion

Dr. Barr asked if this plan would permanently solve the problem. Mr. McLaughlin answered that, barring any unforeseen problems; the new sources should create a continuous process without barriers. He noted that it had been quite a process.

Dr. Barr asked if the ACOT should do anything and whether the Secretary was aware that everyone was blind because the PSRs were shut down. He asked how the length of time it took the government to share information was perceived in the community, and wondered if the agencies know the magnitude of the problem.

Mr. McLaughlin said that it had been discussed numerous times at the top levels of HRSA and CMS and he believed it had gone to the Secretary. There was definitely an awareness and concern to get the process back on target. Some things have to be addressed through statutory requirements, however, and efforts are being made to do so. He said that the SRTR felt confident this was the path forward and he committed to letting the ACOT know if it was not successful. Dr. Barr said that the ACOT would be happy to help raise awareness about the problems in statute or in language.

Dr. Kasiske returned to his presentation. The third hot issue was the redesign of the analytic methodology for the PSRs to use a Bayesian approach. This year was the 250th anniversary of the original paper, so it was appropriate for it to be used. The Consensus Conference recommended that SRTR explore Bayesian methodology. CMS commissioned a committee comprised of presidents of statistical societies to look at methodologies for reporting hospitalization mortality data. This meeting occurred around the same time as the PSR Consensus Conference and its report strongly encouraged this type of analytical approach. The SRTR thought it was time to explore it with the PSRs as well.

In a nutshell, the statistical question asked in the PSR is really a *yes* or *no*: Is the center underperforming or not? One can count up how many zeros are in the p-value to semi quantitatively assess that. The Bayesian method is a much better way to look at it because it answered the question: What is the *probability* that a center is underperforming? It indicates the probability that the program's true mortality rate exceeded a given standard — and that standard could be externally applied. In the case of the OPTN, the MPSC could set a standard that a center should meet and produce a probability that the program's results either failed to meet or exceeded that standard. Dr. Kasiske provided some examples and illustrated how one could observe the distribution of the probability of how far performance was from the standard.

Standards could be applied to programs with medium-to-large volume, which have a lot of data to apply to this probability. Different thresholds could be set for small-volume programs, which have fewer transplants.

What is currently out for public comment is having two different thresholds to evaluate programs. One is the 1.2 hazard ratio and 75 percent probability that a center exceeded it; the other way one could get flagged is to have a ratio of 2.5 probability of 10 percent that the center exceeded that 2.5 hazard ratio. Again, the former level is really designed for medium- to large-volume programs while the latter covered smaller programs.

One issue that obviously would arise if this goes forward is CMS' Conditions of Participation. SRTR is currently reviewing these algorithm methods with CMS. CMS regulations may or may not be completed at the same time this would be implemented by the OPTN; there could be a timing issue.

Another issue is how to present this to programs and the public in general. Right now, anyone can go on the website and look at programs; this says whether the center's performance is as expected, lower-than-expected, or higher-than-expected, providing a three-tier rating of each program. The SRTR has looked at a lot of different approaches to come up with the most understandable thing for a large audience, and was gravitating towards a five-tier rating system.

The SRTR is also working to provide a lot more data to the centers. It could show their probability, including the probability a center is doing better than expected or doing as expected. The comparisons were popular data. The SRTR could show a program where it was in terms of the hazard ratio for outcomes with respect to the number of transplants performed in this cohort, compared to all other programs.

The SRTR decided to hold off putting in flagging criteria and previewing the performance criteria until the next July cycle, largely because programs are going to have their hands full digesting three programs to submit reports at the same time. They decided to slow things down a bit. Probably on the next July cycle, the SRTR would give a preview of the results along with the current, standard PSRs. The January 2015 release would, if all went according to plan, convert over to the Bayesian methodology. This was all dependent upon acceptance by the OPTN membership's Standard Committee, the Board, etc. The proposal was currently out for public comment.

Discussion

Dr. Barr said that he has received messages from ACOT members who lacked speaker access; this might account for the lack of questions after some of the earlier presentations. He suggested that ACOT members ask their questions after the break. The operator confirmed that all lines are open.

