Minutes

SRTR Technical Advisory Committee

Monday, January 26, 2015
8:30 AM – 11:30 AM CDT
Teleconference

Voting Members Present:

John Gill, MD, MS (C)
Rebecca Betensky, PhD (C)
Brad Astor, PhD, MPH
David Collett, PhD
Dan Meyer, MD
David Lederer, MD, MS
Kevin Myer, MSHA
James Trotter, MD

(C) = Co-Chair

Voting Members Unable to Attend:

David Naftel, PhD

Ex-Officio Members:

Monica Lin, PhD (HRSA)
Jonah Odim, MD (NIH)
Darren Stewart, MS (UNOS)
Yolanda Becker, MD (OPTN Policy Oversight Committee)
Joseph Kim, MD, PhD (C)

SRTR:

Bertram Kasiske, MD
Bryn Thompson, MPH
Jessica Zeglin, MPH
Susan Leppke, MPH
Nicholas Salkowski, PhD
Jon Snyder, PhD, MS
Amy Ketterer

Minutes

Rebecca Betensky called the meeting to order at 8:30 AM CDT. Jon Snyder and Bert Kasiske reviewed the day's agenda, after which the members introduced themselves. Dr. Kasiske informed the committee of the members rotating off and briefly described the roles of the new members.

Dr. Betensky moved to vote on the minutes from the last meeting, held October 29, 2014. There were no objections and the minutes were approved. Dr. Kasiske reminded the committee that the SRTR contractor is obliged to ensure that deliberations of the STAC do not constitute a conflict of interest (COI) for its members, and that committee members should recuse themselves from any discussion or vote regarding which they may have a COI.

First Bayesian PSR Release Review

Dr. Snyder began the meeting by presenting the results of the first release of the Bayesian models in the program-specific reports (PSRs). He gave a brief overview of the difference between the previous release and the new reports' highlights. He covered how the appearance of the web site had changed along with the new model, and finally noted that we now include a separate MPSC report on our secure site for programs.

Open discussion followed. John Gill was curious about subgroup analyses being covered. Dr. Snyder pointed out the separate figures for each subgroup. Dr. Gill asked about a global assessment; has SRTR done that? Dr. Snyder said that there is no composite yet. We present adult and pediatric data separately and at 1

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month, 1 year, and 3 years (a 5-year conditional is being considered to replace the 3-year.) The programs visiting the site and looking at the reports are concerned with the breakout, rather than a composite.

Dan Myer asked about patient advocacy groups and whether there has been any input from them on the new methodology. Dr. Snyder explained that we don't have any formal interaction with patient groups; typically programs are more interested in the reports than patients. We are focusing on ways to present these data to patients also in the coming years. The question was asked whether SRTR had patients review the reports and give feedback. Ajay Israni discussed his initiative to develop patient friendly PSRs. Dr. Israni is looking at other resources to develop such PSRs because it will take a lot of effort. Currently, he's looking into the feasibility. Susan Leppke explained how SRTR currently collects patient feedback through the SRTR helpline and email, and how we track that information.

Risk Model Updates

Dr. Snyder continued with his presentation by covering the progress of the risk model rebuilds. First, he gave an overview of the release cycle for rebuilt models. The review of the kidney models is underway and they will be released in the spring release cycle. The heart model is being completed for review in that same cycle. Lung, liver, and pancreas models will follow, in that order, over the next 3 years.

Dr. Snyder explained the new standardized structure analysts follow to build the model, and he outlined the specific structure, emphasizing the reason for "refitting" the models each cycle and "rebuilding" them every 3 years based on variables existent at the time of rebuild. Dr. Snyder described the heart model rebuild under way. Finally, Dr. Snyder pointed out a "safety net" process being considered to supply to the MPSC for centers with too little data.

There was a brief discussion of this topic. Dan Myer brought up the subject of CPRA, asking how it is different. Dr. Snyder explained the process of committee approval of the models and said it had been determined CPRA was not a predictive element. There was some discussion of what specific alleles were included in the CPRA. Darren Stewart clarified and then asked how interactions are considered in the new model-development process. Dr. Snyder explained that we include only interaction terms that OPTN has suggested. This segued into a question from David Collet about ex-vivo lung perfusion (EVLP) and ischemic times. Dr. Snyder said that we do include total ischemic times but not yet EVLP. Dan Meyer added that EVLP will become important in the future. Dr. Snyder assured him that SRTR will consider it with the committee when the lung model is rebuilt.

