SRTR Visiting Committee Minutes

Tuesday, October 13, 2015
8:30AM – 1:00 PM CST
Teleconference

Voting Members:
John Gill, MD, MS (C)
Rebecca Betensky, PhD (C)
David Collett, PhD
Dan Meyer, MD
James Trotter, MD
Kevin Myer, MSHA
Brad Astor, PhD
[(C) = Co-Chair]

Members Unable to Attend:
David Lederer
Joseph Kim, MD, PhD (OPTN-DAC)

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

Other Guests:
Maureen McBride (UNOS)
John Rosendale (UNOS)

SRTR:
Bertram Kasiske, MD
Ajay Israni, MD, MS
Bryn Thompson, MPH
Jessica Zeglin, MPH
Jon Snyder, PhD, MS
Larry Hunsicker, MD, PhD
Nicholas Salkowski, PhD
Susan Leppke, MPH
Amy Ketterer, BA

Welcome and Introductions

Dr. Bertram Kasiske called the meeting to order at 8:30 AM CDT. He reviewed the day's agenda, and noted the members present. A quorum was present. Dr. Kasiske moved to vote on the minutes from the last meeting, held July 27, 2015. There were no objections and the minutes were approved. Dr. Kasiske 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.

Overview of the new SRTR contract (Slides 6-29)

Dr. Kasiske first brought to the committee's attention to its name change from Technical Advisory Committee to Visiting Committee.

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He showed slides covering the overview, scope, Project Officer title change to Contracting Officer Representative, key committee leads, and key SRTR meetings, and reviewed the key changes to the contract.

Dr. Kasiske highlighted several action items included in the Technical Proposal portion of the new contract. Discussion followed his description of the Annual Data Report (ADR), including suggestions to address more special topics in addition to the typical surveillance data. Dr. Kasiske noted that we approach most special topics with a goal of producing original peer-reviewed articles before including information in the ADR, citing the analysis of the effect of the new kidney allocation system as an example of what might be included in future ADRs once the peer-reviewed article has been published. The ADR is an important publication for the transplant community and many researchers use it as a reference for important facts and figures. It was decided to continue to explore ways to make the ADR as informative as possible and avoid its becoming stale.

Dr. Kasiske continued with the overview of the action items by discussing improvements slated to be made to the standard analysis files (SAFs) and the program-specific reports (PSRs). He mentioned the continuation of certain other programs such as CUSUMs, simulated allocation models, and geographic disparities research.

In the final portion of the Technical Proposal, Dr. Kasiske discussed the living donor registry feasibility study. He completed the overview of the new contract by covering the specifics of the access and outcomes for each organ.

Discussion

Dr. John Gill asked how we prioritize the many tasks at hand. Dr. Kasiske said that SRTR work prioritization is driven primarily by the OPTN committees. Strategic alignment between SRTR and OPTN is key in keeping ahead of the curve. Susan Leppke explained that with the new contract, SRTR is beholden to more structured timelines for contract deliverables, which will help guide strategic prioritization. The SRTR Steering Committee and SVC will also guide SRTR priorities. Dr. Gill asked if there is a way for key professional societies such as the American Society of Transplantation and the American Society of Transplant Surgeons to have more direct lines of communication with SRTR. Dr. Kasiske said that any and all professional organizations are welcome to submit feedback to SRTR at any time and can hear about SRTR's activities through regular channels of communication, but SRTR would not be creating formal chairs on these committees for representatives of various societies. The members of the committee were supportive of this approach.

SVC charter and membership discussion (Slides 31-35)

Dr. Kasiske covered the SVC charter in detail. Three members rotate off and three new members rotate on each calendar year. SRTR strives to maintain nine voting members. There was discussion of who to bring in as new members. Dr. Larry Hunsicker proposed a pediatric specialist. Keven Myer seconded the proposal and added a pediatric cardiologist. This was approved. Jon Snyder asked if the ex-officio make-up was sufficient and the committee said that it is. The committee accepted the charter, so the topic was considered complete.

Living Donor Registry Feasibility Study (Slides 37-65)

Dr. Kasiske gave an overview and history of the living donor registry feasibility study. He discussed what is to be gained by establishing a living donor registry and described some drawbacks and the overall benefit. He then described the actual feasibility study. He outlined in detail the conceived

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structure of the study and reviewed the kidney and liver steering committees that have already been convened.

Discussion:

In response to Dr. Kasiske's description of a registry that would derive many of its outcomes from registry linkages to other existing data sources, rather than relying on primary data collection, Dr. Eric Engels mentioned that living donors in the SRTR have already been linked to cancer outcomes as part of the transplant cancer match study. Based on this experience, it seems feasible to link a database of donors to outside sources. Over the years the data and potential data sources will improve as more and more electronic health records are established. Dr. Hunsicker and Dr. James Trotter suggested a large cardiovascular database as well as databases such as the INTERMACS database. Dr. Gill asked about the controls and how to track those who fall off. Dr. Kasiske noted the opportunity to study whether or not health outcomes for individuals who are turned down as living donors suggested that turning them down was the right decision. Dr. Engels noted that transplant centers are not reporting all the cancers in living donors that were diagnosed before donation. Collecting DNA samples for registry participants is appealing to offer the chance to study future gene polymorphisms that may affect living donor outcomes. Dr. Ajay Israni noted that it's possible to design the registry such that only a subset of centers would need to collect the DNA information from consented participants.

