

ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION (ACOT)
U.S. Department of Health and Human Services (HHS)
Virtual Meeting * January 27, 2015
Summary

Participants:

Voting Members: Mark L. Barr, MD; Charles Alexander, RN, MSN, MBA; Bryan Becker, MD; Sylvia Caley, JD, MBA, RN; Bernice Coleman, PhD, RN; Stephen W. Crawford, MD; James D. Eason, MD; John Fung, MD, PhD; David A. Gerber, MD; Alexandra K. Glazier, JD, MPH; Ana Hands, MD; Eduardo Lara, BA, MHA; Arthur Matas, MD; Jamie Marie Avolio McDonald, MSW, LISW; Kimberly Molina, MD; Thomas A. Nakagawa, MD; Stephen Pastan, MD; Cynthia P. Puryear; Andrew J. Schaefer, PhD.

Designated Federal Official: Patricia Stroup, MBA, MPA

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

Dr. Mark Barr welcomed returning ACOT members and new members. There were many new members. Dr. Barr commented that ACOT has been involved with a very important task. At the face-to-face meeting in March 2015, ACOT will review further details of past recommendations. The Committee has been involved in multiple areas of transplantation and has made seven recommendations to the Secretary of Health and Human Services in the past five years.

After Ms. Patricia Stroup asked ACOT members to introduce themselves and provide information on their backgrounds and whether they were returning or new members, Dr. Barr introduced Bob Walsh, Director of the Division of Transplantation.

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

Mr. Walsh commented that he spoke with new ACOT members this morning and thanked them for providing their expertise to HRSA throughout the year and especially via participating in Work Groups (WGs). He indicated that he and his colleagues in the Division of Transplantation (DoT) do appreciate the participation of ACOT members; and that their input has been invaluable in ensuring that DoT is doing its job correctly.

Mr. Walsh explained that he would first quickly review some issues which would later be presented in more detail and would spend more time on some other items being addressed in his division that were not scheduled for discussion at this meeting.

On December 04, 2014 the Organ Procurement and Transplantation Network (OPTN) implemented the new Kidney Allocation System (KAS). KAS has been designed to reduce the kidney discard rate. It gives priority to certain compatible blood types in order to make more kidneys available for transplant and to extend the period of time within which a transplanted kidney may retain viability. It is also hoped that the new policy will shorten the waiting time for some groups of people with immune systems that make it difficult for them to find a match. DoT has been tracking the implications of this policy change and providing updates to the OPTN Board of Directors on the status of achieving the goals of the change implemented in December 2014. An update on this change will be provided later in this meeting.

Another update will be given on the efforts of the OPTN Liver and Intestinal Organ Transplantation Committee working with the Scientific Registry of Transplant Recipients (SRTR) to revise the OPTN regional structure and decrease geographic disparity for patients with the greatest medical urgency for liver transplants. A concept document about issues being considered by the committee was released by OPTN and discussed at a public forum on September 16, 2014. Mr. Walsh indicated that it was important to receive full input from the community as these issues are tackled within OPTN. More details about these efforts will be provided later during this meeting.

Mr. Walsh next informed participants about TransNet—the electronic tracking and transport project which was developed as part of the U.S. Department of Health and Human Services (HHS) Entrepreneurs Fellowship Program. The DoT proposed working on this issue to improve processes for organ packaging, labeling and transportation with the goal of reducing errors and ensuring that all processes along the chain of control of any organ are as efficient as possible so that organ transplantation is as safe and efficient as possible. David Cartier has been performing due diligence working within OPTN analyzing the process as part of the development of TransNet. TransNet has undergone beta testing by eight Organ Procurement Organizations (OPOs) and general deployment to OPOs is scheduled to begin in March 2015. A Transplant Center prototype application is under development and should start beta testing this summer.

Later during the meeting, Dr. Jonah Odum of the National Institutes of Health (NIH) will provide details on the development of research criteria for transplantation of Human Immunodeficiency Virus (HIV) positive organs into recipients previously infected with HIV. The HIV Organ Policy Equity (HOPE) Act was signed into law on November 21, 2013. That Act removed a prior prohibition on procurement of organs from HIV positive individuals. OPTN is directed to modify its policies to make possible procurement of organs from HIV positive individuals for transplant into persons infected with HIV. The process is to be conducted only under research criteria being developed by NIH. The final rule with the criteria will be published soon with final criteria in place by November 2015.

Mr. Walsh next mentioned the National Living Donor Assistance Center (NLDAC) operated by the University of Michigan under a cooperative agreement which was recently renewed. The NLDAC makes it possible for living organ donors to travel to a transplant center to donate an organ by covering travel and subsistence expenses. The Health Resources and Services Administration (HRSA) will provide funding of up to \$3.5 million annually for up to five years. The NLDAC has facilitated more than 2600 living organ donor transplants since 2007. NLDAC is an example of a tangible opportunity to support living organ donation.

The Organ Donation and Transplantation Community of Practice is the newest iteration of collaborative processes that began in 2003. This effort engages the community in transplantation to develop processes to increase efficiency and donations and to set goals for the community to increase the number of transplants. The Collaborative Agreement with the Organ Donation and Transplantation Alliance ended in December 2014. A new Collaborative Agreement was put in place with the Lewin Group to build on some of the previous Collaborative Agreement. The Lewin Group will work with HRSA and a panel of experts from the community to set new national goals for HHS. Goals from the previous Collaborative Agreement between 2003 and the present time helped increase donations. Those percentage goals are now starting to plateau so new, challenging goals for HRSA and for the community are being defined in order to increase the number of transplants. The Lewin Group will study all the efforts in the community toward this goal of increasing the number of donations and of transplants evaluating performance patterns of the current Donation Service Area (DSA) as a foundation for creating a new national goal to increase the number of organs transplanted. HRSA met with the expert panel last month to identify opportunities. It is hoped that a roadmap will be created out of this process on possible opportunities such as wastage of organs or improvements in the system of communication between OPTN and the transplant centers. The roadmap will be utilized to ascertain how best to use grant opportunities and resources working with the community to increase the number of transplants. Input from the community will be utilized in addressing the culture of donation, authorization and transplanting more organs as well as in identifying specific actions that those in the donation and transplantation community can take toward meeting the national goal.

Mr. Walsh next updated participants on public and professional education efforts which are concentrated in the areas of mass media and the *Workplace Partnership for Life*. The website www.organdonor.gov provides links and information on the process of donating and transplantation for patients and the general public. It also serves as a base for outreach efforts linking individuals to state registries where they can express their intent to become an organ donor. There were over 105,000 clicks from the website to state registry pages in 2014.

TV and radio placement of public service announcements (PSAs) promoting individuals to register with their respective state organ donor registry and talk to friends about donation have aired: 10,981 TV PSAs and 47,179 radio PSAs. The TV media impression earned value was \$3,014,984 with 237,290,398 gross impressions while the radio PSA earned value was \$2,077,297 with 2,452,847 gross impressions. Radio traffic ads also have been purchased. Print PSAs were placed in 69 publications with a total media value of \$655,000. Recently, an opportunity arose for some paid ads to target specific audiences with good pricing and a sports theme. The ads focused on a transplant recipient, Chris, who restarted his sports career as a triathlete after undergoing kidney transplant. Those ads were placed in the Major League Baseball (MLB) National League and American League Championship Series programs, in the MLB World Series program, the National Football League (NFL) Pro Bowl and will be placed in the NFL Super Bowl program and in the National Basketball League All-Star Game program. Facebook Page fans increased from 60,000 to 180,000 and social media campaigns generated 55 million impressions. Other opportunities for outreach primarily through Facebook are being explored. It is anticipated that Facebook fans will help further push out the message about the great need for organ donation to their friends and families. On Facebook, the message is disseminated using interesting graphics and videos. One of the most successful digital videos was, "Organ Donation and Transplantation: How Does It Work?" which was viewed more than 52,000 times on Facebook and on YouTube. It is believed that those viewing numbers are conservative and that the video has been shared many more times. The message expresses to the community how important organ donation is and how simple it is to register to become an organ donor and share the gift of life. Another outreach effort is Walgreen's offer to place organ donation messaging on the back of over 51 million prescription receipts across the country just in the past year. Walgreens also placed a web banner on their website, www.walgreens.com Since April is "Donate Life" month, new "Donate Life" ads will be on the radio and in print and videos will be on Facebook. These ads are focused on the need for pediatric organ donation via personal stories of younger people who benefitted from organ transplantation. Three young heart transplant recipients have shared their stories in compelling videos which will be rolled out in the coming months.

The DoT has worked with a number of partners in the Workplace Partnership for Life (WPFL) initiative to engage community gatekeepers such as educational institutions, businesses, medical facilities, faith communities, etc. to share donation messaging with their communities on organ, eye and tissue donation. A contractor helps put these materials together from PSAs and other messaging to get those out to thousands of persons. A recent campaign in the WPFL launched in 2011 focused on hospitals with the goal of increasing registry enrollments. In the first three years more than 300,000 confirmed registrations to become organ donors on state registries have been tracked. Phase IV began in September 2014 with a goal of 100,000 registrations by April 30, 2015. Current partners include 1146/4471 hospitals, 26/52 state hospital associations, 156/247 transplant centers, 58/58 OPOs and 11 national partners. Support from ACOT and from corporate partners is necessary to help get the message out.

OPTN Update—

Brian Shepard CEO, United Network for Organ Sharing (UNOS); David Klassen, MD, CMO, UNOS; Maureen McBride, Ph.D., CCOO, UNOS

Mr. Shepard thanked Dr. Barr and ACOT Members for this opportunity to speak with them. He then updated participants on OPTN strategic planning efforts. Currently, OPTN has been working from a 2012 Strategic Plan. Most of the items in that plan have now been accomplished and it is time to design a new plan for the 2015-2018 timeframe. OPTN began its strategic planning by soliciting input from the donation and transplantation community at five regional meetings to date and in preliminary discussions with the Board of Directors. In the coming months, OPTN will work with the Executive Committee in a drafting session and will then ask for comments from the transplantation community in the spring and then present the plan to the Board for further discussion and approval in June 2015. The 2012 Strategic Plan lays out six goals. The first four goals have been in every plan created by UNOS for the past 30 years: "Increase number of transplants; Increase access to transplants; Improve survival for patients post-transplant; Promote transplant patient safety." The goal of "Living Donor Safety" was broken out as a separate goal about ten years ago since it was deemed to be very important. Managing system efficiency was named a specific goal in itself in 2012. Mr. Shepard added that UNOS goals are to be the OPTN

contractor serving members' needs and being a world leader. Discussions with the community asked if these goals are the right ones going forward and if any changes are needed. Feedback received did not stipulate that changes should be made in the goals although there was some discussion about the goal to "increase access to transplants." That goal pertains to equity or fairness. The wording of the goal may need to be updated although the underlying strategy of that goal would remain the same.

