

SRTR Visiting Committee Minutes

Teleconference

January 28, 2020, 1:00 PM- 3:00 PM CST

Voting Members:

Ken Newell, MD (Co-Chair)
Jeffrey Orlowski, MS, CPTC (Co-Chair)
Jonathan Chen, MD
Richard Formica, MD
Richard Knight, MBA
Brent Logan, PhD
James Markmann, MD, PhD
Sumit Mohan, MD, MPH
James Pittman, RN, MSN

Ex-Officio Members:

Shannon Dunne, JD (HRSA)
Alexandra Glazier, JD, MPH (OPTN-POC)
Jonah Odum, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)

HRSA:

Chris McLaughlin

Guests:

John Rosendale, MS (OPTN/UNOS)

SRTR Staff:

Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Bertram Kasiske, MD, FACP
Donald Musgrove, PhD
Caitlyn Nystedt, MPH, PMP
Nicholas Salkowski, PhD
Jon Snyder, PhD, MS
Andrew Wey, PhD
Mona Shater, MA
Bryn Thompson, MPH
Amy Ketterer

Welcome and Opening Remarks

The SRTR Visiting Committee (SVC) meeting was called to order by Dr. Jon Snyder and Dr. Kenneth Newell. Dr. Snyder introduced the new SVC committee members:

- Jeffrey Orlowski, MS, President & CEO, LifeShare of Oklahoma
- Sumit Mohan, MD, MS, Assistant Professor of Medicine and Epidemiology, Columbia University
- James Pittman, RN, MSN, Assistant Vice President of Transplant Services at HCA

Dr. Snyder also introduced the new SRTR Surgical Director, Ryutaro Hirose, MD, Surgical Director at UCSF, to the SVC committee. Dr. Newell reviewed the agenda with committee members. Dr. Snyder reminded committee members that SRTR collects COI from Committee members and publicly displays this information on the SRTR website. All members have completed COI statements.

Potential Donor Conversion Metrics & OPO Performance

Dr. Snyder reviewed the CMS Notice of Proposed Rulemaking (NPRM) issued on December 23rd regarding proposed performance metrics and standards for Organ Procurement Organizations (OPOs). CMS has proposed two new measures for OPO performance and SRTR conducted an analysis for the proposed rule. Dr. Snyder requested the committee members' recommendations on additional work SRTR could do regarding the proposed performance measures. SRTR has asked HRSA about the potential to submit a public comment on the proposed rules. Dr. Snyder indicated SRTR's analysis of the proposed rules was presented in San Diego at the AOPO Executive Directors' meeting.

Dr. Snyder detailed the proposed metrics which include an *organ donation rate* and an *organ transplantation rate*. The denominator of the metric would be potential donors as identified using

the Multiple Cause of Death (MCO) data made available by the Centers for Disease Control and Prevention (CDC). The CMS qualifications for a potential donor include ages 75 or younger, died in-hospital, with no exclusionary diagnostic codes. Dr. Snyder noted that the CDC Wonder tool cannot be used to estimate the metric because the data available through CDC Wonder only captures the decedent's place of residence and not the place of death, and excludes deaths of non-US citizens. CMS proposes changing the definition of a donor to a person with at least 1 organ transplanted or having the pancreas sent for research or islet transplant. CMS was not clear if a donor would be defined by the date of death or the date of organ recovery.

Dr. Snyder continued the presentation detailing the flagging rule for both proposed metrics. The CMS flagging rule states the flagging standard will be calculated based on the prior calendar year. In the year of evaluation, an OPO cannot be statistically significantly lower than the 75th percentile of the prior year's metrics. CMS would de-certify the flagged OPOs and the service areas would be recomputed to other OPOs. Based on SRTR's analysis, 31/58 OPOs would fail the donation rate standard and 36/58 OPOs would fail the transplant rate standard for the 2017 evaluation. Overall, 64% of OPO's would fail at least one of the two proposed performance standards. Dr. Snyder explained there would be a significant 2-3 year lag before the CMS evaluation is available for the performance year in order to wait for CDC data to become available.

The committee members discussed several questions and concerns regarding the proposed metrics and performance standards. Mr. Orłowski stated the flaw of the metric is that you are effectively always behind the curve if the OPO is improving. Mr. Orłowski explained that an OPO could be decertified if they have a low performance year, but meet the standard subsequent years due to the amount of lag time. Dr. Orłowski also expressed concern that there is no mitigating factor or appeals process.

Dr. Snyder explained that CMS will not plan to risk adjust for their proposed metrics. If CMS were to include risk adjustment for age, race, and Hispanic ethnicity, for example, a number of OPOs would change whether they met the performance standard. Dr. Snyder commented that without risk adjustment, there is an assumption that the differences in the distribution of potential adjusters is irrelevant when evaluating an OPO's performance. Dr. Richard Formica explained that although this is potentially an improvement from the previous evaluation based on the eligible death conversion rate, there is concern that the proposed standards may decertify over half of the nation's OPOs.

