

ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION (ACOT)
U.S. Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
Virtual Meeting
November 22, 2016, 11:00 a.m. - 4:00 p.m.

ACOT Participants

Voting Members

Mark L. Barr, M.D. (Chairperson); Charles Alexander, R.N., M.S.N., M.B.A.; Bryan Becker, M.D.; Sylvia Caley, J.D., M.B.A., R.N.; Bernice Coleman, Ph.D., R.N.; Stephen W. Crawford, M.D.; John Fung, M.D., Ph.D.; David A. Gerber, M.D.; Ana Hands, M.D.; Arthur Matas, M.D.; Suzanne McDiarmid, M.D.; Jamie Marie Avolio McDonald, M.S.W., L.I.S.W.; Kimberly Molina, M.D.; Thomas A. Nakagawa, M.D.; Stephen Pastan, M.D.; Cynthia P. Puryear; Andrew J. Schaefer, Ph.D.

Non-Voting (Ex Officio) Members:

Diane H. Corning, Esq.; Scott A. Brubaker

Designated Federal Official

Executive Secretary Robert Walsh

General Counsel Staff

Rina Hakimian, J.D., M.P.H.

Welcome and Opening Remarks

Mark Barr, M.D. Chair, ACOT

Dr. Barr called the meeting to order at 11:10 a.m. and introduced the first presenter, CAPT Melissa Greenwald, M.D., who provided an update on HRSA Division of Transplantation (DoT) initiatives.

HRSA DoT Organ Transplantation Program Update

Melissa Greenwald, M.D., Director, DoT

CAPT Greenwald began by providing a brief overview of the three statutes that authorize HRSA's organ transplant activities:

- The National Organ Transplant Act (PL 98-105), which provides for the Organ Procurement and Transplantation Network (OPTN); the Scientific Registry of Transplant Recipients (SRTR); and the congressional report on the Scientific and Clinical Status of Organ Transplantation;
- The Organ Donation and Recovery Improvement Act (PL 108-216), which provides for public and professional education to increase awareness of the need for organ donation and improve organ procurement practices; the authority to provide public awareness grants to states and public entities; living donor assistance, which is a mechanism to reimburse travel and subsistence expenses for living organ donors; and the congressional Report on Organ Donation and the Recovery, Preservation and Transportation of Organs.

- The Charlie W. Norwood Living Organ Donation Act (PL 110-144), which provides for statutory support for organ-paired donation with the clarification that organ-paired donation is not “valuable consideration; and the congressional report on the Long-Term Health Effects of Living Organ Donation

She then displayed a slide showing the flow of authority under which OPTN and SRTR function, describing high-level roles and relationship of the HHS, HRSA, and the OPTN and SRTR

CAPT Greenwald explained that OPTN is the national system that maintains the organ recipient waiting list and develops policies for the allocation of donor organs. The United Network for Organ Sharing (UNOS) is the private contractor that manages the nation’s organ transplant program.

The SRTR provides analytical support to the OPTN in formulating and evaluating OPTN policies and conducts performance evaluation of U.S. solid organ transplantation. The Minneapolis Medical Research Foundation is the current SRTR contractor.

CAPT Greenwald pointed out that allocation policy development is both important and challenging because more organs are needed than are available, and the waiting list continues to grow from slightly more than 80,000 potential recipients in 2003 to just over 120,000 people today. She also noted, however, that 2015 was the third consecutive year during which a record number of transplants were performed. She highlighted that in 2015, for the first time, the number of organ transplants performed exceeded 30,000 (30,973).

She then went on to discuss HRSA’s activities to increase access to organs, beginning with its organ donation public awareness program, which involves outreach and education efforts to increase donor registration and increase public understanding of transplantation; and issuing research grants to identify and study social and behavioral interventions that can increase solid organ donation. HRSA has also formed partnerships with stakeholders that share this mission, such as Donate Life America, UNOS, the American Society of Transplantation, and the American Society of Transplant Surgeons.

CAPT Greenwald also highlighted HRSA/DoT initiatives to increase organ availability through policy and practice improvement, such as the Collaborative Improvement and Innovation Network (COIIN) pilot project, which is being conducted under the OPTN contract. HRSA and the OPTN began the project at the end of FY 2015 and in FY 2017; about 20 kidney transplant programs will participate, focusing on improving utilization of moderate- to high-risk kidneys.

She also highlighted several recent OPTN developments, which supported innovation to increase organ availability including:

- the implementation of the HIV Organ Policy Equity (HOPE) Act, which authorizes clinical research and the revision of rules about organ donation and transplantation to allow organs from donors with HIV to be donated to HIV-positive recipients;
- increasing the number of vascularized composite allograft (VCA) (e.g., hand and face) transplants.
- supporting efforts to implement TransNet (an automated packaging and labeling process) improvements to ensure that donated organs are matched with the identified organ recipient, use of which was which was made mandatory for organ procurement organization (OPO) once the OPTN Board’s action becomes effective on June 1, 2017.

HRSA has supported several relevant research initiatives in 2016, including joining the National Institutes of Health (NIH) and other stakeholders to support the Institute of Medicine’s study of Issues in Organ Donor Intervention Research, which began with a kickoff meeting last September.

HRSA participated in the White House Organ Summit, held in June, during which stakeholders, including researchers, universities, hospitals and patient advocacy organizations convened to announce actions designed to build on the Administration's efforts to improve outcomes for potential organ transplant recipients. HOPE Act research and the COIIN were announced at this meeting.

HRSA also hosted with the White House Office of Science and Technology Policy an Innovation in Transplantation Research Workshop in October, the findings of which will be published in an upcoming issue of the *American Journal of Transplantation*.

In addition, HRSA, in collaboration with the American Society of Transplantation and the American Society of Transplant Surgeons, announced a coalition to support living donors, which will include patient organizations and other transplant community stakeholders. The coalition seeks to assist in providing education and resources potential living donors can use to make informed decisions about donation, addressing financial and other barriers to donation and ensuring that living donors have long-term medical follow-up and access to care. The first in-person meeting between these organizations will be held in early December.

Another new initiative will build on a study the SRTR conducted in FY16 to evaluate the feasibility of establishing a national registry of living donors that can be used to follow long-term health outcomes after living donation. A pilot project will be conducted, beginning this year, through which the SRTR will collect, through surveys and linkages with external data sources, long-term living donor health data. Fourteen transplant centers (nine kidney and five liver) will participate in the project (coordinating staff at the centers will be paid for collecting data), which will test the feasibility of enrolling potential living donors and collecting relevant data without relying on OPTN's data collection efforts.

The OPTN, meanwhile, conducted a study in FY16 to examine the feasibility of collecting data that can be used to support a new measure of OPO performance. The study resulted in a recommendation that a new measure be introduced requiring OPOs to collect, for the first time, a new type of data for use with a new metric, which will be explained in Dr. Klassen's presentation. HRSA plans to work with the organ transplant community in FY17 to develop a plan for collecting and using the recommended metric data and will work with the OPTN and the SRTR to consider developing a new measure to evaluate OPO identification of potential donors based on the new eligible death definition.

CAPT Greenwald moved on to discuss OPTN's liver distribution policy, which, she said, has sparked intense interest in the organ transplant community. The OPTN recently published a draft liver allocation policy proposal to change the geographic distribution system to decrease geographic disparity in access to such transplants. The document triggered a broad range of comments and the proposal will not be sent in its current form to the OPTN's board of directors. Instead, the Liver and Intestinal Organ Transplantation Committee is considering the comments received and responses will be posted. A second-round proposal is expected to be released for public comment in spring or summer 2017 and a final proposal could be submitted to the OPTN board in December 2017.

