Minutes

SRTR Visiting Committee

Friday, January 29, 2016
10:00 AM – 1:00 PM CST
Teleconference

Voting Members:
Rebecca Betensky, PhD (C)
John Gill, MD, MS (C)
Scott Biggins, MD, MAS
David Collett, PhD
Bethany Foster, MD, MSCE
Walter Kremers, PhD
Dan Meyer, MD
Kevin Myer, MSHA

(C) = Co-Chair

Ex-Officio Members:
Sue Dunn (OPTN-POC)
Eric Engels, MD (NCI)
Joseph Kim, MD, PhD (DAC)
Jonah Odim, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)

Unable to participate:
Monica Lin, PhD (HRSA)
David Lederer, MD, MS

Guests:
Bob Carrico (UNOS)
David Klassen (UNOS)
Joyce Hager (HRSA)

SRTR Staff:
Katherine Audette, MS
Larry Hunsicker, MD, PhD
Ajay Israni, MD, MS
Bertram Kasiske, MD
Amy Ketterer
Susan Leppke, MPH
Nicholas Salkowski, PhD
Dorry Segev, MD, PhD
Jon Snyder, PhD, MS
Bryn Thompson, MPH
Andrew Wey, PhD
Jessica Zeglin, MPH

Agenda:

Welcome & Introductions

Dr. John Gill called the meeting to order at 10:00 AM CDT. He reviewed the day's agenda, and roll-called the members present, who constituted a quorum. Dr. Gill asked for a vote on the minutes from the last meeting, October 13, 2015. There were no objections and the minutes were approved.

Susan Leppke, SRTR Program Manager, reminded the committee that the SRTR contractor is obliged to ensure that deliberations of the SRTR Visiting Committee (SVC) 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.

Dr. Jon Snyder introduced new members to the SVC: Dr. Scott Biggins, Dr. Bethany Foster, and Dr. Walter Kremers.

Current state of transplant program performance monitoring (slides 5-55)

Dr. Snyder began by presenting on program performance monitoring. A concern of programs regarding accepting higher-risk organs and candidates has always been that doing so will negatively affect outcomes and possibly cause the program to be flagged for review by the MPSC. SRTR has

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addressed how higher-risk organs and candidates actually affect outcomes. This is also of great interest to regulatory groups such as AAAU and MPSC.

The first part of Dr. Snyder's presentation covered the background of recent AAAU and MPSC initiatives. He posed the questions that are being seriously considered:

1. Do transplants using high-risk donors or in high-risk recipients increase the likelihood of poor outcomes evaluations?
2. How well do risk adjustment models account for donor/recipient risk?
3. What might happen to programs' evaluations if kidneys currently discarded were used?
4. Should we exclude high-risk transplants from MPSC evaluations?

At this point there was a brief discussion about this being a kidney-focused topic. Dr. Snyder confirmed that the conversation was centered on kidneys, but the issues also apply to other organs.

Dr. Snyder continued with the next section of his presentation, exhibiting several graphs that illustrated how the models adjust with high-risk transplants included, and concluded that high-risk transplants affect outcomes very little. There was no discussion of this section.

In the next section of his presentation, Dr. Snyder discussed the "carve out" that the MPSC proposed as an additional second screen concept. Programs would need to meet the following criteria to be flagged:

- Bayesian flagging criteria* are met for all recipients AND the same criteria are met for standard-risk recipients: KDPI ≤ 0.85 OR EPTS ≤ 0.80.
- Criteria are met for the standard-risk subset alone: KDPI ≤ 0.85 OR EPTS ≤ 0.80.
- Criteria are met for the high-risk subset alone: KDPI > 0.85 AND EPTS > 0.80.

He showed an analysis performed by Dr. Andrew Wey showing no decrease in the number of programs flagged if the above algorithm were used. In fact, the same programs would be flagged as under the old criteria.

Dr. Snyder informed the committee of the task force that had been instituted to identify objective measures that define clinically relevant outcome differences. This group is set to present its findings at the June 2016 OPTN Board meeting. Dr. Snyder reviewed the slides that had been presented to the working group in a January 25 meeting (slides 20-55). These slides compared current MPSC criteria with proposed alternatives.

There was a brief discussion over some details, primarily certain parameters the MPSC used to develop the Bayesian flagging system, e.g., consideration for small-volume programs and the goal of keeping the false positive rate near 5% regardless of program volume.

Dr. Snyder said that Dr. Nicholas Salkowski is in the process of running multiple simulations designed to analyze algorithms with lower false positive targets. These results will be brought to the next meeting. Relative to this, Dr. Gill added that SRTR has already looked at this monitoring system in several ways, and the committee can feel confident that this is a worthwhile project.

Dr. Gill posed a question about the current duration of the cohorts. Dr. Snyder confirmed that the results were 1-year outcomes estimated over a 30-month cohort of transplant recipients. Dr. Salkowski said that a longer period may not be meaningful as programs change over time. Darren Stewart of UNOS confirmed that the MPSC would want to look at the most recent results for review and consideration. The idea of a CUSUM-type monitoring tool for MPSC was raised. Dr. Larry Hunsicker noted that underperforming programs may not trigger on CUSUM charts in the same way they would flag on the PSRs. Dr. Salkowski agreed, explaining that consistently underperforming programs would be difficult to identify via a CUSUM method. Dr. Gill suggested a "deep dive" into CUSUMs and Dr. Snyder agreed that it could be done at the next SVC meeting.

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Monitoring kidney transplant program acceptance practices (slide 56-84)

SRTR's new biostatistician, Dr. Wey, was introduced. He gave a presentation on SRTR's effort to develop an offer acceptance model. Pursuant to the Contract, SRTR is required to develop this model to better inform the public. Dr. Wey explained the merits of such a model, and discussed the parameters for the cleaning and selection of match run data in detail.

