Minutes

SRTR Visiting Committee

Date: May 9, 2017
Time: 9:00 AM-3:00 PM CTD
Teleconference

Voting Members:

John Gill, MD, MS (C)
Susan Gunderson, MHA (C)
Scott Biggins, MD, MAS
Bethany Foster, MD, MSCE
Walter Kremers, PhD
Dan Meyer, MD
David Lederer, MD, MS
Rachel Patzer, PhD
Luke Preczewski (via phone)

(C) = Co-Chair

Ex-Officio Members:

Monica Lin, PhD (HRSA)
Jonah Odim, MD (NIH, via phone)
Darren Stewart, MS (OPTN/UNOS)
Sue Dunn (OPTN-POC)
Eric Engels, MD (NCI, via phone)

Guests:

Chris McLaughlin (HRSA, via phone)
Cory Schaffhausen, PhD (MMRF)
Melissa Greenwald, MD (HRSA, via phone)
Janet Kuramoto-Crawford, PhD (HRSA)

SRTR Staff:

Ajay Israni, MD, MS
Bertram Kasiske, MD
Nicholas Salkowski, PhD
Jon Snyder, PhD
Andrew Wey, PhD
Katherine Audette, MS (via phone)
Bryn Thompson, MPH (via phone)
Jessica Zeglin, MPH (via phone)
Larry Hunsicker, MD, PhD (via phone)
Amy Ketterer (via phone)

Welcome & Introductions

Co-Chair Dr. John Gill called the meeting to order at 9:05 AM EDT. Dr. Gill roll-called the members. Participating voting members constituted a quorum.

Regarding conflicts of Interest (COIs), Dr. Bertram Kasiske reminded committee members that SRTR must ensure that they manage any potential COIs, and asked them to bring forward any potential COIs during committee deliberations and possibly recuse themselves from related discussions. Dr. Kasiske reminded the members to contact SRTR with any changes to their COI disclosures.

5-Tier Assessment Rollback (Slides 6-28)

Dr. Melissa Greenwald, Director of the Division of Transplantation at HRSA, was introduced to the committee. She had prepared a statement regarding how SRTR, with the support of the SRTR Visiting Committee (SVC) and HRSA, should move forward on continued development of the tier system and SRTR public reporting of transplant program performance. Dr. Greenwald thanked the SVC and SRTR for the work they do, outlined the 5-tier history from HRSA's standpoint, and explained why the rollback to the 3-tier system was necessary. She noted that it was not a permanent situation. She said that patients are the primary focus of HRSA's decision to present an assessment system, but we lack quantitative data about what patients want to know; if we have that, we can go forward with a more amicable solution for both patients and programs.

Dr. Greenwald mentioned several items HRSA, SRTR, and the SVC need to consider while making decisions regarding anything SRTR produces:
- How to better communicate the needs of patients.
- How to better prepare the medical community for changes.
- How to give programs and OPOs the data they need.
- How to avoid risk aversion on behalf of programs and OPOs.
- How to present the data on both pre- and posttransplant outcomes in a way that provides patients with a more balanced view of the program's outcomes throughout the phases of transplant.

HRSA is looking to the experts for input and the SVC plays a major role in charting a course forward.

The charge to the SVC is:
Take into consideration patient needs, unintended consequences, and communication processes to best convey information to patients and to provide information they need regarding access to care. Consider feedback from transplant professionals to find a way to balance these sometimes competing priorities.

After Dr. Greenwald's address, Dr. Gill had a few comments:
The SVC and SRTR need to think about our engagement with patients and the strength of the data we are getting from that engagement. The AHRQ grant led by Drs. Ajay Israni and Cory Schaffhausen is achieving some of those goals. The SVC should think about SRTR's need for more resources to better support engagement with patients to determine whether the data are meeting their needs, and should work with HRSA to recommend areas of need. A tremendous amount of work went into development of the 5-tier rating system, and communications throughout the process attempted to include various stakeholders. We need to understand where the gaps in communication occurred and find ways to ensure those gaps do not continue.

Dr. Jon Snyder presented on the 5-tier system's rollback to the 3-tier system and the 5-tier system's move to the new beta website (beta.srtr.org). He noted that the new SRTR website reverted to presenting the old 3-tier system with "Worse than Expected," "As Expected," and "Better than Expected" labels. He noted that SRTR has been soliciting feedback since the roll-back and launch of the beta website. He mentioned several generalized feedback points that SRTR has received, both positive and negative.