Mr. Shepard next detailed current community projects by strategic goal explaining that all projects must support the strategic plan. Mr. Shepard showed a slide with bar graphs depicting percent of current resource allocation broken out according to each of the six strategic goals. There is no priority order to the six current goals. The system is built on the community and is responsive to the community's needs and to HRSA requests; there has not been a strategic decision on the front end about where the new projects ought to be considered. Recently, more time has been spent in the area of patient safety. The liver access project has taken much time as have computer efficiency projects that are underway; those are worthy goals, but those came to OPTN rather than OPTN intentionally pursuing those activities as part of achieving its goals. Discussions were held with the community, the Board and the ACOT about whether some of these goals are more important than others and where the most "bang for the buck" can be achieved in a fairly short time period. Some things might move closer to the top while others might move down in terms of priority order, but OPTN will not move backward on any of the goals. The Board said that more transplants is the most important goal and where committees' and staff and IT resources should be spent. There has been a flat number of transplants over the last few years so that recommendation reflects this fact. The Board prioritized the goals as follows: More transplants, access, survival, patient safety, living donor safety and efficiency. This map of the goals is similar to that received from regional and from committee meetings.

At the November Board meeting, the Board reviewed a summary of regional discussions and conducted a straw poll on prioritization. The Board talked about the over-emphasis on outcomes at the expense of volume which has the potential to harm patients. If the metrics are discouraging transplants, that result also puts patients at risk. The trick is to get the balance of the goals right. The Board thinks that OPTN is currently promoting outcomes over increasing the number of transplants. This input is important as part of the planning process. On March 2, 2015 in Richmond the Executive Committee will meet and discuss fleshing out the priorities and draft a proposed Strategic Plan, but it is clear that the focus is to make more transplants happen. The regions and the public will comment on the proposed plan in the spring and the Board will meet in June 2015 to review and approve the new Strategic Plan.

Mr. Shepard informed participants that there is now entirely new leadership in the IT department since the ACOT last met. The Chief Technology Officer and his whole second level of leadership in the department are all new. This is an indication of the increase in volume in that department. There were two IT projects in 2013; six IT projects in 2014 and twenty-seven IT projects are planned for 2015. Therefore, the IT Department has been retooled and has new energy. Focus has also been placed on the user experience and a new Customer Council has been formed so the IT staff can hear directly from those using the technology.

OPTN partnered with HRSA on the TransNet Project. Mr. Shepard acknowledged the involvement of David Cartier and Chris McLaughlin in this activity. The original project started in December 2012 with goals of reducing incorrect transplantation, minimizing transplant errors, accelerating organ information transfer and capturing organ procurement/transport data. This organ validation, labeling and tracking system helps streamline the process and get organs "out the door." Ultimately, an electronic check-in system will be at transplant centers to make sure organs have been sent to the correct recipients. A voluntary roll-out of the system will take place soon. OPTN is providing three-day, high-level training sessions in Richmond to teach OPO staff how to use the software. Spring training sessions are already full and summer and fall training sessions are being scheduled. TransNet covers the entire process from the donor management phase of sending serology specimens from the Intensive Care Unit (ICU) to printing on-demand labels, to scanning and shipping organs with the ability to track their transport to the end goal of receiving the organ at the transplant center. This product will help minimize transportation problems, minimize errors and get information from one place to another faster. It is more than

packaging and labeling. This project helps streamline the process and it will be further discussed at the March 2015 ACOT meeting.

Mr. Shepard next presented information on the Deceased Donor Potential Study (DDPS) conducted by the Lewin Group. More detail will be provided at the March meeting, but Mr. Shepard provided a brief overview for participants. The study objectives were to accurately characterize the current size of the potential donor pool, predict the size of the donor pool in the next 5-10 years, provide an empirical foundation for national goals and inform strategic planning processes. The study found that there is a significant donor potential which is not uniformly distributed by donor age or geography. The majority of donor potential is in the older population, i.e. seventy percent are greater than 50 years old. The study findings predict that there will be minimal growth of donor potential through 2020 (i.e. about five percent over the 2010 estimates). Therefore, in order to make substantial changes in the number of donors, that older age group needs to be the focus of efforts in OPOs and transplant centers to increase the number of transplants; we cannot rely upon finding new donors based just upon population increases. The DDPS suggests the following: OPO performance metrics must be changed since the current systems provide a disincentive to increasing organ volume; Policy must be changed in order to increase timely, complete hospital referrals; Transplant Center performance metrics must also be changed in order to reduce risk averse behavior; Less than ideal donors must be shared more broadly; Maximizing results may require multiple interventions; OPOs, OPTN, transplant programs, HRSA, Centers for Medicare & Medicaid Services (CMS) and patients all need to take action. Mr. Shepard mentioned that it might be useful to look at how OPOs and transplant centers align. Although hospitals are outside the purview of OPTN, they are influenced by some other organizations involved in donation and transplantation. It might be useful to see if some of the OPTN metrics discourage transplant centers to do transplants. The system could be improved all along the chain. Findings from the DDPS will be released officially at the next ACOT meeting. The report suggests looking at registration, referrals at OPOs and the transplant center process as well as the OPTN system; in other words, look across the system. The study does not pinpoint any silver bullet fixes or blame specific players for not meeting the need.

KAS Implementation Update—David Klassen, MD (CMO, UNOS)

Dr. Klassen updated participants on implementation of the Kidney Allocation System (KAS) which went live on December 4, 2014. UNOS is tracking some of the data elements used by the system to look for unintended events as a result of implementing KAS. Dr. Klassen presented some slides with data on predicted changes that have occurred since implementation. These data are also on the OPTN website and that information will be updated over the course of the first year.

Initial data on pre versus post KAS implementation deceased donor kidney recipient characteristics show a decrease in donor and recipient age mismatch, i.e. a difference in donor and recipient age greater than 15 years. This is an intended outcome of the KAS revision and is a result of longevity matching. There is also a significant increase in geographic sharing of organs. The percentage of non-local transplants rose from about 25% to 35% in just the first month of data. This is due to priority given to high Calculated Panel Reactive Antibodies (CPRA) recipients which was a major goal for the new system. Transplants of patients with CPRAs of 99 and 100 are given strong priority in the system and the percentage of those transplants rose from about 2.5% to 17.4%. That was one of the goals of the revised system. There may be a bolus effect in that a lot of those patients have accumulated on the list and that percentage may gradually change. There was a small decrease in the percentage of kidney transplants allocated to pediatric recipients. It is not clear if that number is accurate and this data element will be carefully monitored. Although the data are limited at this point it appears that the percentage went from 5.1% to 2.2% in the first month.

In terms of kidney recovery and discard rates, there was no significant difference in the number of kidneys recovered. The kidney discard rate is being monitored. In the higher Kidney Donor Profile Index (KDPI) group of 86-100, the number of donors recovered is the same. Overall, the kidney discard rate appears to have increased from about 17% to 22% and this element will be monitored.

In summary, overall, in the first month of implementing KAS, there is no change in the number of deceased kidney donor transplantations. There were fewer zero-mismatches (8.4% went to 5.2%) probably due to the higher KDPI or CPRA transplants done. There was a slight drop in registrations, which might be a registration issue. There was also an increase in the 18-49 age group getting donations. The system will be carefully monitored over the next month and, again, information will be posted on the OPTN website. There are no sharp changes in transplants geographically as measured by regional variations. There has been a slight drop in the number of kidney registrations which may just be due to the small sample size. This is not an issue at this point and it will be monitored on a regular basis. There are other factors which are also being reviewed. There has been an increase in the percentage of younger patients being transplanted, i.e. in the 18-49 age group compared to the greater than 50 years age group.

Dr. Klassen concluded this part of his presentation saying that the system will be monitored carefully over the next month. He again mentioned to participants that they can check the report on the OPTN website.

Redesigning Liver Distribution to Reduce Geographic Disparity— David Klassen, MD (CMO, UNOS)

Dr. Klassen next updated participants on the major effort underway to redesign liver distribution and reduce geographic disparity. In June 2014, the Liver Committee released a concept document looking at redefining boundaries to reduce the median Model for End-Stage Liver Disease (MELD) score at transplant. The median MELD at transplant was identified as potentially a good metric to look at disparity. There has been robust feedback to this concept document. A Public Forum was held in September 2014 in Chicago. It was well attended—the largest event historically that UNOS has hosted. Based upon feedback received, three Ad Hoc Subcommittees were formed to work on: Metrics of disparity and ways to optimize distribution; Financial issues related to alternative sharing methods; Logistics and transportation issues associated with potential broader sharing. The Subcommittees are currently meeting and will develop additional recommendations which will be shared with the broader transplantation community and the public. Another Public Forum will be held in late spring 2015.

Update on Vascular Composite Allografts (VCA)-- David Klassen, MD (CMO, UNOS)

Collaboration with HRSA on an OPTN Final Rule and VCA began in 2008. The final rule in the Code of Federal Regulations was amended in December 2011 to include VCAs as a “covered human organ” in the final rule which became effective in July 2013. The consensus of VCA physicians and surgeons was that incorporating VCA under OPTN was appropriate since clinically VCA has similar characteristics to solid organ transplantation rather than to tissue which is regulated by the Food and Drug Administration (FDA). The amendment included nine criteria that must be met for a graft to be considered a VCA. If all nine criteria are not met, the graft is classified as human tissue regulated by FDA. OPTN was charged with formulating policies for VCA transplantation prior to implementation of the final rule modifications on July 3, 2014. UNOS/OPTN formed a national VCA Transplantation Committee last year which is working on policies and program guidelines and how to list patients and do distribution and data collection. Dr. Klassen presented a map showing geographic locations of approved VCA transplant programs as of January 09, 2015. There are now more than 21 active programs distinguished according to whether or not they have active patients currently on the waiting list. Official OPTN oversight of the program began in July 2014. In the period of time since July 2014 there have been two craniofacial transplants, one bilateral upper limb transplant and one unilateral upper limb transplant. This is not the full scope of what has occurred over the past years preceding OPTN oversight. Approximately eight face transplants have been done and about thirty upper extremity transplants have been done. Guidelines will likely be amended and updated going forward.

OPTN/UNOS KPD Pilot Program Update—Maureen McBride, PhD (CCOO, UNOS)

Maureen McBride presented an update on the OPTN Kidney Paired Donation (KPD) Pilot Program. The Pilot Program began in late 2010 when the first KPD match runs with transplants took place. The first

phase of programming around KPD—UNet KPD—with increased technical capabilities and more integrated programming was released in 2011. The Board approved Policy 13 for participation in the KPD Program a year later (2012) and Policy 13 was implemented early in 2013. In 2014 the Board of Directors made KPD a free-standing program within the network. At the June 2014 Board meeting the Board of Directors voted to remove the “Pilot” label from the OPTN/UNOS KPD Program and make it permanent. Currently, OPTN/UNOS is awaiting HRSA approval of the permanency of the KPD Program.

Note:

ACOT approval is critical to move that decision forward.