There was a brief discussion of the effect this would have on the number of candidates on the waiting list and on time to transplant, and of how candidates would be affected. It was determined that this was pertinent to results, but was not an issue for the modeling process.

Dr. Wey explained how the offer acceptance model was to be built. He presented several slides illustrating the process, the considerations, and the results. Finally, he summarized how the acceptance model was assessed and gave examples of how the models could be used to support an offer-acceptance CUSUM monitoring system. He concluded by showing a conservative and an aggressive example, and posed some questions to the committee.

A lengthy discussion followed. Drs. Kremers and Hunsicker talked about how the apparent aggressiveness of programs varies across regions. Aggressiveness in Iowa would not necessarily be the same as in New York. A regional focus would be best, especially when including data in the PSRs for public consideration.

The question was asked, "Should average KDRI be included in the model?" Dr. Kremers' opinion was that the purpose of the analysis is to identify which programs are too conservative or not conservative enough. Including the KDRI increases the difficulty of interpreting the model results.

Dr. Salkowski explained that it is difficult to design a measure of kidney supply that is not affected by the aggressiveness of programs in the region. Program acceptance behavior affects results, creating a feed-back loop. It's difficult to adjust for that.

Dr. Joseph Kim suggested that we are trying to build a model that determines a reasonable level of acceptance. We must consider that whatever covariates are used are informative in that process and those covariates will change over time, the more and the longer this process is considered.

Concern was expressed over whether we are trying to look at structural or process measures. Is the purpose to identify underperforming centers or to increase utilization and allocation?

Dr. Snyder summarized, saying the process is meant to increase efficiencies in offer acceptance practice. An acceptance model could be used to identify ways to intervene with programs and spur their quality improvement initiatives, and encourage programs with low acceptance practices to better use the screening fields so they do not receive offers they will not accept.

It was decided that this topic needs further consideration. Other elements should be considered, and the committee will discuss it in future meetings.

Several agenda items were not discussed due to lack of time. The website development topic was postponed. It was decided to discuss the website after the meeting adjourned, for those who were interested.

Statement of the SVC to HRSA regarding OPTN-SRTR data quality (slides 98-114)

The statement letter drafted by the Chairs concerning data quality was reviewed and the contents discussed. Overall, no members were concerned about the content itself. However, there was a suggestion to order the "recommendations" bullet-points by some sort of priority. Also, there was general concern expressed over the idea of removing the data review period altogether. It was suggested the letter be circulated among the committee members to add comments before a final draft is reviewed again and put up for an approval vote.

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Closing business

Dr. Snyder said that the next meeting will be held May 20 in Washington DC. Dr. Gill called for additional business. There was none and the meeting was adjourned.

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Minutes

SRTR Visiting Committee

Friday, May 20, 2016
8:30 AM – 3:30 PM EST
In Person Meeting

Voting Members:
Rebecca Betensky, PhD (C)
John Gill, MD, MS (C)
Scott Biggins, MD, MAS
David Collett, PhD
Bethany Foster, MD, MSCE
Walter Kremers, PhD
Dan Meyer, MD
David Lederer
Kevin Myer, MSHA

(C) = Co-Chair

Ex-Officio Members:
Monica Lin, PhD, (HRSA)
Joseph Kim, MD, PhD (DAC)
Jonah Odim, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)

Unable to participate:
Sue Dunn (OPTN-POC)
Eric Engels, MD (NCI)

SRTR Staff:
Ajay Israni, MD, MS
Bertram Kasiske, MD
Susan Leppke, MPH
Nicholas Salkowski, PhD
Jon Snyder, PhD, MS
Andrew Wey, PhD

Via Phone:
Larry Hunsicker, MD, PhD
Amy Ketterer
Katherine Audette, MS
Bryn Thompson, MPH
Jessica Zeglin, MPH

Welcome & Introductions
Dr. Bert Kasiske called the meeting to order at 8:35 AM EST. Co-Chair Dr. John Gill roll-called the members present, who constituted a quorum. Dr. Gill asked for a vote on the minutes from the last meeting, January 29, 2016. There were no objections and the minutes were approved.

Susan Leppke, SRTR Program Manager, reminded the committee that the SRTR contractor is obliged to ensure that deliberations of the SRTR Visiting Committee (SVC) 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.

Additionally, some COI renewals are needed. Ms. Leppke will send emails with the necessary information and paperwork to those who need to renew their COI statements.

HOPE Act (Slides 6-23)
Dr. Jon Snyder gave an overview of HIV transplants since implementation of the HOPE Act. The main question was, “How will SRTR handle evaluation of HOPE Act transplant recipients in the OPO and program-specific reporting?”

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Dr. Kasiske added to Dr. Snyder's talk by discussing how to determine expected outcomes. He guided the committee through a historical look at HCV, and hypothesized that HIV might compare to HCV as a model.

Generally, programs are afraid of HOPE Act transplants because they think they will affect risk adjustments. Dr. Snyder showed slides to summarize the Consensus Conference and MPSC and SVC decisions on the subject. Dr. Snyder discussed several more slides to illustrate the SRTR analysis and demonstrate that HIV status does not affect programs' risk adjustments. He further explained through graphs that if there is an adjustment for HIV status, any bias disappears. Programs should not be affected. The first HOPE Act transplant occurring in March 2016. These are scheduled to first appear in outcomes reports in December 2016 for OPOs and June 2017 for transplant programs.

