

Minutes

Teleconference

January 30, 2019, 12:00 PM- 3:00 PM CST

Voting Members:

Susan Gunderson, MHA (Co-Chair)
Ken Newell, MD (Co-Chair)
Jonathan Chen, MD (not able to attend)
Richard Formica, MD
Richard Knight, MBA
Brent Logan, PhD
James (Jim) Markmann, MD, PhD
Rachel Patzer, PhD
Luke Preczewski

Ex-Officio Members:

Shannon Dunne (HRSA)
Jennifer Milton, MBA (OPTN-POC)
Jonah Odum, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)

Guests:

Chris McLaughlin (HRSA)
Joyce Hager (HRSA)
Janet Kuramoto-Crawford (HRSA)
Marilyn Levi (HRSA)

SRTR:

Bertram Kasiske, MD, FACP
Ajay Israni, MD, MS
Jon Snyder, PhD, MS
Larry Hunsicker, MD
Caitlyn Nystedt, MPH, PMP
Mona Shater, MA
Nicholas Salkowski, PhD
Andrew Wey, PhD
Katie Audette, MS
Bryn Thompson, MPH

Welcome:

- a. Introductions (Gunderson & Newell)
 - i. Run-down of membership and introductions
 - ii. New SVC membership (Gunderson & Newell)
 1. Richard Knight, MBA: currently president of the American Association of Kidney Patients, transplant recipient.
 2. Brent Logan, PhD: Medical College of Wisconsin, biostatistician, Center for Blood and Marrow Transplant Research.
 3. James (Jim) Markmann, MD, PhD: liver, kidney, pancreas, islet transplant surgeon, research interests in transportation of organs.
- b. SRTR COR transition (Kasiske)
 - i. Monica Lin, PhD, retired on January 3, 2019.
 - ii. Shannon Dunne, JD, assumes the responsibilities of the SRTR COR at HRSA.
- c. Agenda overview (Gunderson & Newell)
- d. Conflict of interest management (Kasiske)
 - i. COI forms for all members are publicly available on the SRTR website. Individuals should self-police depending on the topics at hand.
 - ii. Ken Newell: please send out the link to the COI documentation for updates.

2. Brief update on SRTR websites (Snyder)

- a. Review of beta version 3 of the SRTR public website
 - i. Approved by SVC on September 11, 2018.
 - ii. Approved by HRSA on January 8, 2019.
 - iii. Launched communications campaign and updated version of site on January 16, 2019.
 - iv. HRSA approved moving to the public site on February 5, 2019; beta.srtr.org will be moved to www.srtr.org and beta.srtr.org will be decommissioned until SRTR has new updates to preview.
 - v. Darren Stewart: Questioned the image on slide 8 regarding whether kidney search results will include a column for waitlist mortality tier; Dr. Snyder confirmed that the

kidney pages will not show the waitlist mortality tier, as the SVC previously decided at its September 2018 meeting.

- vi. SRTR will continue to receive and compile comments and feedback from site users and will present to the SVC.
- b. New version of the SRTR secure site: Brief description of use and contents of the SRTR secure site.
 - i. New site has been in development for nearly 2 years.
 - ii. Set to launch on February 20, 2019, to allow 2 weeks between launch of beta site contents and launch of the new secure site.