A lengthy discussion occurred at this point. Discussion points from the committee included:

There is a "lexicon" here. We know and understand this stuff, but we forget others on the outside do not. We need to take a step back and think about this from another perspective.

We need to take some time to develop this, while communicating with transplant programs, OPOs, patients, and providers to get feedback during development. Engaging the community can make the process a long one, but it could be implemented incrementally.

This rating concept is being done, including in the medical industry. If SRTR does not do it in a data-driven, transparent manner, someone else likely will. Other sites with provider ratings already exist in various fields within medicine.

This is the right thing to do, as it brings more transparency to patients. Our fiduciary responsibility is to patients, but we still must be sensitive to the transplant community. Education regarding what is included must go hand in hand with communication.

Generally, those criticizing the 5-tier system are expressing concerns that also apply to the 3-tier system, and often are worse under the 3-tier system, e.g., a smaller program being rated higher than a larger program even with a worse point estimate of the hazard ratio. Thinking about how patients read and interpret the data, perhaps more explanatory text and/or disclaimers would be helpful.

The committee members noted that there is not a timetable, so the committee can take some time to consider options and explore modifications to the presentation. Patient feedback is important, but there is perhaps deceptive simplicity in the way the rating is displayed. Those who do not understand the statistics may believe that they understand more than they do. They may not be able to or willing to dig into the data. However, SRTR must balance the AHRQ recommendations for best practices in public reporting, e.g., simplifying and interpreting the data for users, with providing enough context so the data are not misinterpreted or over-interpreted.

We need further research on other metrics that could be included in the simple summary presentation along with posttransplant outcomes. In response to feedback that the current display over-emphasizes posttransplant outcomes at the expense of conveying the importance of undergoing transplant at all. The committee supports further efforts to display concepts such as transplant rates and waitlist mortality rates in a manner that offsets or adds to the presentation of posttransplant outcomes.

Consider that different assessments need to differ by organ, too. Something that concerns a lung patient may not concern a kidney patient.

What about the programs we haven't heard from? Perhaps SRTR should find a way to reach out to all programs to better gauge the feelings of the community with regard to the presentation of program search results on the public website.

From this conversation, a tentative list of tasks was developed:

1. Continue efforts to determine what is important to patients. The AHRQ initiative is ongoing and the SVC supports finding ways to reach out to more patient groups to solicit feedback.
2. Consider adding more metrics to the summary presentation on the website, including the following:
    a. Convert transplant rate to a deceased-donor-only transplant rate and convert that transplant rate ratio to a 5-tier system to be presented alongside the 5-tier outcome assessment.
    b. Create a 5-tier assessment of the waitlist mortality rate ratio to be presented alongside the outcome assessment and the transplant rate.
    c. Rather than present the total program volume, split the volume into deceased and living donor volumes separately.
    d. Continue to work on the descriptive language surrounding the presentation to better highlight meaning and contextualize the data, providing appropriate caveats where possible.
3. Communicate with and educate programs during the process.

Additional questions from the committee included:

Would longer outcomes, i.e., 3-year outcomes, be a better metric? SRTR staff noted that longer-term, i.e., 3-year, metrics are available in the full report. The trade-off with using longer-term metrics is they necessarily reflect older data and may not represent current practices at the program.

What about the tier borderline factor? What makes a low 4 better than a high 3? What is the difference in assessment that can make it jump from one tier to the next? Dr. Snyder presented a slide showing the hazard ratios and *P*-values across the tiers to explain how we show the statistical difference between the tiers. Any time we create a categorical evaluation system, some programs will be near the edge of a group. There is a tradeoff between presenting the underlying metric as a continuous metric vs. categorizing into groups to make it easier for the general public to understand, as highlighted by the AHRQ report on best practices in public reporting.

No credible interval is presented along with the 5-tier assessment. SRTR noted that this was a direct recommendation of the AHRQ guidelines to avoid the use of confidence intervals in the primary display of the data. The job of the rating system is to summarize and highlight meaning for patients, and confidence intervals or other measures of uncertainty have been found not to be beneficial to public reporting.

Can we present metrics in a way that allows users to choose and sort the metrics in the order that matters most to them? The current website allows users to sort results on distance, volume, transplant rate, or outcome assessment. The concept of a composite score of a number of metrics has been proposed; however, we would likely need to determine a way for users to weight the metrics in a manner that meets their needs. This could be quite challenging to implement.