A question was raised about LASSO and gaming the elements. Are there gameable elements we should pay attention to? Dr. Snyder said that we have worked with the organ-specific committees to minimize inclusion of potentially gameable items. UNOS/OPTN worked with SRTR in committees to determine which elements could be gameable and worked to minimize that possibility. Finally, on this topic, the committee was made aware that models had been released and the members should review and give feedback.

Nicholas Salkowski discussed the topic of the C statistic, how it is used and criticisms of it. He demonstrated several possibilities based on different data ranges and showed how it can be interpreted. He said that while predicting individual patient risk is challenging, the models do a much better job of discrimination at the program level. One possible explanation is that important risk factors are missing from the models, which make individual patient predictions difficult, but the missing risk factors are more or less evenly distributed at the program level, so when multiple patients are aggregated together, the missing risk factors are much less important. These calculations suggest that focusing on the patient-level C statistic when evaluating whether the models are adequate for regulatory use may be short-sighted.

Open discussion followed. Several committee members expressed their opinion of the C statistic, how it is in some ways adequate and in other ways not. Dr. Snyder left it open for the committee members to share their expertise in the future as we continue to use and monitor this method.

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Program Risk Tolerance Concept for the PSRs

Dr. Snyder spoke on the topic of program risk adjustment and its necessity for the sake of monitoring management of transplants and donors. Based on recommendations made at the 2012 Consensus Conference, SRTR developed a method by which using the PSR models we can estimate each transplant program's "risk tolerance" using the linear predictor from the Cox proportional hazards models used in the PSRs. Using a web-based tool that SRTR developed, Dr. Snyder demonstrated how one can plot the risk tolerance distribution of each individual program against the distribution of all other programs in the nation. Furthermore, one can plot each program's average patient risk vs. all other programs in the nation. These may be viable metrics and graphs to include in future versions of the PSRs.

There was a brief discussion of this topic. Committee members were primarily interested in seeing the results over the longer term and also capturing the accept/decline rate. Dr. Snyder explained the various dimensions one can look at, but based on the Consensus Conference recommendation, this process demonstrates the tool sufficiently to answer questions as to whether we can measure risk. The committee overall agreed this is a useful tool and could be applied in other ways also.

Multi-organ Evaluations Update

Dr. Snyder reminded the committee of the reasons SRTR is tackling this issue. He presented a flowchart developed for classifying multi-organ transplants. Dr. Snyder updated the committee on the progress on this topic since the last STAC meeting in October. He verified that the option of using separate cohorts and separate models (option D) was accepted and he showed graphs illustrating the results.

Miscellaneous Project Updates

Bert Kasiske and Joe Kim mentioned the Data Advisory Committee meeting and results. It was determined first that data should be mapped as to how they are distributed and interpreted. This mapping process is now in progress. The next DAC meeting is February 10, 2015. Dr. Kim praised Dr. Kasiske's systematic approach to organizing the data.

On the topic of the Donor Potential Collaborative Study with AOPO, Jon Snyder briefed the committee on the progress and illustrated some findings based on data collected so far. The study goals were to collect data from various OPOs on "potential" and use the results to start a conversation about a consistent definition, to seek to understand how various OPOs define potential, and to seek to understand how OPOs use death record reviews to identify missed potential. Dr. Snyder showed slides to explain how these data currently appear.

A question was raised as to whether this was fueled by the liver debate. Kevin Myer explained that getting to the definition of common denominator was seen as needed by the OPOs for some time. He briefed the committee on the difficulty of finding commonality throughout the OPO's history. He said this did not have to do directly with the liver debate.