Ms. McBride next provided an overview of the KPD Pilot Program (KPDPP). To date, one hundred twenty seven total transplants have been facilitated, five transplants are scheduled and nine are either accepted or pending cross-match results. The number of transplants has greatly increased since the KPDPP was instituted in 2010 rising from two in 2010 to fifty-two in 2013, forty-six in 2014 and two already as of January 23, 2015.

In terms of governance and policy development, the OPTN/UNOS KPD Program will be governed soon only by policy. The Board approved priority points and the KPD waiting time reinstatement proposal in June 2014, effective September 1, 2014. In November 2014, the Board approved the KPD histocompatibility testing requirements proposal which is scheduled for implementation in 2015. Two proposals were distributed for public comment in the fall of 2014. One proposal pertains to Informed Consent for candidates and KPD donors. That proposal was sent through the Joint Societies Work Group process to ensure maximum input from the transplant community. The second proposal concerns additional KPD operational guidelines to be moved into policy, e.g. responsibilities of KPD contacts and the donor pre-select requirements for candidates with a CPRA greater than 90%. Feedback has been positive and the KPD Work Group and Kidney Committee are currently discussing whether modifications to these proposals are needed before presenting them to the Board for approval at the June 2015 meeting.

In terms of KPD system development, Ms. McBride reported that an automated KPD system has been successfully implemented. It is user-friendly and data entry is intuitive allowing transplant programs to manage their pairs and create reports. Transplant programs are able to view and respond to match offers in UNetSM. The contact information for the matched center and the entire exchange can be viewed with the match offer. Each transplant program has its own center-specific dashboard to check eligibility of their pairs for match runs. They can also view the number of candidates with donors in need of pre-selection and manage any bridge donors they may have. The system automatically sends match offer emails to primary contacts at transplant programs. Additionally, transplant programs may complete the donor pre-select in order to make the match process more efficient. The donor hospital may upload the entire donor medical record at the time of the match offer; it is easy to view. The KPDPP tries to respond to user feedback and make enhancements, accordingly. Since the community was interested in more frequent runs, this past summer the match started running twice a week on Mondays and Thursdays. The KPD Work Group is currently prioritizing future enhancements to the KPD system. Among the proposed enhancements is a message board to facilitate inter-hospital communication. Such enhancements will be prioritized individually in the overall OPTN/UNOS IT queue. A project already in the queue is the “data streamlining project.” The KPD Work Group reviewed all donor and candidate data entry fields and offered suggestions to make data entry easier for users by hiding optional fields.

HOPE Act Update—Maureen McBride, PhD (CCOO, UNOS)

Ms. McBride updated participants on the status of implementing the HOPE Act for OPTN. The Act was passed in November 2013. Following passage of the Act, the OPTN formed a Work Group to evaluate policy considerations in preparing for implementation. Representatives from the OPO Committee, Disease Transmission Advisory Committee, Operations & Safety, SRTR and HRSA were on the Work Group. The first public comment period was September through December of 2014. That public comment proposal in the fall of 2014 removed the prohibition on the recovery and transplantation of HIV positive organs. The second round of public comment opens now and runs through March of 2015. This

public comment proposal contains additional changes to the language proposed in the new section 15.3, moves section 15.3 to 15.5 creating an open variance for the recovery and transplantation of organs from HIV positive donors, revises the requirements for allocation of kidneys and livers under the policy and updates terminology (serology is updated to infectious disease testing results). The Work Group develops proposed policy changes through two rounds of public comment. All the currently proposed policy changes will be reviewed by the Board at the June 2015 meeting. There may be another public comment period in the summer of 2015 once the final criteria are available.

Ms. McBride informed participants that programming to implement the HOPE Act will impact most of the UNetSM system. The membership database will need to be updated for transplant hospital approval. Donor screening and the wait list will need to be changed to incorporate donor and candidate screening. The match system will need to be changed to incorporate screening into the match list. It will also be necessary to limit the OPOs' ability to only run liver and kidney matches if they have an HIV positive donor. In summary, a significant programming effort will be needed. The IT personnel have planned for this implementation which will require a significant amount of resources in order to implement the HOPE Act this year. The public comment period opened on Tuesday, January 27, 2015 at <http://optn.transplant.hrsa.gov> and runs through March 27, 2015. The public comment section on the website allows reporting in blog style and is open to the public and provides transparency. Comments will be moderated and posted in a timely fashion. The blog can be "liked" similar to Facebook. The goal is to facilitate a more open public comment system. Topics for public comment this cycle include the following: Re-execution of the match when donor information changes; Report aborted living donor recovery procedures; Membership requirements for intestine programs; HOPE Act requirements; ABO verification policy; Modification to internal vessels label; Individual wait time transfer process; Pediatric training and experience requirements; Collection of perfusion data for lung recipients; Membership requirements for VCA programs.

Ms. McBride closed her presentation asking participants to check the OPTN website for these proposals and to provide feedback.

Discussion

Question #1—Elimination of Donor Service Area (DSA) as first unit of allocation:

Dr. James Eason commented that he is familiar with the ongoing efforts of the OPTN Liver and Intestine Organ Transplant Committee and the public forum. Three years ago the ACOT recommended eliminating DSA as the first unit of allocation. The goal was to make a change to remove geographic boundaries. Dr. Eason asked if the presenters could comment on progress being made on that recommendation?

Response

Dr. Klassen responded that within the liver distribution plan the first step in trying to reduce geographic disparity was Share 35 where high MELD recipients were given priority under a regional basis. This has been ongoing for a period of time and has been successful in getting transplants more successfully. The analysis of the effects of that policy has been ongoing. That Various Subcommittees are looking at effects of Share 35 in terms of costs and effectiveness to see if it has implications for broader sharing.

Additional Comments

Dr. Eason responded that he knows Share 35 was enacted and it seems to be successful, but it does not address the DSA as an arbitrary unit of allocation except for that small group of patients. Dr. Klassen added that the Liver Committee concept document recommends going beyond Share 35; that is part of that broader conversation. Mr. Bob Walsh said he would like to speak to the context in which OPTN is handling implementation of that recommendation to remove DSA as the first unit of allocation. When that recommendation was made, OPTN was encouraged to take steps to talk about concepts from the Liver Allocation Committee and the Public Forum, etc. and to do due diligence before making changes to policy. Mr. Walsh said he understands that that recommendation is being handled through activities of OPTN discussions mostly in Liver, but also identifying how to move forward. Dr. Eason said he was aware of the complexities of this process and recalled that the recommendation was not specific to liver; it could be applied to kidney or other organs. He expressed concern that the entire liver redistribution plan

is still missing that point which could be an incremental change done prior to redistribution on a much broader scale. Dr. Barr commented that this was a big topic at the American Society of Transplant Surgeons (ASTS) Winter Symposium held a week ago. He suggested that this topic could be added to the agenda for the March meeting. There are pros and cons to this recommendation not only for liver, but for other organs as it relates to a lack of unified recipient criteria. He added that a lot of programs have a problem if you talk about sharing so there are positives and negatives. This is very complicated. Dr. Barr added that, as Bob Walsh just mentioned, the OPTN Liver and Intestine Organ Transplant Committee is clearly trying to be responsive to this. Dr. Barr suggested that a better discussion of this topic could be done at the upcoming two day meeting in March. This is certainly something about which everyone is aware. He assured Dr. Eason that his concerns are heard, "loud and clear."

Dr. Barr said it would be possible to come back to any questions during the discussion session at the end of this meeting.

Dr. Eason thanked OPTN and UNOS presenters. He said that he was aware that this topic is contentious and he did appreciate their moving slowly and thoughtfully on this recommendation.

Follow-up:

1. Please put the topic of the recommendation to remove DSA as the first unit of allocation on the agenda for the ACOT meeting in March.

**CMS/HRSA Harmonization—Danielle Cornell, RN, BSN, CPTC (LifeQuest),
Chris McLaughlin (HRSA); Daniel Schwartz, MD (CMS)**

Dr. Barr opened this session with some brief background information for new ACOT members. The CMS/HRSA Harmonization Work Group's efforts eventually led to Recommendation 55 from the ACOT a couple of years ago. Dr. Barr then introduced Danielle Cornell who recently rotated off the ACOT and was instrumental on the Harmonization Work Group as were Chris McLaughlin of HRSA and Dan Schwartz from CMS. Dr. Barr added that there will be more time to discuss the harmonization effort at the face-to-face meeting in March. He then turned the meeting over to Danielle Cornell for her presentation.

Background—Danielle Cornell, RN, BSN, CPTC (LifeQuest)

Danielle Cornell opened the presentation with a review of the timeline on progress since ACOT Recommendation 55 was published. The topic of the realignment, now termed harmonization, came up at the 2010 ACOT spring meeting. The ACOT believed that the CMS performance metrics for OPOs and Transplant Centers conflicted with one another as well as misaligned with the HRSA goals as outlined in what was then known as the "HRSA Organ Donation and Transplantation Breakthrough Collaborative." Essentially, these are regulations and goals that can penalize an OPO for pursuing marginal donors and can penalize a transplant program for the use of marginal organs. And yet the goal at the time was, "Every organ, every donor, every time." Ms. Cornell stated that her overview was a real simplification of the background shortened due to time constraints. The Harmonization Work Group was formed in the fall of 2010 with representatives from the areas of organ transplantation and donation including ACOT, ASTS, CMS, HRSA and other organizations. The Work Group agreed that when CMS performance metrics were published they may have been the best solution at the time, but much had been learned in the interim so the performance metrics needed to be aligned and maximized. The Work Group developed a comprehensive recommendation which was approved by the ACOT in August 2012. A letter with the final version of Recommendation 55 was then sent to the HHS Secretary in September, 2012. Recommendation 55 is now two and a half years old. Recommendation 55 reads as follows:

The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to

confer with the OPTN, SRTR, the OPO community, and TC representatives, to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs. The ACOT recommends that this review be completed within one year and that action be taken within two years.

Follow-up on progress regarding implementation of Recommendation 55 was provided at ACOT meetings in March and September of 2013.

Update on HRSA/CMS Alignment Activities—Christopher J. McLaughlin (HRSA)

Mr. McLaughlin reported that in keeping with ACOT Recommendation 55, HRSA and CMS have been jointly working for several years on harmonizing oversight and regulation of transplant centers and OPOs. They created a crosswalk of transplant center requirements in the CMS transplant center Conditions of Participants and the OPTN Bylaws and Policies. The crosswalk will be useful in modifying OPTN and CMS requirements and in surveying processes to find areas that are similar although not identical. The findings may lead to subsequent modifications of OPTN and CMS oversight activities. The crosswalk specifically identifies requirements which are reviewed by OPTN and CMS during site visits to transplant centers as well as similarities and differences between the organizations in how areas for site visitor review are approached. This provides guidance for the transplant centers about how each organization views these areas. Identification of differences has led to changes in the process by both organizations. An updated version reflecting changes was posted last summer on the OPTN website. A plain language rewrite of OPTN policies was done in 2014. CMS and HRSA committed to continual review of that document and are discussing possibly developing a similar document for OPOs, i.e. an OPO requirement crosswalk.