Lengthy discussion focused on several points such as: What kind of impact would this make with so few instances? Will the data be risk adjusted or protected? Should it be included in LASSO? Should the covariate be unpenalized?

Overall, the committee agreed that this is a good step forward. More donation should be encouraged, and this will help, and will decrease grief on waiting list, which is the purpose of the HOPE Act. These data help support the initiative.

The committee supported unpenalized outcomes and suggested that SRTR put the numbers together when the data arrive and consider ways to address certain difficulties that arose in the HCV instance, while waiting for the results of the HRSA workshop.

OPTN MPSC Screening Criteria (Slides 25-35)

Dr. Snyder explained the MPSC's current approach to flagging programs. A revised system of program screening was needed that would identify substantive clinical differences among programs flagged for outcomes review.

Dr. Snyder discussed the history on the MPSC flagging criteria and why they are being revisited. The MPSC created a task force, which recommended a multi-tiered flagging system that will combine concepts of quality control and quality improvement flagging zones. In April 2016, the MPSC formed a mini working group to continue the development of the system.

Dr. Snyder presented several slides showing the current criteria compared with alternative criteria.

The discussion was tabled for later in the meeting.

Kidney Offer Acceptance Model Update (Slides 37-46)

Dr. Andrew Wey gave a follow-up presentation on SRTR's progress on the offer acceptance model since he presented at the last SVC Meeting. Pursuant to the contract, SRTR is required to develop this model to better inform the public.

Dr. Wey presented several slides outlining the model structure, the implementation, and the PSR reporting timeline. He finished by showing a table that could be used in the forthcoming PSRs.

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A lengthy discussion followed, specifically regarding the table. The committee expressed concern over how the data are presented in the table. Is the table too complex for programs to understand? Will it be misinterpreted by patients who may simply look at the numbers and be scared away by straight non-acceptance numbers? Can it be married to OPTN/UNOS' "Root" report on offers? Is this over-simplifying the monitoring of a process that actually has many layers? Dr. Wey and Dr. Nick Salkowski explained that it is meant to give centers an idea of their acceptance performance in relation to regional and national performance.

Other ideas expressed included that this is overall a great effort and moving in the right direction, because we are all trying to increase acceptance, but we need to be careful to use the right language. We need to make sure programs understand it as a method to help them understand their acceptance behaviors and not another qualitative assessment. Education for programs may be required.

Ultimately, the goal is to release this information in the PSRs, possibly as soon as the fall release. SRTR can delay that until we have a better way to represent the data. SRTR will work to release the data to the centers privately in the fall, without a determination of when the data can go public until the committee approves a final and appropriate format.

At this point there was a brief discussion relating back to the MPSC ruling.
Overall, the committee's opinion was that programs should know that they are underperforming before a problem occurs, and work to remedy the issues. Many tools are available to allow them to watch their programs progress. Dr. Gill noted that the MPSC seemed to express appreciation for the support from SRTR, not just for the data and analysis, but for the way it is provided.

Inclusion of Multi-Organ Transplants in Public Reporting (Slides 48-63)

Dr. Snyder presented on how SRTR will report on multi-organ transplants. SRTR is tasked with showing data for ALL organ transplants and has been pursuing appropriate methods to do so. How will SRTR include these transplants in the PSRs? Will the overall program evaluations include them?

Dr. Snyder showed several tables for the various organs to demonstrate how the data would appear. It was proposed that initially SRTR include a table in each program's PSR indicating which multi-organ transplants were performed, along with Kaplan-Meier estimates of patient and graft survival, and with a national comparison. As new PSR models are developed that include multi-organ recipients, SRTR would include multi-organ recipients in overall program evaluations and adjusted performance estimates in the multi-organ tabulation.

During a lengthy discussion, the committee pondered the best practice for reporting. Concepts considered were stratification, creating models for only the most common multi-organ transplants, such as SLKs, creating a model similar to what was done with SLK, then including an indicator. The committee expressed concern over the practicality of reporting on every type, since it would be a lot of work to build models for each. The numbers of events would be too small to be meaningful.

At the end of the discussion, it was determined that the best approach would be to build a separate SLK model with indicators and report on it until we can review the data for more analytical substance.

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Handling of Correlated Data in PSRs (Slides 65-68)

Dr. Wey reported on a newer topic, correlated data. The PSRs include some instances of correlated data, i.e., post-survival and offer acceptance statistics. This can affect the variance more than the mean.

Dr. Wey discussed the offer acceptance example in detail and outlined some pros and cons. A brief discussion followed. In all, it was determined that this is worth considering, but the way SRTR currently handles it works and is sufficient. SRTR should focus on other issues.

Intercept only Prediction Models (Slides 70-75)

Dr. Snyder presented on the concept of "intercept only" models. In the event of too few results to build a meaningful model, concerns have been raised by programs trying to monitor their performance. The MPSC did not ask SRTR for input on this, but SRTR felt it was a worthy question to address.

What if an "intercept only" model were used to determine outcomes in the case of too few events? Dr. Snyder presented a model in this style. He showed how outcomes reports look when data to build models are lacking and why this is problematic. He also discussed the "safety net" application.

Dr. Snyder asked, "Should SRTR produce an expected value based on the intercept-only survival model and report as an unadjusted comparison?"

The committee expressed the opinion that the "gap" is a problem. Can there be a longer timeframe for the cohort? Dr. Salkowski pointed out that a longer timeframe would not necessarily allow for collecting data that are relevant because of various changes that can occur in the transplant community. Something that was relevant 5 years ago is not necessarily relevant today. The committee discussed the relevancy of the data if models are created for too few events. Consider not changing the process, but continue to assess whether there is another way to get at the expected outcomes.