Dr. Snyder gave an update on the Donation and Transplantation Community of Practice (DTCP) and the effort to establish new national goals in the field of organ donation and transplantation. He briefly reviewed the "5000 more organs transplanted over 5 years" goal with the committee, and mentioned the new study commissioned by HRSA to The Lewin Group to develop new national goals for the field. He reviewed attendees of a recent technical expert panel convened by The Lewin Group and the purpose of the meeting. Dr. Myer presented slides on The Lewin Group study. A 1-year study whose goal is to increase the number of annual organ transplants. Dr. Myer presented several graphs that illustrated how performance measured up to the goals previously set in 2003. He further explained the specifics of the study goals, the approach to be used in achieving them, and the next steps for implementation.

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A brief discussion followed Dr. Myer's presentation. John Gill asked about the disparity between donation rates of living vs. deceased donors and increasing the number of living donors. Dr. Gill also asked about the age 70 cut-off, and whether it will be raised. Kevin Myer responded to the living donor question by saying that the DTCP goal (5000 transplants) combines living and deceased donors, but The Lewin Group would be focusing on the deceased potential. Dr. Snyder said that regarding donation rates in the over 70 age category, raising the ceiling has been discussed in past committee meetings, but nothing has been determined. This study may help.

Dr. Kasiske briefed the committee on the biopsy study. Fifty percent of deceased donor kidneys undergo a procurement biopsy before being offered. The biopsy result is often the reason for declining the organ offer. Much study evidence points to these biopsies being not truly predictive of outcomes and possibly causing more harm than good. There are no fewer than 13 different scoring systems for biopsies, and it appears none is superior. SRTR would like to lead a pilot study on the role of procurement biopsies in organ acceptance decisions. SRTR is currently exploring funding sources for the pilot study.

Open Brainstorm

Dr. Snyder mentioned that we had intended to do some brainstorming with the committee, but considering time constraints, we would do that at the next meeting. Meanwhile, the committee should think about what SRTR should focus on in the coming years. What do we really need to do to advance our field? Any ideas committee members bring will be discussed at the May meeting.

Closing Business

During the closing discussion, John Gill commented that, as a first time participant, he was impressed with how much SRTR does and the richness of the topics. A lot of great information was presented. He was curious if there are templates for the kidney models. Dr. Salkowski said the models are available online. It was asked if we had an overview of the various tools SRTR provides. Jon Snyder mentioned that we had been planning on doing just that. It was also asked if we have some sort of "user group" that gives feedback on these tools. It was explained that we do have a user group selected from the transplant administrators and they give feedback. Susan Leppke added that the most frequent users are the programs' quality professionals. They are the most frequent communicators because they use both the public and the secure sites the most.

Dr. Gill asked if any members had additional business to bring forward. Hearing no other business, the meeting was adjourned at 11:30 AM CDT.

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Minutes

SRTR Technical Advisory Committee

Wednesday, May 21, 2015
9:00 AM – 3:30 AM EST
In-person

Voting Members:

John Gill, MD, MS (C)
Rebecca Betensky, PhD (C)
Brad Astor, PhD, MPH
David Collett, PhD
Dan Meyer, MD
David Lederer, MD, MS
James Trotter, MD
Kevin Myer, MSHA

[(C) = Co-Chair]

Ex-Officio Members:

Monica Lin, PhD (HRSA)
Chris McLaughlin (HRSA)
Darren Stewart, MS (OPTN/UNOS)
Jonah Odim, MD (NIH)
Yolanda Becker, MD (University of Chicago Medical Center)
Eric Engels, MD (NCI)
Joseph Kim, MD, PhD (DAC)

SRTR:

Ajay Israni, MD, MS
Bertram Kasiske, MD
Bryn Thompson, MPH
Jessica Zeglin, MPH
Jon Snyder, PhD, MS
Larry Hunsicker, MD, PhD(via phone)
Nicholas Salkowski, PhD
Susan Leppke, MPH

Minutes

Dr. Gill called the meeting to order at 9:00 AM EDT. Dr. Snyder and Dr. Kasiske reviewed the day's agenda, after which the members introduced themselves. A quorum was present. Dr. Kasiske informed the committee of the members rotating off and briefly described the roles of the new members.

A request was made that meeting minutes and saved materials also include meeting slides for future reference

Dr. Gill moved to vote on the minutes from the last meeting, held January 26, 2015. There were no objections and the minutes were approved. Ms. Leppke reminded the committee that the SRTR contractor is obliged to ensure that deliberations of the STAC do not constitute a conflict of interest (COI) for its members, and that committee members should recuse themselves from any discussion or vote regarding which they may have a COI.