HRSA is supporting an SRTR study to assess the effects of reimbursing lost wages associated with living donation; a report will be delivered in the summer of 2017, which could lead to a pilot study. CAPT Greenwald noted that the current living donor assistance program, which receives HRSA funding already provides living donors with expenses to defray donation-related travel and expenses.

CAPT Greenwald provided an overview on the implementation of the HOPE Act. She noted that the law includes a requirement that the HHS secretary will "review the results of scientific research in conjunction with the OPTN" no later than four years after the law's enactment (Nov. 21, 2013) and annually thereafter. She

noted, however, that, the mechanism/framework for secretarial review has not been established. CAPT Greenwald and NIH provided an update to the assistant secretary for health and to the Blood, Organ and Tissue Safety Senior Executive Council in March 2016, and HHS is considering this issue.

CAPT Greenwald ended her program update by providing an update on Zika virus research focusing on non-human primates. In the first study, which is being conducted at the University of California, Davis under contract administered by the U.S. Food and Drug Administration (FDA), samples will be tested to see if the non-human primate disease model can be detected in various organs and tissues. The second study, which is being co-funded by HRSA and FDA and performed at the University of Wisconsin-Madison, will assess cells and tissues that support the growth of the virus and the duration of Zika viral RNA in body tissue during pregnancy in non-human primates.

With regard to getting Zika testing available for organ donors, Hologic (a Bedford, Mass.-based medical technology company that manufactures and develops diagnostic and medical imaging systems) has received FDA feedback on such testing under an investigational new drug protocol and is preparing the protocol for submission to the agency, perhaps by early December. The OPTN Disease Transmission Advisory Committee is working with the American Society of Transplantation and the American Society of Transplant Surgeons to develop updated clinical guidance on Zika's transplant-specific implications.

Discussion

Dr. Fung asked whether HRSA has made progress in selecting a contractor for paired kidney donation at the national level. CAPT Greenwald said that HHS is considering organ-paired donation, as was indicated in a notice in the agency's unified agenda that was published last spring, but she had no updates on this topic.

Dr. Fung also asked whether the Zika virus had influenced U.S. turn-down rates in the affected areas. CAPT Greenwald said that she did not have any information on turn-downs and explained that there are no tests that have been licensed, cleared or are available now to test organ donors. She also noted that there is no authorization to test organ donors for the virus.

Dr. Pastan asked for more information on the organ transplant public awareness programs HRSA is conducting and about any research grants that might be available. CAPT Greenwald said that HRSA conducts research activities throughout the year, including print and radio ads that are released around the Thanksgiving travel period. Videos are produced as well, including one on the organ transplant process that is designed for public consumption, and English- and Spanish-language Facebook pages recently were developed. Many available outreach materials are used by organ procurement organizations. Upcoming research funding opportunities have not been posted but are expected to be announced over the next month or two.

Expanding Transplantation Through Policy, Payment and Technological Advances

Lauren Oviatt; Indira Jevaji, M.D., M.S.L.; Jesse Roach, M.D., CMS Center for Clinical Standards and Quality

Lauren Oviatt is an analyst and end-stage renal disease (ESRD) team lead for the Clinical Standards Group in the CMS Center for Clinical Standards and Quality. She is also the Kidney Health Affinity Group Champion and a member of the Affinity Group Leadership Team. She and her co-presenters represented the Kidney Health Affinity Group, formerly called the ESRD Affinity Group, which was formed in September 2015. This is one of several ad hoc groups — not associated with a specific center within CMS — that have representatives from almost every component within the agency except for the operational component. They are part of CMS's quality improvement committee. These groups also have representatives from the NIH, HRSA, the Centers for

Disease Control and Prevention, FDA, and the HHS Office of Minority Health. They welcome participation from other agencies but all membership is at the federal level.

In spring 2016, the Kidney Health Affinity group responded to a call to action from CMS and the White House to address the ESRD system of care in the priority areas of patient safety at the onset of dialysis, home dialysis, ESRD payment and incentives and transplantation, with the goal of promoting healthy outcomes among people with chronic kidney disease and ESRD. The affinity group set up four subgroups to address these four issues and held large group meetings as well as smaller subgroup meetings to ensure examination of all underlying issues. Based on their work, the group drafted preliminary policy recommendations to transform the ESRD system of care.

Dr. Jevaji is a medical officer and advisor in the Division of ESRD Population and Community Health in the CMS Center for Clinical Standards and Quality and served as the Kidney Health Affinity Group's Transplant Subgroup co-lead.

She explained that all four of the Kidney Health Affinity subgroups conducted an inventory of ESRD programs, policies and activities for use in identifying areas of opportunity for additional action. They identified 34 federal programs, 14 of which are within CMS; the remaining 20 are divided equally among HHS and outside organizations. Of the 13 programs relevant to transplantation, six are housed in CMS, five are in other federal agencies and two are in non-federal organizations. These include the White House Initiative for Reducing the Organ Waiting List, the HRSA-supported National Living Donor Assistance Center, Donate Life America, HRSA's Project with the OPTN and the Kidney Health Initiative.

The transplant subgroup also examined various policies and existing and proposed statutes affecting transplantation, including CMS's ESRD Conditions for Coverage and Conditions of Participation, the HOPE Act and the Organ Donation Clarification Act of 2016, which was introduced in the 114th Congress.

Finally, the subgroup examined relevant research and new and emerging treatments, technologies and devices.

To develop recommendations, the subgroup gathered insights from experts inside CMS and across HHS, conducted a review of relevant scientific literature and identified and inventoried existing transplant programs, policies and activities.

The transplant subgroup divided itself into three task workgroups to focus on priority transplantation areas: innovative technologies under development, led by Dr. Jevaji, transplant disparities, led by Ms. Oviatt, and donor pools, led by Robert Walsh.

Dr. Jevaji provided examples of research into emerging technology development and innovative approaches that her subgroup explored, which she divided into two categories: emerging technology development and kidney regeneration and repair. Among the new technologies under development are normothermic and hypothermic machine perfusions, which can reduce delayed graft function, the development of donor registries and matching algorithms, the development of a wearable artificial kidney — in effect, a miniature hemodialysis machine — an implantable bio-artificial kidney, to treat ESRD and the expansion of plasmapheresis to remove antibodies in desensitization protocols. Examples of emerging kidney regeneration and repair approaches included kidney regeneration and renal repair through the National Institute of Diabetes and Digestive and Kidney Disease's (Re)Building a Kidney Project (which provides research grants) and the University of Alabama at Birmingham Comprehensive Transplant Institute's xenotransplantation program.

Dr. Jevaji provided a list of references in her presentation that discuss some of these developments in more detail.

Discussion

Dr. Fung said he had observed African-American patients who are hindered by lack of education and resources, such as transportation options, to accessing care and asked whether the Kidney Health Affinity Group had examined this issue and ways to address it. Ms. Oviatt, who led the workgroup that studied transplant disparities, said that subgroup examined that issue, focusing specifically on African-Americans, which is the largest minority population challenged with kidney disease and at some Asian communities in San Francisco. She explained that a lot of effort is being devoted to look at public education from the standpoint of cultural appropriateness and ensuring access to care. Just as there are “food deserts” there are “health care deserts” as well, she noted. She added that these concerns are on the subgroup’s radar but no solutions have been formulated yet.