SRTR Strategic Direction (Slides 67-99)

Strategic discussion of SRTR performance metrics for public consumption (Slides 67-78)

Dr. Snyder described the SRTR contractual obligations as they pertain to the dissemination of the program- and organ procurement organization-specific reports. He described in detail what the reports currently cover and what SRTR will work on improving or adding. He asked the committee for input on what SRTR should show.

Chris McLaughlin of HRSA noted that the activities of the HOPE Act for now are in a research capacity. Whether this information will appear publicly will need to be decided between HRSA and SRTR, but we certainly will want to hear what the community thinks of it.

On the topic of overall survival following listing, Dr. David Collet provided insights into how this is reported in the United Kingdom and mentioned the potential unintended consequence of influencing which candidates are allowed to list. Dr. Trotter noted that some programs are more conservative than others regarding who is accepted as a candidate. Dr. Snyder suggested that we work with Dr. Collet to further explore the idea.

MPSC Outcomes Working Group Update (Slides 80-86)

Dr. Snyder reviewed the current status of the Membership and Professional Standards Committee's (MPSC) exploration of removing high-risk donors from program evaluations. SRTR performed an analysis showing what would happen to program evaluations if high-risk kidneys were removed from the evaluation sets. The analysis demonstrated that program evaluations would not be significantly affected. SRTR also presented an alternative weighting function that could effectively down-weight high-risk transplants in the evaluation and up-weight low-risk transplants. The MPSC workgroup favored the strict removal rather than the weighting function.

Additional discussion of the PSRs ensued. The Policy Oversight Committee had asked about SRTR's timeline for including multi-organ transplants in the PSRs. This is still being explored pending decisions of the MPSC multi-organ workgroup. This workgroup's decisions will influence how and when

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SRTR begins to include these metrics in the PSRs, specifically for simultaneous liver-kidney (SLK) transplants. Dr. Gill questioned the accuracy of the pretransplant information regarding kidney function, time on dialysis, etc., and whether it will be captured in the posttransplant reporting. Darren Stewart mentioned that OPTN/United Network for Organ Sharing (UNOS) has considered this with SLK transplant recipients and the reporting will likely become more granular if the policy governing SLK transplants is implemented.

On the topic of conditional survival metrics (long-term outcomes beyond 1 year), Dr. Snyder noted that SRTR is still hoping to include longer-term outcomes in the PSRs. SRTR has received feedback that some insurance companies continue to use the 3-year data, which may cause concern if the 3-year outcomes are removed or replaced with something different. Dr. Dan Meyer noted that, for cardiothoracic organs, longer-term outcomes would be important and might influence the use of hearts and lungs. There was some discussion regarding the source of variation in longer-term outcomes; i.e., how much of the long-term outcome can be attributed to the transplant program. The committee noted that this is likely to be perceived differently for the different organ types.

Dr. Snyder noted that the SRTR contract requires us to consider publishing program-specific data on offer acceptance behaviors, and SRTR will continue to research this in the coming year.

The current contract asks SRTR to consider reporting cost and resource utilization data by transplant program. Currently, the only cost information readily available to SRTR is Medicare payment data, which covers approximately 50% of kidney recipients and less for recipients of other organs. The committee questioned the rationale behind SRTR reporting cost information. Dr. Snyder explained that this requirement was in the previous contract as well, and SRTR added the economics chapter to the ADR with the thought that we would continue to explore the feasibility of reporting by program. Dr. Snyder said that SRTR could show the SVC what is currently being published in the ADR and attempt to stratify by program and organ type so we can begin to explore options for future reporting.

OPTN contract modification #1: COIIN

Dr. Maureen McBride of UNOS gave an overview of the OPTN contract modification to explore alternative ways to evaluate and promote continuous quality improvement among transplant programs, termed COIIN (Collaborative Improvement and Innovation Network). The COIIN program will bring together transplant center quality professionals and former MPSC members. A workgroup/advisory council is being formed to guide the project. SRTR will cooperate as requested to provide quality assessment and help explore alternative monitoring methodologies such as CUSUM. We will keep the SVC apprised of the progress as the project progresses.

Kidney Pumping (Slides 90-91)

Dr. Snyder presented follow-up on the kidney pumping issue. Mr. Stewart described what action UNOS has taken in this area. He referred to the data shown on slide 90. Some of the discrepancies between program-reported and OPO-reported pumping status are due to shipped organs moving through multiple OPOs.