UNet Changes (Slides 5-10)

Dr. Snyder began the meeting by presenting the changes in UNet that occurred in March 2015 to inform the committee of the impact these changes had on the production of the program-specific reports (PSRs). He explained the removal of the optional fields as well as other board-approved changes

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to the system (over 700 changes) that required SRTR to substantially modify its data processing to support the PSR production. SRTR had received an optional field removal list in mid-2014 and another list from UNOS IT in the fall of 2014. SRTR did not appreciate that these lists were different, containing more than just the optional fields that were to be removed, and focused on handling the optional fields. SRTR also did not anticipate that programs would no longer be able to edit data for fields that no longer exist in the UNet system, requiring them to request changes to their data through the UNOS help desk. UNOS created a system to collect the data from removed fields that SRTR required for its models.

SRTR made adjustments to the heart risk adjustment models that are under development to avoid use of any removed fields. However, a few removed fields remain in the other PSR models. Dr. Snyder presented a slide illustrating a table of the removed variables. The committee discussed how SRTR can attempt to avoid similar issues in the future. Suggestions included trying to improve communication between SRTR and UNOS and setting a time to review new models with UNOS prior to implementation.

This segued into the next issue on this topic: how to deal with the removal of elements that affect the models in the future. Dr. Snyder presented more slides, providing some ideas on how to handle this issue going forward.

For the newly rebuilt kidney models, SRTR will investigate removal of the fields and attempt to rebuild the models without the removed fields. SRTR will bring results of this analysis to the July STAC meeting. The removed fields in the lung models should be available through the use of the LAS fields within the UNet Waitlist application. For the liver models, we will investigate the impact of simply removing the fields that have been removed from UNet, and keep to our original schedule of fully rebuilding the liver models in 2016.

Posttransplant Risk Model Development (Slides 11-20)

Dr. Kasiske explained the issue regarding the use of the CKD-EPI formula to estimate GFR in pediatric and neonatal kidney donors. SRTR received a request from a program to reconsider the use of the CKD-EPI equation in favor of the Schwartz formula, particularly for neonatal donors.

For now, SRTR removed the upper limit of 250 when processing eGFR in the PSR models. We will investigate further the proper way to handle GFR estimation in the PSR models, likely using the Schwartz formula for pediatric donors with an additional indicator for neonatal donors (under the age 1 year).

Kidney Pumping (Slides 21-25)

Dr. Snyder presented an issue regarding how kidney pumping is reported. He explained the risk adjustment and how it is defined. SRTR received a request for STAC to consider including the program's indication of whether the kidney was received on a pump rather than considering only the OPO's report of pump use. There was concern that the OPO designation on the DDR is inaccurate, and SRTR should use the program's report of kidneys received on a pump, particularly imported kidneys. SRTR does not know whether the OPO report or the transplant program report is correct when the reports disagree. In a 3-year period, these fields disagreed 1484 times, or about 5%, for imported kidneys, about 16% disagreement vs. 1% for local kidneys.

Dr. Snyder suggested a new algorithm, which could be: pumped = OPO indicates pumping OR center indicates kidney was received on pump. There was discussion of how the data are collected and when and how the errors arise, and some thoughts regarding different metrics for collecting accurate data. Ultimately, Mr. Stewart of UNOS suggested that UNOS look into this to assess the possibility of more quality control.

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New Risk Adjustment Models (Slides 26-31)

New kidney models were previewed for all programs during the December 2014 PSR release. Kidney models are being used for the first time for the June 2015 PSRs. Draft heart models will be previewed during the spring 2015 PSR release. Lung, liver, intestine, and pancreas model redevelopment will follow, in that order. Dr. Snyder used slide 31 to demonstrate the systematic redevelopment timeline.

There was a brief discussion after Dr. Snyder's presentation. Dr. Gill suggested thinking about putting together papers/thoughts on "how good do we expect these models to be?", as there is inherent risk in what we're doing. Dr. Kasiske said that we are inherently trying to predict program outcomes rather than patient outcomes, i.e., we are attempting to infer program-level effects rather than patient-level effects. Perhaps we can describe model performance in this regard rather than using the traditional C statistics commonly presented. Dr. Trotter commented that performance monitoring may have the unintended consequence of stifling innovation. It is imperative that SRTR develop the most robust risk adjustment models possible in order to counter the perception that taking on high-risk patients will lead to worse performance reviews.

