

OPTN/UNOS Kidney Transplantation Committee
August 4, 2006
Conference Call - Microsoft® Live Meeting®

Mark Stegall, MD, Chair
Peter Stock, MD, PhD, Vice Chair

The OPTN/UNOS Kidney Transplantation Committee met via conference call and Microsoft ® Live Meeting ® to discuss the progress of the kidney allocation review. A specific focus within this meeting was to begin formulating strategies for communicating the work of the Committee to develop a modified, national kidney allocation system. Within this context, the Committee discussed holding an educational public forum, as well as methods for communicating with other OPTN/UNOS Committees and Regions and organizations external to the OPTN.

Public Forum

Dr. Stegall briefed the Committee on a discussion that had taken place regarding the possibility of convening a public forum to introduce concepts being discussed as part of a potential modified national kidney allocation system. During the 2006 World Transplant Congress in Boston, Massachusetts, Dr. Stegall met with the OPTN/UNOS President, Sue McDiarmid, MD, as well as representatives from UNOS and HRSA. Previously, a public forum was planned for October 2006 to gain feedback on a proposal. Since there is currently not a finalized proposal for presentation, the topic of this discussion was whether to continue to plan for a public forum and what the focus and purpose of the forum should be.

Dr. Stegall suggested that rather than having a forum for the purpose of presenting a proposal, this forum could be educational in nature and introduce the main concepts behind the system that the Committee is developing. Since simulation modeling results are not yet available, the primary focus could not be on the projected effects on specific patient populations. Rather, the forum would be a one day session in which members of the transplant community and other interested parties could attend and learn about net lifetime survival benefit (NLSB) and the quality of life modifier, among other matters. Dr. Stegall and other members of the Committee agreed that the community will need to hear about the concepts frequently in order to understand them.

One member of the Committee expressed a concern that, without simulation results, the concepts may not be clear because the impacts of the policy changes cannot be assessed. Dr. Stegall agreed but also offered that members of the Committee and other interested parties have expressed that the concepts alone are worthwhile to discuss. Additionally, if the Committee postpones holding a forum until the simulations are finished, the community and general public may think that the proposal is finalized and that their feedback will not be considered or incorporated. Ginny McBride, RN, MPH, CPTC, of the Health Resources and Services Administration (HRSA), offered that she and her colleagues at HRSA very much support the idea of an educational conference. HRSA believes that the efforts to reach the patient population and others who will be affected by these policy changes must be deliberate and well-planned. Ms. McBride also expressed that she and her colleagues at HRSA are willing to provide

assistance as necessary and will be discussing possible communication strategies and topics for the forum at its upcoming Project Officers Meeting with UNOS staff. Dr. Stegall expressed the Committee's appreciation for this assistance.

Robert Wolfe, PhD, of the Scientific Registry for Transplant Recipients (SRTR), described to the Committee some of the communication efforts that had been used during the development of the Model for End Stage Liver Disease (MELD). In its policy development process, the OPTN/UNOS Liver Transplantation Committee discussed the project in phases. Initial presentations were more general so that the community could discuss major issues and concerns. The Committee was then able to respond to these concerns before a final proposal was developed. Dr. Wolfe explained that this process of requesting and obtaining feedback prior to the presentation of a final proposal will make it easier for people to understand the concepts and also to become involved in policy development. One member of the Committee remarked that the patient population affected by the changes to liver allocation policy is substantially smaller than the patient population who will be affected by changes to kidney allocation policy. Therefore, the Committee will need to allow sufficient time for a period of response between its first public forum and presentation of a proposal. As another source for example of how to structure the forum, one member suggested that the 1997 Standardized Listing Criteria forum that was held in Bethesda, Maryland should be reviewed as it was well attended.

Public Forum Themes

Dr. Stegall asked the Committee to offer suggestions regarding the overall strategy and possible themes for the public forum. Keith McCullough, MS, of the SRTR offered that two potential topics could be the goals of the new system and reasons for wanting to change the current system. Dr. Wolfe agreed that these would be two topics to which people could react and understand. Additionally, it will be important to explain the paradigm shift from allocation of kidneys based primarily on waiting time to allocation based on extra years of life for candidates.