This item is up for further discussion.

OPO Yield Model Redesign (Slides 77-83)

Dr. Snyder addressed the topic of an OPO Yield Model rebuild. He reiterated that SRTR is attempting to move the yield to a Bayesian approach, and handed the presentation over to Dr. Wey.

Performance on the OPO yields will be flagged. What is the best way to gauge performance? Dr. Wey showed the current model and described SRTR's current approach as well as the proposed Bayesian approach. He described in great statistical detail the differences between the former and proposed models. The largest difference would be the implementation of LASSO. SRTR would like to present this to the OPO Metrics group this summer.

A brief Discussion followed. The committee asked, "Why the change and what is the expected impact?" and, "Who is determining the covariates?" The covariates were selected some time ago; it was a backwards selection process and some covariates are no longer consistent. (Drug use was given as an example.) The MPSC committee workgroup has an OPO metrics group and has recommendations on which covariates to use.

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This issue will take more time to resolve. Dr. Snyder requested an "off-line" meeting with statisticians on the committee who might be interested in helping SRTR develop this further.

PSR Modeling: The Pediatric PA Pressures (Slides 85-88)

Dr. Snyder addressed a new issue that arose since the last PSR release. Several programs expressed concern that there was no way to get PA readings from some patients (i.e., pediatric patients too small to cath) and about how this affects their risk adjustments. Dr. Snyder explained the variable and what was happening. He asked the committee for some input as to how SRTR should account for this, and he presented some feedback from clinicians on this topic.

Dr. Dan Meyer expressed surprise that more data are not missing. He suggested that applying lowest risk is fine as long as programs aren't penalized and this should be tracked to see if it truly affects outcomes. Dr. Salkowski expressed the opinion that it doesn't affect the outcomes enough to be of concern. The committee concurred that it is an important variable and should not be removed.

Data Quality Follow-up (Slide 89)

Dr. Snyder re-addressed the statement letter that had been prepared and then revised per the SVC's previous requests. The committee voted and approved the letter. It will be sent to and disseminated by HRSA.

Living Donor Registry (Slides 91-100)

Dr. Kasiske gave a quick refresher on the Living Donor Registry progress. He discussed the reason SRTR was tasked with it and the benefits it could have. He then presented new information on how the data collection will occur, i.e., a pilot program first, and which centers have agreed to participate in the pilot program.

Committee members made several comments. It was suggested to link data with a cancer registry. Also, a suggestion was made to include information on donor socio-economic factors. Dr. Kasiske said that the NHANES survey format would be used for follow-up. The project outline was generally well received by the committee. Members seemed excited about the potential.

SRTR Website Redesign (Slides 103-106)

Dr. Snyder quickly updated the committee on the progress on SRTR's new website. There was no discussion.

AHRQ Funded R01: Collaboration with SRTR (Slides 108-109)

Dr. Ajay Israni informed the committee of the new AHRQ grant that he received to create patient friendly report cards. There was no discussion.

Closing Business

Dr. Gill said that the next meeting will be held August 2 as a teleconference. Dr. Gill called for additional business. There was none and the meeting was adjourned.

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Minutes

SRTR Visiting Committee

Friday, August 2, 2016
10:00 AM – 1:00 PM EST
Teleconference Meeting

Voting Members:
John Gill, MD, MS (C)
David Collett, PhD
Walter Kremers, PhD
David Lederer
Kevin Myer, MSHA

(C) = Co-Chair

Ex-Officio Members:
Monica Lin, PhD (HRSA)
Jonah Odim, MD (NIH)
Sue Dunn (OPTN-POC)

Unable to participate:
Scott Biggins, MD, MAS
Dan Meyer, MD
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Joseph Kim, MD, PhD (DAC)

SRTR Staff:
Ajay Israni, MD, MS
Bertram Kasiske, MD
Susan Leppke, MPH
Nicholas Salkowski, PhD
Jon Snyder, PhD, MS
Andrew Wey, PhD
Larry Hunsicker, MD, PhD
Amy Ketterer, BA
Katherine Audette, MS
Bryn Thompson, MPH
Jessica Zeglin, MPH

Guests:
Corey Schaffhausen (MMRF)
Bob Carrico (UNOS)

Welcome & Introductions
Dr. Jon Snyder called the meeting to order at 10:05 AM EST. Co-chair Dr. John Gill roll-called the members present, who constituted a quorum. Dr. Gill asked for a vote on the minutes from the last meeting, May 20, 2016. There were no objections and the minutes were approved.

Susan Leppke, SRTR Program Manager, reminded the committee that the SRTR contractor is obliged to ensure that deliberations of the SRTR Visiting Committee (SVC) 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.

Offer Acceptance (slides 5-27)
Dr. Andrew Wey presented on the offer acceptance model build process. The purpose of the research he presented was to determine how organs can be allocated more efficiently by creating an algorithm that identifies centers that accept organs more aggressively and those that do not. More precisely, the purpose is to create a public report that summarizes “organ acceptance and utilization” while providing

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information to programs for implementing quality improvement processes. Two methods were described: a public PSR report and a private CUSUM report.

Dr. Wey began with Slide 14. (The material on slides 5-13 was a recap, with which most committee members were familiar.)

Dr. Wey explained a table that could be included in a PSR and showed an example of a typical report. Some discussion followed. Kevin Myer raised a point about centers that say they will accept certain organs, but 100% of the time they don't. The OPOs know which centers these are. This is a good way to identify the "who" and the "why," or "the low hanging fruit." Dr. Larry Hunsicker supported the idea and commented that this is a good opportunity to standardize the process.

