

## **Minutes of the SRTR Technical Advisory Committee Meeting**

**Date: January 8, 2008**

**Time: 9:30 am – 3:00 pm (Eastern Standard Time)**

### **Voting S-TAC Members:**

Jerry Lawless, Ph.D.  
Kim Olthoff, M.D.  
Janis M. Orlowski, M.D.  
Richard N. Pierson, M.D.  
Mark S. Roberts, M.D., M.P.P.  
Mark Schnitzler, Ph.D.  
Mike Seely, M.S.  
Terry Therneau, Ph.D.  
James J. Wynn, M.D.

### **Ex-Officio S-TAC members:**

Leah B. Edwards, Ph.D.  
Gregory Fant, Ph.D.  
Paul Eggers, Ph.D.

### **SRTR:**

Jack Kalbfliesch, Ph.D.  
Alan Leichtman, M.D.  
Greg Levine, B.A.  
Robert Merion, M.D.  
Tiffani Pace, B.A.  
Katherine Pearson, M.P.P.  
Friedrich K. Port, M.D., M.S.  
Bobette Schrandt, L.M.S.W., A.C.S.W.

### **Other Attendees:**

James Burdick, M.D.  
Christopher McLaughlin  
Eva Neider, M.P.H.

## **Opening Remarks**

Dr. Olthoff opened the meeting and introduced the new S-TAC members: Jerry Lawless, Paul Eggers, Richard Pierson, and Mark Schnitzler. Everyone in the room introduced themselves. Dr. Port announced that as of December, 2007 he is no longer the SRTR Project Director. Dr. Robert Wolfe is now the SRTR Project Director. The combined effort between Dr. Port and Dr. Wolfe will remain unchanged.

## **Approval of Minutes from October 4, 2007 S-TAC Meeting**

Dr. Orlowski moved to approve the minutes of the October 4 teleconference, Dr. Edwards seconded the motion. The minutes were unanimously approved as written. The minutes of the October meeting will be posted on the SRTR website.

## **Approval of S-TAC Charter and Bylaws**

Mr. Seeley moved to approve the S-TAC Charter and Bylaws, Dr. Lawless seconded the motion. The Charter and Bylaws were unanimously approved as written.

## **Annual Goals**

The committee reviewed the S-TAC Annual Goals. Dr. Fant emphasized that the S-TAC should be a forum to discuss methodology in detail. Input from the S-TAC is essential to the work of the SRTR, and a thorough discussion of the methods used is helpful.

## **Conflict of Interest Forms**

Dr. Olthoff asked the committee members to fill out the Conflict of Interest forms included in the meeting materials and return them to the SRTR. She noted that any conflict that needs to be declared can be written on the form.

## **Review of SRTR Annual Research Plan for Contract Year Three**

The committee reviewed the SRTR Research Plan for Contract Year Three. There are a large number of projects listed on the plan. Dr. Port noted that the SRTR is particularly interested in receiving input on methodological research from the S-TAC.

Committee members noted that they would like to have more background information on the topics, why they came up, and how much work has already been done on each. With regard to the development of new methodologies, the committee noted that it would be helpful to know the research that the methodology would be applied to.

Dr. Olthoff suggested that each item on the Research Plan should be linked to achieving OPTN strategic goals. Mr. McLaughlin agreed, saying that work of the SRTR is to support the work of the OPTN; the structure of the Research Plan should reflect the work that is done in support of the committees. Dr. Fant noted that the items that were most interesting to HRSA are methods for measuring organ donation rates, metrics for program evaluation, CUSUM methods and reports, and Small Center methodology.

The committee agreed that this Research Plan should be reviewed again at the next in-person meeting in July. The SRTR will give the S-TAC more information on topics and goals, which should lead into a discussion of methods.

The S-TAC must return recommendations on the relative priority of these projects to the SRTR no later than January 15, 2008.

## **Current Research Topics for S-TAC Information, Discussion, and Advice**

### **OPO-Specific Report methods**

Mr. Levine and Dr. Kalbfleisch spoke about the OPO measures reported by the SRTR. Mr. Levine reviewed the difference between the crude and the standardized donation rate and the measures that the SRTR reports in the various tables of the OPO-Specific reports. Members of the committee asked whether crude rates are skewed because they do not reflect the fact that certain donors are not worth pursuing. Mr. Seeley noted that the current SRTR reports are an improvement over the past, when some OPOs were penalized for recovering organs that others would not have pursued. Mr. Levine noted that if an OPO tried to game the report, it would actually hurt their donation conversion rate. All agreed that it is important to focus on definitions and the array of available measures in order to come up with a standard set of expectations for OPOs.