The Committee continued the discussion of concepts that should be presented during the public forum with one recommendation to more clearly define which kidneys will be affected by the proposed system. The proposed allocation system is not expected to affect all deceased donor kidneys; rather, it is limited to kidneys from standard criteria donors (SCD). The opportunities for a kidney from an expanded criteria donor (ECD) or a living donor will likely remain largely unchanged. Other members agreed that these alternative means of obtaining a kidney transplant need to be fully explained during the forum and that the percentage of kidneys affected by the proposed modifications should be shared. Anticipated enhanced efficiencies in a modified system also should be discussed.

One member explained that the Committee may want to generally describe what the new system is expected to look like for various groups of candidates, (e.g., elderly candidates, diabetic candidates) and to discuss more general issues of predictability and utility. Rather than discussing the intricacies of the system, Committee members suggested that a better approach would be to address the major questions that the community may have. Additionally, a member added that the Committee should emphasize its emerging understanding that a kidney allocation system that is based on net lifetime survival benefit (NLSB) has the potential to provide

thousands of more years of life collectively than the current system. To the extent that net benefit is not integrated, these life years are being lost.

Post-Forum Communications

One member asked how updates, including results of simulations, might be provided to interested parties after the forum. Ms. McBride offered that, following the forum, information could be disseminated to interested parties through methods other than in-person meetings such as conference call or Microsoft® Live Meeting ®. Dr. Stegall also explained that a second forum would be anticipated to take place in early 2007. This forum would be intended to provide simulation results and a formal proposal. Ideally, this second forum would occur during the first public comment cycle of 2007, thereby allowing participants to provide additional input and feedback as part of this established process.

While the forum will be open to the public, the Committee discussed how to identify specific organizations (e.g., patient advocacy groups) to invite. Ms. Sommers explained that the patient groups that were identified and invited to the kidney allocation review hearings could also be invited to the forum. These patient groups were identified in collaboration with the OPTN/UNOS Patient Affairs Committee. Additionally, mailing lists and other contact databases that UNOS has access to will be used to invite individuals and organizations. Dr. Stegall explained that these efforts are being undertaken by the UNOS Communications staff which is developing a comprehensive communications plan. As part of this communications plan, one member requested that UNOS staff send out a notice that includes the time, date, and location of the public forum to patient groups no later than 6 weeks in advance of the forum. This time frame would provide groups with enough notice to make arrangements to have representative(s) attend. Ms. Sommers proposed that a “save the date” notice could be sent immediately and then a more detailed notice, containing an agenda could be sent at a later time.

Public Forum Logistics

Ms. Sommers provided details regarding some of the forum logistics. Current plans are to hold the forum on Friday, October 13, 2006, at the O’Hare Hilton Hotel and Conference Center. Times have not yet been determined.

Regional Meetings and Other Communication Channels

The Committee discussed the importance of the upcoming regional meetings for communicating not only the date of the public forum, but also providing more information concerning proposal concepts. These meetings were viewed as an ideal environment for delivering detailed information to the constituencies of transplant centers who are going to be most interested in the changes. Transplant surgeons and nephrologists whose patients are going to be affected by the policy changes are a core target audience to be reached. Another Committee member added that the regional meetings were essential to the communication of changes to the pediatric allocation policies and also noted that participants in regional meetings further disseminate information to their colleagues and patients. Dr. Stegall agreed and remarked that the Committee’s Regional Representatives will be some of the most important conveyers of the proposal’s concepts. Therefore, Dr. Stegall encouraged these members to become comfortable with presenting the concepts.

Policy Oversight Committee

Dr. Stock asked if the OPTN/UNOS Policy Oversight Committee (POC) has had the opportunity to review the progress on the modified, national kidney allocation system. Since this will be a major policy change, Dr. Stock explained that receiving the POC's feedback *during* the policy development process would be more useful than only receiving feedback at the end of the process when changes will be more difficult to make. Janis Orłowski, MD, Chair of the POC agreed and remarked that while the majority of her committee's time and effort have been directed towards the project to reduce OPTN data collection, it did have the opportunity to review and approve the objectives statement that the Kidney Committee provided. Going forward, the POC plans to begin fulfilling its charge to determine if existing policies are fulfilling their objectives and to approve policies that are submitted by committees for Board consideration. Along these lines, Dr. Orłowski explained that the POC will begin actively working with the Kidney Transplantation Committee. Additionally, several members on the POC have been individually involved in the Committee's work and have provided informal updates as necessary.