Mr. McLaughlin next updated participants on OPTN activities related to the HRSA/CMS harmonization effort. The first edition of the crosswalk highlighted one area with significant overlap in requirements: Review of living donor policies. HRSA and CMS began discussing possible joint surveys in that area. HRSA and OPTN/UNOS staff attended CMS surveys and CMS staff attended OPTN surveys. In this process, OPTN developed a set of new policies for living donor kidney programs that cover some areas not covered by CMS. At the end of this process it was clear that although some requirements are similar, a joint review would not work. HRSA and CMS revised the crosswalk to reflect the differences. HRSA has since worked with UNOS on the feasibility of combining the two OPTN on-site reviews into a single survey. OPTN Living Donor Review is separate from the Stand-alone Kidney Transplant Program Review. The Living Donor Review is more process-driven while the Transplant Program Review is more data-driven. The OPTN tested a combined on-site review for Living Donor and Stand-alone Kidney Programs and performed six such reviews in 2014. OPTN has also tried combined reviews for Living Donor and Multi-Organ Transplant Programs conducting nine of those reviews in 2014. Many lessons were learned in from this process. HRSA and OPTN will continue experimenting with the feasibility of combined reviews, but feedback to date has been mixed. Some programs like the joint survey while others find it too resource-intensive. Mr. McLaughlin concluded his presentation saying that HRSA and CMS are continuing to learn from the crosswalk process to identify changes as OPTN revises its policies and CMS does the same. They will continue to evaluate ways to improve the survey process in order to make it easier for the centers. The reviews are different in nature and require different skill sets on the part of reviewers.

Update on HRSA/CMS Alignment Activities—Daniel Schwartz, MD (CMS):

Dr. Schwartz updated ACOT on harmonization efforts from the CMS perspective. He stated that since ACOT Recommendation 55 was published, CMS uses it in much of their work to reduce the burden on OPOs and on Transplant Programs. CMS wants to be in alignment with HRSA and OPTN.

Since Recommendation 55, CMS has made regulatory changes as follows: Revision to OPO Outcome Requirements in the Conditions of Coverage; Change in survey intervals; Mitigating factors. Those changes may not always significantly impact daily practices, Dr. Schwartz commented, but there have been some significant changes. CMS had a recertification cycle of three years meaning every Transplant Program needed a survey every three years. That was changed a couple of years ago to every three to five years which is a significant increase in the interval of surveys for Transplant Programs. The Outcome requirement in the Conditions for Coverage was changed for Transplant Programs in late 2013. Previously, the Conditions stated that Transplant Programs had to meet all three outcomes measures or they would be de-certified from the program. HRSA and CMS collaborated with participation from the Clinical Standards Group at CMS and changed the regulation to say that if an OPO or Transplant Center meets two out of the three outcomes measures the OPO or Transplant Center can stay in the program. Dr. Schwartz added that HRSA and the OPO community helped CMS to make this change; otherwise they would have decreased the number of organ transplants. The final regulatory change pertains to the Mitigating Factors requirement. If a Transplant Program is out of compliance, they can apply for Mitigating Factors at CMS to ask that the program be granted Mitigating Factors status and remain in the program or go into a year-long quality effort to stay in the program. CMS wanted to recognize innovative programs in the transplant community so if a program were doing something innovative, but was out of compliance with the program it would be possible to separate out that group of patients and help the program stay in the system. The Mitigating Factors regulation also pertains to harmonization. The OPTN method to calculate survival is a Bayesian analysis of outcomes which is now utilized for the Transplant Programs to check outcomes measures while a program is being evaluated for compliance.

Dr. Schwartz next discussed changes related to survey activities. He explained that CMS surveys are unannounced while UNOS surveys are announced. CMS is comfortable that it covers Living Donor Regulations in its surveys and will make no changes in its approach in this area. HRSA continues working to decrease one survey on the UNOS side. CMS introduced a Focused Quality Assessment and Performance Improvement (F-QAPI) Survey. These surveys are few in number—twenty or less per year. CMS may use those as part of the recertification survey and would love to have few stand-alone F-QAPI surveys. They are working on the proper place for that survey. Friday, January 30, 2015 CMS will hold a Webinar on the F-QAPI Survey and the Mitigating Factors Policy change.

Dr. Schwartz informed participants that CMS meets regularly with Christopher McLaughlin and his HRSA team every two weeks. Over the last six months, they have started improving the Clinical Compliance Group and discussions with HRSA include how CMS regulatory changes could affect OPTN as well as how OPTN changes could impact CMS regulations and the impact of changes on the OPOs and the transplant community. Discussions also cover how to minimize any potential impact of a change. As the harmonization efforts move forward, staff in the CMS Clinical Standards Group talk about OPO regulations; their input in these joint meetings is important in order to make sure everyone is on the same page. Additionally, in many forums feedback was received asking about how to align regulatory outcomes measures for Transplant Programs and OPOs. A lot of work is going on in this area and suggestions are welcome. The best place to start is with recommendations from the community on how to best write new regulations. CMS is open to this input and has talked to professional organizations about this issue and stands ready to continue such discussions.

Mr. McLaughlin added that in this harmonization effort, HRSA and CMS will work with the ACOT on an in-depth review and reform of the performance metrics for OPOs and Transplant Centers. The ACOT is a good venue in which to talk about the history of some of those metrics and how those are used and intended. There are limitations to those metrics despite the fact that they have been updated over the years. Those metrics rely on data and data can be flawed. Mr. McLaughlin welcomed a public discussion on the best metrics going forward to improve system performance as well as discussion of data and potential new sources of data and broad discussion of the best and most appropriate metrics going forward to monitor system performance. Mr. McLaughlin said he looks forward to having an in-depth discussion.

Discussion

Dr. Barr thanked Dan Schwartz, Chris McLaughlin and Danielle Cornell for their presentations. He clarified for new ACOT members that some presentations are informational while others help identify areas where ACOT can be of help. He asked Mr. McLaughlin and Dr. Schwartz to communicate to ACOT if there are things with which the Committee can be of help after Recommendation 55 although he does not see any further recommendations in the near future on this issue. Dr. Barr added that there has been a conversation with Thomas Hamilton and his people. For the March meeting, Dr. Barr hopes to have an informational session to bring everyone up to speed on that philosophy. He also mentioned that participants who are members of ASTS or AST have received information on the upcoming webinar. That information was sent out from each respective organization. Participants who are not ASTS or AST members could request information on how to join that webinar.

Follow-up:

1. Please add a discussion of the CMS/HRSA harmonization efforts to the agenda for the ACOT meeting in March.

Discussion-Work Group on Performance Metrics

Danielle Cornell commented that it seems that HRSA and CMS would like the ACOT to work on performance metrics for OPOs. She asked if that effort would involve a Work Group similar to the original Work Group that worked on this issue or if it would just be the ACOT?

Bob Walsh responded that from his perspective it would be helpful for the ACOT to talk about revitalizing the Work Group on Harmonization Issues. He said there is interest in engaging with ACOT on these issues and looking at some metrics and having more detailed conversations on those. He noted that a lot of the work really happens in those Working Groups. Many of the Work Group members have rotated off the ACOT. Mr. Walsh suggested that perhaps the ACOT could talk about which members would like to serve on that Work Group so he and his colleagues at HRSA will know to whom to reach out to have these discussions in-between the full ACOT meetings.

Charles Alexander commented that the goal of this ACOT Work Group would be not just harmonization of CMS and HRSA regulations, but harmonization of multiple groups of people now working on this. The ACOT leads the list in terms of having the authority to make changes and having the ear of the Secretary and participation of CMS and HRSA simultaneously. Mr. Alexander added that UNOS, OPTN, organ-specific groups, the OPO Committee, and AOPO are all interested in identifying better metrics and risk adjustments that would lead to the goal to increase the number of transplants. ACOT may advance the work of groups already looking at this.

For those new to the Committee, Dr. Barr explained that the way the Work Groups have been functioning for the last three to five years is to look for interested voting members of ACOT and *ad hoc* members and reaching out to experts who are interested. He said that even though Danielle Cornell has rotated off the ACOT he hoped she would still be very much involved in this effort. This is the standard operating procedure for other Work Groups—we reach out to people. He informed participants that the other reports they were going to hear today would all be in that mode where the Co-Chairs of these Work Groups are not ACOT members, but have expertise. Dr. Barr added that what Charlie Alexander is saying about not reinventing the wheel is something ACOT definitely does not want to do, but if there are things that Chris McLaughlin, Dan Schwartz and Bob Walsh feel the ACOT could actually help through the process, we would put that on the agenda for that Work Group. Also, a Work Group could morph into a different Work Group than the one that originally led to Recommendation 55.

Danielle Cornell commented that she would like to assist that Work Group in the future. Dr. Barr thanked her for staying involved in this effort. The ACOT may be a vehicle for advancing the work.

Follow-up Item:

1. Interested ACOT voting members and *ad hoc* members and others who are interested may form a Work Group to address issues related to harmonization of oversight and regulation of OPOs and Transplant Centers. Danielle Cornell would like to be involved.
2. Christopher McLaughlin, Dan Schwartz and Bob Walsh should communicate (perhaps to Pat Stroup) items with which the ACOT could be of help and those could be put onto the agenda for the Work Group on Harmonization.

Donor Management Research and Innovation—David Gerber, MD

Dr. Barr introduced Dr. David Gerber, Co-Chair of the Work Group on Donor Management Research and Innovation to summarize the work of that group to date and its goals.

Dr. Gerber presented a summary of the efforts to date of the Donor Intervention Research Expert Panel adding that more time can be spent on this issue at the March meeting. The Expert Panel has been working for one and a half years. Dr. Gerber commended the contributions of Alexandra Glazier who wears many hats in the ACOT, OPO and transplant communities. Ms. Glazier and Dr. Barr have directed the Expert Panel to others outside of the ACOT with expertise that has been helpful.

Dr. Gerber reported that the Donor Intervention Research Expert Panel has had several conference calls and has participated in two meetings coordinated through HRSA and several other organizations (i.e. not through this Work Group). The basic issue is how to successfully conduct innovative research involving deceased donors in order to ultimately expand donor activity and transplantable organs. This is complex. Dr. Gerber informed participants that certain trials have been done, but we do not really have an established mechanism and the concern in the community as we have seen the evolution of the donor population is that we need to think of ways to do the research that will allow us to expand the potential quantity and quality of transplantable organs that will meet the needs mentioned in earlier presentations.