Members of the committee also asked about the difference between eligible deaths and notifiable deaths. An eligible death is a person aged 0-70, with death by neurological criteria only, and no exclusionary medical conditions. A death can only be determined as eligible after review. The definition of a notifiable death is DSA-wide in-hospital deaths not meeting any of the OPTN exclusionary criteria for organ donation. Additional donors are those over 70 and donors after cardiac death (DCD). Dr. Orłowski helped to clarify by noting that in practice there are certain deaths for which the hospital has to call the OPO. The hospital then gets a quarterly report on which deaths should have been called in and which ones actually were. Mr. Seeley confirmed that AOPO encourages hospitals to perform chart reviews on notification on an ongoing basis, and that the referral rate on mandatory calls is very good. Dr. Port added that Dr. Ojo wrote a paper in 1999 outlining the definitions of deaths and the distribution by type. Dr. Wynn also noted that these definitions are on the SRTR website's technical methods.

Dr. Schnitzler questioned whether the SRTR should adjust for different notification rates in different DSAs. He notes that this could lead to a measurement error because the reason for the variation is unclear. If the reasons for variation are changeable, the SRTR may flag the wrong OPOs. Dr. Burdick added that this was intended as a quality improvement measure for the OPOs. Other members questioned the process for adjusting for case mix and trauma centers.

Dr. Therneau questioned whether or not the SRTR would want to adjust for differences among groups based on age, race, sex, and cause of death. Knowing the differences among groups might help the OPOs to improve their

policies. There was some discussion surrounding the very large number of OPOs that would be flagged using the simple z score, and it was noted that the current models do not account for enough of the variation to give reliable test statistics. Dr. Edwards suggested that the SRTR could look at OPOs in unique geographical situations, like Hawaii and Puerto Rico. These OPOs might help describe characteristics at either tail.

The SRTR will continue to work on improving the OPO models. There is hope that the models can be made more predictive as more data become available. It may also be necessary to account in some way for unexplained nonsystematic variation between OPOs and mixed models may provide an approach to this problem.

### **Working Lunch**

Dr. Wynn presented his talk “Ethical Considerations in the Allocation of Scarce Medical Resources.” Following the talk, Dr. Port presented Dr. Wynn with a certificate to recognize his service as S-TAC Chair.

### **KARS Update**

Dr. Leichtman presented an update on the work that the SRTR has done in support of kidney allocation since the last S-TAC meeting. The Kidney Committee has selected a simulated allocation model run (Run 28) as the basis for a new allocation system. In the course of this presentation, there were questions about the quality of life adjustment used in the allocation model. Dr. Schnitzler commented that such adjustments are commonly employed and appropriate to this methodology. He also discussed discounting future life-years. Some members of the committee were skeptical that life expectancies could be predicted as much as fifteen years into the future.

The committee members also had questions about the years of life gained from changes in the allocation system. Members noted that when the allocation policy changes, practices of transplant centers may change as well. Dr. Leichtman noted that the system that the Kidney committee has picked increases the years of life gained for all patients, though not as much as other proposed systems might have. In closing, Dr. Port noted that the SRTR presents options for the Kidney Committee to choose among, but it is the Kidney Committee, not the SRTR, that ultimately decides which allocation system to choose.

### **2008 Annual Data Report**

Dr. Merion invited the S-TAC members to review the tables that are currently included in the Annual Report and provide the SRTR with feedback. Dr. Merion also provided some background information for new members on the chapters that are included every year and the special focus chapters. Possible topics for special focus chapters in 2007 are: Liver Allocation by Net Benefit, Background ESRD Rates, CUSUM (Transplant center quality assessment using a continuously updatable, risk-adjusted technique), and Small Center Methodology.

### **Input for April 10, 2008 S-TAC Meeting**

Several members of the committee gave suggestions for the April teleconference. Members expressed interest in a research topic on the Donor Profile Index (DPI). There is also interest in a research presentation on the active kidney waiting list. The committee members requested that the materials for the April teleconference include a few pages explaining the topics in a straightforward way. Dr. Port also asked for volunteers to give the lunchtime lecture at the July meeting. Mr. Seeley volunteered to give a talk on OPOs. Dr. Port suggested that the July meeting could be held in Detroit or Chicago.

### **Updates**

Dr. Port announced that the SRTR has participated in 28 OPTN committee and subcommittee meetings since the last S-TAC meeting. The SRTR has completed 4 OPTN data requests, with an additional 12 in progress. Dr. Merion gave an overview of the meetings, abstracts, and publications that the SRTR has completed since the October 3 S-TAC meeting.

### **Closing Comments**

Dr. Olthoff thanked the committee and the meeting was adjourned.