Dr. Orłowski also briefed the Committee on a recent meeting of the Scientific Technical Advisory Committee (STAC) during which the modified kidney allocation scheme was discussed. The STAC raised thoughtful comments and concerns and Dr. Orłowski expressed that the Committee will need to determine how to respond to and integrate such comments.

Questions to be Answered and Path Forward

Peter Stock, MD, PhD, Vice Chair of the Committee asked about the predictability of the modified system and whether it will be possible to differentiate between candidates with NLSB scores close to the median. Currently, it is unknown what impact other factors such as HLA and waiting time will have on this group of candidates. Dr. Wolfe explained that the SRTR is developing a calculator that will help candidates understand what their NLSB score would be and that the effect of donor characteristics are expected to be small on the overall priority. Essentially, with this calculator, candidates should be able to have information about their likelihood of receiving a SCD kidney offer.

The Committee discussed possible questions and concerns that will need to be addressed in the coming months regarding the modified system. One of the most critical questions identified by the Committee will be how to convert from the current system to the modified system. Additionally, a couple of members expressed concern that newly listed candidates may receive higher priority than candidates who have been on the list for a longer period of time. Another member asked if inclusion of waiting time in the model could result in candidates with lower NLSB scores moving up to the point where they may receive a transplant, or whether the addition of candidates with higher scores will continue to preclude these candidates. Dr. Wolfe explained that the simulation modeling will not be able to provide this level of detail, especially when the idiosyncrasies of local lists and variations in practice are considered. Generally speaking, the longer the waiting time, the less benefit that a candidate will experience, all else being equal; so for SCD organs, the proposed system appears to move candidates farther from the top of the list over time. One member remarked that this situation may not be a negative

occurrence since it means that candidates who will experience the greatest amount of benefit from a kidney transplant will be receiving organ offers.

The Committee discussed the psychology that may support maintaining the current system. One of the long-held perceptions in the nephrology and transplant communities has been that kidney transplantation is a lifestyle enhancing operation rather than a life-saving operation. Many on the Committee agreed that transplantation has had superior outcomes to dialysis for the past two decades, but that the perception of kidney transplantation as a life enhancing procedure will need to be changed for many in the community. With lifestyle enhancing procedures, the idea of a queue is acceptable. For life-saving procedures, however, the Committee agreed that more attention must be given towards allocating to the candidates who will experience the most benefit. One member expressed that rather than changing the perception of many in the community, the Committee is actually correcting an important misconception because it is well known that diabetics in donor service areas (DSAs) with longer waiting times are not likely to survive until they receive a kidney transplant.

A couple of members remained concerned that candidates' NLSB scores would decline over time, potentially putting a transplant out of reach. One member remarked that this is why the ECD system is remaining unchanged and primarily based on waiting time. The Committee agreed that the changes to the SCD system must be presented with an explanation of the ECD system and how it will serve as an option to patients who are unlikely to receive an SCD kidney.

A member requested that the term net lifetime survival benefit be changed to be more in line with terminology in the medical decision making literature. Additionally, he remarked that the Committee's direction and decisions regarding use of net benefit appear to be in line with the fields of evidence based medicine and medical decision making. The Committee agreed to look into possible alternatives for the term and expressed that any chosen term should be in line with the literature and clearly describe the concept. For example, since median survivals are now used in the model, use of the phrase "lifetime survival" probably is no longer appropriate.

A couple of Committee members remarked that not everyone on the Committee agrees with all aspects being developed for the modified system and that it will be difficult to communicate proposed changes to the public without consensus. Dr. Stegall responded that it is unlikely that everyone on the Committee will completely agree with all parts of the modified system. However, some of the disagreement may be resolved when the results of the simulation models are available and more is known about the implications of the proposed changes.

Response to Sue McDiarmid, MD, OPTN/UNOS President

The Committee briefly discussed a letter from Sue McDiarmid, MD, OPTN/UNOS President regarding the work of the Committee over the coming year (**Exhibit A**). One member asked how Dr. Stegall planned to respond to the request for a plan to achieve the short and long-term goals detailed in the letter. Dr. Stegall responded that he has conversed with Dr. McDiarmid and will be having a conference call with her, Walter Graham, Executive Director of UNOS, and other UNOS staff to discuss this further, including a timeline. Dr. Stegall also relayed that Dr. McDiarmid supports the plan to hold an educational forum in October 2006, to present a formal

proposal to the public around January 2007, and to present the formal proposal to the OPTN/UNOS Board of Directors around June 2007.

