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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