Minutes

Minneapolis, MN
September 11, 2018, 9:00 AM– 3:00 PM CDT

Voting Members:	Ex-Officio Members:	SRTR:
Susan Gunderson, MHA (Co-Chair)	Monica Lin, PhD (HRSA)	Bertram Kasiske, MD
Ken Newell, MD (Co-Chair)	Jennifer Milton, MBA (OPTN-POC)	Ajay Israni, MD, MS
Walter Kremers, PhD	Darren Stewart, MS (OPTN/UNOS)	Jon Snyder, PhD, MS
Rachel Patzer, PhD		Laura Klein, MPH
Luke Preczewski		Andrew Wey, PhD
	Guests:	Nicholas Salkowski, PhD
	Chris McLaughlin (HRSA)	Katie Audette, MS
Unable to Attend:	Joyce Hager (HRSA)	Alyssa Herreid, MPH
Bethany Foster, MD	Janet Kuramoto-Crawford (HRSA)	Larry Hunsicker, MD
Richard Formica, MD	Cory Schaffhausen, PhD (HHRI)	Mona Shater, MA
Jonathan Chen, MD		Ryan Follmer

Joining by Phone:
Scott Biggins, MD, MAS

Welcome:
The meeting was called to order at 9:00 AM CDT. Dr. Ken Newell lead introductions and provided an overview of the meeting agenda. Dr. Bert Kasiske made some opening remarks and discussed SVC membership as three members will be rotating off at the end of 2018.

Update on death data and PSR production (Slides 41-45) (moved up the agenda to allow Dr. Rachel Patzer to arrive)
Dr. Jon Snyder provided an update on the programs-specific report (PSR) delay caused by a change in UNOS' process of obtaining additional death information. The anomaly was discovered when a decrease in death counts was observed beginning in April 2017. The issue has been resolved and Dr. Snyder presented data comparing pretransplant death counts before and after the fix was implemented. PSR production resumed as of August 2018. PSRs will be released to the SRTR secure site on Thursday, September 13, and the public release is scheduled for October, after which the regular PSR schedule will resume.

Committee discussion themes: Concern was expressed about whether a similar issue could recur, as the data merge process and the CMS subcontractor structure are not transparent. The committee discussed the agreement UNOS has with CMS for monthly updates going forward. The committee did not criticize SRTR for delaying the reports, but noted that the impact on programs has been significant. The committee would like to see a more transparent, documented process. How would we verify that the new process is better than the old, and whether it is "working"? Public trust and communication are priorities. SRTR should be deliberative in communication with the community and request that CMS provide a root cause analysis report, as this will foster good will and confidence in the process.

Brief updates to committee:
A previously approved change to the pediatric patient definition for program-specific reporting purposes will go into effect in the secure site PSR release on September 13. This change will classify pediatric or adult patients based on the age at the time of waitlisting.

Expected outcomes will now be reported for expanded subcategories, even if no risk adjusters are found to create a risk-adjusted assessment. This improvement will provide evaluation (unadjusted) even in cases of small populations, which will be important for pediatric populations. The expanded evaluations will be reported for all four major organs (heart, liver, lung, kidney). The new evaluation cohorts has been communicated to the MPSC leadership at OPTN.

SRTR continues to build new risk-adjustment models that are capable of predicting expected events for multiorgan transplant recipients. SRTR plans a future discussion with the committee about how multiorgan transplants will be handled in the PSRs. Currently, they are reported separately from the single-organ recipients.

Response to beta site feedback and proposed actions (Slides 5-40)
Dr. Snyder reviewed main themes from public comments received along with SRTR's draft responses point by point. Twelve general themes, and a white paper critical comment from ASTS/AST, were discussed.

Theme 1: Compare programs within region rather than nationally.
The committee previously discussed providing national vs. regional comparators. A new web application could potentially allow for recalculation based only on region or a narrower geographic location. Other potential search parameters could include national, regional, state, and local sorting. The committee also suggested exploring ways to allow users to perform side-by-side program comparisons. SRTR could continue to work on this if the committee agrees it would be valuable. Any input received will be considered for this or any future tool.

Theme 2: The timeframe covered by metrics should be noted on the search results page.
The date ranges are listed in the educational materials linked from the search results. These date ranges will be updated every reporting period. SRTR's planned response is adequate and further action is low priority.

Theme 3: Combined deceased and living donor transplant rate should be eliminated from the website.
SRTR is exploring adding deceased and living donor transplant rates, in addition to the all-donor rate, to the Program Summary Data page. Including all three rates is sufficient, accurate, and reasonable; the committee is supportive.

Theme 4: Living donation transplant rate should be featured.
Theme 3 addressed this comment. The committee supported including a caveat emphasizing the importance of having a living donor as a factor. Wording to this effect will be added to the site.