3. Continuous distribution allocation policies (Snyder)

- a. Recent historical setting: Donation service areas (DSA) and OPTN Regions have been used in organ allocation. This has been recently challenged in court, resulting in the commissioning of an OPTN Ad Hoc Geography Committee that examined other frameworks for allocating organs in the United States. At the most recent UNOS Board of Directors meeting, continuous distribution was selected as the framework for eliminating use of DSAs and Regions in organ allocation. SRTR will be involved in developing these new allocation policies, and this will require a large portion of SRTR effort in the coming year.
- b. Dr. Snyder reviewed the longer-term historical setting and development of NOTA and the Final Rule (slides 11-27).
- c. Dr. Snyder and Dr. Kasiske presented the basic continuous distribution framework to familiarize SVC members with the concepts. The members briefly discussed the framework.
 - i. Susan Gunderson: The distance factor in miles may not be the right variable. Travelling time for the same distance in miles could differ drastically depending on location. There might be better ways to assess travel time/cold ischemia time.
 - ii. Jim Markmann: Seemed like the best of the options presented. Do we have the data to make this functional? Data on time versus distance? Can we truly assess the difference in cold tolerance?
 - a. When we developed a travel-time model for liver allocation modeling, SRTR worked with Sommer Gentry, PhD, using Google API resources to model a better "travel time" not solely reliant on distance. SRTR currently has this type of model only for liver allocation, and will be working to develop similar models for other organ systems.
 - b. Regarding cold time, data are reported that SRTR can use to investigate these questions, but the data are only as good as they are reported.
 - iii. Ken Newell: Can we look at other resources, such as a recent NEJM paper showing a spike in lung posttransplant mortality at 13-14 months? One-year outcomes may look "normal" but longer-term outcomes could look very different. How are we going to capture these outcomes when assessing the implemented systems?
 - a. It will be a challenge to incorporate the "correct" metrics in assessing the "success" of any system that is developed and implemented.
 - b. Part of this will be discussed in the future during talks about the feasibility of any allocation system.
 - iv. Susan Gunderson: Heard this presented to OPOs recently, and the language and style are currently well able to help other groups understand these concepts.

4. Structure of program-specific reports as it pertains to multi-organ transplants

- a. SRTR is moving toward eliminating kidney-pancreas and heart-lung as separate PSRs.

- b. SRTR acknowledges that these are different patient populations. The goal would be to incorporate the information in these reports into sections of the other relevant reports (e.g., include kidney-pancreas information in the kidney and pancreas reports).
- c. PSR goal: Unique to the hospital and organ, with details for each regarding multi-organ transplants involving the target organ.

5. Measuring OPO performance (Gunderson & Snyder)

- a. Postponed this discussion until April 2019 in-person meeting.

6. The role of biopsies and biopsy results in donor and recipient risk adjustment

- a. Background: Traditionally, SRTR has been hesitant to include biopsies in the PSR models. We want to revisit the issue because various members of the transplant community have independently requested integration of biopsies into PSR models for different reasons.
- b. Posttransplant outcomes models: Currently, posttransplant graft and patient survival models are not adjusted for biopsy results.
 - i. Biopsy results may not predict outcomes well, and adjusting for results could encourage more biopsies to be performed, which could make organs more difficult to place.
 - ii. Although OPOs often have standards for determining when to perform a biopsy, these standards were likely developed cooperatively with transplant programs; thus, biopsies are available when the transplant programs want them, making the biopsy procedure an element in the program's care decisions.
- c. Concerns: Lack of adjustment for biopsy results is a common concern:
 - i. Not adjusting for biopsy results may discourage programs from accepting and transplanting organs with relatively poor biopsy findings.
 - ii. Other donor factors are included in risk adjustment.
 - iii. Adjusting for biopsy results may encourage programs to participate in trials in which biopsy results are blinded.
- d. Randomized control trial (RCT) to evaluate kidney biopsies: Mid-America Transplant Services and its transplant hospitals in Saint Louis are creating a pilot study for an RCT to show whether kidney biopsies improve posttransplant outcomes.
 - i. In order to ensure transplant hospital participation, SRTR is considering including the results of kidney biopsies in the national PSR model, which potentially reduces the risk of inability to view the biopsy results at the time of the organ offer.
- e. Liver yield model: SRTR received a request from an OPO asking that the liver yield model include macrosteatosis because it affects programs' decisions to accept livers, and programs may not consider a liver without a biopsy.
 - i. SRTR is willing to include liver biopsy in the yield model, because program decisions and protocols are partly out of OPO control.
- f. Kidney biopsy results:
 - i. Kidney % glomerulosclerosis: 0-5, 6-10, 11-15, 16-20, ≥20, indeterminate.
 - ii. Liver % macro vesicular fat.
 - iii. Predictors would be categorical:
 - 1. For example: No biopsy/low/medium/high.
 - 2. Results would thus never be treated as missing data.
- g. Discussion: SVC feedback on the potential integration of biopsy results into PSR models. Posttransplant and yield models serve different purposes, and SRTR does not necessarily need the same decision for each model.