Creating a Patient-Centered Report Card (Slides 29–58)

Dr. Schaffhausen presented a follow-up report on the status of his and Dr. Israni's AHRQ-funded project. He gave a brief overview of the project, which is designed to make recommendations to SRTR regarding how to present information that will help patients find and compare programs.

Dr. Schaffhausen updated the committee on the work done so far. In the previous SVC meeting, Dr. Schaffhausen had presented some concepts that he intended to further develop and test with patient groups. He gave the committee an overview of the results of applying those concepts and the feedback he had received thus far.

Some principles Dr. Schaffhausen covered were results of new surveys of patients regarding the new 3-tier system vs. the 5-tier system.

He discussed patients' understanding of what the transplant rate means.

Other findings included: patients believed that an outcome assessment was very important to have. Patients rated their priorities of concern as "outcomes" first, then "volume of transplants," and finally "transplant rate." Dr. Schaffhausen surmised that these priorities may not be in the correct order, possibly because patients don't fully understand what they are looking at. It comes down to "trade-offs" in patients' minds, and they will make decisions based on what is most important in their minds, which currently is "my chance of long-term survival."

Dr. Schaffhausen thought that patients should have a better understanding of what transplant rate means. He looked deeper into whether patients had a reasonable understanding of risk of death while on the waiting list. He also looked deeper into the transplant rate and how it is portrayed on the website, showing patients other ways of viewing it to understand it better. He presented results of a randomized study presenting transplant rate as the numeric transplant rate per 100 patient-years vs. a 5-tier rating of the transplant rate and found a statistically significantly higher proportion of patients chose the program with a higher transplant rate when it was presented as a 5-tier assessment.

Dr. Schaffhausen finished his presentation by outlining the future tasks of the project, such as adding patient narratives to the website to help explain what the statistics mean, and possibly adding infographics that better illustrate the results. Additionally, focus groups will be used to study the following concerns:
- How do patients think about tradeoffs? (Program A has the best outcomes, program B has the best transplant rate.)
- How can the website help patients understand and make trade-offs?
- Previewing recommendations based on research about trade-offs on the beta site.

Finally, Dr. Schaffhausen summarized:
- The new website results in less confusion about labels.
- The 5 tiers better convey variation across programs and result in less confusion than the "As Expected" label.
- Patients value outcomes data in decisions.
- Additional refinements, e.g., presenting transplant rate as a tiered system, are supported by his findings.

General comments by the committee were:
There are as many "right" decisions as there are patients, because all patients have their own concerns and underlying factors.

How do we present for them what they should know, instead of what we think is the right metric to consider? We should not "box in" the patients.

Finally, it was noted that patients' own contributions make a difference in their outcomes. How do we factor in patient characteristics? For instance, some programs choose not to accept some patients, so after these patients go through the process of selecting a program based on transplant rates and outcomes, they may find that the program doesn't accept candidates like them. How can the SRTR help steer patients to programs that will accept patients like them?

Dr. Schaffhausen responded that we are considering these concepts, and there is room for improvement, but this is only the developmental stage. We are attempting to study what is meaningful to patients and why.

Transplant Rate: Removal of Living Donors (Slides 62-69)

Dr. Nick Salkowski presented on the transplant rate metric and the fact that living donor transplants are currently included (rather than censored) in the statistical analysis. Programs performing a large number of living donor transplants may influence their transplant rates simply by their practice of listing patients on the deceased donor transplant list. Using a deceased-donor only transplant rate, censoring living donor transplants, may better reflect access to transplant at the program, and is less prone to influence by living donor listing practices. However, if we switch to a deceased donor-only transplant rate, we still want to give programs performing living donor transplants due credit for these efforts. It was proposed to censor transplant rate metrics at living donor transplant but then present the living donor volume at the program along with the deceased donor volume to highlight programs that perform many living donor transplants. It was noted that we should not attempt to produce a living donor transplant rate, given that this metric could be highly influenced by the listing practices at the program, i.e., timing of listing relative to the living donor transplant.

The committee seemed to consider this approach valid, but discussion occurred regarding the current method.

Sometimes patients register on the deceased donor waiting list, not expecting a living donor, but then tests are done and a living donor is found to be available; or conversely, patients expect to have a living donor, but have to register anyway, and the living donor does not come through. So where to draw the line? What refinements can be made to make it more targeted?

Taking this metric out and not considering living donors at all could have unintended consequences for programs that actively look for living donors. We should consider presenting both, side by side.

Based on the above, Dr. Snyder presented slide 59 as an example of a better way to show patients information that may be meaningful. The slide displayed a web page with transplant volume broken out by living and deceased donors in one column and the transplant rate shown with 5-tier assessment bars along with the 5-tier outcome assessment. All columns were presented together to give a broader overview of the various metrics.