The Expert Panel has identified three key focus areas to move this process forward. The first area is development of protocols and oversight. In this area some of the questions concern key elements, how information is shared, where an investigator's study should be conducted (i.e. hospital, OPO, etc.). Additionally, who provides oversight in this area of research activities? Oversight and conduct for human subject research are clear, but this is not in that category of research. The second area identified is donor-focused issues such as authorization for research and ethical considerations. The third area identified includes the Transplant Center and recipient issues, the ability to get consent and what that means, risks to the recipient and to the Transplant Center and questions such as whether the research could be done on a broader level without jeopardizing patients or centers trying to expand transplantation.

The last Donor Intervention Research Expert Panel meeting was held in November 2014. At that meeting, several Work Groups were identified or formed and they may overlap each other somewhat. The groups are as follows: the Donor Focused Issues Work Group to cover donor authorization for research, donor family communication and donor-side review and approval of research; the Oversight Work Group to discuss national review, access to protocols, uniform study approval process and adequacy of monitoring; and the Transplant Center Issues Work Group to work on recipient consent, levels of risk, knowledge about research protocol and implications for acceptance and allocation.

A "Donor Intervention Research Issues Package" was developed based upon Work Group activities in 2014 and served as a foundation for the Expert Panel meeting in November 2014. The Package outlined the process for each of the three focus areas and identified resources needed to put the steps together to make this a process. Part of the process is conceptual, part of it is operational and part of it is marrying both of those together. Experts in research activities needed to be brought together. The final part of the Package is getting a tool for implementation and moving this forward. The goal is to expand availability, utilization and viability of increased number of transplantable organs. The Expert Panel meeting held on November 19-20, 2014 was built upon the consensus process from the September 2013 conference. Among the topics addressed at that meeting were requirements for a Review Body (Institutional Review Board)—registration, composition, process. One Action Item from that November 2014 meeting was to

establish a process for an Institutional Review Board (IRB) whether it is a regional or national IRB and the process it should follow. The second key topic addressed was the protocol process. Protocols should be evaluated for their scientific merit and should be low risk at first, but would move the research knowledge forward and establish a foundation for more innovative studies. The third topic addressed concerned donor-focused issues. It is necessary to remove the barriers to this research which is conducted at times at hospitals not familiar with research because often the hospital is not the Transplant Center. From the donor-side, authorization for the research is needed under UAGAs given the dual purpose of transplant and research. Standards for OPO review and participation are needed and donor hospital considerations need to be addressed. The fourth topic area addressed concerns transplant-focused issues. Transplant Centers need to quantify the risk and communicate information about the protocol to the accepting team and obtain the informed consent of the recipient. The research does not impact just one recipient; how is the risk analysis transmitted to the receiving centers of other organs and their patients?

Dr. Gerber explained that the key has been developing a roadmap which leads to creation of an environment that supports donor intervention research. It is necessary to communicate the mission and the necessity for a sanctioned research process. More work is needed in the areas of authorization, risk, recipient consent and an Institutional Review Board. The Expert Panel can provide recommendations related to infrastructure for this research and assist in aligning efforts in the community.

Dr. Gerber then outlined a proposed Institute of Medicine (IOM) Study. IOM would be approached about possibly performing a study to examine ethical considerations surrounding donor intervention research. This is a novel concept that touches so many areas in the healthcare field. We are trying to find folks, Dr. Gerber said, who can best facilitate and guide this forward. The key is creating a roadmap or process, i.e. creating an environment to allow moving this forward and to be transformative. The authorization process needs to address risk and recipient consent. The proposed IOM study would include transplant centers, practitioners, OPOs, recipients, donor hospitals and donor families. This is a complex study. One parallel activity was though an ASTS initiative. Sandy Feng and Peter Abt have been two champions in this process from ASTS. They have met with the IOM about the possibility of doing an IOM-based study on ethical issues in donor transplant research. A future planning meeting with IOM and stakeholders including representatives from IOM, National Academy of Sciences and transplant professionals is going to be held although no date has been set yet. The Expert Panel hopes to have a proposal ready by the March meeting for the ACOT that would bring forward a recommendation for the Secretary which would be complementary to the activities of those in the Donor Management Research Consensus Conference.

Dr. Gerber concluded with some specific actions to be considered including implementation of oversight and regulatory mechanisms to support donor intervention research. It is necessary to think about where the ACOT fits into this effort. A key area which came up at the last meeting is collaboration with OHRP on requirements and the potential for regulatory relief or a waiver. An effective communication network needs to be developed for these activities as well as tools to ensure that risk and the impact to organs and to recipients are articulated. The Expert Panel is looking at concrete recommendations that the ACOT can make to the Secretary.

Ms. Alexandra Glazier added that one primary issue upon which the Expert Panel has been working on is inconsistency in practice on the donor side; clarification and building consensus in this area are underway. The second primary issue concerns regulatory barriers to the conduct of large-scale clinical trials to move the needle for the field. Related issues include how to get prospective informed consent from recipients in advance of allocation or how does allocation complement or interfere with this whole process? ACOT could assist in helping resolve the second issue, in particular. Public trust and transparency are the hallmarks for the organ donation and transplantation field and for human subject research and we need to be mindful of those and preserve those two pillars as we work toward resolving some regulatory barriers and facilitating innovation in this field.

Dr. Barr thanked Dr. Gerber and Ms. Glazier and added it was hoped that this topic will be discussed in more detail at the March meeting.

Follow-up:

1. Please add this topic of Donor Management Research and Innovation to the agenda for the March meeting.
2. Please follow-up to see if Sandy Feng and Peter Apt will be available to attend the March meeting.

HOPE Act—Background—Emily Marcus Levine, JD (HHS OGC)

Ms. Levine opened her presentation informing participants that she would provide a broad overview of the change in the legal landscape since the passage of the HOPE Act on November 21, 2013. Prior to enactment of the HIV Organ Policy Equity (HOPE) Act federal law prohibited all transplants of organs from donors known to be infected with HIV. OPTN had to have standards in place to prevent donation of organs from HIV positive donors and had to arrange testing to prevent acquisition of HIV positive organs. The HOPE Act changed these standards and processes. Three criteria must be met now for an HIV positive organ to be donated. First, organs from HIV positive donors may only be transplanted into HIV positive recipients. Second, transplant recipients must be enrolled in clinical research approved by an IRB under HHS published research criteria. Third, as an alternative to the second criterion, if the Secretary of HHS determines that participation in clinical research is no longer warranted, transplant recipients must meet other requirements imposed by the HOPE Act in order to ensure organ transplantation is safe.

Ms. Levine explained that the HOPE Act retained the prohibition against an HIV positive person knowingly donating or selling or attempting to donate or sell blood, tissues, semen, organs or other bodily fluids for use by another person. In addition to previous exceptions (for medical research or testing), the HOPE Act adds an exception for donations done in accordance with HHS Secretary's guidelines and regulations under the HOPE Act. There is still a criminal prohibition against buying/selling organs.

The HOPE Act was enacted, as previously mentioned, on November 21, 2013 and by November 21, 2015 the HHS Secretary must develop and publish research criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into recipients infected with HIV. The National Institutes of Health (NIH) are now working on these research criteria. Additionally, amendments must be made to the OPTN Final Rule which currently prohibits donation by an HIV positive donor. That Final Rule must be amended in accordance with the HOPE Act.

By the date of November 21, 2017 the HHS Secretary must, in conjunction with OPTN, review the results of scientific research to determine whether the results warrant revision of the OPTN standards of quality related to donated organs infected with HIV, safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV. The Secretary could, therefore, revise the Final Rule or decide that these transplants could continue regardless of whether or not they are done as research. Data from research is critical. The Secretary must review the available research and make decisions. Annual reviews must be conducted each year after November 21, 2017. Ms. Levine encouraged participants to make sure that good quality data are available to the Secretary through the OPTN or through publication of research or through submission to the Secretary.

HOPE Act Research Criteria: HHS/NIH Update—Jonah Odum, MD, PhD (NIH)

Jonah Odum, MD, PhD, Chief of the Clinical Transplantation Branch in the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) thanked Ms. Levine for providing excellent background information on the HOPE Act. He then referred to the delegation of authority from the Secretary of Health and Human Services to NIH. NIH was delegated the responsibility of developing research criteria for the conduct of research relating to "transplantation of organs from donors infected with human immunodeficiency virus (HIV) into individuals who are infected with HIV before receiving such organ." The Director of NIH, Dr. Francis Collins then re-delegated that authority from NIH to NIAID. A

small group at NIAID with expertise in transplantation and HIV formed a Working Group along with the Centers for Disease Control (CDC).

Dr. Odum next outlined the process. The NIH/CDC Working Group has met every one to two weeks for the past nine to ten months to review the evidence base for this research. An initial teleconference was held with HRSA in March of 2014 to partner in this effort and there have been three Public Health Service (PHS) Blood Organ and Tissue Safety (BOTS) teleconferences over the past year to present findings. Additional meetings and calls include one with the Office of General Counsel and a teleconference with representatives from ACOT, OPO, SRTR, University of Michigan, Johns Hopkins University, Vanderbilt, University of California Los Angeles, Northwestern, University of California San Francisco, Duke, Cleveland Clinic, Diabetes Atherosclerosis Intervention Study (DAIS), Division of Allergy, Immunology, and Transplantation (DAIT), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and CDC and included investigators in the community and surgeons and physicians. The research criteria were presented at the World Transplant Congress (WTC) Town Hall Meeting in July 2014. A month later a meeting was held with representatives from NIAID, HRSA, HHS/OD, HHS/Office of Assistant Secretary for Health on data collection. Research criteria were presented at the "Interscience Conference on Antimicrobial Agents and Chemotherapy" (ICAAC) sponsored by the American Society of Microbiology in September 2014. The research criteria were presented one month later at the HIV Medical Association (HIVMA) Infection Disease (ID) Week and at a follow-up conference call with the HIVMA Board of Directors. Several conference calls have been held between NIH and various interested federal agencies.

Dr. Odum next provided a broad overview. Without much evidence base except the experience in South Africa of HIV positive to HIV positive organ transplantation the overarching goals of the research criteria were to protect the safety of research subjects and the general public without being too prescriptive; that is the first criterion. The second criterion pertains to Transplant Centers which the Working Group felt must have experience with transplantation using uninfected donor organs into HIV positive recipients before doing HIV positive to HIV positive transplantation. Experience in an NIH trial over the last ten years showed that there is a significant learning curve for centers and individuals transplanting uninfected organs into HIV positive recipients. Therefore, Transplant Center experience is important for the program. Currently, that experience in the U.S. is with only kidney and liver transplantation. There are only anecdotal single case reports about other organs. Fourth, the research criteria only address the minimum safety and data requirements for clinical research; they do not cover all the details and necessary components of an IRB-approved research protocol for HIV positive to HIV positive organ transplantation. Fifth, these criteria do not replace or supplant current policies and regulations governing organ transplantation, human subject research, the consent process, confidentiality and privacy; rather, these criteria supplement existing policies and regulations. These are research criteria, not standards of care or transplant guidelines.