Dr. Wey showed an example of a CUSUM report, which would be included on each center's secure site. It would present the two- and one-sided CUSUM charts, show the offer acceptance rate overall and stratified by KDRI (in this example, which is for kidneys), and list the rejected offers with the highest probability of acceptance. He explained in detail (slides 23-27) the methodology behind the CUSUM and what it will show and how centers will use it to monitor their performance.

In conclusion, SRTR is working toward improving offer acceptance behavior and is open to including additional information that may improve offer acceptance practices. Dr. Wey asked the committee for any input.

The committee discussed stratifying by center characteristics, such as size. Dr. Wey and Dr. Nick Salkowski assured the committee that characteristics had been considered. Dr. Salkowski made a supporting comment, saying that characteristics may not be factor. There is no correlation because, for instance with size, some large centers show low acceptance behavior and some small centers high acceptance behavior. SRTR is trying to develop a *program* metric. Kevin Myer said that with the proposed methods, we can see the overview of acceptance practices, and a pattern, and make general assumptions, but he wondered if we could look more closely at the characteristics to support our assumptions. Dr. Wey affirmed that a characteristics table could be created and provided with the CUSUM tables.

The committee discussed why there are so many offers and so little acceptance: 750,000 offers with a 1% acceptance rate. What clinical or statistical factors are causing the "skew?" The committee discussed what it might mean that one organ requires 100 offers before being placed and another only 10 offers, and whether that could bias the offer acceptance model. The median number of offers was briefly discussed. Dr. Salkowski explained how the model adjusted for the number of offers

Finally, the committee agreed that the offer acceptance assessment was an important step in gauging the patterns at centers, but suggested it should not be considered in isolation. The centers align with the efforts of the OPOs, and it is important to connect center acceptance behaviors with OPO efforts. It is valuable to align, so the relationships are apparent.

Dr. Jon Snyder said that SRTR can consider these additional options and present at the next SVC meeting, where we would then ask for approval to put the PSRs and CUSUMs up for private preview by

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the centers. Once approved, the plan would be to have the preview reports in the PSRs by the December 2016 preview and the functional reports in the public release on June 2017.

SRTR Website Redevelopment (slides 28-45)

Dr. Snyder presented on the SRTR website redevelopment. In the most recent contract, HRSA asked SRTR to make the website more user-friendly, especially for patients. For the past year, a subcontractor for SRTR has been working on the redevelopment. This issue has been brought up sporadically in previous meetings, but the website had been in earlier stages. As we now plan to have it ready by December, more consideration is due at this time.

Dr. Snyder showed the website online in detail, describing how the site map is laid out and demonstrating how the functionality is more logical and intuitive than the current site.

Dr. Snyder noted that the OPO metrics were not yet included and asked the OPO representatives if they are needed. Sue Dunn from UNOS and Kevin Myer said they are needed. It is good to have the information, as it is good for the public to understand how the OPOs and centers relate. Dr. Snyder offered to allow them an opportunity to review and give feedback on the language if they wished.

Dr. Snyder continued with the functional characteristics of the site and paused after covering the "About the Data" menu, asking for input again. Dr. John Gill noted that it might be a good idea to have the information segregated and presented in two ways, one for transplant professionals and one for patients. Patient information would be in layman's terms and patients would be able to see only what was designated. There would be more detail for doctors/centers and researchers.

Dr. Snyder acknowledged Dr. Gill's suggestion by affirming that we have some time to think about that. Dr. Gill also asked if sorting by ranking first was the best way to sort. Dr. Snyder explained that it was set up that way as suggested by AHRQ (he offered to circulate the article if anyone was interested), but he would go into that in more detail in the next section. He finished this section's presentation by inquiring about any other comments on the site, and there were none.

Dr. Snyder continued with the final topic of the ranking bars on the search pages. He discussed several slides, explaining the history of the ranking system and how SRTR had arrived at it (slides 30-37). Two years ago, a primary SRTR concern was to develop some sort of ranking. The AHRQ's suggestion was to increase consumers' understanding of dimensions of quality that are relevant to their needs.

The five-tier assessment was SRTR's effort to fulfill that recommendation and was approved previously by the SVC (then Technical Advisory Committee). Dr. Snyder explained what each of the five tiers meant and demonstrated the scoring models (slides 38-40) used to arrive at the tier ranking.

Dr. Wey added an overview of the differences between the previous three-tier system and the new system (slides 41-45).

There was a lively discussion of this issue. The committee expressed a concern over how centers may look at the ranking and become confused, thinking that if they are a 2 or 1, they can expect to be flagged. How does this align with the MPSC and CMS criteria? Dr. Salkowski explained that there is not a 1:1 correlation. Some centers in the 2 zone may have been flagged, while some in the 1 zone may not

have been. The committee recommended that SRTR be clear that these assessments are *not* in alignment with MPSC or CMS assessments. Dr. Snyder assured the committee that we can make this clear; we can work on it and report at the next meeting.

A question was posed about the parameters for the scoring function and whether a more gradual curve with different cut points would be more accurate. Dr. Salkowski explained that SRTR had considered different cut points and presented to the previous SVC, and this was the version approved. Ultimately, the same results will be attained. Dr. Hunsicker supported that by saying that the people looking at it would likely not delve into the scoring function.

Finally, the question was raised as to whether SRTR had considered using an assessment tool like this for other concepts, such as "access to transplant?" Dr. Snyder indicated that it had been considered for other areas, but it would be difficult. Other than patients on dialysis, we don't know who the candidates may be. Dr. Salkowski added that this was an interesting question and could be good if used for an overview, but it gets complicated, as it's hard to narrow down for a "center-specific" metric. More discussion would be required.