Dr. Barr asked whether a pilot program would be devised to address these disparity issues, perhaps supported with HRSA or CMS funding or whether such support should be requested through the congressional appropriations process. He mentioned that these types of challenges to access can be found in both rural and urban areas and that the need for social service support to overcome barriers to care can be misinterpreted as patient noncompliance. Dr. Barr also suggested that this issue might be explored through the formation of an ACOT workgroup. Ms. Oviatt said that these types of issues tend to be outside CMS’s scope of authority and that it’s unclear what portion of the agency’s budget will be devoted to future research and innovative projects, which is why the affinity groups are looking for partners. Dr. Barr said that ACOT workgroups often bring experts from various agencies and other entities to work together. He, Dr. Pastan, who is from Emory University, and Sylvia Caley at Georgia State University expressed interest in participating in such a workgroup. Dr. Barr said he would work with Robert Walsh to gauge the level of interest in pursuing the formation of such a workgroup and from there, would determine who else to reach out to beyond ACOT. Dr. Barr stressed, however, that the committee’s role is strictly advisory and, as such, can help to draw attention to an issue that needs to be recognized and addressed, in part by making recommendations to the secretary of HHS. Part of the challenge will be to identify a purpose for the workgroup that would result in a relevant recommendation, not to duplicate work that other groups already are doing.

Dr. Gerber asked Dr. Jevaji whether her subgroup had explored, the research and innovations that are being developed not only by academic institutions and other federal grant recipients but in the commercial space. Dr. Jevaji said that about \$3 billion in federal grants have been given out for bioengineering research and such supports and developments can also expand the number and types of providers who are involved in transplantation. This could involve not just typical dialysis providers but also surgeons and nephrologists. Ms. Oviatt added that there is a need to help developers position themselves to meet regulatory requirements to ensure that their treatment approaches will receive FDA approval and be covered under Medicare. She noted that a new technology or device that does not fit within a current transplantation model may require the creation of a new payment structure or program. Dr. Jevaji suggested that those who are interested in this issue examine the Kidney Health Initiative being spearheaded by FDA and the American Society of Nephrology, adding that the FDA is developing a roadmap of regulatory guidance on innovative devices. Part of her group’s effort is to align such developments with FDA and CMS policies and NIH research.

Mr. Walsh shared comments from ACOT member Jamie McDonald who, as an advocate on the committee and a social worker, praised the presentation. She said that challenges to access to care is an issue that social workers are particularly knowledgeable about and said she hoped nephrology social workers would express interest in participating in the ACOT work group if it is created. Mr. Walsh also expressed gratitude for the opportunity to work on the donor pools workgroup and said that one of the major benefits the affinity group offered was in bringing together experts from across CMS and HHS to work together rather than at cross purposes. He also invited anyone at the meeting to pass on comments by email to him on programs being

conducted in the transplant community that were not mentioned in the affinity group presentation, which he could pass on to CMS.

Organ Procurement and Transplantation Network Update

David Klassen, M.D., Chief Medical Officer, UNOS

Dr. Klassen provided an update on the OPTN's current activities and began by reminding those present that UNOS is the federal contractor that runs the network. He noted that almost 31,000 transplants had been conducted in 2015, a substantial increase over previous years and that about 27,000 have been completed thus far in 2016, about 7 percent more than this time last year, and that 32,000 are expected to be performed by year's end. The number of organs from deceased donors is also substantially higher this year, having reached 8,100, an 8 percent increase compared with the same time last year. Meanwhile, living donations, which rose in 2015 for the first time in some years, but is relatively flat this year, are running at about 1 percent behind the number of donations reported in November of 2015.

Dr. Klassen explained that one of the major challenges the OPTN seeks to address is increasing equity in liver distribution, in connection with which three distinct but interrelated policy proposals are being developed. The first is the hepatocellular carcinoma (HCC) proposal, which would involve examining automatic MELD (model for end-stage liver disease) exception requests and revising the current definition for them. This proposal, which he described as being the least controversial of the three, was submitted for public comment this fall. This proposal calls for the ability to request automatic exception points for patients who present with large lesions but after treatment could be classified as T2. The proposal also addresses exception points for candidates with poor transplant outcomes, (i.e., those with high AFP levels). Dr. Klassen noted that this proposal would bring current policy in line with current clinical science and practice. Minor changes were made to the proposal in response to received comments and the proposal is expected to be voted on by the OPTN board in December.

The next proposal, involving the National Liver Review Board would take the liver candidate review process from a regional to a national basis. This would develop a single, unified approach to granting exception score points, which is currently being done on a regional basis, sparking concern that there is a lack of uniformity between regions, thus contributing to geographic disparity issues. A working structure for the review board would be set up to arrive at a consistent nationwide policy and every liver transplant program would be eligible to participate and contribute to the review board process. Dr. Klassen noted that this proposal has been released for public comment but some concerns have been expressed about its potential effect on access to transplants and unintended consequences. It should be released for another round of public comment in late January and be submitted to the board for a vote for at its June 2017 meeting.

The third proposal involves the redesign of the liver distribution system; this has proved to be fairly controversial. This proposal would conduct liver distribution over eight districts rather than over 11 regions as is done currently. An overlay of proximity points would also be added, based on where each liver is coming from. It has been suggested that the proposal should have been based on lab MELD rather than allocation MELD and some expressed disagreement over how the supply and demand and disparity metrics on which the disparity metric is based on median MELD at transplant and some have argued that more contemporary data for modeling should have been used, so additional modeling will be done. Alternative proposals have been suggested, including a neighborhoods proposal submitted by an independent group. The proposal will be modified and additional input from the SRTR will be sought. As CAPT Greenwald noted earlier, it should be put out for public comment again in the summer of 2017 and submitted to the board in December of next year.

Dr. Klassen went on to describe several metrics-related projects the OPTN has embarked upon. A workgroup of the Membership and Professional Standards Committee (MPSC) has proposed an alternative review process to

address risk-averse metrics — those that promote risk-averse behavior in connection with organ — specifically kidney — selection or program assessment. The proposal calls for removal of high-risk cases from the PSR calculator and to flag both the total number of high-risk cases and those that are removed from consideration. (“High-risk” would be defined by both donor and recipient factors.) The MPSC approved this change, which, Dr. Klassen explained, is not a policy but an operational definition. Although it will be presented to the OPTN board, the change does not require board approval and the SRTR is expected to implement it in the next round of PSRs.

A workgroup proposal, which Dr. Klassen believes was introduced by an American Society of Transplant Surgeons representative during a board meeting held a year ago calls for a tiered approach to program assessment and includes a random survey component. This complex proposal did not attract widespread public support when it was put out for comment and there are no plans to pursue it but it could be revisited in the future.

Another metrics-based study that focuses on OPOs involves defining a new denominator for OPO metrics. The proposed denominator would be ventilated in-hospital deaths but it is not clear whether this data could be collected reliably. The OPTN has completed this study and is awaiting feedback.

Dr. Klassen briefly described the three-year, HRSA-funded COIN pilot project that is designed to examine risk-avoidance behaviors and design an ambitious new monitoring strategy. It would remove existing performance flagging criteria for participating kidney transplant programs, develop and test a data-rich, quality monitoring framework and support a collaborative approach toward performance improvement and best practices. Its primary goal is to lead to increased transplantation of a broader pool of organs; specifically, high kidney donor profile index (KDPI) kidneys. This approach to metrics directs focus away from one-year patient and graft survival and on program quality structures.

Dr. Klassen went on to discuss items that the OPTN board approved during its last meeting, the first of which was a policy for ABO (blood type) verification. The policy: provides protocols to resolve primary blood type conflicts; institutes testing of two donor samples prior to match run; requires complete ABO determination before living donor registration in the OPTN system and; requires a the development of a written protocol for organ check-in. This policy aligns with CMS’s Conditions of Participation and clarifies expectations of OPWs, transplant hospitals and living donor recovery hospitals, thus improving patient safety.

Dr. Klassen went on to discuss TransNet, an automated system that uses barcoding and printed labels to replace the manual system to verify organ identification and shipping contents. The system has been rolled out to OPOs, which will be required, through OPTN board approval, to use it beginning in June 2017. The OPTN hopes that transplant centers will also adopt the system to handle organs upon their receipt.