Theme 5: Labeling rates "per 100 years of waiting" is not technically accurate.
This language was piloted to patients by Dr. Ajay Israni and Dr. Cory Schaffhausen and found to be preferred over the more technically correct "per 100 person-years of waiting." No change is

recommended at this time. SRTR will also make the language on the Program Summary Data page consistent with this language.

Theme 6: Five-tier system over-emphasizes 1%-2% changes across tiers.
No action recommended. For organs other than kidney, differences are larger than 1%-2% across tiers. This has been previously addressed. The committee discussed that the response must acknowledge this common perception that the differences across tiers are small. The committee believes that the 5-tier system is an improvement over the 3-tier system, in which the middle tier spanned a broad range of program outcomes. The definition of success should be clarified, and the complexity of the multiple factors should be clearly framed. For kidney, it should be emphasized that undergoing transplant faster is the most important factor, which the new version of the site attempts to do. The concept of a universal score encompassing pre- and posttransplant outcomes was discussed. The committee touched on limitations of using first-year outcomes, particularly in light of a large number of kidney patients who stay on dialysis and perhaps never undergo transplant. SRTR is continuing efforts to develop a life-years-from-listing metric. The SRTR draft response will be reworked to better address these concerns.

Theme 7: The observed-to-expected formulation is confusing. What about just showing comparisons to national rates?
The "learn more" section of the site has been built to provide better information about the observed-to-expected framework in contrast to the national average rates. The committee recommended further clarifying the national rates table by including the ranges within each tier, and making the "learn more" section organ-specific rather than providing a generic example of interpreting the national rates table.

Theme 8: Distances for searches should be more granular, suggest something between 100 and 250.
No action. The distance will be presented; by searching for 250 miles and sorting by distance, it will be evident which centers are in the 175-mile range.

Theme 9: Colors of tier icons should be the same.
No action. The fading was a suggestion in the AHRQ Best Practices in Public Reporting.

Theme 10: Programs with 100% survival should be rated 5 tier.
Added more education material regarding how the tiers are calculated and why a program with 100% survival is not automatically classified as a tier-5 program.

Theme 11: Transplant rates are not meaningful for intestine.
SRTR is working to implement outcomes assessments for all organ types including intestine, which will be reported as they become available.

Theme 12: Inclusion of waitlist mortality is misleading because kidney programs have little/no control over waitlist mortality.
No action. Committee members hypothesized that waitlist management largely determines the waitlist mortality rating. Response should say that the purpose of the website is to inform patients, and some topics are very important to patients despite being outside programs' control. The

importance of waitlist mortality is relatively organ specific. There is potential for confusion in how this nuanced information is presented.

The committee recommended that SRTR present information in the order of importance as patients will read it. Some members believed the waitlist mortality rating will do more harm than good because programs will restrict access to the list.

Motion from Chair: Recommend dropping waitlist mortality from kidney program search results (the information will remain in the full PSR). The reasons must be very specific and explicitly explained. Kidney transplant programs are less involved in pretransplant day-to-day management of underlying kidney disease. Some symmetry will be lost, but with sufficient explanation, dropping this metric should be fine.

Vote: Drop waitlist mortality for kidney only. Yes: 6; No: 0; Abstain: 0.

ASTS/AST critical comments

SRTR appreciates the ASTS/AST feedback and will provide a written response. General themes included the following:

Unintended consequences of public reporting: Reducing organ supply, limiting patient access, barriers to innovation.
This is feedback about reporting any metrics publicly and not a specific criticism of the current SRTR website under consideration. SRTR is contractually obligated to publicly report the metrics. SRTR recognizes that risk adjustment is not perfect and supports ongoing efforts to improve data collection.

The white paper stated that Medicare conditions of participation and private payer centers of excellence hinge on SRTR data. The response will restate that SRTR is charged with publicly reporting program evaluations to the best of its ability with the data provided, presented in a way that is accessible to multiple audiences, patients in particular.

The paper stated that patients often have little or no choice of programs. SRTR is contractually obligated to publicly report these data.

A concern was raised about a high rate of false positives (in reference to CMS metrics in the conditions of participation). However, the tier methodology is not based on the flagging algorithm used by either the MPSC or CMS. SRTR works with MPSC to develop a flagging threshold that meets the MPSC's need, but the ultimate decision of where to place the flag boundary lies with the MPSC. SRTR has no direct influence on the CMS flagging threshold.

Need to include patient-reported outcomes.
The committee thought that SRTR's response to this critique was adequate. It is out of scope and no data are currently available to incorporate patient-reported outcomes. SRTR would be supportive of exploring options.

Programs may not be responsible for graft failures or deaths.

SRTR addressed this complaint in the draft response, and the committee thought the response was adequate. SRTR cannot adjudicate which deaths were the responsibility of the program.

