Welcome and Opening Remarks

The SRTR Visiting Committee (SVC) meeting was called to order by the co-chairs Dr. Kenneth Newell and Ms. Susan Gunderson. Dr. Jon Snyder welcomed participants to Minneapolis, and participants introduced themselves. After the announcement that Dr. Bertram Kasiske had handed over the SRTR Directorship to Dr. Snyder, committee members thanked Dr. Kasiske warmly for his years of leadership. Dr. Snyder reminded members about management and disclosure of relevant conflicts of interest. After these introductions, Dr. Snyder commenced with the agenda.

Exploration of Period Prevalent Posttransplant Outcomes Metrics

Dr. Snyder provided some background and introduced Dr. Andrew Wey. Dr. Wey introduced period prevalent follow-up cohorts as an alternative to incident cohorts, which are currently used in posttransplant evaluations. Because period prevalent cohorts include patients who underwent transplant before the evaluation window, but only outcomes that occurred during the evaluation window, they allow for longer-term follow-up while maintaining a focus on recent experience at a program. Dr. Wey's current example allows for follow-up through 5 years posttransplant.

Several participants contributed questions or comments. Dr. Lawrence Hunsicker suggested that the metric should adjust for a patient's condition at the beginning of the evaluation window. Dr. Kenneth Newell suggested that older transplants extending into the current evaluation period may not be relevant to current patients' decision-making. Dr. Hunsicker and Dr. Rachel Patzer raised several questions about the challenges of distinguishing between program effects and population effects. Dr. Richard Formica raised questions about unintended consequences of longer-term metrics, such as how they may be used by insurance companies.

Dr. Wey and Dr. Nicholas Salkowski provided several clarifications of these topics. Dr. Wey said that there are reasonable arguments for short- and long-term metrics but a current lack of empirical evidence regarding their relative impact on patient decision-making. He emphasized that a good metric should primarily function to inform patient and program decision-making.
Dr. Wey then described the design of the study, which investigated the association of 15 different posttransplant evaluation frameworks with subsequent posttransplant outcomes. These evaluations varied according to the possible length of follow-up (1, 3, and 5 years) and the possible width of the period prevalent evaluation window (6, 12, 18, 24, and 30 months).

A first set of results showed a high level of correlation (.90) between the estimated hazard ratios given by incident and period prevalent metrics out to 30 months. Dr. Patzer noted possible missing data concerns with the period prevalent frameworks caused by data collection changes over time, and suggested paying attention to this and noting any effect of more missing data.

The remaining results compared the estimated hazard ratios of various period prevalent metrics for kidney, liver, and heart transplant. In each case, the level of correlation generally increased with increased length of follow-up and width of period prevalent cohorts. Dr. Salkowski raised a possible concern that if cohorts are too large they may not reflect program changes. However, of the metrics studied, those including longer follow-up windows and wider period prevalent cohorts had greater predictive power for future patient outcomes. Dr. Wey said that based on these results, the investigators prefer a 5-year evaluation period with a 24-month cohort.

Subsequent discussion raised a number of questions about how these metrics would work in practice.

Mr. Richard Knight observed that patients sometimes have to choose between programs with the best results and programs where they can be listed. Dr. Formica observed that kidney transplant practices are rapidly changing, which affects how patients are listed. Dr. Patzer mentioned the many regional differences to consider. Mr. Darren Stewart asked whether this type of metric can identify time-varying program effects.

Dr. Formica suggested possibly using a metric that identifies the quality of organ function posttransplant. Dr. Wey said that this may be a data collection issue, and Mr. Stewart said that the Data Advisory Committee is currently considering it. Dr. Brent Logan noted a logistical barrier regarding the amount of time required to collect new data for longer cohorts.

In conclusion, Ms. Gunderson made a motion to vote on a recommendation to continue pursuing and funding this research. The motion passed with unanimous support from the committee.

**Organ Procurement Organization Performance Metrics**

Dr. Snyder updated the committee regarding SRTR's ongoing efforts to explore deceased donor conversion metrics. SRTR currently reports a conversion metric based on eligible deaths only, which has been criticized as not reflecting true organ donor potential and suffering from subjective reporting by organ procurement organizations (OPOs). Dr. Snyder presented a preliminary analysis of development of a metric using the CDC Multiple Cause of Death data. This metric data would use a denominator of in-hospital deaths of patients aged 75 years or younger with at least one inclusionary cause of death ICD-10 code and no exclusionary ICD-10 codes. Strengths of such a metric include its independent nature not reliant on OPO reporting; however, a weakness is overestimation of donor potential due to lack of data on which deaths were ventilated deaths and lack of granularity in comorbid conditions present at the time of death. Dr. Snyder described a few remaining analyses to be performed, including developing an adjusted model and comparing results with data obtained as part of the SRTR-AOPO Region 8 Donor Potential Pilot Study. In addition, SRTR
is working on formalizing recommendations for future data collection to allow for more detailed evaluation of donor conversion.