Dr. Klassen then displayed a graphic of UNOS Connect, an online learning management system to centralize and manage all of its educational offerings for transplant professionals. The system offers a single sign-on process for UNet users to access a broad range of videos, containing information on transplant policy, kidney, lung, liver and pancreas transplantation and other issues, ranging from recipient compatibility and patient safety to ethics. The system allows the user to start, stop and resume each video.

Dr. Klassen moved on to a discussion of the OPTN board and committees and their efforts to address transparency in their formation and to set goals and design processes to accomplish this. He expressed awareness of a perception that the selection process for participation has been less inclusive than it could be and that the membership could be more diverse. He explained that policy requires board membership to consist of an equal number of physicians and non-physicians. He noted that about 70 percent of the physicians are

surgeons, the majority of whom are kidney (30 percent) and liver (25 percent) specialists. Pancreas, heart and lung and intestinal transplant specialists also are represented; VCA surgeons are not represented. Among the non-physician members, about a quarter are patients or donor family representatives.

Dr. Klassen also noted that 90 percent of the 2016-2017 board members are white/Caucasian and that 65 percent are male; he said that the board is aware of and wants to ensure its membership becomes more diverse.

He also noted that UNOS has about 20 standing committees and that efforts will be made to assess the committee structure and consider whether it should be changed. The typical committee slate consists of one representative for each of the 11 regions and three at-large representatives, in addition to the chair, vice chair, immediate-past chair and a HRSA representative.

Dr. Klassen went on to provide a review of the first 18 months of a new kidney allocation system (KAS) that was introduced in September 2014, under which a substantial number of highly sensitized and high-dialysis-time patients have received transplants although the number has tapered over this time period. He reported that deceased donor transplant volume has increased by 7 percent — which may not be directly related to the introduction of the new system; however, utilization of recovered kidneys has not improved. In other results: delayed graft function has increased but is trending downward. Meanwhile, post-KAS initial six-month graft patient survival is at 95.3 percent and recipient survival is at 97.6 percent; both results are excellent although slightly lower than pre-KAS results. The overall discard rate rose from 18.5 percent to 18.8 percent and was most evident for KDPI 86 percent to 100 percent kidneys.

Dr. Klassen then described some initial results from transplants authorized under the HOPE Act (HIV-to-HIV) transplants. There are currently 20 approved kidney (13) or liver (7) programs that are being conducted at 13 centers. One of the centers is interested in performing living donor liver transplantation.

He reported that from March 2016 through part of November, 19 transplants have been conducted, at least 16 of which were conducted at three transplant centers. Eleven kidney transplants also were conducted at three centers as were five liver transplants. Twenty-four potential donors were identified across eight regions through serology and NAT testing. Other than potential donors, the median KDPI has been 62, only four of which are PHS-increased risk donors. Eleven donors produced 33 match runs, of which six were procured (2.7 organs per donor). The median KDPI is 28 and one is PHS-increased risk.

On the waitlist as of Nov. 11, there were 82 kidney candidates at seven centers (65 at two centers) — among 13 total centers — and six liver candidates (at two centers); median age is 53, 74 percent are African-American and 70 percent are in active status.

Dr. Klassen also provided some statistics on VCA transplant programs. There are 14 abdominal wall programs, 17 head and neck (consisting primarily of face transplants) and 18 upper limb programs. The remainder are chest wall, genitourinary, penile, lower limb and uterine for a total of 61 programs across 26 transplant centers. From July 3, 2014 through Nov. 4, 2016, 21 VCA transplants were performed at 14 transplant centers. Twelve candidates are awaiting VCA transplants at seven centers.

Discussion

Dr. Barr asked why, based on the numbers Dr. Klassen provided, only 17 percent of cases were PHS high risk. Dr. Klassen explained that many of such cases are time limited and behavioral and he theorized that these donors may have been HIV-positive for some time and may have “aged out” of their increased risk status.

Dr. Barr also asked whether the number of overall transplants is equally distributed across organs. Dr. Klassen responded that, the availability of up to two kidneys per donor would contribute to a hike in the number of these transplants but otherwise, transplants were up across all organ categories.

Dr. Gerber noted that the kidney utilization rate has not changed under the new KAS system and wondered when additional analysis results might become available to indicate whether this is a benefit that will result from the new system. Dr. Klassen said that there was not an assumption that the system would decrease the discard rate and that the reasons programs accept or decline a kidney may warrant study.

Dr. McDiarmid asked whether the MPSC has considered the difficulty low-volume programs, such as pediatric programs, have had in flagging for outcomes. Doctors in such programs often see risk-averse behaviors, which can have significant consequences on access. She asked whether MPSC had focused on this issue in connection with pediatric patients. Dr. Klassen said that the majority of focus has been on adult or high-volume transplants and that separate criteria have been applied to the flagging methodology for low-volume transplants. He said he would convey the need to keep the unique challenges pediatric programs face back to MPSC. Dr. McDiarmid said she hoped that ACOT would discuss this as well and also commented on the number of VCA transplants that have been conducted to date, saying that this number — 21 — since July 2014, equals the number that had been performed over the previous two decades, showing that, although activity may seem small, the amount of interest in these transplants is high. As a result, the VCA transplant community, although not currently represented, should be at the table.

Dr. Fung said that that he has found the MPSC has taken an adversarial and even punitive role in reviewing adverse events. Dr. Barr concurred with this impression, saying that, when site auditors review programs, they will flag very minor variations as violations (such as rounding up an inotrope dose up or down by one decimal point). He added that there are no guidance documents readily available to indicate what auditors are looking for. He noted that new potential, pre-emptive flagging methods have been discussed at UNOS region meetings, and that initiatives for broader allocation schemes will request more data to establish additional metrics which also will be subject to review during site audits.

Dr. Klassen acknowledged these concerns and said that the goal is to move away from a punitive environment toward promotion of a quality improvement structure and that there is an effort underway to move the site survey process toward a more quality-focused approach.

Dr. Pastan asked why outcomes data is not released more frequently — one-year graft survival data, for example. Dr. Klassen said that available data had been posted monthly but is now being posted every six months on OPTN's website but that one-year-graft survival data is not always reported or reported fully right away; he added, however, that this information is posted as soon as possible. He also acknowledged that some adverse event data could be published in a more timely manner allow risk analysis to prevent future errors and referred those present to safety videos on OPTN's website. He added that issuing an annual report or some other summary document describing some of these findings from the MPSC's perspective might be useful.

OPTN Collaborative Improvement Innovation (COIIN) Project

Henrisa "Henri" Haskell, R.N., M.S.H.A., C.M.Q./O.E., Director, Member Quality —UNOS

Ms. Haskell explained that the three-year, HRSA-funded COIIN project is intended to examine the large organ demand/supply gap and to find ways to increase transplantation with a particular focus on the use of moderate- to high-KDPI kidneys. She noted that there has been a nearly three-fold rise in the kidney discard rate over the past two decades and that the discard rate climbs precipitously as KDPI moves toward the 90th percentile although the decline in graft survival rates are much more shallow and asked whether the spike in the number of

discards is due to risk-avoidance behavior associated with current monitoring efforts, whether they are done through UNOS's MPSC, CMS or third-party payers. The objectives of COIIN are to:

- Reduce risk avoidance behaviors that are associated with the current monitoring system;
- Remove existing performance flagging criteria for participating kidney donor programs;
- Develop and test an alternative data-rich quality monitoring framework; and
- Support a collaborative rather than a punitive approach toward performance improvement and implementation of best practices to increase transplantation.