AST/ASTS suggested that the SRTR rank order performance by default; this is currently the default behavior of the website, and users also have the option to select a different sort order if preferred. The white paper suggested using symbols rather than numbers, which is currently done on the site with the 5-tier icons. The paper also suggested providing an overall summary measure. SRTR is working on developing a summary measure of survival following listing and hopes to roll this metric out in the future. The committee noted the difference between an overall measure, such as survival from listing, and a composite measure. SRTR favors the overall measure approach rather than assigning weights to pre-existing pre- and posttransplant metrics.

The AST/ASTS paper suggested including fewer reporting categories and combining data over multiple years to increase precision. The current waitlist mortality and transplant rate models have significant precision, while longer follow-up for posttransplant outcomes risks including data that are no longer relevant to current performance.

There was a suggestion to incorporate process measures. The committee thought that process measures are challenging and arguably only relevant if they correlate with patient outcomes. Currently, process measures do not exist in the OPTN data. SRTR is happy to work with AST/ASTS to develop the concept further.

A suggestion of better reimbursement for better data was out of scope of the current website discussion.

SRTR agreed with the AST/ASTS that better collection of important data is necessary. We will work with the societies to identify better metrics. This should be discussed with DAC, patient groups, etc.

The paper suggested that SRTR should be more collaborative with stakeholders while developing reports. SRTR has worked to improve communication and collaboration and will continue to do so. We look forward to continued feedback, appreciate stakeholder feedback thus far, have made many changes in response to feedback, and look forward to continuing the process.

Website path forward:
Recommendation that we make changes as described and agreed upon during the discussion. The committee requested a formal written response to the feedback received, including a response to the AST/ASTS white paper. Pending these last recommended changes, the committee recommended that SRTR move the beta site to the public site and take down the beta site until the next iteration of the website will go out for comment.

Motion: Prescewski
Second: Biggins
Vote: 6 yes, 0 no, 0 abstentions

The committee thought that the process has been extremely thorough. Direct communication to AST/ASTS is preferred, asking for feedback regarding whether we understood the concerns accurately. The committee recommended sending our response document to the executive

directors of both societies. The committee also recommended that the responses be made publicly available on the website.

Alternatives to 1-year outcomes (Slides 82-108)

SRTR often hears that first-year outcomes are not the right metric to be measuring. SRTR presents 1-month, 1-year, and 3-year outcomes. Dr. Nicholas Salkowski presented a prior analysis that compared 1-, 3-, and conditional 5-year (not including 1-year) outcomes. In an updated analysis presented by Dr. Andrew Wey, standard deviations of program outcomes from frailty models were shown. Variability in program outcomes is highest within the first 30 days and decreases over time. We believe there are two distinct timeframes with different posttransplant failure processes: early (stabilizes at about 90 days), and late (1-year variability stable for many years).

Discussion: "Successful outcome" should be better defined (quality of life, return to work, etc.). Return to dialysis is included in a graft failure definition. Patients care about long-term survival. It is understood that an acute period of risk occurs immediately after transplant.

SRTR's questions for the committee: What are measures of success that the SRTR could implement? What type of data do we need? The transplant community will determine the definition of success over time. What is the goal?
-    If the objective is 10-year survival, all the data are necessarily gleaned from transplants over 10 years prior, which may be irrelevant to future outcomes.
-    How predictive are 1-year data for 5-year survival?

Long-term and short-term goals:
1. Collecting data on different outcomes (long-term project).
2. Determine what can be used that is predictive in the data we have.
3. Rather than basing decision on what we have, determine what we need to make appropriate decisions on a successful outcome.
4. Need an actionable item:
     a. Likely a data collection issue. Community needs to decide what is important, and we in turn will determine how to model/predict.
5. Being able to measure both short-term and long-term outcomes is preferable. Long-term outcomes would be arguably better if short-term outcomes could be improved.

Three options to move forward were discussed: traditional 1-year outcomes; conditional long-term survival (2-, 3-, or 5-year, conditional on 1-year survival); recognition that what happens at 10 years is informed by what happens at earlier time points. SRTR wants to be responsive to criticism that 1 year is not sufficient.

Discussion centered on the definition and dimensions of transplant "success." SRTR will need to explore metrics that answer useful questions for the appropriate audiences for the metric in question. Traditional analytical techniques need to go back in time so long that relevance of the data comes into question compared with current experience. CMS and MPSC should decide which metrics are most related to quality, and that would drive the appropriate data being collected. Patients are interested in long-term outcomes and are not satisfied with just 1-year outcomes.

Is SRTR's role to develop a better metric, or should we wait until other stakeholders identify what they consider to be a better metric? SRTR should consider criticisms, consider how many programs take advantage of the tools on the secure site (3-year data, CUSUMS, tracking 5- and 10-year outcomes). It will be important to align with where the field is moving.