## **Minutes of the SRTR Technical Advisory Committee Meeting**

**Date: April 10, 2008**

**Time: 1:00 pm- 4:00 pm (Eastern Daylight Time)**

### **Voting S-TAC Members:**

Kim Olthoff, M.D.  
Jerry Lawless, Ph.D.  
Richard Pierson III, MD  
Mark Schnitzler, Ph.D.  
Mike Seely, M.S.  
Terry Therneau, Ph.D.  
James Wynn, M.D.

### **Ex-Officio S-TAC members:**

Leah B. Edwards, Ph.D.  
Eric Engels, M.D., M.P.H.  
Gregory Fant, Ph.D.  
Janis Orłowski, M.D.

### **SRTR:**

Robert Wolfe, Ph.D.  
Alan Leichtman, M.D.  
Greg Levine, B.A.  
Doug Schaubel, Ph.D.  
Tiffani Pace, B.A.  
Katherine Pearson, M.P.P.  
Friedrich K. Port, M.D., M.S.  
Jessica Kreiner, B.S.  
Erik Roys, M.S.  
Jack Kalbfleisch, Ph.D.  
Panduranga Rao, M.D., D.N.B., M.S.

### **Other Attendees:**

James Burdick, M.D.  
Christopher McLaughlin  
Robert Walsh  
Mark Barr, M.D. (*Emeritus member*)  
Steven Goldman, Ph.D. (*Emeritus member*)

## **Opening Remarks**

Dr. Olthoff opened the meeting and welcomed everyone. SRTR staff introduced themselves and Ms. Pearson called roll from the S-TAC membership list. Dr. Wolfe informed everyone that the S-TAC meeting is an important process and that the SRTR welcomes input and suggestions from the Committee members. Dr. Fant also welcomed everyone and informed them that HRSA would like input from the members on DPI and DRI.

## **Current Research Topics for S-TAC Information, Discussion, and Advice**

### **Donor Profile Index**

Dr. Rao and Dr. Schaubel presented the Donor Profile Index for kidney transplantation. Dr. Rao reviewed the background of ECD kidneys and also presented graphs on ECD kidneys. Dr. Therneau questioned whether calculating the number of turndowns before an organ was transplanted would be a good measure of the desperateness of the recipients. Dr. Schaubel was not sure whether those data would be available. Dr. Wolfe added that selection factors cannot be accounted for and will continue to change.

Dr. Orłowski questioned the significance of each of the factors in the KDRI equation because of her interest in transplant centers being able to calculate this equation. Dr. Wolfe noted that all factors in the equation are significant and the relative risk shows the weight that each factor contributes to the DRI. Dr. Burdick suggested that the SRTR reference the extreme graft lifetimes by KDRI quintile, as well as the median.

The committee members suggested creating separate models for pediatrics and adults. Dr. Edwards added that looking at recipient characteristics may also be useful. Dr. Lawless questioned whether KDRI is adjusted for time dependent effects. Dr. Schaubel noted that interactions with time were looked at and follow-up times were split into windows. Dr. Schaubel was confident that ECD components do not have an interaction with time. Dr. Lawless also suggested looking at variability in the chances of survival.

Dr. Wynn questioned why the relative risk of some ECD donors is being mischaracterized. Dr. Leichtman stated that the purpose of the ECD definition was to reduce discard rates, however the discard rates for the worst ECD kidneys went down and the discard rates for the best ECD kidneys went up. The DRI would help to further indicate the best and worst of the ECD kidneys. Dr. Leichtman also stated that DRI ranks organs relative to the organs available not just the best organs. Dr. Wolfe asked the members whether they felt the reference should be the best organ or the typical organ. Dr. Therneau suggested using the average of the non-ECD kidney as a reference. The Committee members all agreed that the reference should be the typical or median organ, not the best.

Dr. Wolfe informed the members that the next steps in the process for the KDRI are going to be publishing the study and then presenting it to the Kidney Committee. Eventually, the SRTR would like to publish the KDRI calculator on the SRTR website as a useful tool for the public.

#### **Approval of Minutes from January 8, 2008 S-TAC Meeting**

Dr. Olthoff moved to approve the minutes of the January 8 meeting. The minutes were unanimously approved as written.

#### **Review of Patient-Identified Request**

Dr. Wolfe presented the research proposal for Solid Organ Transplantation in HIV: Case-Control Study to the Committee members. The objective of this study is to evaluate the safety and efficacy of solid organ transplant in HIV patients. The study proposes a case-control study between cases (already identified) and controls to be provided by the SRTR. The members questioned why the study was considered patient-identified, since the requester was receiving de-identified data. Mr. Levine stated that the request needs approval because the study will be linked with the SRTR database. The study is requesting use of the SRTR database to ensure that the control group does not contain any HIV patients and is as clean as possible. The members also questioned whether this study should be considered a case-control study.

Dr. Wolfe added that this would be one of the largest studies of HIV patients. The members agreed that this study would be interesting and beneficial. This request was unanimously approved. The SRTR Project Officer will review the request following the meeting.