- i. Rich Formica: How could you make this standardized given different types of tests, different material collected, different criteria, and different interpretations based on who reads the biopsy? If we cannot guarantee the data that are being collected, we might end up causing more problems.
 - 1. Would have to focus on as-standard-as-possible results.
- ii. Ken Newell: Agrees with Dr. Formica. Wedge versus needle biopsy is also a large issue.
 - 1. Biopsies as currently performed do not necessarily provide enough additional useful information in predicting transplant outcomes.
- iii. Rich Formica: Article in AJT, even counting the number of glomeruli is variable. David Axelrod is leading an effort to standardize how biopsies are performed. There would be potential in working together on that effort.
 - 1. Standardizing the biopsy procedure is outside of SRTR's control. It would probably not be feasible for SRTR to be involved in that type of initiative.
- iv. Jennifer Milton: Would we not already have proxies for the risk factors found in biopsies accounted for in the PSR risk-adjustment modeling?
 - 1. This is likely, at least in the case of kidney transplants. The goal of this trial would be to reassure that this is the case.
- v. Larry Hunsicker: If people knew that the models are adjusted for the biopsy results, would this increase kidney acceptance?
 - 1. SRTR currently thinks that the answer is yes.
 - 2. Larry Hunsicker: That would then provide an incentive for doing this study. If this does lead to increased use of kidneys, that would make it worthwhile.
 - a. Trialing this does not appear to involve a large amount of downside, with the possibility of increased organ use.
 - b. Will the risk of changing "biopsy behavior" make some organs even more difficult to place?
- vi. Susan Gunderson: All OPOs do not have the same criteria for performing routine biopsies, but there are protocols at the local level (i.e., within each OPO).
 - 1. Would this push OPOs to perform more biopsies, or change local protocols in some way to make some organs or more organs harder to place?
- vii. Jennifer Milton: Given the problems with biopsies that have been mentioned, this still seems like a rush to include something that is unreliable.
- viii. Ken Newell: After multiple readings of a biopsy, how is it decided which to use? This could add even more variability in the use of these biopsies.
 - 1. Jonah Odum: Could there be a common reader or interpretation to use as a comparison?
 - 2. Ken Newell: This would likely be infeasible. Perhaps criteria could be agreed upon at a more localized level.
- ix. This would be a nationwide adjustment for the models. Perhaps biopsy results have no effect after going through the model selection process.
- x. Jim Markmann: The argument is more compelling for liver. Data would show a stronger correlation between outcomes and steatosis.
 - 1. Susan Gunderson: Is there a more standardized interpretation in liver?
 - 2. Jim Markmann: Not necessarily. It is not perfectly quantitative, but good enough to correlate with outcomes. It would be nice to have a centralized common reader, but it would still come down to the surgeon's reading for organ acceptance.

- xi. Rich Formica: Getting a rough model of what biopsy would do within the risk adjustment modeling would be very valuable to the discussion.
 - 1. SRTR should be able to provide some additional modeling of how this might look for the in-person meeting in April.
- xii. Rich Formica: Should consider how including biopsy results would affect behavior. Can we look at possible scenarios of increased/decreased biopsies, and then how might this affect offer acceptance?
 - 1. SRTR will bring more data to the next SVC meeting to help provide more context around these questions.
- xiii. Rich Formica: How “protocolized” are biopsies on paper versus in practice?
 - 1. Jim Markmann: If the surgeon wants to have it done, it is generally done.
- xiv. Larry Hunsicker: Whether we should do this on a national basis would depend on whether we can agree on a consistent protocol for performing biopsies. Having the pilot in one OPO but adjusting nationwide could cause a lot of chaos.
- xv. Jennifer Milton: Can we get access to quality biopsies? Are programs using “wrong” information to make acceptance decisions?
- xvi. Richard Knight: Does APOL1 have any effect on biopsy performance? Can we get more information from the kidney transplant studies done elsewhere?
 - 1. Ken Newell: No protocol mandated biopsies in the APOL1 study, but it could be a good and valuable data addition.
- h. Summary: SRTR will investigate adding biopsies to various models and return to the SVC for more discussion at the April 2019 meeting.