Dr. Odum explained that research criteria were put into six buckets as follows: Donor eligibility; Recipient eligibility; Transplant Program qualifications; OPO responsibilities; Mechanisms to prevent inadvertent transmission of HIV; Minimum outcomes measures that may be needed in future evaluations such as wait list, donor organs (deceased and living), living donors (post donation) and transplant recipients.

There are three categories under Donor Eligibility:

- Deceased donor with known history of HIV infection:
Must have CD4+ T cell count greater than or equal to 200/uL or greater than or equal to 14%; HIV-1 RNA less than 50 copies/mL; no history of viral load greater than 1000 copies/mL in the prior 12 months and no active opportunistic infection.
- Deceased donor with newly diagnosed HIV infection:
Must have CD4+ T cell count greater than or equal to 200/uL or greater than or equal to 14%; There is no requirement for viral load, but there must be no active opportunistic infection.
- Living HIVpositive donor:
Must have well controlled HIV infection with CD4+T cell count (lifetime nadir) greater than or equal to 200/uL; CD4+ T cell count greater than or equal to 500/uL for the six month period

before donation; HIV-1 RNA less than 50 copies/mL, no opportunistic infections and must have a pre-transplant donor allograft biopsy.

The OPO and the transplant team must make the best effort to get data on the donor. The transplant team ultimately has to assure the recipient that they have a tolerable and safe anti-retroviral regimen for the recipient.

The research criteria pertaining to recipient eligibility were developed by groups doing uninfected donations in HIV positive recipients in the U.S. Many of these criteria have been adopted by transplant teams around the world. For an HIV positive recipient to be eligible, he/she must have a CD4+T cell count greater than or equal to 200/uL for kidney recipient, CD4+ T cell count greater than or equal to 100 uL for liver within sixteen weeks prior to transplant or greater than or equal to 200/uL with a history of opportunistic infection; HIV-1 RNA less than 50 copies/mL and on a stable anti-retroviral regimen; no active opportunistic infection or neoplasm and no history of chronic cryptosporidiosis, primary Central Nervous System lymphoma or progressive multifocal leukoencephalopathy.

Research criteria for Transplant Programs begin with the stipulation that the program must be a medical center with an established program for care of HIV positive subjects. There must be HIV program expertise on the transplant team. The program must have experience with HIV negative to HIV positive organ transplantation and must have Standard Operating Procedures (SOPs) and training for the organ procurement, implanting/operative and post-operative care teams for handling HIV infected subjects, organs and tissues. The research must be done under an IRB-approved research protocol in HIV positive to HIV positive transplantation. The transplant program must have an institutional biohazard plan outlining measures to prevent and manage inadvertent exposure and/or transmission of HIV. The program must provide each living HIV positive donor and HIV positive recipient with an "Independent Advocate" and must have policies and SOPs governing the necessary knowledge, experience, skills and training for Independent Advocates. The transplant team must have experience with at least five HIV uninfected to HIV positive transplants with designated organ(s) over the last four years at a minimum. The local IRB will evaluate key personnel (i.e. HIV physicians, transplant surgeons and transplant physicians) in the context of total expertise and experience. Some study protocols that get funded, for example through NIH, may have other opportunities at other levels for oversight depending upon the sponsors.

Dr. Odum next provided details on the responsibilities of OPOs in this research. OPOs must have SOPs and must have procedures for training staff for working with deceased HIV positive donors and their family and kin in taking pertinent history, in medical chart abstraction, in the consent process and in the handling of blood, tissues, organs and biospecimens. Additionally, OPOs must have a biohazard plan to prevent and manage HIV exposure and/or transmission. These tissues are regulated by FDA not by HRSA and can be recovered from HIV positive donors for transplantation. If a donor is ineligible the tissues can be used for research purposes. Although the HOPE Act was passed, Dr. Odum clarified that Transplant Centers and OPOs are not required to participate in this research. However, each participating Transplant Program and OPO must develop an institutional biohazard plan for handling of HIV positive organs designed to prevent and/or manage inadvertent transmission or exposure to HIV. Dr. Odum stressed that procedures must be in place to ensure that human cells, tissues and cellular and tissue-based products (HCT/Ps) are not recovered from HIV positive donors for implantation, transplantation, infusion or transfer into a human recipient; however, HCT/Ps from a donor determined to be ineligible may be made available for non-clinical purposes.

Some required outcome measures in the research criteria regardless of the specific aims of the particular scientific protocol pertain to the wait list, all donors, living donors and transplant recipients. Criteria pertaining to the wait list include the following: HIV status, CD4+ T cell counts, co-infection (HCV, HBV), HIV viral load, ART resistance and removal from wait list (due to death or other reason). Some outcome measures covering all donors that must be included in the research include status as living or deceased, HIV status (new diagnosis or known diagnosis), CD4+ T cell count, co-infection (HCV, HBV), HIV viral load and ART resistance. Some outcome measures among the research criteria pertaining to living donors include progression to renal insufficiency in kidney donors (serum creatinine greater than 2 mg/dl, serum creatinine level twice the pre-donation creatinine level or proteinuria), progression to hepatic insufficiency

in living donors (INR greater than 1.5 and/or total bilirubin greater than 2.0), change in ART regimen as a result of organ dysfunction, progression to AIDS, failure to suppress viral replication (persistent HIV viremia) and finally, death. Outcomes measures pertaining to transplant recipients include rejection rate (years 1 and 2), progression to AIDS, new opportunistic infections, failure to suppress viral replication (persistent HIV viremia), HIV-associated organ failure, malignancy, graft failure, mismatched ART resistant versus donor and finally, death.

Dr. Odum concluded his presentation with some thoughts about the future. The Work Group will continue working with HRSA to facilitate OPTN accommodation of these criteria. Adjustments to guidelines and policies within the OPTN may be needed. The NIAID leadership completed its review of these research criteria and has approved the work to date; these research criteria are now being sent to Dr. Collins for NIH approval and it is hoped that the criteria will be published in the *Federal Register* within the next two to three weeks for sixty days of public comment. An email address and a FAX number will be included for submission of public comments (HOPEAct@mail.nih.gov and FAX: 301 451 5671 which is an e-FAX). After the first round of public comment the comments will be reviewed and compiled and revisions will be made to the research criteria as necessary and subsequently sent for approvals. It is hoped that the final version of the research criteria will be published in the *Federal Register* by November 21, 2015 as stipulated in the HOPE Act.

Dr. Odum informed participants that his division in the NIAID has indicated support for this research and the DIT has issued guidelines for research that colleagues in the private sector might want to use if they are thinking about sponsorship. The Clinical Trial Planning Grant Program (R34) supports development of a clinical trial. R01 and U01 are Investigator-initiated Clinical Trial Implementation Grants that are available. The R01 is for a low-risk clinical trial while the U01 is for a high risk clinical trial.

Dr. Odum ended his presentation stating that he provided these recommendations on behalf of the Working Group which extends its thanks to HRSA, CDC, FDA and colleagues and partners from other federal agencies as well as members from the HIV, transplant and OPO communities for their ongoing assistance. The Working Group welcomes feedback from the ACOT members. Dr. Odum added that there will be opportunities to comment during the public comment period which opens shortly as well as prior to the publication of the final research criteria for the conduct of HIV positive to HIV positive organ transplantation.

Discussion

Comment/Question

Dr. John Fung commented that the research criteria stipulate that a deceased donor with known history of HIV infection should not have a viral load greater than 1000 copies/mL in the prior 12 months preceding death. He questioned whether that criterion would be pertinent. Most patients he sees are donors who never knew they had HIV, e.g. young males who are killed by a gunshot wound or in a motorcycle accident. Only through the donation process are they found to be HIV positive. They tend to be naïve donors with no drug exposure and with low risk for acquisition of mutant, but have viral loads greater than 1000 copies/mL. That population of donors composes the prime donors for diseased organs. Donors with known HIV will be limited in number.

Response:

Dr. Odum agreed that Dr. Fung's point was well taken and was probably correct. He added, however, that there was a sense that there are probably some candidates in that pool that are HIV infected--their loved ones tell us they are HIV infected and they are followed at the clinic- and we have the data showing they have pristine physiologically functioning organs which could be used in some circumstances; this was the consensus. To completely eliminate all deceased donors with a known history of HIV infection might jeopardize what we would like to learn.

Dr. Barr thanked Dr. Odum and Emily Levine for these presentations and added that Jim Bowman, Bob Walsh and others from HRSA have participated on this interagency Working Group. ACOT does not have a specific Work Group itself dedicated to this issue; these presentations were informational in nature.

Dr. Barr asked Dr. Odim to please communicate to the ACOT if there is anything with which they can be of help. Currently, the ACOT is not involved in this effort, but it is an important area for the organ donation and transplantation community and also relates to the importance of the tracking system discussed by Brian Shepard earlier in this meeting. That product will dovetail with implementation of the HOPE Act in a practical and safe fashion. Dr. Barr concluded saying that the ACOT will touch base with Dr. Jonah Odim regarding the ACOT meeting in March. Dr. Odim again welcomed comments from the ACOT which represents important stakeholders in this area.

Follow-up:

1. Please add Dr. Jonah Odim (NIAID/NIH) to the agenda for the ACOT March meeting to speak about the research criteria for implementation of the HOPE Act.

Kidney Paired Donation-Review of the Recommendation— Andrew Schaefer, PhD, Work Group Co-Chair and Dorry Segev, MD, PhD, Work Group Co-Chair

Dr. Segev informed participants that he would provide some background information on what has been happening in the field as well as what was happening in the field that informed the Kidney Paired Donation Recommendation from the Kidney Paired Donation Work Group. He said that Dr. Schaefer would follow him to talk about the recommendation itself.

Dr. Segev began with a review of KPD providing an abridged version of information he previously presented to the ACOT and a summary from a consensus conference on KPD in held in March 2012. He explained that a straightforward 2-way (or N-way) paired donation is an exchange that happens simultaneously—all pairs exchange donors among themselves meaning the donors need to go to the operating room at the same time. A domino (closed chain) is a paired donation, 2-way (or N-way) that starts with a Non Directed Donor (NDD) and ends in the waiting list. Again, all donors go to the operating room at the same time. In a non-simultaneous domino (closed chain) some transplants happen at one point then one donor waits around and then continues that domino at another point again ending in the waiting list. In a non-simultaneous chain (open chain) or what some call a “Never Ending Chain,” there are multiple segments that occur at different points of time with a goal of never ending up on the waiting list, but of continuing the perpetual chain. Eventually all of these chains end in the waiting list so the perpetual chain is just a concept.

Paired donation has become a huge component of living donor transplantation in the U.S. There has been continued growth with now more than six hundred transplants facilitated via kidney paired donations in the U.S. annually. The number of non-directed donations (NDD) most of whom are used to start chains or dominos, has continued growing since 2011 in the U.S. If you add the kidney paired donations and NDDs together in 2012 that represents about 12% of living donor transplants performed in the U.S. This, again, has increased. For the 20% of the live donor transplants performed in the U.S. someone other than the donor decides who the recipient will be for that organ; there is an intended recipient so there is a recipient that will benefit from that transplant in the setting of pure exchanges. In the setting of chains, at the end of the chain on the waiting list there is also a decision about who the recipient will be. There is also a decision about which pairs are involved in exchanges, etc. The donor no longer controls who will get the kidney.