Dr. Gill summarized: to define how SRTR's ability to predict outcomes varies across donor vs. recipient risk, pure graft failure vs. other items, patient-specific vs. program-specific measurement, and different organ types. Then return to this issue at the next meeting.

Strategic Prioritization and OPTN-SRTR Alignment (Separate Slide Deck: John Gill's presentation "Quality and Value in Transplantation")

Dr. Gill presented on the Transplant Quality and Value Initiative.
Current definition of value is quality/cost. How do you measure quality? What is important to consider, process measures or outcomes/cost? Dr. Gill explained the outcome measures in use and described their advantages and disadvantages. He used examples from research on alternatives.

He surmised that we need to better refine outcome measures. Right now, we focus on first-year patient and graft survival and we need to look beyond that.

A great deal of discussion followed this presentation. Topics included challenges such as data collection, cost, burden, and whether outcome measures respond to patient needs, i.e., survival measures. Some options were considered based on committee experience. HRSA said it would be open to moving toward a quality assessment type of model, if that is the direction OPTN wants to go. OPTN would need to figure out how this would work with the OMB as the OMB is very concerned about burden. It is uncertain whether OPTN can collect the necessary data.

Discussion Summary: the committee recognized the need for more comprehensive outcome assessment and wants to look into how to demonstrate value and practicality.

OPO Performance Metrics (Separate slide deck: "SRTR OPO Performance Metrics")

Dr. Snyder presented on the background of work SRTR has engaged in regarding OPO performance metrics, working in collaboration with representatives from AOPO. Concept metrics and data were presented to an AOPO subcommittee regarding donor conversion metrics, donor yield metrics, and research organ metrics. The AOPO subcommittee recommended using reported deaths as the denominator for the conversion metric rather than eligible deaths because imminent/eligible deaths are not well defined. SRTR raised the issue of need for a special study to assess the feasibility of collecting patient-level data on ventilated deaths, rather than using all reported deaths. Mr. McLaughlin

of HRSA informed the committee that HRSA is considering a special study to look into this further. The Secretary in the past has not required data to be collected for this purpose, but it could be a possibility.

Dr. Collett explained how the UK audits are done for the OPOs. Dr. Israni suggested that we could work with the current UK study to help us identify criteria that would identify "potential donors."

Finally, the committee suggested that SRTR try to include all stakeholders in conversation, possibly holding a consensus conference to develop starting points and a plan for moving forward. The committee's general feeling is that a consensus conference would generate great interest. Another idea was to involve other people who use the data in ways we normally don't —bring in additional expertise.

Data Request Review (Slides 41-44)

Four current requests, signed data use agreements, and research plans were sent out for review. Completed security plans have been received for all requests and none raised any security concerns on internal review. All four data requests were approved.

Dr. Kasiske mentioned that the data request process will change to include a new review process that includes OPTN. Ms. Leppke elaborated on how this differed from the current process.

Waitlist Calculators (Slides 35-39)

Dr. Snyder presented the liver waitlist calculator. He spoke about the background of the development and the launching of the tool on the public site as a BETA. He demonstrated the tool for the committee and discussed the feedback that SRTR has received to date.

The committee discussed merits and draw-backs of the tool. Much discussion centered on the "snapshot" patient samples being used and the use of allocation vs. laboratory MELD scores. Additional ideas addressed how this could be done for kidney.

Overall, the committee agreed, this was a useful tool, but it needs tweaking, e.g., adding text on how to interpret it, increasing the sample from the current 8 days to perhaps 24 days, and a more visible disclaimer. Additionally, the committee expressed interest in tracking who is using the tool.

Miscellaneous/Updates (Slide 40)

Dr. Kasiske updated the committee on the Data Advisory Committee's kidney risk factor project. A subcommittee was formed and is in the process of determining what additional variables should be considered. It is a burdensome task and cost needs to be considered. Who's going to do it? What resources are there? Much more consideration is needed.