For risk adjustment, we want to avoid including any variables that might be part of the program's treatment decisions. Some OPOs appear to pump at the request of the receiving transplant program. Dr. Hunsicker said that we could contact OPOs to ask if they pump based on the request of transplant centers or on their own institutional criteria. Kevin Myer said that the default assumption by OPOs is to put kidneys on pump, assuming they will stay local. If kidneys are to be shipped, OPOs put them on ice rather than on pump. In most cases, the decision to put a kidney on pump is at the OPO

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level at the time of recovery. A standard practice is complex and difficult to define. The committee felt that as determining whose decision it was to pump the kidney is unlikely to be possible, SRTR should continue to use pump status as a proxy for kidney quality. Dr Hunsicker suggested first adjusting for more objective measures of donor quality and then adding the pumping indicator as a subsequent predictor that may not improve prediction at all given the donor characteristics already included. SRTR will take a look at the effect, and based on the size of the effect determine whether or not to keep pump status in the model without trying to adjudicate which entity is responsible for the decision to pump.

ADR (Slides 93-94)

Dr. Snyder explained the current approach to the ADR, which is mainly to serve a surveillance function for the national data. He briefly explained the direction SRTR would like to take, producing an interactive data query system. Dr. Snyder demonstrated a prototype of the query system that SRTR has developed. The future of the query system will need to be decided in conjunction with HRSA and UNOS to ensure alignment of resources and efforts. Dr. Gill, as an associate editor of the American Journal of Transplantation, publisher of the ADR, noted that the ADR could potentially be more attractive to the community if it contained more timely topics of special interest. SRTR will continue to target independent peer-reviewed publication of special articles and use the ADR to present surveillance data and other data after any peer-reviewed publication.

Publications (Key manuscripts to focus on in the coming year) (Slide 96)

In addition to the ADR, Dr. Snyder asked the committee for input on topics for SRTR to potentially cover as peer-reviewed articles. Dr. Gill recommended a report on the impact of the new kidney allocation system, which we noted was already in progress through UNOS and other researchers.

SRTR Public Website (Slide 98-99)

Dr. Snyder described the rebuild of the SRTR public website that is underway. He demonstrated the existing prototype and gave an overview of the new direction and some of the new tools. Mr. Myer suggested a focus group made up of the public, and Dr. Gill added that content management should be malleable so other content can be added as needed. The committee approved of the direction SRTR is taking with the website, so SRTR will proceed and keep the committee updated as the project progresses.

OPO metrics update (Slides 101-102)

OPO Metrics Status

Dr. Snyder gave an overview of the work that has been done to explore additional OPO performance metrics**.** Two projects have been completed: 1) a study of donor potential that collected data from 41 OPOs, and 2) a pilot data collection on ventilated referrals. The Association of OPOs has proposed a set of metrics to CMS that include a donor conversion metric, i.e., donors per ventilated referrals, and a yield metric, i.e., transplants per donor. The work is ongoing and will be transitioned into another OPTN contract modification as discussed next on the agenda.

OPTN contract modification #2: OPO metrics (John Rosendale presented)

John Rosendale of UNOS presented to the committee the Task 17 contract modification to explore the feasibility of the new OPO performance metrics. The project will assess five research questions: the feasibility, availability of patient-level data, level of effort required, auditability of the

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data, and the data collection tools. The project began in October 2015 and runs through September 2016. A "think-tank" will be made up of professionals from the PINS, DAC, OPOs, MPSC, and others. Dr. Snyder has been asked to participate in this advisory council. SRTR will assist with the analyses as requested.

Dr. Israni asked if the project will be looking at obtaining data that can be verified independently. Mr. Rosendale indicated that this will be part of the discussions and they will be taking a comprehensive look at external data sources.

Dr. Gill mentioned the referral to the OPO as a potential gap and wondered if this study specifically addressed that issue. Mr. Rosendale indicated that this project will consider obtaining data directly from the donor hospitals; this will be an independent source of data and will also ease the data collection burden on the OPOS.

OPTN data quality update (Slide 103)

Dr. Snyder updated the committee on the data quality exploration and the report that has been submitted to HRSA on the topic. UNOS also has received a copy of the report. Future discussions between SRTR, UNOS, and HRSA will take place, and we will keep the committee informed.

Dr. Trotter mentioned the A2ALL study on data quality, which found that the OPTN data were lacking in agreement with the A2ALL data. Chris McLaughlin requested a formal statement from the SVC regarding the importance of collecting high-quality data in the OPTN system to support both research and quality oversight of the transplant system. Dr. Snyder agreed and suggested to Dr. Gill and Dr. Rebecca Betensky that we schedule a separate call to discuss with the SVC co-chairs how to proceed with a formal statement.

Closing Business (Slide 105)

Dr. Snyder asked if any members had additional business to bring forward. None was presented. Dr. Snyder said that the next SVC meeting will be a teleconference held in January or February. Dates are yet to be determined, and SRTR will inform the committee.

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