#### **Office of Civil Rights Update**

Dr. Wolfe informed the members that the SRTR recently presented to the Office of Civil Rights on the LYFT score. Dr. Wolfe explained that there are factors other than age that affect the LYFT score. Candidate's health status can have a greater effect on LYFT than 30 years of age, for example a 31 year-old candidate and a 65 year-old candidate can have the same LYFT score. BMI and diabetes are actually the biggest factors in determining LYFT. There were no objections from the members on this issue.

#### **OPTN Requests and Meetings Update**

Dr. Wolfe informed the members of all of the OPTN committee work that the SRTR has been doing. Dr. Wolfe presented on the OPTN data requests and goals addressed for the Thoracic, Pancreas, Liver, Organ Availability, MPSC, Kidney, Pediatric, Policy Oversight, and Minority Affairs Committees.

Dr. Barr expressed his strong feelings on expanding the donor-recipient matching into broader age groups, to ensure that lungs taken from young donors are transplanted into the younger donors before they are being transplanted into the older donors. Mr. Levine noted that this suggestion should be shared with the liaison at the OPTN and Dr. Barr agreed.

Mr. Roys informed the Committee members that the Pancreas Committee was on the verge of requesting the DRI, also. Dr. Wolfe added that the SRTR should find out how much of a difference the DRI makes for each organ.

Dr. Wolfe also informed the Committee members of the Pittsburgh-Tribune Review article on low MELD score recipients.

Dr. Olthoff suggested that the Committee members receive information on the OPTN Committees for the next S-TAC meeting. Dr. Olthoff noted that receiving OPTN Committee summaries and goals would be helpful to the S-TAC members.

## **Current Research Topics for S-TAC Information, Discussion, and Advice**

### **ACOT Meetings and Requests**

Dr. Wolfe presented on the 3 ACOT data requests in progress regarding Pediatric Mortality, Living Donor Outcomes, and Data Collection. The Pediatric Workgroup is reducing the mortality of pediatric patients on the waitlist. The Living Donor Workgroup desires to understand the potential demand for solid organ transplantation among those who agreed to be a living donor. The Data Collection Workgroup is interested in the long-term data collection, data analyses, and the cost of collecting data.

### **Publications Update**

Ms. Pearson presented an update of the SRTR manuscripts that have been published or accepted for publication. Mr. Levine added that the SRTR Report on the State of Transplantation was also published and that the Annual Data Report is intended to be posted to the SRTR website on April 23, 2008.

### **Abstracts Update**

Ms. Pearson also updated the members on the nine abstracts that were accepted by the American Transplant Congress in anticipation of its meeting May 31-June 4, 2008, in Toronto. There will be 4 poster presentations and 5 oral presentations at the ATC meeting.

## **Research Questions Related to PSR's**

### **Missingness Indicators**

Dr. Wolfe presented on missing data that are reported by the transplant centers. Dr. Wolfe informed the members that poorer outcomes are expected when centers have missing data, making it easier for the centers to do better than expected, and asked the members if this seems to be a bad incentive. Dr. Wolfe also questioned whether the missing data should be replaced with the worst value, which would cause the centers expected outcome to be higher.

Dr. Orłowski questioned whether there was reason to believe that the centers are purposely not reporting specific data. Dr. Port added that the purpose is for the SRTR to ensure that the incentives are in the right place. Dr. Orłowski suggested that there should be a disincentive for required data that are not reported, but no penalty for the optional data. Mr. Levine noted that the SRTR only uses required data for the reason that optional data would be largely missing and likely not ever be significant in the models.

Dr. Fant questioned the OPTN's role in this question. Dr. Wolfe noted that the SRTR would not only be making this decision, but that the OPTN would also have a part in the decision. In general, the committee seemed to be in agreement with the disincentive for not reporting the required data, and suggested that it just needs to be communicated with the appropriate committees. A question was raised regarding how the SRTR would control the missing data that transplant centers receive from the OPO's. Dr. Wolfe noted that this was a good point and the SRTR would have to follow-up on ensuring that centers are not penalized for data that was not completed by

the OPO and is beyond the center's control . The SRTR will move forward with the process of developing this idea and presenting it to the appropriate committees of the OPTN.

#### **Pancreas Graft Failure**

Dr. Wolfe presented on the inconsistency of reporting pancreas graft failure. Dr. Wolfe questioned the committee on how to evaluate and present good information to the community when there are differences in reporting pancreas graft failures. The Committee members had no comments on this issue. Dr. Wolfe asked that the Committee follow-up with the SRTR with any ideas they might have.