The project focused on design in year one and, now, at the beginning of year two, is moving toward deployment. Year three will be devoted to evaluation. The University Research Consortium is partnering on the project; the consortium has experience in collaborative improvement in working on women's health issues, improving medication compliance among people with HIV and reducing tuberculosis in under-served areas.

Ms. Haskell stressed that COIIN is focusing, not on research but on performance improvement and provided a table comparing the way the methodologies between quality research and quality improvement differ. The purpose of quality research, for example, is to provide proof of effectiveness while quality improvement is intended to achieve sustained improvement. In quality research, enough data are collected to authoritatively study for effect and control for all known variables. Data collection for quality improvement, on the other hand, involves collecting just enough data to inform improvement and collecting data on only one or two variables, as needed. In terms of methodology in quality research, one large test would be conducted involving a fixed hypothesis and efforts to control bias as much as possible. By contrast, quality improvement methodology would involve conducting rapid, sequential tests with a hypothesis that changes as learning occurs with no effort to control bias. Quality research results evaluation would consist of pre- and post-assessment while quality improvement results evaluation consists of regular, ongoing assessments involving frequent touch-points with organizations and using run charts. COIIN is intended to focus on sustained improvement of practices that are known to be effective, as identified by organizations that, in this case, are successful in using moderate- to high-KDPI kidneys. The process is intended to produce rapid cycles of improvement.

During year one, a project plan was developed under HRSA's oversight and with an advisory council of OPO representatives, patients, surgeons, nephrologists and CMS representatives. A COIIN performance improvement team was developed to support project design. Criteria were developed to identify successful "practice model" hospitals. The COIIN project team visited five of the 11 hospitals it identified and invited representatives from each to UNOS in June to weigh in on three areas the team identified as key drivers of improvement in the utilization of moderate- to high-KDPI. The three areas were: effective waitlist management, effective organ offer/acceptance processes and care coordination from inpatient to discharge. The team then developed outcome, process and relationship measures, criteria for the process of selecting hospitals for participation and then selected an initial cohort of participating hospitals.

The initial cohort was selected through an open application process that ended in August of this year. The process was open to all OPTN transplant programs that had a volume of at least 45 kidney transplants, living- and deceased-donor combined, within the past 12 months. Forty-four hospitals applied, 17 percent of which were OPTN transplant centers; seven applicants were practice model hospitals. However, the project could accept no more than 20 for the first cohort although the next one could be larger and those not selected for the first cohort could be considered for the next one. The criteria used to review the applicant hospitals were donor volume, current utilization rate of 50 percent or more KDPI kidneys, geographical and regional criteria and their capacity for quality improvement, based on dashboards they submitted and their quality assurance/performance improvement assessments. Any hospitals that had been flagged during an MSPC review for kidney outcomes were excluded as were those about which concerns could be raised during a CMS review. Any hospitals that

might be found to be in noncompliance with OPTN policy or through a site survey also were excluded from consideration.

Through this process, 19 hospitals were selected, with representation from all regions. Region 7 had the highest number of participating hospitals, followed by regions 5 and 6. The cohort included one high-volume hospital; the rest are in a somewhat lower and generally similar range. The group also includes three OPOs and one hospital in Chicago.

The overall objective for the first cohort is to improve kidney transplantation substantially in at least 15 transplant centers by December 2017, with the sub-objective being to improve offer and acceptance rates for moderate- to high-KDPI kidneys.

During year two of the pilot project, which already is underway, the intervention process for the first cohort of hospitals will kick off in January 2017, and coaching visits will be conducted to assess capabilities and capacities to improve. They will be assessed on their workflows related to waitlist management, organ offer and acceptance and care coordination, followed by three 90-day cycles of improvement focusing on these intervention areas. From mid-October through mid-December 2017, the first cohort will be evaluated and lessons learned from working with the first cohort will be used in working with the next cohort, starting in July 2017.

Ms. Haskell stressed that the COIIN project focuses on and promotes collaborative learning, along the lines of what the Institute for Healthcare Improvement (IHI) and the Organ Donation Breakthrough Collaborative. She pointed out that IHI's motto is "All teach, all learn, all share" and that COIIN seeks to follow this approach by focusing on the four areas she described early and using the "Plan-Do-Study-Act" quality-improvement process to achieve rapid-cycle improvement. This creates a model for improvement which involves asking "What are we trying to accomplish?" followed by "How will we know that a change is an improvement?" and concluding with "What changes can we make that will result in improvement?"

She explained that the COIIN project incorporated performance improvement tools called "key driver diagrams" — a simple, visual way to map out where the hospitals' work will take them as they focus the three areas described above (organ offer and acceptance, waitlist management and care coordination). This work, along with COIIN's initial engagement with the practice model hospitals resulted in the development of intervention guides or "change packets," which include change concepts or general notions of desired change the intervention hospitals would adopt, such as "know your waitlist," or more targeted changes, such as "maintain an active waitlist" or "create protocols for timing re-evaluation schedule." The guides contain a description of a specific intervention, resources and tools, recommended process measures and "practice in action" vignettes provided by practice model hospitals. The results of this work are vetted during the coaching visits and the practice model hospitals serve as a resource as the COIIN project proceeds.

Ms. Haskell went on to describe relational coordination, the notion that relationships shape the communication through which coordination occurs. She showed a diagram that depicts the linkages between the various players, ranging from donors to procurement organizations, to the transplant team, to advocates and others, all of which link in various ways both to each other but, most importantly, to the potential organ recipient. However, the communication and collaboration between all of these players must be tight and result in a strong understanding of shared goals and knowledge, mutual respect, timely, accurate communication and an emphasis on problem solving rather than on assigning blame. Thus, strong relational coordination will ensure that transplant hospitals arrive at a desirable outcome. She referred to work done by Jody Hoffer Gittel, who studied a successful player in the airline industry, Southwest Airlines, which has forged strong relationships throughout its organization to achieve consistent quality outcomes in air travel, customer satisfaction and employee morale.

COIIN is conducting initial and follow-up surveys to evaluate the hospitals' key internal and external relationships — such as with their OPOs.

COIIN is using a balanced score card approach to measure outcomes, processes and relationships. Examples of measure include offer acceptance, transplant and waitlist mortality rates and post-transplant graft and patient survival rates.

The next steps as year two begins are coaching site visits to the hospitals in the first cohort, which began in October and will run through December, followed by a face-to-face kickoff in January during which cycles of improvement will begin and a baseline relational coordination survey will be conducted. Collaborative learning will continue throughout and will inform improvements for the next cohort, which starts in July.

Discussion

Dr. Fung asked whether there's concern that, even though CMS has said it will not take outcomes into account in connection with this project, third-party payers might. Ms. Haskell said that the advisory council, stakeholders and participating hospitals have asked this question as well but COIIN has not engaged with third-party payers because the current focus in this pilot phase is on working with OPTN, HRSA and CMS, but private insurers could be involved later. Ms. Haskell confirmed that MPSC has issued a waiver for hospitals regarding outcomes in connection with the COIIN project but CMS has not been able to provide a formalized process for obtaining such a waiver; however CMS has a mitigating factors process, which it may be possible to exercise in connection with outcomes associated with the COIIN project.

Dr. Fung also suggested doing a cost-benefit analysis of these kidneys, to compare outcomes to the the survival rate of patients who do not receive transplants and then to those of patients not involved in the COIIN project who received transplants. Ms. Haskell said that OPTN does not have access to cost data but that this might be obtained by partnering with HRSA and CMS.