Dr. Segev next posed questions discussed at the consensus conference. Questions related to chains included the following: “Are longer chains really better or do they just attract more media? When do you stop the chain? To whom does the last kidney go? Which center’s waiting list gets to benefit?” There are also continuing questions about matching (allocation) priorities and optimization. Use of mathematical optimization has become standard in the last ten years, but there are multiple ways to do it. Dynamic optimization versus batch optimization—both methods are controversial. Additional questions pertain to shipping kidneys. There are issues with safety and logistics with multiple segments, risk of loss or misplacement in shipping. There are also questions about cost. Usually the donor bills the recipient’s insurance, but this becomes more complex when done at different centers. Who covers donor complications and who pays for multiple donor/NDD evaluations are among the outstanding questions.

Dr. Segev delineated eight types of costs of KPD as follows: Evaluation of incompatible donors, not knowing if those organs will ever be used; Evaluation of NDDs; Histocompatibility testing; Center-level administration; KPD program administration; Kidney shipping costs; Donor surgeon professional fees; Donor complications/follow-up. These are all unique to KPD.

Some KPD financing strategy goals are as follows: 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 CMS regulations. Dr. Segev commented that Mike Rees and his colleagues proposed a fee for KPD be defined and agreed upon by CMS and other payers. Each center would be paid the KPD Standard Acquisition Cost (SAC) for every kidney transplant they perform, above and beyond payment for conventional live donor transplant. Whether the SAC would be at the national level or at the center-level is also an outstanding question.

A Consensus Conference was held in March 2012. A number of the people involved in that conference were part of the ACOT Work Group that put together the recommendation. The Consensus Recommendations were as follows:

- “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 in the United States financial model.”

Payer Recommendations were as follows:

“...the designation of a national organization to administer and provide oversight to KPD would best meet the needs of expanding access to KT 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 KT 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 HRSA.” (Irwin et al, AJT, 2012).

Dr. Segev thanked members of the Working Group and HRSA Staff. Alexander Schaefer, PhD, the Working Group Co-Chair added that this Recommendation #57 from the Working Group was previously voted upon and unanimously approved by the ACOT. Mr. Schaefer then read the Recommendation for participants. The final recommendation is as follows:

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.

Discussion

Question/Comment #1 and Responses:

Dr. John Fung asked Dr. Segev if all paired kidney donation organizations in the U.S. outside of UNOS are in alignment with this recommendation. Dr. Segev responded by showing the PowerPoint slide listing the names of Working Group members and HRSA staff that participated in the development of the recommendation. The Working Group tried to get representatives from larger functioning KPD registries including the National Kidney Registry which is probably the largest one currently and the UNOS program. Dr. Segev said it was difficult to know if everyone from a certain organization bought into this recommendation, but representatives from UNOS and from the National Kidney Registry did approve of this concept. Now there are competing registries in the U.S. which have advantages since they bring new ideas, but they have disadvantages since they create a competitive environment which causes fewer people to have potential matches. This was discussed at the Consensus Conference in 2012. The national consensus appears to be that if there were a single, well-functioning program that would be best for the U.S., but the problem is how to define a well-functioning national program and who gets to run it. The thinking behind the recommendation is that if you have a KPD contractor like you have an OPTN and a SRTR contractor then the transplant community could help decide who gets to run it.

Dr. Barr informed new members that Recommendation 57 was voted on and approved and sent to the Secretary in October-November of 2013. He asked if Dr. Segev or representatives from UNOS could comment on the impact of Recommendation 57 versus what would have been a natural evolution of the Consensus Meeting that pre-dated the ACOT Working Group. He asked if Recommendation 57 has helped in the community.

Dr. Segev responded that a national KPD contractor has not yet been identified; that function would involve funding, etc. He does not know that Recommendation 57 has changed KPD practice. Mr. Bob Walsh commented that for him the greater impact of ACOT Recommendation #57 which is eliciting much conversation in OPTN/Division of Transplantation is about how to approach KPD and how to address a number of the questions that Dr. Segev detailed in slides 11 and 12 (i.e. questions about chains, matching, optimization, shipping kidneys and financial considerations). Those are the issues and their implications about which OPTN would like to have some in-depth discussions with the ACOT at the meeting in March. He said OPTN would like to lay-out in-depth some of those questions and their implications and discuss those with the ACOT as we move forward with how we are going to respond to Recommendation 57 and what is possible for a national KPD system.

Dr. Barr responded that the chance of the ACOT being able to answer the questions outlined by Mr. Walsh is limited at the face-to-face meeting unless some preliminary work is done. The work that led to Recommendation 57 coming out was the first step. That is why Dr. Barr was asking about its impact and what the next step would be and whether Recommendation #57 is sufficient from the ACOT's point of view or as Bob Walsh was just saying, if the ACOT can further serve in moving this effort along in the implementation phase or if others rather than ACOT could make this happen. Dr. Barr added that the ACOT can certainly follow-up on this issue, but the next conversation should be in a Work Group (i.e. the KPD Work Group) format and then hopefully we can talk about it at the face-to-face meeting in March.

Bob Walsh agreed especially about the importance of the Work Group in this discussion. It would be helpful, he said, to get the KPD Work Group together at least once or twice to put some structure around the discussion to be held in March so progress can be made. Regarding the other recommendation on harmonization, Mr. Walsh said it would be beneficial to have a Work Group discussion, but he suggested first having a more detailed laying out of the issues with the full ACOT and then progress could likely be made going forward after that meeting perhaps in Work Group discussions.

Action Item (All ACOT Members):

1. Those interested in this Working Group on KPD and those interested in Dr. David Gerber's Donor Intervention Research Expert Panel and those interested in serving on a Work Group on Harmonization should email Pat Stroup if they would like to be involved in conference calls for those groups.

Action Item (Pat Stroup):

1. Please set up one or possibly two conference calls prior to the March meeting for the KPD Work Group.

Action Item (Dorry Segev):

1. Dr. Barr asked Dr. Segev if there are other people who should participate on the KPD Work Group and should be invited before Ms. Pat Stroup convenes the KPD Work Group. Dr. Segev will follow-up to make sure the relevant group of stakeholders are still represented on the Work Group.

Affordable Care Act and Transplantation—Update

Ms. Pat Stroup of HRSA informed participants that a full discussion of the Affordable Care Act and transplantation will be on the agenda for the March meeting. Speakers will be invited to present on the Affordable Care Act. In the meantime, Ms. Stroup presented a reminder that open enrollment for the Health Insurance Marketplace continues through February 15, 2015. She urged people to go to www.healthcare.gov for more information.

Dr. Fung commented that in reviewing the plans available under the Affordable Care Act it is not obvious which ones cover transplant services and which ones do not. He asked Ms. Stroup if she could shed some light on this issue. Ms. Stroup replied that someone more informed than she would have to answer that question. Dr. Barr added that Transplant Programs have reported that since the ACA roll out there have been wide variances in coverage of immunosuppressive pharmaceuticals, i.e. the formulary co-pays covered by the insurance plans have decreased. Therefore, the topic concerns not just transplant coverage issues, but post-care prescription issues. Some patients cannot afford the huge co-pay.

Follow-up:

1. In selecting someone to speak at the ACOT meeting in March on the ACA, please ensure that the presentation covers transplant coverage issues as well as post-care pharmaceutical coverage issues.

New Business

No members voiced any recommendations for new members of the ACOT.

Dr. Barr commented that the KPD Work Group, CMS/HRSA Harmonization Work Group and the Donor Management Expert Panel presented multiple suggestions and will probably expand. He again reminded ACOT new members and returning members should email Pat Stroup if they wish to participate on conference calls for any of those groups.

Recommendations for the March 2015 Meeting Agenda:

Dr. Arthur Matas asked if any work is being done to reconcile innovation in Transplant Programs with the oversight and need to meet certain goals in terms of patient outcomes. Perhaps this is being done in the Harmonization Work Group? He said he knows this was mentioned in terms of donor and OPO outcomes, but it is a problem in terms of innovation and clinical protocols. Dr. Barr responded that has been brought up before. Dr. Dan Schwartz briefly mentioned that issue in his presentation today. Thomas Hamilton and Diane Corning at CMS have been involved in that discussion. He said that this issue will be added to the list of issues to be addressed by the Work Group on Harmonization. This issue also dovetails with Dr. David Gerber's presentation. If you are going to start doing novel research with

donors while at the same time stretching the envelope then risk adjustment has to be made so that programs are not penalized for stretching that envelope in the effort to improve the organ or getting more organs. This issue has been raised although in a circular manner rather than directly. Dr. Barr said the ACOT could certainly try to add to that discussion and perhaps talk offline about possible presentations on this issue for the ACOT in March. This issue has also been discussed with SRTR. We could task someone to present an overview of the issues and the potential path(s) forward. Chris McLaughlin added that this is part of the discussion on performance metrics and what innovation activities are being affected by the current model and what other sorts of metrics could be utilized to look at system performance going forward. Dr. Barr added that this issue came up when emails were sent to the ACOT regarding kidney transplant programs that were doing highly sensitized patients and doing de-sensitization protocols, etc. People are very aware of this issue. Lung transplant has a similar issue. That issue will be added to the March meeting agenda.

Follow-up for Agenda of ACOT Meeting in March:

1. Please add to the agenda for the March ACOT meeting a discussion of the issue of reconciling innovation in transplant programs given oversight and the need to meet certain goals in patient outcomes. These relate to performance metrics and impact on innovation activities by the current model and metrics to look at system performance going forward as well as Donor Management Research and Innovation issues.