#### **Input for April 10, 2008 S-TAC Meeting**

Dr. Wolfe informed the Committee that the July 24 meeting will be in Detroit and that Mr. Seely has volunteered to give the luncheon talk. Ms. Pearson stated that the SRTR would give updates on research topics and would also provide the OPTN Committee goals per Dr. Olthoff's earlier suggestion. Dr. Olthoff also made a suggestion, from an e-mail that she received from Dr. Eggers, to present on the large inactive status on the waitlist. The Committee members agreed that the inactive status on the waitlist would be an interesting topic. Dr. Olthoff suggested presenting on donor transplanted malignancy because of the recent publicity of this issue. Mr. Roys is interested in helping with this presentation.

#### **Closing Comments**

Dr. Fant stated that the members should e-mail the SRTR with any thoughts on DRI and that the SRTR will inform the S-TAC when the DRI paper is published. Dr. Fant also informed the members of the KAS calculator that was circulated to the Kidney Committee. Dr. Olthoff thanked everyone for participating and the meeting was adjourned.

## **Minutes of the SRTR Technical Advisory Committee Meeting**

**Date: July 24, 2008**

**Time: 9:30 am- 3:00 pm (Eastern Daylight Time)**

### **Voting S-TAC Members:**

Kim Olthoff, M.D.  
Jerry Lawless, Ph.D.  
Richard Pierson III, MD  
Mark Schnitzler, Ph.D.  
Mike Seely, M.S.  
Paul Eggers, M.D.  
Mark Roberts, M.D., M.P.P.

### **Ex-Officio S-TAC members:**

Eric Engels, M.D., M.P.H.  
Gregory Fant, Ph.D.  
Leah B. Edwards, Ph.D.

### **SRTR:**

Robert Wolfe, Ph.D.  
Alan Leichtman, M.D.  
Brad Dyke, M.D.  
Robert Merion, M.D.  
Tiffani Pace, B.A.  
Katherine Pearson, M.P.P.  
Friedrich K. Port, M.D., M.S.  
Kate Meyer, M.S.  
Erik Roys, M.S.  
Jack Kalbfleisch, Ph.D.  
Alyce Whipp, M.P.H.

Charlotte Arrington, M.P.H.  
Diane Steffick, Ph.D.  
Jeff Moore, M.S.  
Bruce Robinson, M.D.  
Keith McCullough, M.S.

### **Other Attendees:**

Christopher McLaughlin

## **Opening Remarks**

Dr. Wolfe opened the meeting by announcing Dr. Olthoff's attendance via telephone due to a flight cancellation. He thanked everyone for their attendance and participation. Dr. Olthoff then thanked everyone for attending and expressed regret for her absence in person. Dr. Fant announced that this will be his last meeting. He will be beginning a new position with the HRSA HIV/AIDS division on August 18<sup>th</sup>. Dr. Wolfe thanked Dr. Fant for his participation and said that he has been a great asset. Monica Lin will be the new SRTR Project Officer. Everyone present then introduced themselves.

## **S-TAC Administrative Matters**

### **Approval of Minutes from April 10, 2008 S-TAC Meeting**

Dr. Wolfe asked for a motion to approve the minutes of the April 10 meeting. The minutes were unanimously approved as written.

### **Review of SRTR Annual Research Plan for Contract Year Three**

Dr. Wolfe described the components of the Annual Research plan to the members. He described the relevancy of the plan to the SRTR's current projects, deliverables and ongoing research. Dr. Wolfe also stated that members' input is welcome when choosing the topics and projects.

Mr. Roys pointed out a few specific topics from the plan to discuss in detail, including CUSUM and LYFT. Development of Organ Acceptance Rates (which is currently awaiting DonorNet validation) will undergo revision to reflect improved data. Mr. Roys also addressed the donor yield model. He explained that the model is currently awaiting eligible death data to be complete.

Dr. Merion added some information about the tricontinental transplant outcomes study that has ongoing collaborations with UK transplant and ANZDATA. Dr. Engels is involved with the cancer match study with NCI and mentioned that he is eager to move forward. Dr. Roberts commented on the good work that the SRTR has done to create methodologies that influence policy. Dr. Fant shared that sentiment and stated that the SRTR contract indeed has a purpose to better the health/transplant community.

## **Current Research Topics for S-TAC Information, Discussion, and Advice**

### **Update on the PSR risk adjustment models**

Mr. Roys presented the “Update of Program-Specific Report (PSR) Risk Adjustment Models” to the group. These models are constantly being updated with the most recent improvements and findings.

Ms. Kate Meyer gave a presentation on the update of pancreas PSR models. She noted that there are three types of pancreas transplants: simultaneous pancreas kidney (SPK), pancreas after kidney (PAK) and pancreas transplant alone (PTA). Currently the SRTR models adjusted transplant outcomes for SPK recipients. The SRTR is now evaluating whether it would be appropriate to model SPK, PAK and PTA recipient outcomes together.