Conveying Transplant Program Quality Assessments to the Public

Jon Snyder, Ph.D., Director of Transplant Epidemiology, Scientific Registry of Transplant Recipients, Minneapolis Medical Research Foundation

Dr. Snyder began by explaining that the SRTR's mission is to support HHS oversight of the national organ transplantation system by providing advanced statistical and epidemiological analysis on solid organ allocation and transplantation. He also pointed out that the OPTN final rule requires the OPTN and the SRTR to make transplant program performance information publicly available in a form and at a level that the public can understand and use. The SRTR has been posting these data on its website for five years but is now working to make the information more accessible and comprehensible to the public, in keeping with its contractual requirements, which include the OPTN final rule requirements. The SRTR is charged with providing waitlist data, pre-transplant outcomes organ acceptance and utilization and post-transplant outcomes and updating these data every six months. The SRTR also must list transplant programs and OPOs with comparatively better or worse outcomes.

Dr. Snyder acknowledged that the metrics the SRTR has been publishing on its current website can be difficult even for transplant centers to understand. The website itself is technologically out of date in some ways; it cannot be accessed on mobile devices, for example, and does not meet accessibility standards set forth by the Americans with Disabilities Act. As a result, a project is underway to refine and update the website to make the information on transplant programs it provides easy for anyone to understand.

Dr. Snyder then demonstrated how a member of the public would access data on the current website. If a user searched for a transplant center by state rather than by a specific center's name or code, the statewide center list would appear in alphabetical order and cannot be searched in any other way. To learn more about the center's performance, the user would have to view a detailed, complex report in PDF format that is available for each one, the metrics for which could be hard for anyone who is not math literate or health literate to understand.

To address this, the project team has adopted a "Bayesian" approach to assessing transplant program outcomes, a statistical model that can estimate and display a range of probability for a program's performance and compare it to identified thresholds or national norms in a bell curve display format. The curve illustrates a hazard ratio — a relative metric of program outcomes relative to what the program could be expected to achieve based on national performance involving similar patients and donors. The SRTR's technical advisory committee, which is now called the SRTR Visiting Committee, and members of a consensus conference held in 2012, said that this type of statistical model would be useful in this project. Dr. Snyder referred the ACOT audience to a paper by Christiansen and Morris published in a 1997 issue of the *Annals of Internal Medicine* that describes Bayesian statistical models.

In an effort to make the results of the statistical analysis of transplant program outcomes the SRTR produces more understandable to the public, the project team drew on the Agency for Healthcare Research and Quality's (AHRQ) report (<https://archive.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/pubrptguide1/pubrptguide1.html>) on best practices in public reporting by Judith Hibbard, Dr.P.H., and Shoshanna Sofaer, Dr.P.H., which advises data presenters to "reduce the cognitive burden by summarizing, interpreting, highlighting meaning and narrowing the options for the consumer of these data." Dr. Snyder noted that Dr. Hibbard has worked with the SRTR on the metrics redevelopment portion of the website project. The AHRQ report says that these types of data analysis and findings reports can improve health care quality by:

- Increasing consumer understanding of dimensions of quality that are relevant to their needs;
- Stimulating quality improvement among providers;
- Encouraging purchasers and health plans to use higher quality providers in their networks and;
- Affecting the public image of clinicians and facilities by clearly identifying their performance compared to their peers, thereby encouraging them to improve the quality of the care they provide to protect or enhance their reputations.

The AHRQ recommended various changes to the way data are presented, including making relevant choices visible on a single screen and using easy-to-understand symbols (that don't require legends), not numbers, and simple language and concepts. For example, consumers who do not understand what terms such as "confidence intervals" mean are less likely to trust the data such terms describe or define. The AHRQ also recommended summarizing information when possible and listing centers in order of performance — high to low — and highlighting high performers and using labels such as "excellent," "good," "fair," or "poor," to help the user interpret information. The agency also suggested that if performers will be grouped into performance tiers, reducing the number of tiers from nine to five.

Dr. Snyder displayed several screen shots of the new website, and demonstrated the user's ability to search for transplant centers by program name, center code or by zip code in addition to seeing a listing of all centers nationwide. The search feature will be made available on each website page. The search results provide the center's name, distance from the zip code area, each displayed center's transplant volume and rate (how quickly patients on waitlists are receiving transplants) and an outcome assessment, which is based on the Bayesian assessment approach and users can sort results by any of these criteria. The website also allows the user to switch to pediatric metrics.

The website also allows the user to access a Google map to show a center's location, indicates the types of transplant programs it offers and provides infographics with the types of information that the public may wish to consider in researching a center, including the outcomes data listed above and detailed waitlist information (number on the waitlist as of a certain date, how many joined or were removed from it and the most current available data on the size of the waitlist). Wait list mortality rates are also available. The data are updated every six months and reflect patient outcomes over two-and-a-half years. The site also allows the user to see what percentage of patients received transplants within 30 days and at the one-, two- or three-year mark, both at a specific center and nationally. Among the additional data that are represented are data on transplant patient demographics (race, organ receipt by living or deceased donor and combined) and percentage, when available, of recipients who were alive with a functioning transplant one year after receipt. Pancreas and kidney-pancreas recipient outcomes can be reported separately or combined. PDF reports containing more detailed information are will also be available on the site.

The five-tier outcome assessment system the project team will roll out will categorize centers, reflecting the Bayesian assessment results, as 5, better than expected; 4, somewhat better than expected; 3, good (as expected); 2, somewhat worse than expected; and 1, worse than expected. Color intensities also will be assigned to each classification with high-performing centers receiving the most vivid hue.

Programs also are divided into five tiers, two more than a previous three-tier system to better differentiate between different centers' level of transplant volume (small, mid and large) and program performance. HHS is also using a five-tier system to assess and assess and compare the quality and performance of dialysis facilities, nursing homes and Medicare plans, Dr. Snyder noted.

The methodology used to design and the updated the SRTR website was reviewed by the SRTR Technical Advisory and Visiting Committee and the launch is scheduled for late this year or early in 2017. Dr. Snyder said that Ajay Israni, M.D., the SRTR's deputy director, will hold AHRQ-funded patient and family focus groups to gauge their ability to understand the reports the website generates and make recommendations for future improvement.

Discussion

Dr. Fung asked how much of a difference there is in outcomes between one performance tier and another. Dr. Snyder explained that the project team ran a computer simulation to gauge this and found that a Tier 5 program has a 98 percent probability of producing better outcomes than a Tier 1 program, a 91 percent change of better outcomes than Tier 2, an 81 percent chance of outperforming a Tier 3 program, and a 72 percent chance of performing better than a Tier 4. He explained that these statistics are available on the website and the team is trying to craft guidance and supporting documentation to provide context to these findings.

Dr. Matas followed up, asking how much of a difference, stated in percentages, there would be between adjoining tiers (e.g., Tier 2 and Tier 3). Dr. Snyder said that the range would vary depending on organ type with the narrowest one occurring with kidneys, for which outcomes are generally good. He estimated that there would be about a three-fold difference across the tiers but didn't have specific statistics on hand to provide actual percentages. Dr. Matas pointed out that patients and other stakeholders might wish to know when a variation between the centers in two tiers reached, not necessarily 1 percent but 5 percent to 10 percent. Dr. Snyder reminded him that the assessments are relative to how other centers have performed but again promised that guidance would be made available to help visitors to the site understand and use the data. He also noted that a 2015 issue of *Clinical Transplantation* that provides useful information on this topic.

Dr. Barr asked whether this tier system might affect what data centers report. He offered as an example, the possibility that some centers might not report as wait-listed patients who are likely to become poor transplant candidates over time or those who have been listed early because their inclusion could seem to indicate a low transplant rate. Dr. Snyder that programs can do things to inflate or deflate their transplant rates. But it's possible to request more data from programs, such as how many patients were young or old or the transplant rate for MELD 20 patients versus MELD 35 patients.