No vote was required or called for; however, the committee expressed support for continued exploration of this important topic.

**Extracranial Cancer at Time of Procurement, Adjustment for Organ Yield (Wey)**

Dr. Wey presented an analysis he performed in response to feedback from an OPO about potentially adjusting donor yield models for presence of extracranial cancer noted at the time of procurement. He presented data on the frequency of extracranial cancers by location and organ type, and noted that 49 kidneys were transplanted from donors with kidney cancer discovered at the time of procurement. Dr. Hunsicker noted that very small kidney cancers almost never metastasize. Dr. Wey found that yield was indeed much lower from donors with a cancer identified at the time of procurement; however, posttransplant graft survival was similar for recipients of organs from donors with and without extracranial cancer.

Ms. Gunderson expressed concern about consistency of data collection across OPOs. Dr. Snyder noted that a subcommittee of the DAC and OPO committees is currently reviewing the Deceased Donor Registration (DDR) form and may enhance the definition of this data element. Dr. Newell noted that, although the effect is large, the event is rare and may not affect OPO donor yield evaluations. Dr. Wey demonstrated this to be true, given very high correlation between evaluations with and without adjustment for extracranial cancer. The committee expressed concern about encouraging OPOs to procure organs from these donors perhaps inappropriately; however, Ms. Gunderson noted that this is unlikely to change OPO behavior since most cancers are not discovered until the donor is in the operating room. Dr. Newell noted that other issues with a greater impact on donor yield evaluations may be more important to explore. The committee suggested revisiting this issue after receiving any clarifications from the subcommittee reviewing the DDR data collection form.

**Liver Risk Adjustment Modeling Request Regarding Hilar Cholangiocarcinoma Patients (Snyder, Salkowski)**

Dr. Snyder briefly introduced the topic of potentially adjusting liver posttransplant outcome models for patients diagnosed with hilar colangiocarcinoma. A program suggested to SRTR that hilar colangiocarcinoma should be adjusted for separately from other malignancies for liver transplant candidates given the elevated risk associated with this diagnosis. Dr. Salkowski presented his analysis of the effect of adjusting specifically for hilar colangiocarcinoma. He found that it did not affect the living donor liver transplant models, which currently include no risk adjusters given the current model-building process using cross-validated LASSO. Dr. Salkowski did find an effect of this diagnosis for the deceased donor liver outcomes models. SRTR asked the SVC’s opinion regarding this issue.

The committee discussed whether special adjustment should be made for this patient population, or whether there is controversy about the appropriateness of these transplants given the poor outcomes noted. Dr. Newell said that this seems to be a small issue affecting a small number of programs, and further suggested that issues like this be brought to the SVC even before preliminary analyses to potentially avoid expending staff time exploring controversial issues. Dr. Salkowski
noted that SRTR avoids second guessing clinical judgment and does not want its risk adjustment models to drive clinical care decisions.

After discussion, the committee voted unanimously not to make a specific risk adjustment for patients with hilar colangiocarcinoma.

**Implementing Expected Outcomes for Intestine Transplant Programs (Salkowski)**

Dr. Salkowski informed the committee that SRTR recently attempted to build new risk adjustment models for intestine transplant program outcomes. The model-building process identified no risk predictors that improved cross-validated prediction error, so SRTR will implement unadjusted outcomes evaluations starting with the January 2020 release of the program-specific reports. Dr. Newell asked for clarification of which intestine transplants the evaluations will include; Dr. Salkowski said they will include single-organ intestine transplants and intestine transplants involving a liver or pancreas, but not other multi-organ transplants. No vote was called for, but the committee expressed support for releasing evaluations for intestine transplant programs, even if unadjusted. Dr. Salkowski clarified that there are other current examples for other organs of presenting unadjusted outcomes evaluations when no predictors are found during the model building process.

**Implementation update for biopsy risk adjustment (Wey)**

Dr. Wey presented some follow-up analyses of enhancing the OPO yield models by adjusting for biopsy results. Dr. James Markmann had requested a follow-up analysis exploring the interaction between donation after circulatory death (DCD) status and percentage macrosteatosis. Dr. Wey's analysis demonstrated a significant interaction; however, the additional adjustment had no noticeable effect on OPO yield evaluations. Ms. Alexandra Glazier noted that, while the current effect on evaluations is small, the adjustment may become increasingly more important as use of DCD donors increases.

The committee voted unanimously to include the interaction in future risk adjustment models for donor yield. SRTR will incorporate this adjustment into the July 2020 reporting cycle.