Possible Face to Face Committee Meeting

Dr. Stegall asked the Committee to consider whether or not it needs a face-to-face meeting, or whether conference calls with Live Meeting ® support were sufficient to plan the public forum. The Committee would then reconvene with a face to face meeting when simulation results become available. Another possibility would be to have an in person meeting on October 12, the day prior to the forum. One member expressed concern that having a meeting immediately before the forum would not allow enough time for changes to be made to presentations should any be necessary. Another member expressed concern that if the Committee does not have an in person meeting until October 12, it will not have met face-to-face for five months.

One member suggested that the Committee should focus on identifying topics for the forum and begin developing presentations. If during this process it becomes evident that a face-to-face meeting is necessary, one could be scheduled. Dr. Stegall agreed, noting that the flexibility of teleconference meetings may be necessary due to the busy travel schedules for many members. Additionally, this approach would also allow the UNOS Communications team time to prepare a communications plan and for HRSA to offer suggestions for forum topics.

Dr. Stegall invited members to provide additional input regarding specific topics or questions that should be covered at the October public forum, talking points for Region meetings and other venues where the kidney allocation review is being discussed, and suggestions for how to structure the forum. An e-mail communication will be distributed to members following the meeting outlining these questions and requesting responses.

**Attendance During Meeting of
OPTN/UNOS Kidney Transplantation Committee
Conference Call – Microsoft® Live Meeting®
August 4, 2006**

Committee Members Attending:

Mark D. Stegall MD	Chair
Peter G. Stock MD, PhD	Vice Chair
Robert L. Madden MD	Region 1
Michael E. Shapiro MD	Region 2
Stephan Busque MD	Region 5
Jonathan A. Fridell M.D.	Region 10
Paul F. Gores MD	Region 11
Margo L. Akerman MS	At Large
Dale A. Distant MD	At Large
H. Albin Gritsch MD	At Large
Daniel H. Hayes MD	At Large
Mary S. Leffell PhD	At Large
Alan B. Leichtman MD	At Large
Ruth A. McDonald MD	At Large
Kevin J. O'Connor MS, PA	At Large
Janis M. Orłowski MD	At Large
Milton (Sandy) Sander III, RN, CCTC	At Large
Mark A. Schnitzler PhD	At Large
Henkie P. Tan MD, PhD, FACS	At Large
Trent E. Tipple M.D.	At Large
Winfred W. Williams MD	At Large
James J. Wynn MD	At Large
Marla Jill McMaster M A	BOD - Liaison
Gregory Fant Ph.D.	Ex. Officio
Ginny McBride RN,MPH,CPTC	Ex Officio

Members Unable to Attend:

Thomas C. Pearson MD, PhD	Region 3
Francis H. Wright Jr, MD	Region 4
Christian S. Kuhr M.D.	Region 6
Dixon B. Kaufman MD, PhD	Region 7
John L. Smith MD	Region 8
Stuart M. Greenstein MD	Region 9
Kenneth A. Andreoni MD	At Large
Clyde F. Barker MD	At Large
Bryan N. Becker MD	At Large
Kenneth L. Brayman MD, PhD	At Large
Fernando Cosio MD	At Large

Mark D. Fox MD, PhD	At Large
Rainer W. G. Gruessner M.D.	At Large
Tammie S. Peterson RN, BSN	At Large
Velma P. Scantlebury MD	At Large
Rodney Spangler	At Large
Jennifer K. Thompson RN, MSN	At Large
Richard J. DeSanto	BOD - Liaison
James F. Burdick MD	Ex Officio

UNOS Staff Attending:

Ciara J. Gould, MSPH	Policy Analyst
Cindy M. Sommers Esq.	Director of Allocation Policy
Maureen A. McBride Ph.D.	Senior Biostatistician
Dielita J. McKnight	Business Systems Analyst
Sam E. Perry	Business Systems Analyst
	Applications System Analyst and Programming Supervisor
Kristal D. Wood	Regional Administrator
Chrystal Oley-Graybill	Applications Engineer
Karen Williams	

SRTR Staff Attending:

Robert A. Wolfe Ph.D.	SRTR Liaison
Keith McCullough	SRTR Liaison



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Walter Graham, Executive Director

July 21, 2006

Mark D. Stegall, M.D.
 Mayo Clinic Transplant Center
 Charlton Building, 10A
 200 First St., SW
 Rochester, MN 55905

Dear Mark,

First let me thank you for undertaking the responsibility of leading the Kidney Transplantation Committee over the next year. I would like to invite you to participate with me, UNOS staff, HRSA, and the Board, in developing a plan for your Committee's work ahead. The results of your efforts will directly affect our ability to achieve the goals of UNOS, in its role as the OPTN contractor. It seems essential that we develop together a plan forward that is congruent with the expectations of the partnership between the transplant community, and our colleagues at HRSA as now included in the OPTN contract.

HRSA has established Program Goals for organ transplantation in the United States over the next decade. Achievement of those goals is included in the OPTN Strategic Plan. As the OPTN contractor, UNOS has the responsibility of doing everything it can to effect those goals. Of the Program Goals set for us by HRSA, the most important for your Committee, is the goal to increase the number of donors, and the number of organs transplanted. While there are many other questions and issues to be debated and considered, we must keep our focus clearly on this fundamental objective, and arrange our priorities accordingly. As you may know, actual target numbers and timelines for increasing donors and numbers of transplants have been set by HRSA. Achieving these goals will be very challenging. Whereas the intent is not to be held hostage by numbers without consideration of the process, resources to achieve them, and outcome after transplantation, we must put forward a considerable effort of will to address the critical questions of how to transplant more patients successfully.

The success of the HRSA Organ Donation Breakthrough Collaborative has demonstrated a conundrum – an increased number of donors but no increase in the number of organs transplanted per donor. A national conference in New Orleans, on October 18-19, to which you will be invited, will begin the process of understanding this divergence and addressing the solution to it.

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Mark D. Stegall, M.D.
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After consultation with UNOS staff and your Committee's UNOS liaison, Ciara Gould, I am asking you to consider the following objectives as you plan your committees' work:

- KARS proposal – as the proposal develops, estimate how well it will be expected to meet the HRSA Program Goal shown below. Other Program Goals may be impacted as well, and any estimations or references to such expected impacts also would be welcome.

Long-Term Goal

By 2013, increase the total expected life-years gained for kidney transplant recipients in the first 5 years after the transplant to 8,543 compared to what would be expected for these recipients had they remained on the waiting list.

(Outcome)

Short-Term Goals

Increase the average number of life-years gained in the first 5 years after transplantation for deceased kidney/kidney-pancreas transplants by 0.003 life-years until the goal of 0.436 life-years gained per transplant is achieved in 2013.

Increase the total number of expected life-years gained in the first 5 years after the transplant for all deceased kidney and kidney-pancreas transplant recipients compared to what would be expected for these patients had they remained on the waiting list.

- Provide a stepwise plan of the priority of elements to be introduced into KPSAM
 - Estimate the timelines for each stage of the modeling plan
- Consider incorporating the probability of positive cross match into the current allocation system as soon as implementation is possible – final proposal for Board vote in December

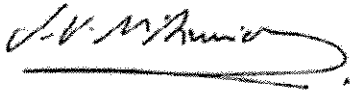
As you consider the objectives please keep in mind that data requests should be focused and precisely stated. Your UNOS liaison will advise you if the data request should be sent to the UNOS research group or to the SRTR.

After your review, and in consultation with your Vice Chair, I would like to schedule within the next four weeks a phone call between you and I, Walter Graham and your UNOS liaison, to discuss these objectives, your own ideas, and together develop a plan and timeline for your Committee's work. I would envision one-year objectives, and would be interested in your vision of five-year objectives. Your Committees' plan will be sent to the Board members prior to the September meeting for their ratification and input.

Mark D. Stegall, M.D.
July 21, 2006
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I believe it is the combined efforts of the Committee's work, the Boards engagement, and the advice of the OPTN/UNOS leadership, which together will be most successful in achieving our goals. I am most appreciative of the commitment of your time, experience and skills as a leader that will be essential for us to achieve our common objective of saving more lives for those in need of organ transplantation in our country.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Sue McDiarmid", with a long, sweeping underline that extends to the right.

Sue McDiarmid, M.D.
President

cc: Ciara Gould
Cindy Sommers