Dr. Barr also asked whether some outcomes support a metric more than others or whether the transplant rate and transplant volume have equal footing in the general final score. Dr. Snyder said that the website will not weigh all outcomes together to create a composite score. He explained that the outcome assessment is, at this point, based on first-year graft survival.

Insofar as meeting one of the key objectives of refining the website — providing patients and other non-specialists with the type of information they most value, he said that the various metrics will be explored in the focus groups to determine what metrics website users prioritize — for some it might be distance and some may be more concerned about how quickly they are likely to receive a transplant than post-transplant outcomes. The team hopes to learn whether patients would like to see a similar assessment across transplant rate, volume and distance. The team is considering ways to allow the patients to weigh each metric in the order that it matters most to them and this could lead to a composite score. Currently, the assumption is that transplant rate is important to a prospective recipient. He also pointed out that there is an effort to get away from focusing solely on transplant rates and moving instead toward focusing on program quality. Ultimately, the five-tier system may be reduced to four but it depends on what patients say they want to see.

Dr. Snyder also noted that the time-to-transplant metric is calculated based on the day a patient is enrolled in a transplant program and tracks what percentage of patients are transplanted within 30 or 60 or 90 days, etc., of being put on that list, with the understanding that the kidney allocation system backdates to include dialysis time. The metric listed indicates how likely someone is to receive a transplant from the time they are listed to a specified later date (six months, one, two or three years, etc.).

New Business

Dr. Barr asked the committee whether the ACOT members had any new business to address; no topics were proposed. Mr. Walsh said that members had expressed interest in having an in-person meeting in the spring of 2017 but that such a meeting cannot be scheduled until the committee has a budget for next year. This decision will be circulated to the committee once it becomes available.

Public Comment

Mr. Walsh explained that the amount of time for public comment is limited and invited those who had lengthy remarks to submit them to him by email so that he can ensure they are included in the public record. He reported having received an email from Dr. Sigrid Fry-Revere, president and co-founder of the American Living Organ Donor Network with an extensive proposal regarding a living donor registry and ideas on how HHS might develop such a registry that would allow living donors to donate organs to patients at the top of the organ transplant waiting list, the OPTN waiting list and others. Dr. Fry-Revere did not wish to speak about the proposal during the public comment period but asked that it be made available and Mr. Walsh said he would distribute it to ACOT members after the meeting.

Mary Harty delivered oral comments, which are presented, verbatim, below:

Ms. Harty: This is Mary Harty. It is my understanding that the SRTR numbers are basically self-reported information. It is kind of a compiled and compounded without any outside reviewer independence. Is there a conflict for the public?

Dr. Barr: “That’s actually not true. It is not voluntary. John Snyder, if he’s still on, can explain to you how the SRT works. It is audited data that comes from UNOS auditing. The centers submit information that is all audited and verified, and then analyzed by the SRT. John, are you still on? Can we tap into you there to just briefly explain how the data is actually gathered and analyzed?” Dr. Snyder: “Sure, happy to. The data the SRT are using are of the assessments of the programs is coming directly to us from the OPTN. So the OPTN has their policies in place that oversee the structure, the quality of the data, the reporting by the programs. In terms of auditing those data, the UNOS auditors do partly oversee that data collection system and do go after programs that violate the data collection policies per their bylaws. We also merge those data sets with other external sources; the publicly available death master file made available by the national ... the NTIS group, and data from the Centers for Medicare & Medicated Services ... additional failures.”

Ms. Harty: I know what you’re saying but isn’t it all just collectively part of the alliance, and also the chartered alliance, and then my question would be ... let’s say for example Mr. Snyder, a sentinel event occurs, so how is the death reported to the SRTR? Is it considered a positive transplantation only related to the failure of the patient’s care? So that’s the question I had. Is it reported as a successful transplant? Even though the patient passed away?

Dr. Snyder: By policy the center has to report that death to the OPTN, and we do check other sources to identify those deaths in case there’s one that’s missed. We would capture those through the sources that we check against, assuming those sources are also know about it. A center experiencing a sentinel event that doesn’t report it to the OPTN would be a violation of the OPTN policy, and they may subject themselves to additional ...

Ms. Harty: But what if the OPTN, or the OPOs, excuse me, are not actually being monitored as they should and basically of a conditional level failures. How does the skewed information get reported to the public?

Dr. Snyder: I’m not sure I’m following your question about the OPOs.

Ms. Harty: ... OPTN or OPO that is of a conditional level deficiency, there’s issues and problems that are ongoing, how does that number get skewed because of their lack of reporting? ... There’s no outside ... this is the OPO reporting to UNOS. Who’s the correct one to make sure those numbers are in compliance, and in order and true?

Dr. Snyder: I think all I can do is point back to OPTN policy that governs data submission. They have standards for completeness and timeliness of reporting that the OPOs and the transplant programs have to meet and the OPTN monitors the compliance. It’s not the SRTR doing that monitoring, it’s the OPTN doing the monitoring.

Ms. Harty: So there’s no one independent. And so then my question is what would be the fine involved in that reporting, or incorrectly reporting information that is then later put out to the public? Is there any kind of a fine by UNOS regarding their OPO’s failure to comply?

Dr. Barr: I think we understand the question. So the information that comes from transplant centers, there’s an equivalent set of data that comes from OPOs on their side. This information goes to UNOS. UNOS, MPSC, has sub-committees that oversee data as well as having an all audit section of UNOS that verifies information that comes from both OPOs and transplant centers. So OPOs are also under the same type of scrutiny as transplant centers are, and if data is either not verifiable then what will happen is ... then that would be something that

would be moved up into MPSC as a violation. As far as verification ... the verification of the data does get done at the audit level, and the audits are being done by non-transplant, non-OPO investigators, as well as, remember that, centers and OPOs are also audited by CMS separately, so there's two different entities, the OPTN and CMS both audit the transplant centers and the OPOs.

Ms. Harty: The last time I was on I asked for the secretary [to be] there, and I've yet to receive it regarding the concerns I presented to you, which is included in independent team for such things as sentinel events and concerns that have not been addressed and it's good to see everybody seems to be getting on board now, but I must ask, where's everybody been?

Dr. Barr: This has been the same process for years and years and the ... auditing of transplant centers and OPOs, it's not a new process. This has been going on for a very long time. Bob, did you something you wanted to say?

Mr. Walsh: I just wanted to say that the requirements that you are referring to Mark, about the CMS regulations and the OPTN policies, are all publicly available, so if there are ... they're available and can be reviewed by anybody who has interest in this ... and have them submitted in writing and we can address them in that way.

Ms. Harty: Yes, I'm going back to my comments from November 17, and again about an independent team regarding such things as sentinel events. There's ... definitely validate those numbers to the public and to the UNOS for reporting and SRTR. I'm going back to independent counsel for reviewing the federal form for consent and validation of the patient's rights. I'm going back to an independent team that would allow for oversight, independent counsel for validation of policies for the patient rights, the public site, the provider of all, including the gift of life. I've asked the secretary ... and it doesn't seem to be forthcoming and considering the concerns that have been found along the way I would think it would be available, and without a filter. Perhaps that could happen, Dr. Barr. (End of Ms. Harty's first round of comments.)