Dr. Snyder mentioned that the Liver Redistricting Forum is coming up and SRTR is preparing for it. Dr. Gill commented that SRTR needs to keep the STAC aware of major policy issues at UNOS/OPTN, and bring feedback to the STAC after the liver forum regarding proceedings/issues it may want to consider.

Closing Business

Dr. Gill asked if any members had additional business to bring forward. None was presented. Dr. Gill mentioned that the next SRTR Technical Advisory Committee teleconference will be held on Monday, July 27, 2015.

Minutes

SRTR Technical Advisory Committee

Monday, July 27, 2015
8:00 AM – 11:00 AM CST
Teleconference

Voting Members:

John Gill, MD, MS (C)
David Collett, PhD
Dan Meyer, MD
David Lederer, MD, MS
James Trotter, MD
Kevin Myer, MSHA

Voting Members Unable to Attend:

Rebecca Betensky, PhD (C)
Brad Astor, PhD

[(C) = Co-Chair]

Ex-Officio Members:

Monica Lin, PhD (HRSA)
Darren Stewart, MS (OPTN/UNOS)
Jonah Odim, MD (NIH)
Eric Engels, MD (NCI)

SRTR:

Bertram Kasiske, MD
Bryn Thompson, MPH
Jessica Zeglin, MPH
Jon Snyder, PhD, MS
Larry Hunsicker, MD, PhD
Nicholas Salkowski, PhD
Susan Leppke, MPH
Amy Ketterer, BA

Minutes

Dr. John Gill called the meeting to order at 8:00 AM CDT. Dr. Bertram Kasiske reviewed the day's agenda, after which the members introduced themselves. A quorum was present. Dr. Kasiske informed the committee that Dr. David Naftel and Dr. Yolanda Becker were rotating off the committee. Ms. Sue Dunn will replace Dr. Becker representing the Policy Oversight Committee (POC) of the Organ Procurement and Transplantation Network (OPTN), and Dr. Naftel's replacement will be sought this fall once the new SRTR contractor has been announced.

Dr. Gill moved to vote on the minutes from the last meeting, held May 21, 2015. There were no objections and the minutes were approved. Dr. Kasiske reminded the committee that the SRTR contractor is obliged to ensure that deliberations of the STAC do not constitute a conflict of interest (COI) for its members, and that committee members should recuse themselves from any discussion or vote regarding which they may have a COI.

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Update on UNet Changes (Slides 5-13)

Dr. Nicholas Salkowski began the meeting by reviewing material presented at the prior STAC meeting regarding changes to the data collection in UNet, which occurred in March 2015, and the resulting impact of these changes on production of the program-specific reports (PSRs). Dr. Salkowski first reviewed a list of the fields that were removed (slide 6). At the May STAC meeting, the committee asked SRTR to remove the affected fields from the PSR models to assess the effect on the models. Dr. Salkowski presented results for the kidney models after removal of the *History of Drug-Treated COPD* and *History of Transfusions* fields. The effect of removing these fields was minor with only small changes to the models' C statistics. Dr. Salkowski explained that these fields were also removed from the CUSUM models because the cohorts used in the CUSUM models are more recent than the cohorts used in the PSR models and would be affected sooner by the removal of these fields. The committee recommended removal of the fields before the fall 2015 PSR cycle so UNOS staff would no longer need to assist with changes to removed elements and so the PSR models would not differ from the CUSUM models. SRTR will drop the following removed fields from the affected PSR models:

- Kidney Models:
  - History of drug-treated COPD
  - History of pretransplant blood transfusions
- Liver Models:
  - Spontaneous bacterial peritonitis: LDADGS3

Committee members reiterated their previous sentiment that better communication is needed between UNOS and SRTR regarding all data elements that may be dropped in the future. Dr. Snyder noted that UNOS is waiting to hear about the STAC recommendation regarding removal of the affected fields. SRTR will notify UNOS of STAC's approval to remove the fields for the fall 2015 PSR cycle.

Estimating Glomerular Filtration Rate in Pediatric Kidney Donors (Slides 14-15)

Dr. Kasiske refreshed the committee's memory regarding use of the CKD-EPI formula to estimate glomerular filtration rate (GFR) in pediatric and neonatal kidney donors. SRTR received a request from a program to reconsider use of the CKD-EPI equation in favor of the Schwartz formula, particularly for neonatal donors.