**Recognition of Outgoing SVC Members**

Dr. Snyder recognized three outgoing committee members whose terms expire at the end of 2019; Ms. Gunderson, Dr. Patzer, and Mr. Luke Preczewski will be rotating off the committee. Ms. Gunderson then recognized Dr. Kasiske for his service to SRTR as Director from 2010 to 2019. Dr. Snyder then noted three incoming members starting in 2020: Mr. Jeffrey Orlowski (co-chair), Dr. Sumit Mohan, and Mr. James Pittman.
Standing Updates:

A. Data Advisory Committee (Kasiske, Patzer)

Dr. Kasiske presented an informational update on OPTN’s Data Advisory Committee (DAC). He had presented at the recent in-person DAC meeting and provided the SVC a summary of the discussion, including principles of data collection and the DAC’s evolving role in OPTN database management. Dr. Hunsicker asked for clarification about the role of research as a reason for data collection, and Dr. Kasiske said that research is not a sufficient reason for ongoing data collection, but could be considered on a time-limited basis. Mr. Stewart noted that OPTN has also developed five principles of data collection, which are not designed to replace the more detailed principles developed by the DAC. Dr. Patzer said that the DAC is an operating committee of the OPTN Board and will be contributing to new directions of data collection. The OPTN Board will consider the DAC’s data lock policy at its upcoming December 2019 meeting. Dr. Patzer said that the DAC will support a rolling review of OPTN data collection forms.

B. Living Donor Collective Progress

Dr. Kasiske presented an update on the progress of the Living Donor Collective (LDC) pilot project. He noted that the LDC is approaching a crossroads as HRSA prepares for the end of the current pilot project and the pending 2020 SRTR RFA. Dr. Kasiske is exploring the surveying of programs regarding their willingness to participate with ongoing data collection requirements under OPTN. He said that the LDC is developing center-level reports to be shared with programs through the LDC secure site. The reports will summarize current program statistics and provide blinded comparisons with other programs and the national data. Mr. Knight expressed his willingness to contact patients in his area regarding the LDC efforts.

Dr. Snyder noted the ongoing effort by Donate Life America (DLA) to launch a living donor registry. The DLA effort differs from the LDC in that its primary goal is connecting potential living donors with transplant programs. Ms. Glazier said that the DLA effort mission and the LDC are fundamentally different and will not conflict with each other. Dr. Newell said that the DLA effort could lead to significant infusion of non-directed living donors. Dr. Kasiske noted confusion at the recent Living Donor Committee meeting regarding the role of the Fresenius partnership in supporting the DLA registry efforts. Ms. Glazier said that Fresenius is supporting the start-up, but the registry will be owned by DLA.

C. Dr. Israni’s AHRQ-Funded Website Initiative (Irsani, Schaffhausen, McKinney)

Dr. Israni updated the committee on the ongoing efforts of his AHRQ-funded initiatives to develop patient-friendly websites for transplant data. Current efforts focus on creating a patient-centered report card and patient-specific program search functionality as an enhancement to the SRTR public website. Mr. Knight said that many patients are currently unaware of the SRTR website as a resource, particularly in the minority community. He stressed the importance of a broad communications plan. The committee noted that these websites could serve referring physicians in addition to patients, and could be a use case for patients who have been turned down by a program. Many patients do not currently realize that other programs may be willing to accept them. Dr. Formica said that some programs may not like the website pointing out differences in program waitlisting practices, but it
could serve to influence programs’ acceptance behavior. Mr. Knight supported the effort, noting that it is not controversial from a patient’s perspective.

**K12 preparing liver candidates from an organ offer decision (Schaffhausen)**

Dr. Shaffhausen presented his ongoing work on developing offer acceptance aids targeting patients with patient-friendly descriptions of differences in donor quality and what those differences may mean for their future well-being. Dr. Schaffhausen will be meeting with providers to collect feedback on the tools and implementation, with focus groups scheduled at the upcoming AASLD meeting. A few committee members expressed concern about communicating to patients the notion of possible instances when they should decline an offer; this has the potential to do more harm than good, given that a patient’s response to an offer should almost always be “yes.” The committee thought the tool should prepare patients with a “yes” state of mind. Dr. Newell supported this idea and cautioned against making patients think they should perhaps decline an organ offer. Ms. Glazier also supported this, noting that OPOs will not want to hear a “no” coming from the patient at the time of organ offer. Dr. Newell said that how the issue is framed to patients is critically important. Dr. Israni clarified that the tool is intended to be used at the time of listing to educate patients. Ms. Glazier noted ongoing policy development to move the acceptance decision earlier in the process, supplying only offers that programs and patients have previously indicated willingness to accept. Ms. Gunderson also supported this effort.

**Closing Business**

Hearing no other business, the meeting concluded at 3:30 PM. The next meeting is scheduled by teleconference for January 28, 2020, from 1-4 CST.