Mr. Walsh: I did receive an e-mail from a Mr. Rocco Lotito regarding his concerns about the treatment of living donors by the transplant community. It's a fairly extensive comment, but I will have it entered into the record and I'll share it by email with the rest of the committee. I also received an email from Mr. Josh Morrison, executive director of Waitlist Zero. He sent a fairly brief public comment that I'll read now. He stated, "In last year's Fall ACOT meeting, Dr. Bertram Kasiske presented a plan to develop a proposal for a living donor registry, to be funded by HRSA. Despite numerous requests, the Health Resources and Services Administration has refused to make this proposal public; any information concerning it. Improving living donor follow-up is of critical importance for the transplant field, particularly, given the current unacceptably short two-year follow-up requirement. On behalf of the living organ donors we represent, Waitlist Zero would like to register its formal disapproval of HRSA's lack of transparency about this important issue." I would note that Dr. Greenwell did include an update about that living donor registry pilot in the comments at the beginning of the meeting. As it proceeds, we will definitely make it available to all.

Jane Zill delivered oral comments, which are as follows:

Ms. Zill: Thank you for this opportunity to make public comment. Just a little bit about myself, I'm a clinical social worker, I'm a former member of the Living Donor Committee of the United Network for Organ Sharing, and the Organ Procurement Transplant Network, and its living donor task force, and in 1991, I was a living-related kidney donor. I have, I guess a question, and then some comments. There's a disclaimer by CMS, the Centers for Medicare & Medicaid, employees, agents, and staff make no representation, warranty, or guarantee, that this compilation of information is error free, and will bear no responsibility, or liability for the results, or the consequences of the use of this resource. I would just like to say for the record, that as a stakeholder of this system, I ask that CMS personnel do take responsibility for the work that they have done today, and going

forward. My comment now also, is from my perspective, it's not particularly desirable for CMS to collaborate with ACOT, and CMS is the only governmental regulator of this highly privatized and monopolistic industry, that was created in the 1984 ... legislation. I'd like to also continue to address now CMS, but also members of ACOT, that in the CMS presentation, they discussed disparity, and access to transplantation. They may not be aware that in 2012 UNOS ... created several substantial policy changes that impacted disparities, pertaining to international patients who received U.S. deceased donor organs, and regarding data collection on them. It was clearly documented in 2012 that citizenship and residency will not be a consideration in the assignment of the deceased donor organs in the United States. That residency is designed simply as whether a patient considers the U.S. as the primary place of residence. What good is that data collection? That OPTN surgeons may privately negotiate the terms in which they will care for foreign patients, and the 5 percent audit trigger from foreign patients has been removed. In terms of this concern about disparity, and access to transplantation, I think we need a much clearer data collection effort on organs that are going to foreign nationals, and perhaps a revisiting of that 2012 policy. I would also just like to quickly note that on today's agenda, I see absolutely no mention of the huge controversy that erupted this summer, and has extended into the fall, regarding the state sponsored use of organs of murdered prisoners of conscience in China, or about the desire of the national, and international transplant community to expand business with the transplant community in China. CMS, did you know that the 2012 policy changes also allow for an unlimited number of organ import of foreign organ procurement organizations, and the 2012 policy revisions state that ethical practices are subjective? At a congressional hearing last June, and towards organ harvesting, Dr. Frank Delmonico discussed the many advances made in China in the area of transplantation. He and others have written about how much can be learned by the Chinese transplant community. Now, how might this tie in today, to the CMS presentation? The CMS affinity work group has mentioned kidney regeneration, and real repair and xenotransplantation. Based upon my research, it's my understanding that the lead researchers for these initiatives have come from China, meaning that prisoners of conscience were likely used as human subjects in the development of this technology, and that this will continue. CMS, before going any further with collaboration with the National Institute of Diabetes, Digestive, and Kidney Disease, and the University of Alabama at Birmingham Xenotransplantation program, I think it'd be important to know if those researchers are collaborating with Chinese researchers. Then you also highlighted that the technological advancements ... organ perfusion and transport devices, the new technology on the scene. 2014, the *Washington Post* reported the United States and China agreed on a plan to eliminate tariffs on dozens of high-tech products, including GPS devices, medical equipment, and game consoles. Given the number of deceased donor organs that can now be imported in the U.S. and the terrible data recording by U.S. centers, how are we to determine that organs and tissues from murdered people are not flowing into our country? In my opinion, it is more important to address the sloppy, and unethical data reporting, and organ assignment in the United States, the unethical use of living people for their organs, and the reality of poor recipient outcomes in the U.S. due to poor matching in section, cancer, and cardiovascular disease than it is to make transplantation a more widely available service, or continue to increase funding for it. Thank you for your patience. (End of Ms. Zill's oral comments).

Ms. Harty contacted ACOT again to deliver additional comments, which are as follows:

Ms. Harty: Yes, this is Ms. Harty again, and I did have another question. I was wondering where Mr. Hamilton's concerns that were presented for immediate action, in bureaucratic time, that's 30 days, for patient safety ... safety, and the Medicare trust safety ... Where it sits, or if it's still being kicked around as a draft. I see a lot of conversation today regarding increasing volume, research funding, contracts, and volume ... I'm wondering about, where's the conversation on patients' safety. With that, I will bring to light the questions I have for you UNOS, regarding the record keeping that they offer, such as the validation of testing of organs, the consent of the patient, the notice to the patient of changes within the listing, and other concerns that have been presented to them, that they have not made available. Obviously, they don't exist. I'm wondering if they just

take the word of the OPO, and the transplant center, as far as that goes, as far as whatever they have to type and transmit? My other concern is based on Ms. Zill's comment, which I just heard. I would say that the international program that she just spoke about, and the changes that were made in policy might sit very nicely with *[unintelligible name]*, the head of the international relations committee for UNOS. While the University of Miami is one of the only programs that checks Memorial Hospital, I believe there's only two in the nation that have the ability to import organs. Both of these facilities outrun and operate international programs for health tourism, which is inclusive to transplantation. I see a number that Mr. Schneider pointed out, while we were on line, about the thousands of people that appear to be on your list, over a thousand, and I must address how any one transplant center, that one or any other in the country, is allowed to carry such a heavy load. I'd like to just add about the failures of the OPO down there, which I mentioned the last time in my November 17th *[from the 2015 meeting]* comments. It took so long to get out, maybe they're in the collective world of transplantation, patients' safety, real numbers, and care, and concern by the community that likes to seem to have a lot of meetings, and seminars, and different things like that, can actually act. That goes back to an independent team that can oversight, and act with strict immediacy, about complaints, and/or particularly sentinel events to get to the truth of the matter, to do as the other physician mentioned, have an actual number, so that you can look at comments, concerns within the community, that could be addressed. (End of Ms. Harty's oral comments)

NOTE: Additional public comments that were submitted separately from the meeting appear at the end of this meeting summary.

Mr. Walsh thanked those who submitted comments for doing so and invited any others to submit them to the committee in writing. He then read a message sent by Richard Knight, a representative of the American Association of Kidney Patients "who wrote that he would like ACOT members to be aware of the large number of patients who are members of the AAKP [American Association of Kidney Patients], that are interested in supporting the research efforts of the various researchers who reported out today. He stated that they look forward to supporting our efforts to increase transplantation, especially transplantation among minorities."

Dr. Barr thanked Mr. Walsh and wished everyone safe, and good Thanksgiving holiday. He said that Mr. Walsh will inform members of ACOT, as well as through public announcement the general public, regarding meeting dates in the spring and whether the meeting will be in-person or virtual.

Mr. Walsh thanked Mr. Barr all ACOT members and the members of the public who participated today and declared the meeting adjourned.

Additional Comments Delivered in writing by members of the public/advocacy groups

Richard Knight, vice president/chair of public policy for AAKP delivered the following comments:

I am listening in on the call. I may not be around to the end of the call when the public comments. Great meeting, this is my second ACOT meeting which I am attending. I want to point out that while you have representation from colleagues in the federal government as well as many academic institutions. I think that the quality of the various groups could be enhanced from participation from patients. AAKP represents the independent patient voice and would be happy to participate. As always, we appreciate your efforts on behalf on the renal community.