For now, SRTR removed the upper limit of 250 mL/min/1.73m^2 when processing estimated GFR (eGFR) in the PSR models. SRTR investigated using the Schwartz formula for pediatric donors with an additional indicator for neonatal donors (aged younger than 1 year) and discussed this with Dr. Schwartz himself. He suggested using the following formulae:

- eGFR = k*height(cm)/creatinine(mg/dL)
  - Use k = 0.41 for ages 1-< 18 years
  - Use k = 0.34 for term babies aged 1 week to < 1 year
  - First week of life: no good estimate since it is the mother's creatinine and there are no good data.

SRTR will implement this in the fall 2015 PSR cycle. A separate indicator for first week of life will be included in the model along with the altered pediatric eGFR equations above. Adult GFRs will be estimated using CKD-EPI as before.

Discussion ensued about including eGFR, serum creatinine, and kidney donor risk index all in the same model given the likely correlation. SRTR noted that the LASSO selection procedure handles the inclusion of correlated variables by penalizing the effect of each predictor, so this should not be a large concern in the current model building framework.

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Kidney Pumping (Slides 16-19)

Dr. Salkowski presented an update regarding how kidney pumping is reported. SRTR received a request for STAC to consider including the program's indication of whether the kidney was received on a pump rather than only the organ procurement organization's (OPO's) reported use of a pump. There was concern that the OPO designation on the deceased donor registration form may be inaccurate, and SRTR should instead use the transplant program's report, particularly for imported kidneys. SRTR does not know whether the OPO report or the transplant program report is correct when the reports disagree.

Alternatives for the committee to consider were:

1. Whether the OPO or the program indicated that ***any kidney*** from the donor was delivered on a pump.
2. Whether the OPO or the program indicated that ***this kidney*** was delivered on a pump.
3. Whether the OPO indicated that ***this kidney*** was delivered on a pump.
4. Whether the program indicated that ***this kidney*** was delivered on a pump.

The committee felt that the main question concerned OPTN guidance for reporting this to OPTN to eliminate inconsistencies between the OPO and program reports. Mr. Kevin Myer indicated that it was generally the transplant programs that dictated the use of a pump, but the issue was less clear in the case of imported organs.

Mr. Darren Stewart of UNOS noted that the UNOS Data Quality team is looking at ways to build consistency checks into the data entry system that would flag any discrepancies between the OPO and program reports.

The committee recommended contacting a few OPOs to get more information on this topic. This may be a topic for the OPTN Data Advisory Committee as well.

Changes to Program Data during June PSR Cycle (Slides 20-28)

Dr. Salkowski began the discussion of changes programs were found to be making to their data during the spring 2015 PSR cycle. Programs are given a period prior to release of the PSRs during which to review their data and make changes as necessary. When SRTR used the draft models (developed before the data review period) to evaluate program data after the data review period closed, we found that the expected event count in the country rose by approximately 50 events. In other words, the changes to the data made patients on average appear to be higher risk than they were before the data review period. Therefore, SRTR refit the draft models to the updated data to recalibrate the models to the new "riskier" patient set. Dr. Salkowski then presented several charts that illustrated the changes programs were making and showed that they appeared to be largely be non-random data corrections. As one example, Dr. Salkowski reviewed changes to the serum albumin field collected at the time of candidate listing. Many changes to the serum albumin fields were the result of programs replacing missing data with known values; however, changes to many other fields appeared to be made in the direction of indicating higher risk, potential gaming by programs. The committee discussed whether "gaming" was acceptable or not. Dr. Kasiske stressed that the data should be accurate or else all analyses using these data are suspect. The committee discussed how to define "gaming" and correct it if it happens. As it doesn't seem that SRTR should be responsible for corrective action, perhaps OPTN's POC or the Membership and Professional Standards Committee (MPSC) could be involved.

Dr. Gill summarized this conversation by setting some potential guidelines: STAC needs to bring this issue to the attention of the POC, decide on the definition of "gaming," let centers know that it is

being monitored and is actionable, provide evidence that it compromises the models, and present a method of identifying offenders.