Closing Business

Dr. Snyder noted that several topics were not covered due to lack of time, including the MPSC program screening criteria and the living donor registry. Dr. Snyder assured the committee that those topics would be addressed at the next meeting. The next in-person meeting in Minneapolis will be held on September 20. There was a call for additional business. There was none, and the meeting was adjourned.

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Minutes

SRTR Visiting Committee, Minneapolis

September 20, 2016
9:00 AM-3:00 PM CDT
In-person Meeting

Voting Members:
John Gill, MD, MS (C)
Scott Biggins, MD, MAS
Walter Kremers, PhD
Kevin Myer, MSHA

(C) = Co-Chair

Ex-Officio Members:
Monica Lin, PhD, (HRSA)
Jonah Odim, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)
Sue Dunn (OPTN-POC)

SRTR Staff:
Ajay Israni, MD, MS
Bertram Kasiske, MD
Susan Leppke, MPH
Nicholas Salkowski, PhD
Jon Snyder, PhD, MS
Andrew Wey, PhD
Larry Hunsicker, MD, PhD
Katherine Audette, MS
Bryn Thompson, MPH
Jessica Zeglin, MPH
Amy Ketterer, BA

Via Phone:
Bethany Foster, MD, MSCE

Dan Meyer, MD
David Lederer, MD
Bob Walsh (HRSA)
Bob Carrico
Chris McLaughlin

Guests:
Joyce Hager (HRSA)
Cory Schaffhausen, PhD (MMRF)

Unable to participate:
David Collette, PhD

Welcome and Introductions
Co-Chair Dr. John Gill called the meeting to order at 9:00 AM EST. Dr. Gill roll-called the members present and those on the phone. Participating committee members constituted a quorum. Dr. Gill asked for a vote on the minutes from the last meeting, August 2, 2016. There were no objections, Dr. Scott Biggins moved to approve, Dr. Dan Meyer (by phone) seconded the motion, and the minutes were approved.

On the issue of conflict of interest, Susan Leppke, SRTR Program Manager, said that the committee members were up-to-date on their COI statements and there were no conflicts.

Decision Tool for Kidney Offers (slides 52-54)
Dr. Jon Snyder began the meeting with a topic scheduled for later presentation, as the topic was of interest to Bob Walsh, who could attend only the first part of the meeting. Dr. Snyder explained the reason that SRTR was developing the kidney offer tool. When kidney offers are made, programs now see the kidney donor profile index (KDPI), a percentile rank for the overall donor quality. This seems to have led to a trend toward offers from donors in the higher KDPI range being turned down. SRTR developed a demo decision tool to provide more detail about the offer and give context to the KDPI.

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Dr. Andrew Wey, who developed the kidney offer tool, demonstrated it. The tool uses specified donor and recipient characteristics that indicate a kidney donor risk index (KDRI) and KDPI based on the input data. The tool then produces a histogram with markers showing the donor's KDPI area and the range in which the donor organ can achieve a 1% better survival probability. The tool also produces a graph that shows the KDRI density, to show the actual distribution of the clinical characteristics.

Another graph shows posttransplant survival. This graph again shows the indicators of where the current donor will fall and where a donor organ with 1% better survival probability would fall across KDPI values. Together, the graphs illustrate that a 1% better KDPI will not create much difference in survival probability.

Dr. Snyder's question to the committee was, would something like this, in addition to the KDPI, be useful? A lengthy discussion followed. Some general comments and questions were raised. It would be useful if it was provided at the time of offer. Coordinators may not have much time to go to a website to check. It is important to provide information at the right time without "overloading" the person making the decision. It would be much more efficient if it were incorporated into the existing system rather than standing alone.

The slope on the graph is very level and clinicians might begin to ignore it if it never changes. SRTR acknowledged that this was the point, to show that outcomes won't change much until the high KDRI range. Mr. Walsh said that HRSA and COIIN originally wanting to look into this issue to get more context for donor:recipient pairing outcomes.

Has it been looked at in the pediatric population? Most kidneys are going to be from donors under 35, if they are 36 or older, is there much difference? Some clinicians aren't taking from donors over 35, but that could be extended. It would be interesting to see this data in peds.

From an OPO perspective, it's hard to tell if providing the information from the tool will change acceptance behaviors. Perhaps a test run could be arranged with people who actually make the decisions.

One important idea that arose from the discussion was that clinicians and their patients should talk to determine what KDPI ranges are acceptable. Acceptance can then be determined more by what the patient wants, and not exclusively what the doctor believes is best.

Patients want to know their time frame for resuming some level of normal function. They are concerned with longer-term outcomes. There may be a disconnect between patient and clinician concerns.

A suggestion was made that SRTR test the tool in real time to override old behaviors with decisions that had been made. First, perform some field work to show to users, possibly cluster studies. Some engagement now was recommended before forging ahead.

A fear of regulatory pressure has always been present, but this tool could change things drastically if clinicians can better understand what the *patient* wants. The more the clinician knows the patient, the better the decision can be. Find ways to force that interaction. This tool is an option.

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Another reason that dialogue with patients is useful is that their health can change over time, which may affect their idea of what is acceptable. After testing the concepts with kidneys, we could apply them to other organs.

Over all, the committee's opinion was that the potential is great. Mr. Walsh said that the input from the committee was remarkably helpful and in line with input he had heard from others. The purpose was to develop a prototype tool, and the idea of a user group is excellent.

The committee proposed that SRTR go forward with presenting to a test user group and consider how to proceed from there. The tool could be reviewed with patients and the results discussed by the patient and clinician regarding what to accept. Put it out there and challenge clinicians to determine an acceptable range of KDPI.