Dr. Merion stated that PTA transplants are more challenging due to variability with donor and recipients. Surgical risks associated with PAK are almost identical to those of PTA. He added that PTA has the worst outcome of the three different types of transplants and SPK has the best results. This is because the kidney and the pancreas come from the same donor and the diagnosis of rejection is easier.

Dr. Roberts commented that a clinical outlook on these outcomes models is a fundamental part of their development and evaluation.

Ms. Meyer then proceeded to address the variables that are in the model. Dr. Roberts added that if a variable is taken out of the model, its effect on other variables should be closely evaluated because taking it out could alter the significance of the other variables that are in the model. Dr. Engels suggested that we address the concerns of the community by including as many adjustment variables as possible.

Ms. Meyer also presented the liver PSR model slides to the group. She went over the methods for updating the PSR models and the most recent update; there were some covariates dropped, added and updated in the 1 and 3 year adult deceased-donor patient survival model.

Clinicians and senior statisticians, such as Dr. Doug Schaubel and Dr. Robert Merion have re-evaluated the final models as a final check.

Mr. Jeff Moore discussed the Thoracic PSR models with the group. He discussed the PSR model modifications, the Thoracic Committee’s input and what the next steps for the models would be (heart, lung and heart/lung). The most recent modification was the addition of new variables in the fall of 2007. The floor was turned back over to Mr. Erik Roys who explained the SRTR strategies for improving the models and discussed issues relating to the possibility of collecting new data elements.

Dr. Fant said that the OPTN and SRTR should work together to help the committees. Adding new data elements to models needs to be explained to HRSA and if the two contractors would work together ahead of time it would help. For example, the data forms are to be re-evaluated in 2010 so now is a great time to work together and look for ways to improve the forms.

Dr. Edwards suggested that new data elements might be obtained by seeking alternative sources for the information. Consulting with the transplant community is an important component of this effort. As an example,

Dr. Wolfe mentioned that the CMS Medical Evidence Form 2728 may be a useful source of comorbidity information for the kidney PSRs.

Dr. Wolfe also posed a question regarding missing data. One option would be for the missing value to be set such that the expected survival is highest; this has the effect of reducing the expected number of deaths for the center and hence increasing the standardized mortality ratio. This would provide an incentive to make the data complete. However, this may also create an incentive for centers to replace missing data with incorrect values. With the current models, missing values for some variables are associated with worse outcomes, and this may create an incentive for centers to have missing data.

Dr. Brad Dyke added that some centers may not submit data as a way of “gaming” the system to get a better evaluation. However, he feels that most centers are not submitting such data intentionally. Dr. Roberts agreed because he thinks that most centers aren’t aware of how the data hurts or benefits them.

Ms. Charlotte Arrington revealed that she is aware of at least one center that has updated their data wherein they changed one variable which made a difference in their PSR report. It’s not common, but centers are discovering how to “game” the system. Dr. Jerry Lawless thinks that if this is happening, he wonders how transparent the process is.

It was recommended that we actively search for other ways to evaluate programs other than post-transplant outcomes like waitlist mortality and transplant benefit.

### **Active Waitlist for Kidneys**

Dr. Kalbfleisch gave a presentation on the “Marked Increase in Use of Inactive Status on the Kidney Transplant Waiting List”. There has been an increase in the use of inactive status since 2003. It is believed to be caused by the OPTN Board of Directors November 5, 2003 approval of accrual of waiting time throughout the entire period that a patient remains in Status 7 (inactive status).

Dr. Kalbfleisch noted that there is little or no variation in inactive status by age, race or preemptive listing before dialysis. However, there were differences by region. Waiting time is driven by geography/OPO, so taking a look at the OPO may be helpful in further understanding this issue.

Dr. Leichtman wondered whether the change in policy regarding inactive status had the hoped for positive effect on acceptance rates of offered organs.

It was noted that providers are not required to indicate why they are listing a patient as inactive.

Dr. Leah Edwards also brings up a good point that the designation ‘inactive status’ can also be due to inactivity of the center.(?)

### **Input for October S-TAC teleconference**

Dr Wolfe asked the committee members for discussion topics for the October 14<sup>th</sup> S-TAC teleconference. Dr. Robin Pierson suggested xenotransplantation for a lunchtime talk.

Dr. Dyke proposed talking about ventricular assist devices and Dr. Olthoff said that she would like to hear about high risk donors and social history leading to disease transmission.

### **Updates**

**Donor Profile Index (Dr. Wolfe)**

Dr. Robert Wolfe gave an update on work on the donor profile index for kidney.

**KAS Calculator (Mr. McCullough)**

Mr. McCullough demonstrated a LYFT calculator to the group. The calculator is a spreadsheet that calculates potential number of life years gained when using the proposed kidney allocation system.