Dr. Kasiske said that we are only bringing the issue to the attention of the committee at this point. Our next step is to create a report for HRSA. Dr. Kasiske asked the committee for suggestions regarding anything else that should be in the report.

There were no other recommendations, but there was a question as to whether any validity checks are currently performed on the data. The question was posed to UNOS as to whether it audits quality. Darren Stewart affirmed that UNOS does audit, but audits generally target elements that affect organ allocation.

Liver Redistricting Expert Panel Review (Slide 29)

Dr. Kasiske informed the committee of a request from HRSA that SRTR convene a technical expert panel to review the optimization models implemented by Dr. Sommer Gentry in her work on the liver redistricting project. This will not directly affect the STAC, but Dr. Kasiske wanted the committee to be aware of this activity. SRTR will update the committee as to the outcome of the technical expert panel review at upcoming meetings.

Outcomes Measures Workgroup on High Risk Donors, High Risk Recipients, and Risk Adjustment (Slides 30-46)

Dr. Salkowski presented on the work SRTR has engaged in regarding risk adjustment and any disincentives to using high-risk organs that result from SRTR evaluations. There were four main concerns: Does transplanting organs from high-risk donors or performing transplants in high-risk recipients increase the likelihood of poor outcomes evaluations? How well do the risk adjustment models account for donor/recipient risk? What might happen to programs' evaluations if currently discarded kidneys were used? Should we exclude high-risk transplants from MPSC evaluations?

Dr. Salkowski presented slides showing the calibration of the current risk adjustment models indicating good calibration across the spectrum of donor and combined donor-recipient risk. He then reviewed slides showing the results of analyzing the hypothetical use of discarded and not-recovered kidneys. The analyses demonstrated that the models are well calibrated to donor and recipient risk such that programs accepting a high fraction of high-risk organs are not currently penalized unfairly and that hypothetical acceptance of organs currently not being used would not systematically put programs at risk of poor outcomes evaluations. These results were presented to the MPSC at its June meeting.

These results are currently being written up as a manuscript. The committee recognized that this would be good manuscript because it demonstrates things that go against conventional wisdom, but it doesn't speak to why organs were discarded. Dr. Salkowski clarified that this was meant to provide an overview for centers showing that accepting higher-risk organs would not necessarily worsen their risk adjustment. There was discussion about looking more deeply into the kidney donor risk index of the discarded kidneys. Dr. Hunsicker said that it needs to be clear why the organs are discarded and also, for the centers with the worst outcomes, what the common characteristics are. OPTN has looked into these issues "broad spectrum" and is refining the process to get closer to the answer.

Waitlist Calculators (Slides 47-48)

Dr. Salkowski presented the liver waitlist calculator. He highlighted the changes made to the tool based on the recommendations from the committee at the last STAC meeting. He demonstrated how the addition of the option to choose laboratory vs. allocation MELD affected the results.

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Overall, the committee agreed that this was a useful tool, but a disclaimer is still needed regarding the lab vs. allocation MELD scores and how to interpret the difference in results. SRTR agreed to work on some additional educational material to accompany the tool. Finally, it was suggested that there should be a method for tracking the usefulness of this tool.

Program Risk and Outcomes Reports (Slides 49-51)

Dr. Salkowski presented a table and a figure that are being suggested as additions to the PSRs. The reports split a center's transplants into quintiles of predicted risk and provide outcomes evaluations within each quintile. The goal of the report is to give programs a tool to focus attention on which patients may yield substandard outcomes in an effort to focus quality improvement efforts. Committee members suggested several ways to make the summaries more useful. Dr. Hunsicker suggested that the overall measures be displayed along with the risk-quintile measures to provide meaningful context. Dr. Gill thought the quintiles concept may be confusing. Dr. Salkowski said that the results could also be produced according to donor or recipient risk separately.

Closing Business

Dr. Gill asked if any members had additional business to bring forward. None was presented. Dr. Gill said that the next SRTR Technical Advisory Committee teleconference will be held on Tuesday, October 13, 2015, unless the Minneapolis Medical Research Foundation is not awarded the SRTR contract, in which case the committee will be notified.