Innovations Conference (slides 6-13)

The presentation reverted back to the intended first topic, which was the upcoming White House Innovations Conference to be held October 20-21, 2016, in Washington, DC. Dr. Gill, who will be attending, summarized the focus of the conference, which will be to encourage programs to do research that would foster innovations in transplantation, to consider ways programs may be affected or the current regulatory structure may be affected, and to determine means to separate the analyses so they don't affect a program or the overall regulatory structure.

Dr. Bert Kasiske, who will also attend the conference, added that the concern is that programs might generally be opposed to trying innovative research for fear of regulatory repercussions.

Dr. Gill posed a challenge to the committee to present some ideas to bring to the conference, such as to how enable programs to go forward with research and be exempted from the regulatory considerations.

Dr. Kasiske said that first it is important to define what is innovative. The scope of what type of research should be considered innovative should be narrowed. Some discussion ensued about the relevancy of pharmaceutical trials as an example.

The committee generally believed that some research will have to be subjective and taken case by case, but many studies are minor and mechanistic in nature, and we can't exclude all and we can't give each program its own adjustment set. We wouldn't want mechanistic studies.

A committee member suggested that the definition should include a focus on increasing donors and transplants.

It should also include enabling patient decision making, as related to the previous topic.

"Innovative" should be as *judged by a* committee. The trial should be reviewed by peers or colleagues, determined to be innovative, possibly risky, but results likely to bring potential large gains. Then whether the trial warrants the use of resources can be determined.

Dr. Jonah Odim of NIH suggested an advisory board to review "transformative research" proposals. A process should be developed to provide guidance regarding what to approve. Also, NIH should be concerned with the purpose of its role. Is it to improve transplantation or develop policy? NIH needs to consider its mission in this process.

Dr. Kasiske suggested an idea that he would like to present during the conference; could we develop a way for studies, such as NIH HIV, to allow a direct pipeline of data from the trial into SRTR and preemptively adjust models and let programs know how the variables are adjusted so they don't have to worry about getting "dinged"? That would be preferable to removing the participants from the program-specific report (PSR) outcomes. What are some barriers? Dr. Odim responded that many process questions need to be worked out.

The conversation turned to how participating programs would be treated. Dr. Nicholas Salkowski noted that if we remove programs that are doing research, we lose the ability to evaluate program outcomes. If a trial is truly transformative, and if we adjust, we shrink the program's performance toward average. Post-trial presents a challenge. SRTR can adjust for trial participation during the research, but afterward we can't readjust that program's outcomes.

Dr. Gill added that we must think about how the data from the trials are distributed so others can use them to ensure that gaps in knowledge are filled in. After the study, what do we still not know and how do we fill in the gaps?

Dr. Gill added that SRTR should not be seen as a tool for regulatory purposes, but instead be promoted as a partner in advancing innovation driving advancements in the field. Engage people in SRTR data use. Increase the value of the SRTR data. SRTR involvement in fostering innovations can further that view.

Dr. Snyder reminded the committee that we're trying to move toward providing more valuable information to patients. Patients want to know, "What will happen to me at that program if I go there." It's our duty to report to patients.

Dr. Gill closed the topic by assuring the committee that there will be life to this project and polling the community will be important, including patient advocates. There will be broader engagement before anything is developed.

Kidney Offer Acceptance (slides 14-28)

Dr. Wey revisited topic of kidney offer acceptance, which was discussed during the SVC teleconference in August. He began by showing a current version of the CUSUM charts and tables as they appear created in R Studio.

He discussed the categories included in the table and pointed out the newly added "Weekend" row to illustrate an increase in acceptance behavior over weekends.

Discussion followed about the categories shown and the parameters used for the data. Committee members were interested in the inclusion of correlations of KDPI to non-renal organs, consideration of cold ischemic times, and whether organs were pumped in these results.

Dr. Wey showed some other examples of a moderately performing program and a conservative program and how the CUSUMs differed.

On the display of the CUSUM, a committee member asked if we had considered a program-level CUSUM vs. one in which outcomes are based on the national adjustments. The answer was "no" because programs should see their performance compared with their peers. The topic shifted back to the tables; from an OPO perspective, the conservative program looked *bad*. If an OPO had these reports for comparison, it would shy away from making the offer to the conservative program. Ultimately the conversation focused on whether this will change acceptance behavior.

Dr. Wey asked if there were any recommendations. One suggestion was to include outcomes of the transplanted organ on the tables. However, it was overwhelmingly determined by the committee that that would not be useful. Dr. Gill brought the committee back to the subject of how to change acceptance behavior by using these data.

There is an existing report UNOS produces that shows what happens to the organs that were offered. We could point to UNOS' resource to cross-reference. Finally, the SRTR report shows transplant programs what they *aren't* taking.

A committee member suggested that there should be a way for programs to see their PSR outcomes relative to offer acceptance so they can see all aspects of the process and get the big picture regarding their behaviors and the effect on transplant rates. For instance, reducing waitlist time shouldn't be just about reducing the list, but also about increasing offer acceptance.

Dr. Wey discussed an additional report that was created, the OPO offer acceptance report. It would not be public, but available only to OPOs. This report separates out different types of high-risk organs. For each organ type, the data show offers, acceptances, expected acceptance rates, and acceptance rate ratios for all programs in the nation. This would give OPOs an "at-a-glance" idea of which programs are more likely to accept certain types of offers.

Kevin Meyer noted that DonorNet was developed to create efficiencies, but sometimes it can bog down the process; this report could be a quicker reference. Darren Stewart explained the ways UNOS is attempting to streamline, especially dynamic screening, because screening is done at the time of offer and should change as time goes on.