Dr. Roberts felt that the numbers in the spreadsheet are represented well but suggests that we use “quality-adjusted life years” instead of unadjusted life years.

Dr. Engels suggested that we present the spreadsheet in a context of evaluating the last 500 kidneys that were transplanted compared to the current kidney that is up for acceptance. Then the recipient’s characteristics could be matched to common organ distribution so that the recipient is aware of where they fall. That way the recipient can evaluate whether they would like to wait for a better kidney that will provide them with more life years after transplant.

Dr. Roberts then stated that a problem could arise because what organ was good for one person may not necessarily be good for another.

Dr. Jerry Lawless asked what if there are two recipients with a 30-40 year age difference but have the same LYFT. How do we address that?

Mr. McCullough also presented the KAS (Kidney Allocation System) spreadsheet to the group. The spreadsheet shows the system of allocation where wait time is a factor depending on the quality of the organ that is being offered is. The higher percentiles on the spreadsheet represent a higher risk organ. The goal is to have less waiting time for the worst organs and longer waiting time for the best organs.

Dr. Wolfe feels that the ability to advise patients optimally is a benefit of this model but it is difficult because the options constantly change. Dr. Diane Steffick added that during the acceptance process, the patient doesn’t have total control because the recipients don’t see every organ they are offered; only the one the surgeon chooses to inform you about.

**Recognition of Outgoing Members**

Dr. Wolfe announced the members of the committee who were rotating off. He presented Dr. Fant and Dr. Roberts with certificates of recognition. There were also certificates prepared for Drs. Terry Therneau and James Wynn who were not in attendance.

**Closing Comments (Dr. Wolfe)**

Dr. Wolfe thanked everyone again for attending and their meaningful contributions. He stated that he enjoys his place on the committee and looks forward to hearing from them at the October teleconference.

## **Minutes of the SRTR Technical Advisory Committee Meeting**

**Date: October 14, 2008**

**Time: 1:00 pm- 4:00 pm (Eastern Daylight Time)**

### **Voting S-TAC Members:**

Kim Olthoff, M.D.  
Jerry Lawless, Ph.D.  
Richard Pierson III, MD  
Paul Eggers, Ph.D.  
Mike Seely, M.S.  
Terry Therneau, Ph.D.  
Edward Garrity, M.D.  
Janis Orłowski, M.D.

### **Ex-Officio S-TAC members:**

Monica Lin, Ph.D.  
Eric Engels, M.D., M.P.H.

### **Other Attendees:**

Steven Goldman, Ph.D. (*Emeritus member*)

### **SRTR:**

Robert Wolfe, Ph.D.  
Alan Leichtman, M.D.  
Greg Levine, B.A.  
Craig Lake, M.S.  
Tiffani Pace, B.A.  
Katherine Pearson, M.P.P.  
Kathryn Meyer, M.S.  
Melissa Fava, B.A.  
Erik Roys, M.S.  
Bradley Dyke, M.D.  
Robert Merion, M.D.  
Emily Messersmith, Ph.D.  
Keith McCullough, M.S.

## **Opening Remarks**

Dr. Wolfe welcomed everyone to the meeting and noted that the vice chair election would be part of the administrative matters on the agenda. Dr. Olthoff was apologetic to not being at the July in person meeting. And the Project Officer, Dr. Monica Lin, welcomed everyone.

Dr. Wolfe introduced the new S-TAC members, Robert Gaston, Ed Garrity, David Glidden and David Howard. These members will begin their terms as of the January meeting.

## **Approval of Minutes from July 24, 2008 S-TAC Meeting**

Dr. Olthoff asked for a motion of approval of the minutes of the July 24 S-TAC meeting. Mr. Seely made a motion to approve and Dr. Pierson seconded the motion. The minutes were unanimously approved as written.

## **Current Research Topics for S-TAC Information, Discussion, and Advice:**

### **Living Kidney Donor Outcome Metrics**

Dr. Wolfe gave an introduction to the analysis of living donor outcomes. The purpose of this work is to examine the outcomes of living donation and determine how many extra years of life the recipient gains compared to alternative therapies, including remaining on the waiting list and also receiving a deceased donor transplant. Ms. Meyer presented models that demonstrate the difference in patient and graft survival in kidney recipients, based on whether they received a living donor transplant or a deceased donor kidney transplant.

Dr. Olthoff and Dr. Eggers asked about the survival curve intervals that were set from 0-4 years and 4-15 years. Dr. Eggers added that he thought significant effects disappeared within 1 year. Mr. McCullough responded by saying that after 4 years there was not significant survival effects. He said that they noticed a change at the 3-4 year mark rather than at 6-9 months. The curve and hazards were consistent after 4 years. Dr. Wolfe will revisit this and recheck the reasoning for using 4 year intervals.