Options:
1. Traditional 1-year outcomes
2. Conditional long-term, e.g., 5-year outcomes
3. Recognize that what happens at 10 years is informed by what happens at earlier time points. Note: we don't want to focus too much on posttransplant when pretransplant is often more important to overall patient survival.

SRTR wants to be responsive to criticisms that 1 year is insufficient. A consensus conference could be proposed. It was noted that SRTR has been supporting the systems performance discussions at OPTN. The possibility of adding a patient representative to the SVC may be discussed with HRSA.

The committee debated whether the 1-month outcomes should be retained and whether they provide any necessary information. SRTR believes that 1-month outcomes are important given the highest variability in program outcomes occurs during the early posttransplant phase. One-year outcomes are more precise, being based on more information. However, if the early and later outcomes relate to different underlying processes, it is important to report each distinct time period. The large variability in the early posttransplant period shows differences between programs, and discarding a metric that uniquely describes perioperative survival seems counterintuitive.

The committee did not feel comfortable voting on specific recommendations at this time. Mr. Prescewski suggested seeking public comment on the pros and cons of 1-month outcomes.

Continued development of a survival-from-listing metric (Slides 46-81)
The Final Rule and the SRTR contract call for reporting on survival from listing. Dr. Wey presented information on continued development of a metric to describe survival from listing. A 2-year period of observation ensures that observed deaths are relatively recent. He proposed setting length of follow-up to 5 years, unless less than 90% of candidates underwent transplant or were removed from the waiting list. It takes 7 years for 90% of the kidney waiting list to be removed, and 9 years to reach 95%, which was considered too long. As it takes 4 years for 90% of the liver waiting list to be removed, following liver candidates for 5 years would be reasonable.

Follow-up could be split into discrete intervals to address the potential problem with non-proportional hazards. Four modeling frameworks were considered:
1. Cox proportional hazard, left truncation not supported by the GLMNet.
2. Piecewise exponential model (PEM) without TD effects (more strict than Cox).
3. PEM with TD effects and without an overall effect (effects assumed to be different, assumed to be non-proportional.)
4. PEM with TD effects and with an overall effect

Conclusion: Allowing models to have time-dependent effects generally improved model performance. While the fourth option was considered the most ideal, framework 3 was considered a good compromise due to time and cost prohibitions.

Race/ethnicity definition revisited (Slides 110-123)
Background: Prior to 2015, "Hispanic" was considered a race rather than a separate ethnicity in SRTR reports. In 2015, SRTR implemented new risk-adjustment model processes and separated Hispanic ethnicity from race. If Hispanic/Latino is chosen but no race is selected, SRTR defaults to white when no other information is available.

1. Five categories for race
2. Two categories for ethnicity (Hispanic/Latino or not)

The federal government prefers the two-question format (first ask about race and second about ethnicity) because it yields better data. UNOS/OPTN collects Hispanic/Latino as an ethnicity/race choice. SRTR received a complaint related to how race and ethnicity data are handled. Due to its format, the OPTN form does not support the two-question format. The commenter felt it unwarranted to assume white race when no race is selected for someone who indicates Hispanic ethnicity.

Question to consider: Should SRTR change the assumption in the modeling to assume white race if no specific race is indicated for someone who checks Hispanic/Latino ethnicity?

The committee raised several points. The veracity of the data is not certain and there is an element of "best guess." "Mexican" is a divergent racial background. A suggestion was made to make ethnicity the risk-adjusted factor rather than race. Since all the unknown races would be Hispanics if the assumption were relaxed (given there is no "unknown race" choice on the form), treating Hispanic as a race does not change to model, but would be a cosmetic difference only. An alternative solution was proposed to make six "dummy" categories that would allow different races to interact in the model independently.

Data collection: The DAC will meet Friday, September 14. A suggestion was made to raise this issue of OPTN/UNOS matching the federal recommendations split into two questions (this would be a long-term solution).

Recommendation: Consider different parameterization that people won't object to, but that won't affect the model. Choosing Hispanic and no other race would be treated as its own group, each racial/ethnic grouping would be its own risk adjuster in the equations. This would allow respondents to report this information in a way they are comfortable with, while retaining the ability to analyze the data.

Closing Business
Three members of the committee will be rotating off: Dr. Bethany Foster, Dr. Scott Biggins, and Dr. Walter Kremers. Dr. Snyder thanked them for their service to the committee and presented each with a token of the SRTR's appreciation for their service on the committee.
New incoming members in January: Dr. James Markman (abdominal surgeon) and Dr. Brent Logan (analyst with bone marrow transplant). One additional member is being sought.

The meeting was adjourned at 3:00pm CST.