Working Group on Research Barriers Management and Innovation / Donor Management Research Consensus Conference - David Gerber, M.D. & Teresa Beigay, DrPH

Dr. Gerber began the presentation by noting that he was going to provide an update on activities since the last ACOT meeting. Since then, the Working Group has followed up with the Office for Human Research Protections (OHRP), because there are several questions about the problems and challenges associated with doing donor research.

The OHRP is very helpful in addressing primary issues, situations that involve minimal risk, and ensuring there are no adverse consequences to doing donor-related research (and especially adverse consequences for the recipient if he or she does not want to participate in a clinical trial). There are questions of practicality assessment and how a study could be conducted without a waiver, as well as the issue of informed consent as applied to the recipient.

Dr. Beigay noted that a large Consensus Conference is occurring in September and would generate even more information. The ACOT Working Group on research barriers management and innovation and the discussion from the August 2012 meeting were triggers that prompted this Conference. DoT also noticed that several of the national societies have done really

wonderful and foundational work on these issues and felt that DoT needs to look at these issues and reach consensus.

The mechanism for this Conference is a cooperative agreement awarded to the Organ Donation and Transplantation Alliance (ODTA) through a HRSA grant. The conference Planning Committee included representatives from the following organizations: The ACOT, American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), Organ Donation Research Consortium (ODRC), the Alliance, and OHRP. The ACOT was specifically represented by Ms. Glazier and Dr. Gerber.

The conference co-chairs are Peter L. Abt, MD, an Associate Professor of Surgery at the Hospital of the University of Pennsylvania and the Children's Hospital of Philadelphia; Richard D. Hasz, BS, MFS, CPTC, the Vice President of Clinical Services at the Gift of Life Donor Program (he represents the OPO committee); and David Nelson, MD, Chief of the Heart Transplant Medicine Division at the Nazih Zuhdi Transplant Institute's INTEGRIS Baptist Medical Center (representing the transplant community).

The Planning Committee reached consensus on the intent to:

- Align separate efforts in the community to address issues in donor management research
- Leverage these efforts in a unified process to foster examination of donor management methods that can optimize organ yield and function
- Encourage a defined and agreed upon network to share information and improvement regarding the donor management research continuum from the donor setting to the recipient's post-transplant care.

The Conference objectives are to:

- Identify challenges related to donor management research
- Understand the requirements for donor and family authorization and consent
- Identify issues related to recipient consent and reach consensus about appropriate procedures
- Recognize and address consent issues regarding the effect of research on organs that are not receiving the direct impact of the research protocol
- Promote donor management research and consent processes that are satisfactory to donor hospitals, donation community, transplant community, and the public.

Several key, guiding principles run through all of the discussions related to the issues:

- Respect for the donor, recipient, and all families is paramount
- Processes in the donor management research continuum will not threaten public trust in the system
- Donor management studies must not have a high risk of causing a transplantable organ to become unsuitable for transplantation
- The donor management research process should not alter the allocation required by policy.

Three work groups came out of this:

1. Donor-Focused Issues: Address issues related to conducting research in the donor

management setting including consent, family discussion, challenges related to IRB submission/approval, and communication with relevant entities about research protocol effect on organs. The Working Group lead is Ms. Glazier.

2. Oversight: Address Institutional Review Board (IRB) and Data Safety Monitoring Board issues, definition of risk for recipients, allocation and distribution implications for organs affected by research interventions, communication about risk, and possibilities related to a national oversight body and national review body. The Working Group, led by Dr. Sandy Feng, is looking at the national system of oversight.
3. Transplant Center Issues: Address communication about research interventions and possible impact on transplanted organs and outcomes, recipient consent at listing and acceptance, standardized recipient follow-up metrics, and minimizing negative outcome and financial impact on transplant centers. The Working Group is led by Dr. Jeffrey Punch.