Dr. Snyder noted that he believes it is not the purview of SRTR to comment on the placement of the performance standard, i.e., how many OPOs meet or do not meet the standard. Rather, this is a policy decision by the regulatory body. However, Dr. Snyder believes it is the purview of SRTR to comment on the statistical properties of the proposed 75th percentile-based standard, e.g., that it is biased in favor of smaller OPOs, and to point out that risk adjustment allows the regulatory body to better determine which OPOs are higher performing. Dr. Orłowski commented that the lack of risk adjustment for OPO's reflects the mentality that every organ recovered should be transplanted, but that is not a realistic policy assumption, as 20% of organs procured are not transplanted. Dr. Ryo

Hirose also commented that it is a poor assumption that deaths are distributed evenly across the US and there are actually large differences within different regions. He stated that the accuracy of the denominator for this metric is critical to deciding if an OPO is performing well or not, which requires risk adjustment.

Dr. Snyder explained that SRTR's analysis attempted to replicate the CMS data contained within the NPRM, but were unable to fully replicate the CMS evaluation. Potential causes include county-to-donation service area (DSA) assignments, errors in the ICD 10 exclusion list within the NPRM, and handling of shared counties. SRTR's analysis had fewer deaths than CMS's, which could indicate CMS double-counted deaths in the context of shared counties. Dr. Snyder discussed that shared counties are rare but CMS did not indicate how they would handle OPOs with shared counties. SRTR wants to understand the nuance of these metrics in hopes of helping OPOs understand this evaluation. Mr. Orlowski commented that he suspects the reason why CMS doesn't want to risk adjust is because the more you have exclusionary criteria, the more disagreement there is on the criteria. Mr. Darren Stewart stated that the degree of exclusionary/inclusionary codes, precision of the definition of the denominator, and risk adjustment should all go hand-in-hand. Dr. Nicholas Salkowski agreed that the metric ought to be as accurate as possible due to rather extreme consequences of underperformance proposed in the NPRM.

Dr. Snyder asked the committee if they are supportive of SRTR's analysis. Dr. Snyder also inquired if they would recommend SRTR draft a public comment for submission or if the SVC would prefer to write their own comment. Mr. Orlowski explained that he supports SRTR to submit a public comment, if it is possible. If not, he would like the committee to make a comment. Mr. Richard Knight asked if the SRTR public comment would focus on risk adjustment and if the Visiting Committee would comment on a separate topic. Dr. Snyder indicated that SRTR would focus on the facts of the metric, point out biases of the proposed performance standard, and clarify some definitions. SRTR would not comment on placement of the performance standard, i.e., how many OPOs pass/fail the standard. Ms. Alexandra Glazier expressed the importance of more than OPOs commenting on this proposed metric, and that this proposal could cause disruption to OPO performance and in turn affect other parts of the transplant system. Dr. Newell also expressed support for SRTR writing a comment if HRSA allows, particularly highlighting how programs are currently evaluated and how this approach differs from the current standard. Dr. Hirose explained that SRTR can only comment on the validity of the metrics and whether it is risk adjusted. He explained two areas that SRTR cannot comment on: the flagging criteria and the consequences of the flagging criteria.

Dr. Snyder asked the committee if there were any members not in favor of SRTR submitting public comment on the CMS metric. The committee unanimously agreed to have SRTR proceed with writing a public comment. Dr. Snyder explained that SRTR will send the written public comment to the committee members for approval, as well as look to HRSA for guidance. Public comment is due February 21st and Dr. Snyder will reach out to the committee for review before the deadline.

Issues requested for SRTR's consideration

Dr. Snyder presented a concern from NYU Langone Lung Transplant program regarding SRTR's estimated first-year survival rate for the program. NYU Langone disagrees with the methodology SRTR uses to estimate first-year survival and feels this methodology biases the results against new programs. Dr. Snyder explained SRTR does not have knowledge of longer follow-up data that NYU included in their calculations. Dr. Ryu Hirose explained that he spoke with the NYU program director and although he does understand SRTR's methodology, he is concerned about the outward facing component of the data on the website. Dr. Snyder suggested adding the word "estimated" to "percentage alive with a functioning transplant at 1 year" on the SRTR website data table showing patient outcomes for the program, in an effort to address the issue.

Several committee members indicated their support of this word addition for program data tables. Committee members also supported the continued use of the Kaplan-Meier method to estimate first-year survival. Committee members discussed the option of adding a disclaimer that would explain that not all patients in the evaluation cohort have had a full year of follow-up and therefore first-year survival is estimated using the Kaplan-Meier methodology. Dr. Ajay Israni suggested alternatively removing the "1 year" designation and adding an asterisk that would direct users to a separate page detailing the calculation, in order to reduce the cognitive burden on patients. Dr. Brent Logan agreed that "estimated" should be included, but asked if an asterisk should also be included to further describe the estimate. Dr. Newell called for a vote to add the word "estimated" to "percentage alive with a functioning transplant at 1 year" on the SRTR website data table showing patient outcomes for the program. The committee voted unanimously in favor of the addition. Dr. Snyder concluded that SRTR would make this addition to the data row for all programs on the SRTR website and notify NYU Langone of the decision.

Brief Updates:

Dr. Snyder determined that updates can be postponed until the next in-person committee meeting in April.

Closing Business

Hearing no other business, the meeting concluded at 3:00 PM. The next meeting is scheduled in Washington, DC (Crystal City) for April 14, 2020.