Dr. Meyer raised the subject of using these data to formalize a placement system model.
Kevin Myer responded that it would be easier for OPOs to achieve compliance, but there's a balance, and one would hate to skip a candidate who may be available because the *system* missed it. But conversely, formalizing it would remove subjectivity.

A side comment was that it would be more valuable to break out "import" vs. "local."

The committee was overall in support of this type of report.

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After that discussion, Dr. Wey said that he had isolated two problems that need to be addressed regarding match run data in the offer acceptance data.

- Patients can continue to receive offers after they die. The problem is that clinicians don't know the patients are dead until we try to find them. If programs don't know the patient was dead, that doesn't change its acceptance behavior.

The consensus regarding how to handle deceased listed patients was to remove those the program identified as having died as a removal reason.

- Approximately 6.5% of kidneys transplanted in 2015 are not in the kidney match run data.

Dr. Wey explained four reasons the kidneys were missing: multi-organ transplants, local backups, kidneys transplanted by different programs, and issues that were difficult to define. He asked the committee for ideas on how to approach solving these problems.

The committee determined that the local back-up kidneys should be included, but the rest can remain omitted.

SRTR Website Redesign: A Final Update before Launch (slides 29-34)

Dr. Snyder presented an overview of the website, focusing on elements that had been added since the last meeting, such as the OPO risk adjustments. He specifically covered the guides for users explaining elements on the site. For instance, "what does the transplant rate mean?" He showed the area on the new website where a list of these items can be found.

Only a couple of concerns were raised. A committee member asked if there was a way to split or organize content into different user levels, such as one for patients, one for researchers, and one for programs. Dr. Snyder said that that could be considered for the future, but for now it would require total restructure of framework.

Another member asked about monitoring who is viewing the site and what their feedback is. Google analytics can tell SRTR how many people visit the site and which pages or elements are of most interest, but further digging into the demographics and other information would require a "pop-up" form. SRTR cannot include a form asking for that information without OMB approval. The process is too complicated.

Finally, Dr. Snyder discussed the currently proposed five-tier assessment and the scoring function being used to develop it. Last meeting, the scoring function was questioned. Dr. Snyder showed the committee an alternative scoring function (slides 36-38 for illustration). The question was whether SRTR should consider a broader hazard ratio range, which would produce a more gradual slope.

Dr. Wey illustrated what the gradual slope would look like. The main question is which function to choose. Primarily, SRTR is presenting it so patients can make decisions about programs. It's ultimately a value judgement about what shows the best value. How patients may distinguish between hazard ratios was taken into consideration.

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It was suggested that a histogram be added as a link showing the distribution of the programs, so patients can see where programs at various assessment levels fall, and that may give patients an overview.

The committee agreed, based on the evidence presented, that the current scoring function is acceptable. SRTR will go ahead with it.

Creating Patient Centered Report Card (slides 40-50)

Dr. Ajay Israni introduced Dr. Cory Schaffhausen as a guest speaker. He presented information on the AHRQ-sponsored RO1, focused on the information patients seek when trying to choose a transplant program. The question is, "how can SRTR help a patient select a program that performs transplants in patients like them?" What are the real concerns? Finally, how can we get the data to patients most readily? The idea was a program-specific report card for patients. Patients interviewed so far have given extremely positive feedback.

Dr. Schaffhausen has been working with Dr. Israni to analyze call logs and emails collected from past SRTR and UNOS communications. He has been conducting interviews with focus groups from Hennepin County Medical Center and University of Minnesota kidney transplant patients.

He explained that his study is in its early stages. Kidney patients are the focus now, but other organs will be considered. The short-term goal is to collect the data. Long term, the suggestions from the study results will be implemented through SRTR.

Dr. Schaffhausen discussed where patients are currently getting information on transplant options. Patients have a limited understanding of the options available, where to find information, and how to compare programs against each other.

Finally, Dr. Schaffhausen explored the challenges to disseminating the information. How do we get the information to the patients? Dr. Schaffhausen gave examples of reports that could appear on the SRTR site.

This presentation was informational. Committee suggestions were taken under consideration and further updates will be presented in future meetings.

Multi Organ Decision Process (No slides Presented)

Dr. Snyder gave a brief overview of the current multi-organ process and discussed an incident in which a program had a patient slated to undergo heart/liver transplant. The heart was transplanted, but the patient died before the liver was transplanted. The patient appeared in the data as a heart-only patient and the failure was counted. The program questioned either the SRTR algorithm or the UNOS data entry requirements, and took the position that the patient should have been considered a multi-organ patient.

Dr. Snyder asked the committee for input, leading to a brief discussion. Primarily, the committee needed clarification of when the organ is considered placed.

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The overall view of the committee was that OPTN's collection process requires the TRR for each organ. It is not SRTR's responsibility to solicit to change OPTN policy or procedure.

The original communication to the program in this regard stands. SRTR cannot change the data.

Living Donor Registry (No slides presented.)

Dr. Kasiske gave a brief update on the status of the Living Donor Registry. It is meant to answer important questions:

- What are the outcomes attributable to living donation?
- What are the outcomes of donor candidates who do not donate?
- How can these questions be answered most cost effectively?

Initially, HRSA tasked SRTR with producing a feasibility analysis. The feasibility analysis was accepted and SRTR has been given permission to proceed with the registry.

Dr. Kasiske informed the committee that the first phase is underway, beginning the pilot study with programs already having agreed to participate. Ultimately, SRTR can build on the initial data collected in the pilot study.

Closing business

Dr. Snyder noted that the next SVC meeting is a teleconference to be held January 20, 2017. There was a call for additional business. There was none and the meeting was adjourned.

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