The recipient characteristics analysis was done using splines with knots. Dr. Terry Therneau suggested using smoothing splines. Dr. Wolfe asked how the clinical community would feel about using the smoothing splines. The response was mixed.

The patient survival model that shows the effect of recipient age, between patients with diabetes and without diabetes, shows that as the age increases the relative risk in death increases. Dr. Therneau thinks having absolute risk would be best instead of the relative risk. In this particular graph, showing both would have been reasonable. He feels that the absolute risk would have been larger but a great compliment to the relative risk.

Dr. Eggers asked to see an analysis of the difference in outcomes by race. Dr. Wolfe noted that race was not included in the model because the Kidney committee strongly opposed it. Dr. Jerry Lawless was also curious to know if the length of time on the waitlist was a factor in these analyses. Dr. Wolfe responded that they weren't in the models.

Dr. Eggers noticed the differences in patient survival and LYFT were the same and wondered if there was an error in the calculations. Dr. Wolfe assured him that it was right because it represented the same patient. Ms. Meyer noted that it was not exactly the same because graft survival provided some variability, but the difference is very close.

Dr. Eggers noticed the patients represented in the graphs seemed to be stratified. Ms. Meyer explained that those were the differences in people who had a previous transplant and were pre-emptive, those who had no previous transplant and those who were neither. Dr. Wolfe suggested that it's likely that those recipients who were previously transplanted received living donor transplants the first time and deceased donor transplants the second time. Dr. Orlowski disagreed with that assumption because in her experience a person who previously had a deceased donor transplant sought out another deceased donor.

Dr. Eggers mentioned that he does not want an allocation system that exacerbates racial disparities and favors whites. Disparities that favor whites have decreased in recent years. Dr. Leichtman notes that case mix is another reason for this.

## **S-TAC Administrative Matters:**

### **Election of Vice Chair**

Mr. Mike Seely nominated Dr. Janis Orlowski to be the next S-TAC Vice-Chair. There were no other nominations. The committee unanimously approved Dr. Orlowski as Vice Chair by a voice vote.

### **Proposal allowing cancer registry staff to view patient-identified SRTR data**

The proposal would allow representatives from cancer registries participating in the Cancer Match Study to come to the SRTR to oversee the matching process. Dr. Engels states that the cancer registry recognizes the sensitivity of the data and will ensure that work is completed within the permissible guidelines. Dr. Wolfe asked for an approval from the committee, no one objected. The committee voted to approve members of cancer registry staff to witness the linkage of their data to the SRTR data; as part of this process, the registry staff will be able to view SRTR patient data on the premises of Arbor Research.

### **Review of Physician Identified Request**

The main objective of this study is to test the hypothesis that transfer of care from pediatric to adult providers for adolescents and young adults who are kidney transplant recipients will have a major impact on health outcomes post-transplant.

The requestor would like to use the NPI/UPIN to identify this transfer of care. Dr. Orlowski noted that it is not clear when a patient is transferred from a pediatric care giver to an adult physician. Dr. Olthoff agreed and said it was confusing since some physicians care for both adult and pediatric patients.

Dr. Wolfe asked if it would matter if the requestor intended to link data with external sources, as the SRTR expects she will need to do this in order to characterize the providers as providing adult or pediatric care. Dr. Eggers responded by saying he will search for a similar request at the USRDS and see what their plan of action was. He believes it was allowed but will follow up with us.

Dr. Merion thought that information on individual providers should not be disseminated. The NPI could be linked to a name, and through that could easily be linked to a center. He thought it would be appropriate to modify the agreement in order to cover all personal identifiers, including patient-identified data as well as physician-identified data. Dr. Eggers and Mr. Levine agreed.

Mr. Roys suggested that we should provide her with another waiver to sign, agreeing not to share the data. The group agreed on this idea. Dr. Orlowski made a motion to proceed with providing the NPI's to the requestor with the condition that she not use the data to identify providers. The committee unanimously agreed.

### **Updates**

Dr. Wolfe reviewed the SRTR publications and ACOT and OPTN data requests since the last S-TAC meeting in July.

### **Input for January 2009 S-TAC Meeting**

Dr Orlowski asked the committee members for lunchtime discussion topics for the January 7<sup>th</sup> S-TAC meeting. Dr. Robin Pierson suggested xenotransplantation and Dr. Brad Dyke suggested mechanical circulator support.

### **Closing Comments**

Dr. Paul Eggers added that after the last S-TAC meeting in July, Drs. Jack Kalbfleisch and Robert Wolfe shared their data on inactive listings with the USRDS. He was exceedingly happy with the generosity of the SRTR and the U of M affiliates and grateful of their teamwork.

Drs. Wolfe and Orlowski thanked the Committee for their participation, wished them well, and adjourned the meeting.