7. Data Advisory Committee:

- a. Identifying PA pressure values in pediatric heart transplant candidates (reoccurrence of an issue from 3 years ago): In the PSR models, missing data are assigned the lowest risk for the given data element. Pediatric heart transplant candidates often have missing PA pressures for valid reasons that may not indicate a low-risk patient.
 - i. Can be dangerous to do this procedure in pediatric candidates, and these are not the lowest-risk patients.
 - ii. The committee at the time said that this was not a major concern and there are other ways to look at this.
 - iii. SRTR is taking this back to the Thoracic and Pediatric Committees in light of a new transplant program bringing it to SRTR's attention.
 - iv. One option would be to remove PA pressures from the pediatric heart models entirely.
 - v. Jonah Odum: PA pressures can be critical in determining the proper donor heart needed for the patient. Still, in some patients it is not possible to measure the pressures.
 - vi. There is currently no way to enter into the system a reason the pressures were not taken.
 - vii. Larry Hunsicker: If this is not a predictor, then not including this information would be the easiest solution.
 - 1. Previously, the risk gradient was small, so this was not as big a concern. However, currently the gradient is larger.
 - 2. The difference between the PA pressure and the wedge pressure is the most important in determining risk.
 - viii. Ken Newell: This change could have the unintended consequence of driving behavior. This might be a reason to not include “cannot do the test” as an option.

- ix. Larry Hunsicker: Are there objective criteria that can be used to determine who cannot have these measurements taken?
 - 1. Jonah Odum: A limited number of programs have the ability to take these type of patients, but it is possible to get these data through other procedures over the course of a patient's treatment.
- b. UNOS center codes: Due to the recent change in the definition of a transplant hospital, OPTN will likely merge program codes. Thus, the old code for every previous and current candidate and recipient will be changed to the new program code.
 - i. Conceptually, the two program codes always identified the same hospital, and only now are they merging under the new transplant hospital definition.
- c. Waitlist transfer process:
 - i. When a program shuts down, its currently listed patients are sometimes transferred en masse to a different program by simply changing the program center code.
 - ii. Without modifications to the cohort, the mass transfer will bias (downward) the transplant and waitlist mortality rates of the program receiving the candidates.
 - iii. SRTR's monthly SAF process creates a dataset that appropriately accounts for the transfers. The PSR evaluations of the transplant and waitlist mortality rates use the dataset that accounts for the transfers.
 - iv. Some residual issues with mass transfers:
 - 1. The public SAF does not include the dataset that appropriately accounts for the transfers. This will bias analyses of program-level effects on waitlist metrics.
 - 2. The dataset that appropriately handles the mass transfers does not have a unique patient identifier (i.e., PX_ID), making it significantly more difficult to use and increasing the likelihood of (non-obvious) mistakes.
 - v. SRTR wants to integrate the appropriate dataset into the public SAF but needs to handle the lack of a unique identifier. SRTR staff are still assessing possible approaches and will update the SVC at a later time.
 - vi. Darren Stewart: Previously, for a Kaiser mass transfer, an ID code convention was used to identify different entries. The audit tables should properly record these changes.

8. Brief Updates:

- a. Continued development of a survival-from-listing metric (Wey)
 - i. Codebase for PSR runs has made significant progress.
 - ii. Online application for model documentation.
 - iii. Example slide 90, will have more for the April in-person meeting.
 - iv. Jim Markmann: Are you considering variation in listing practices? Are geographic variations accounted for?
 - 1. This will be a patient-centric metric and not a center-based quality-of-care metric.
 - 2. Jim Markmann: Should make that clear in the presentation of these data.
- b. Living Donor Collective progress update (Kasike)
 - i. Pilot project is going forward and the current numbers are around 460 registrants.
 - ii. Brief overview of project goals for new members: Register potential living donors when they come into the programs for evaluation, and then follow these potential donors through whether they donate an organ and for longer-term follow up.
- c. Pretransplant expected survival workbooks (Wey)
 - i. In October, Transplant Quality Institute attendees were extremely supportive of SRTR providing pretransplant expected survival workbooks. The increasing emphasis on

pretransplant metrics increased the demand for tools to understand the determinants of transplant rate and waitlist mortality.

- ii. In November, HRSA approved SRTR to develop pretransplant expected survival workbooks for release with the June 2019 PSRs.
- iii. Preliminary versions have been developed and, on request, given to programs.
- iv. Preview slides 98-100.
- d. AHRQ-funded project (Israni)
 - i. Brief update: publications in the works, one accepted in Clinical Transplantation, and two more in review for publication.
 - ii. Cory Schaffhausen has received a 3-year award to use toward further development of these patient tools.
 - iii. More updates will come for the April meeting.

9. Closing Business

- a. Next meeting on April 9, 2019, in Washington D.C.