Action Item (All ACOT Members):

1. Please email any agenda topics for the ACOT meeting in March to Pat Stroup.

Public Comment

Public Comment From Jane Zill, LICSW

Jane Zill, LICSW, member of the UNOS/OPTN Living Donor Committee (2007-2009) and of the Living Donor Data Task Force in 2009 submitted a public comment regarding the “Best Practices in Living Kidney Donation Consensus Conference (2014).” Her statement was is as follows:

The “Best Practices in Living Kidney Donation Conference” (2014) is not the first professional meeting to address the role of living kidney donors in transplantation. Prior meetings and reports have resulted in the articulation of “best practice” principles to guide living kidney donor transplantation. Key meetings and reports include:

- 1) The “Consensus Statement of the Live Donor” (Kansas City, 2002) states: The person who gives consent to be a live organ donor should be ...free from coercion... The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ.
- 2) The Amsterdam Forum on the Care of the Live Donor (2004) emphasized the importance of establishing donor autonomy in decision-making by:
 - Quantifying future renal function in living kidney donors;
 - Providing information about alternative forms of therapy for potential recipients;
 - Creating a meaningful role for independent donor advocacy;
 - And, establishing mechanisms for long-term medical follow-up, data collection, and the creation of living kidney donor registries
- 3) The Institute of Medicine (2006) reported:
 - the need for independent donor advocacy;
 - the need for inadequate data to ensure informed consent;
 - the importance of a risk-benefit assessment when using living organ donors; and,
 - the need for prospective donor registries.(“Organ Donation: Opportunities for Action”, National Academy of Sciences)

- 4) In 2007, Dr. Sue Mc Diarmid, then President of the OPTN, surveyed OPTN member centers for their protocols on living donation. Two protocols were selected to represent “best practice” by the UNOS/OPTN Living Donor Committee, one from North Carolina and another from New York. In both states there had been a death of a living liver donor, which prompted each state legislature to enact laws regarding living organ donation due to an absence of regulation at the national level. It was recognized that:
 - A) Advocacy for a potential donor cannot occur separate from the medical evaluation and informed consent;
 - B) The primary relationship in the donation experience should be between the donor and his/her multidisciplinary Independent Donor Advocacy Team;
 - C) Independent Donor Advocacy must occur free from institutional and administrative pressure fueled by financial motivation to perform transplants; and,
 - D) An advocate’s recommendation to veto a donation could be compromised by negative reactions from those invested in a transplant going forward. For this reason team support is required to deflect this burden from any one individual.
- 5) “The International Summit on Transplant Tourism and Organ Trafficking” (2008) recommend strategies to “minimize the burden on living donors.” It emphasized, “A positive outcome for a recipient can never justify harm to a live donor, on the contrary, for a transplant to be regarded as a success means that both the recipient and the donor have done well.”
- 6) The Third WHO Global Consultation on Organ Donation and Transplantation (Madrid, March 23–25, 2010) asserted that deceased donor organs should be the dominant form of transplantation in every country, “In all countries in which deceased organ donation has been initiated, the therapeutic potential of deceased organ donation and transplantation should be maximized.”

The “best practice” recommendations from the 2014 “Best Practices in Living Kidney Donation Conference” are astounding because instead of bringing forth the messages of caution and the reduction in the use of the living kidney donors, the current consensus is to increase the use of living kidney donors.

Fundamentally, the 2014 recommendations are to establish a philosophical approach that LDKT is the best option for transplant candidates and to “educate” nearly every medical professional in the recipient’s and donor’s life to promote and pursue living kidney donor transplantation.

The new recommendations are diametrically opposed to the consensus that has emerged over the past decade and amount to strategies that are 1) coercive, and, 2) will lead to the continued exploitation of the living for their vital organs. Already, because independent donor advocates are employees of transplant centers intent on increasing the number of LDKT, the well-being of living kidney donors is not prioritized. Standards for the medical evaluation and informed consent of living donors and for data collection are so weak that they are useless.

Even more egregious, many of participants of the 2014 meeting also participated in the consensus meetings in Kansas City and Amsterdam. And, the 2014 recommendations have been made in the ongoing context of inadequate data to support the conclusion that living organ donation is safe.

In 2009 a UNOS task force found its data to be “woefully incomplete” and “useless for research or for making conclusions about living donor safety.” Unbelievably, in 2010 and 2014 the Journal of the American Medical Association published articles that used this same data to conclude that living kidney donation has little risk now widely cited as evidence of the safety of living kidney donation. The algorithm used to verify SSNs for the JAMA research has never been described.

But, in 2013 researchers in Norway reported in Kidney International, an increase in rates in mortality from all causes after kidney donation – over many years. In 2007 the Bulletin of the World Health Organization reported that in Iran, Egypt, and India, where donors are paid, donors report deteriorated health, worsened financial status, and regret for their paid donation.

Transplant medicine in the U.S. is a highly commercial industry and is dependent upon a supply of human body parts to be viable. BizAcumen in 2009 reported, "The global organ and tissue transplantation market stands to gain from the increasing living donor organs..." BCC Research Market has forecasted in "Organ and Tissue Transplantation and Alternatives" (2011), "The global market for transplantation products, devices, and pharmaceuticals was valued at nearly \$54 billion in 2010 and is projected to grow at an 8.3% compound annual growth rate (CAGR) to reach \$80 billion in 2015." This is nearly a 50% increase in the market in four years.

Although donors are not paid, there is profit and profiteering from the donated body parts of living and nearly deceased human beings, ranging from the creation of private contracts to treat foreign nationals seeking placement on the U.S. deceased donor wait list (from, "UNOS/OPTN Revisions to and Reorganization of Policy 6.0 Transplantation of Non-Resident Aliens," 2012), to the development and promotion of products, devices, and pharmaceuticals employed in the practice of human organ Transplantation.

The most recent product developments are organ transport pumps, which are set to revolutionize the exchange (trade) in human body parts. Powerful principals are promoting the commercial use of products related to human organ transplantation, and thus exerting industry influence on U.S. policy related to human organ transplantation. One example of links between industry and government is the appointment of former Secretary of DHHS, Tommy Thompson, to the Board of Directors of Organ Transport System. He has long ties to industry as the initial leader of the Donor Organ Breakthrough Collaborative.

Despite the well-articulated "best practice" principles that have occurred from 2002-2010, in transplant centers around the United States, the donor's well-being is a low to non-existent priority compared to encouraging LDKT. The meaning of the combined lack of quality data on recipient and donor outcomes and weak standards for the evaluation and informed consent of living kidney donor is that U.S. living donors will continue to be a vulnerable, exploited by the transplant community and its commercial interests.

The practice of LKDT will someday be compared to the unethical treatment of research subjects in the Tuskegee syphilis experiments, but will be judged more harshly due to the collusion between industry and government that has resulted in policy creation that prioritizes profit for a callous and ruthless industry that is dependent upon a continuous supply of human body parts.

Public Comment From Christine Wright

My name is Christine Wright. In August of 2008, I donated a kidney to my sister at the Cleveland Clinic in Cleveland, Ohio. My experience led me to become an advocate for greater living donor protections, and establish the comprehensive educational website, Living Donor 101. On a regular basis, I correspond with living donors who suffer from the physical complications donation: chronic fatigue, nerve damage, adrenal dysfunction, and renal deficiency, just to name a few. Others are grief-stricken or depressed, coping with strained relationships, disappointing outcomes, insurance and financial difficulties, and a host of other issues. I have spoken to numerous reporters, written essays, and presented at a bioethics conference about these topics.

Thank you Dr. Barr, and members of the Advisory Committee on Organ Transplantation, for the opportunity to comment on the work of a June 2014 conference entitled "Best Practices in Living Kidney Donation". I am here today as a representative for myself and others who are concerned about the welfare of our nation's living kidney donors.

Every sponsor of this conference has a serious conflict of interest regarding the use of living donors because they financially benefit from living kidney donor transplantation. In addition, more than 90% of the participants listed on the conference's Executive Summary financially benefit from living kidney donor transplantation.

The American Society of Transplantation's Live Donor Community of Practice, the initiator of this conference, identified 9 stakeholder categories. Of the 67 conference attendees, only 3 were living donors. And all are employed by transplant centers. This token representation is evidence that the needs of living donors were not a concern of conference organizers and sponsors. There are many living kidney donors who have been active in promoting safe and ethical practices related to living kidney donor transplantation: Donna Luebke, Kimberly Tracy, Vicki Young, John Hodges, Jane Zill, Michael Murphy, and myself, to name only a few. Some have served on OPTN committees. Others maintain a substantial internet and public presence. All are easy to locate. Yet not a single one was invited to participate in this conference.

Do the conference sponsors and organizers, who represent a large swatch of the transplant industry, believe that a living donor without a healthcare background is incapable of offering insight or wisdom on these issues? Do they believe that the experiences of non-medically educated living donors are irrelevant?

Sixty years after the first successful living kidney donor transplant, we still have no comprehensive data on living donors. Attempts at "education" or "evaluation" may increase living kidney donation, but they have nothing to do with best practices in regards to living donor care.

The Organ Donation Recovery and Improvement Act (ODRIA), passed in 2004, gave the Secretary the authority to "establish and maintain mechanisms to evaluate the long-term effects associated with living donor donations". Arguably, the best method of achieving this goal would be the creation of a living donor registry similar to the one already in existence for transplant recipients. But rather than advocate funding for such a registry, the conference participants recommend the expansion of the National Living Donor Assistance Center so more people can "afford" to be living kidney donors.

Every aspect of this conference: the primary objectives, background, and recommendations, lead to the operating room, and the procurement of a vital organ for a lucrative transplant. None of the recommendations prioritize the kidney donor's well-being, or fulfill the responsibility of the industry and government to safeguard donor health by collecting comprehensive data for use by physicians who care for living donors when they return to the community, or meet the intent of the 1975 Medicare End Stage Renal Disease Benefit for living kidney donors.

"It is our goal", the Executive Summary reads, "to eliminate living donation and LDKT [living donor kidney transplantation] barriers".

If the sponsoring organizations and conference attendees believe living donor transplantation to be a panacea, and that the practice isn't harmful, why haven't more of them donated? Why do they continue to rely on the generosity of the unwitting public to provide their precious medical supply?

Without living kidney donors, there are no living kidney donor transplants. The recipient is not the only patient in the room. Yet time and again, living donors are overlooked or omitted in conversations regarding our own well-being.

It is very clear that living donor safety, both psychological and physical, short and long-term, cannot be left to the interests of those who are professionally involved in kidney transplantation.

We reject the recommendations of, "Best Practices in Living Kidney Donation".
Signed,

Christine Wright, M.Ed., LivingDonor101.com

Donna Luebke, RN, CNP, CCRN

Jane Zill, LICSW

Discussion

Dr. Barr responded to Ms. Wright saying that her comments would be entered into the record. He asked Ms. Stroup about the next step in this process. Ms. Stroup responded that the comment will be in the record. Dr. Barr then confirmed with Ms. Stroup that the second comment which was received would also be entered into the record and both comments will be available for the ACOT members to see. If issues arising from those comments ought to be discussed at another meeting, ACOT members should notify Dr. Barr or Ms. Pat Stroup. Dr. Barr added that there will also be a Public Comment period at the March meeting during which time non-ACOT members will be in the room and able to present to the ACOT.

Adjournment

Dr. Barr thanked the ACOT members and others who participated in this meeting. He informed members that emails will be sent out regarding upcoming meetings of the various Work Groups mentioned earlier. Three Work Groups will have at least one conference call prior to the March meeting. Members should notify Ms. Pat Stroup of any new topics that should be presented at the meeting in March.

In response to a question about the dates for the March meeting (March 12-13, 2015), Dr. Barr replied that the dates for that meeting are firm. Due to a HRSA contract it is necessary to have a meeting prior to the end of the first quarter of this year. There will probably be a second meeting toward the end of this calendar year.

The meeting was adjourned shortly before 4:30 p.m. eastern standard time.