There is a lot of overlap in the issues and several areas of intersection. It is interesting that, throughout almost all of the conference calls and preparation discussions, the issues of communication and transparency are key and pervade everything. Dr. Gerber finished by noting that the Conference is being held September 16 – 17, 2013, in the Washington DC area; anybody who is interested in attending should contact the speakers.

Discussion

Dr. Barr said that he would check on participants' ability to ask questions.

Report on the National Pediatric Donation Summit - Tom Nakagawa, M.D.

Dr. Nakagawa presented a summary of the 2013 National Pediatric Organ Donation Summit, which was held on July 24 2013; about 270 people gathered in Fort Worth, Texas, to learn more about pediatric organ donation and share their experiences. More than a year went into planning the meeting and the Planning Committee brought together pediatric intensive care providers, medical directors, hospital leadership, clergy, and others.

Participants met for a day and a half to discuss important issues focusing on pediatric donations with the intent to:

- Provide current information on pediatric donation and transplantation
- Examine ways to collaborate and improve and sustain conversion rates for organ donation
- Identify appropriate clinical management of pediatric organ donors to maximize organ yield
- Discuss recovery and utilization of organs from neonatal donors for transplantation
- Review end-of-life care for donors and donor families.

Importantly, 90 percent of participants were attending the pediatric meeting for the first time. This indicated the significant amount of interest in the subject, and the need for more education in this area. More than 30 percent of the attendees were physicians, including colleagues from Puerto Rico and Canada.

Things have really improved since the last Pediatric Organ Donation Summit in 2011. In 2011, 24 percent of hospitals with 5 or more eligible pediatric donors had a 50 percent or less conversion rate. By 2013, just 5 percent of hospitals with 5 or more eligible pediatric donors had a 50 percent or less conversion rate. In 2011, 73 percent of hospitals with 5 or more eligible pediatric donors had no donation after circulatory determination of death (DCDD) donors; by 2013, only 46 percent of hospitals with 5 or more eligible pediatric donors had no DCDD donors.

Additionally, in 2013, 39 percent of the hospitals with 5 or more eligible pediatric donors had a conversion rate of 75 percent or greater; 20 percent of the hospitals with 5 or more eligible pediatric donors had a 90 percent or more greater conversion rate. There has been a lot of progress the last two years in improving conversion rates and educating pediatric centers about DCDD donation and recovery from DCDD donors. The number of pediatric DCDD donors mirrored the number of adult donors, but on a smaller scale.

The important thing is that deaths on the waitlist have substantially decreased and great progress has been made in this area. Everyone in the pediatric community wants to get below 100 pediatric deaths among those on the waiting list. There was still a need to improve care, however, since almost double the number of children had been removed from the list due to their condition deteriorating to the point that they could not be transplanted.

The Planning Committee invited a renowned group of pediatric leaders to discuss the following topics on pediatric donation:

- Improving the process of organ donation
- Donor management
- DCD donation
- Neonatal donation
- End-of-life care
- Allocation of donor organs

Many of these topics were solicited from participants of the 2012 National Learning Conference's pediatric sessions. The goal was to focus on improving the process of donation, end-of-life care, and the allocation of donor organs. Dr. Nakagawa described each of the presentations.

There was a lot of enthusiasm from the participants and many took action items back with them to work on in their various institutions. The reception at Cook Children's Hospital was a highlight of the event, and enabled participants to visit a really first-class Children's Hospital.

Dr. Nakagawa thanked all of the Planning Committee members who helped pull the meeting together and make things happen. He extended a special thanks to Ms. Bottenfield and Dr. Beigay for their continued leadership. The meeting could not have occurred without the support of the Organ Donation Transplantation Alliance staff and UNOS. He said that pediatrics was just a small portion of the world of organ donation and transplantation, but it was very important.

Dr. Nakagawa also thanked HRSA and Mr. Walsh. There is absolutely no substitute for a face-to-face meeting that brought people together to network, share stories and protocols, and feel

positive energy. The fact that so many physicians assembled for a special meeting like this was a testament to the need for education in this area, and to the interest in getting this education. He encouraged HRSA to continue to support these important face-to-face meetings because they work and help sustain progress.