A suggested solution was to present the data as deceased donor only with a percentage of living donors. SRTR staff will explore these options and bring working concepts back to the committee at the next meeting for consideration.

Modeling of Pretransplant Metrics (70-75)

Dr. Andrew Wey presented on the history of SRTR's use of the Cox proportional hazards model in pretransplant risk models and proposed a move toward the Poisson model. The proposed model would include a broader set of covariates and no time-varying covariates; it would include only candidate status at listing. This will allow us to identify the effects of clinical care prior to transplant.

The committee had questions about the specifics of what would be considered in the models as covariates, and about the time period.

Some concerns were raised; this way of looking at it could have different implications for different organs. How will it be presented, since we're concerned about presenting transplant rates in a way that is understandable for patients?

Defining Pediatrics (Slides 77-83)

Dr. Salkowski presented work by SRTR to reevaluate how pediatric patients are defined in various metrics in the PSRs. Currently, inconsistencies exist in how pediatric patients are handled in the PSRs, e.g., patients are considered pediatric in the transplant rate evaluation if they are aged younger than 18 years at the start of the evaluation window; however, if they are aged older than 18 at the time of transplant, they are considered adults for the purposes of the posttransplant evaluations. This results in situations in which the transplant program could have a non-zero pediatric transplant rate, but perform zero pediatric transplants. Furthermore, children's programs that only list pediatric patients may occasionally perform a transplant in someone aged older than 18, resulting in adult outcomes assessments based on few patients. SRTR is looking for a consistent definition that could be applied across all metrics, and proposes that a patient's adult/pediatric status be determined based on age at the time of listing.

The committee deliberated and noted that allocation priority can remain following the eighteenth birthday; therefore, transplant rate calculations should define age at the time of listing such that allocation priority can be accurately reflected in the metric. The committee was supportive of the change, but noted that SRTR should seek input from other stakeholders, including broader discussion with MPSC/OPTN leadership and the pediatric committee. Dr. Snyder noted that the issue has been brought to the MPSC leadership and chairs, and that they were supportive of the SRTR decision and believed it was not the MPSC's place to dictate how pediatric patients should be defined or handled in the metrics. Dr. Snyder indicated that he appreciated the MPSC leaderships feedback but wants to continue to explore the change with the full MPSC and other stakeholders.

Dr. Snyder asked for a vote on whether the committee thought the pediatric patients at listing should continue to be considered so after transplant. There was no dissent or abstentions. SRTR will continue to seek input from the OPTN/MPSC and the pediatric committee.

Multi-organ and Offer Acceptance Reports and CUSUMs Preview (Slides 110-120)

Dr. Snyder explained that based on the previous SVC recommendations, versions of the offer acceptance tables and multi-organ tables were included in the draft PSR release on April 1. Communications pathways included the SRTR.org news page, the UNet listserv, and the secure SRTR site notices; in addition, information was presented in the SRTR newsletter "The Data Review."

Dr. Snyder noted that we received only positive feedback on these reports. He further asked the committee for approval to publish these reports in the upcoming PSRs to be released on July 5. There were no objections.

Offer Acceptance Decision Tool (Slides 88-101)

Dr. Wey presented on a new tool SRTR is developing, a kidney offer acceptance decision tool. He presented the "demo" version of the tool. Overall, this tool would inform those involved in the offer acceptance decision process of the potential benefits of accepting an offer versus declining it and remaining of the waiting list for a subsequent offer.

Dr. Wey asked for input from the committee. The major concern was to make sure that the specific information the tool shows is carefully thought out, so as not to lead patients to believe that organ offers occur more frequently than they do, or that they should hold out for a better offer. Likewise, this may dissuade programs from making offers. This tool should be reviewed by people at programs who are responsible for accepting offers, to see what they think. Overall, it's a good tool, with some adjustments and patient education. Dr. Snyder assured the committee that it is still early in development.

Living Donor Collective

Dr. Kasiske gave a brief update on the progress of the Living Donor Collective (LDC). He noted that the name, Living Donor Collective, had been chosen, an LDC committee had been formed, and the first meeting of the LDC committee was held on April 4, 2017.

Closing business

Dr. Snyder noted that the next SVC meeting is an in-person meeting to be held in Minneapolis on July 25, 2017. More information will be supplied regarding meeting logistics. There was a call for additional business. There was none and the meeting was adjourned.