This issue is important not only for pediatrics but also for all other areas of donation and transplantation. The pediatric community looked forward to working with its partners and seeing continued improvement and sustained results over the next two years. The hope is to reconvene in two years and celebrate success, discuss future plans, and help save more lives through the miracle of organ donation. If more pediatric organs were recovered, even if they were transplanted into adults, it would help the general pool — and especially children.

Discussion

Dr. Barr thanked the speaker for providing a report on what sounds like a great meeting. He noted that he had learned that many participants on the call had tried to dial back in after lunch, which might have caused problems in being able to ask questions. He hoped that all of the speakers would stay on so that they could answer questions in the New Business section of the agenda.

Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Update – James Berger, MS MT (ASCP) SBB, Executive Secretary, ACBTSA

Mr. Berger thanked the ACOT for the opportunity to provide an update on the Advisory Committee on Blood and Tissue Safety and Availability's (ASBTSA) June 2013 meeting. The meeting topic was whether the current U.S. blood center system was designed for optimal service delivery. This was an important topic because there have been a number of mergers and acquisitions among blood centers, which were trying to maintain their viability.

The following questions were addressed:

- What services performed by blood centers currently are considered essential to the U.S. Health Care System?
- How do anticipated changes in health care (business models, economic forces, or advancements in medical care) affect blood centers and the provision of essential services?
- How should the transfusion medicine field be defined in the next decade with regard to population health, better patient outcomes, and reduced costs?

The National Blood Collection Utilization Survey, sponsored in 2011 by the Assistant Secretary of Health along with the CDC, CMS, FDA, NIH, and HRSA, showed a significant drop of about 9.1 percent from the last time the data were available, in 2008. And, there were .2 percent fewer units of blood transfused than in 2008.

While there is a lot of dialogue and discussion, no recommendations were made during this meeting (this was the first ACBTSA meeting that did not result in any recommendations). A subcommittee was formed to explore this topic and make recommendations at a future meeting; it will meet next Friday. The next Advisory Committee meeting was scheduled for December 4 – 5, 2013. The subcommittee will report at that meeting.

Discussion

Dr. Barr thanked the speaker and commented on the continued problems with members being able to ask questions. He proposed that ACOT members take a break and dial back in so they could ask questions, then move to the public comment period.

New Business

Dr. Fung asked what caused the small number of pediatric cases: Did it come from a bias not to refer? Dr. Nakagawa said the reason was multi-factorial and hard to assess. DCDD barriers include hospitals with religious objections to transplantation and physicians with ethical objections. For others, it stemmed from a lack of awareness and a need for more education. The reasons are different from adult centers but good progress had been made in this area.

Dr. Barr asked members to email new business to Ms. Stroup. If ACOT members want to serve on a Working Group or have ideas about new Working Groups, they should also email him or Ms. Stroup. He announced that all of the phone lines are open.

Ms. Stroup announced that all of the slides are on the website along with Dr. Bernat's article. There is a *Federal Register* notice published seeking nominations for ACOT membership. The new members would join the ACOT when the Secretary makes the appointments. She thanked everyone for participating and asked members to send her their agenda suggestions.

Public Comment

Ms. Stroup noted that DoT had not been notified of any members of the public who wished to speak in the public comment period. The next ACOT meeting was going to be held at the end of February or in early March; Ms. Stroup said she would poll the members about the best date possible. Dr. Barr commented that all of the telephone lines were open so anybody (ACOT member or not) could comment at this time.

Mr. Orłowski introduced himself as the chair of the Board of Directors of Donate Life America. He wanted to take the opportunity to comment on the public service announcements, described earlier, and to remind everyone that Donate Life was the national brand and trademark for organ donation. Most of the industry used the Donate Life logo and message for public education. He encouraged HRSA, in the future when it undertook this kind of activity, to brand materials with the Donate Life message. This message had the most recognition nationwide. Dr. Barr thanked the speaker and commented again that the video was impressive and fantastic.

Dr. Barr thanked everyone for participating and adjourned the meeting at 3:30 pm