SRTR Review Committee Meeting Minutes

Teleconference

November 29, 2022, 12:00 PM – 3:00 PM CST

Voting Members:	**Ex-Officio Members:**	**SRTR Staff:**
Jeffrey Orlowski, MS, CPTC (Co-chair, '22)	Shannon Dunne, JD (HRSA)	Ryutaro Hirose, MD
Sumit Mohan, MD, MPH ('22)	Nicole Turgeon, MD, FACS (OPTN-POC)	Larry Hunsicker, MD
James Pittman, RN, MSN ('22)	Jonah Odim, MD (NIH)	Ajay Israni, MD, MS
Chris Zinner ('23)	Laura Cartwright, PhD, MPH (OPTN/UNOS)	Grace Lyden, PhD
David Vock, PhD ('24)	**Not in attendance:**	Jon Miller, PhD
Ginny Bumgardner, MD, PhD ('24)	Rachel Patzer, PhD (OPTN-DAC)	Cory Schaffhausen, PhD
Kiran Khush, MD, MA, MAS ('23)		Jon Snyder, PhD, MS
Richard Knight, MBA ('22)	**HRSA:**	Nicholas Wood, PhD
Sean Van Slyck	Adriana Martinez	Allyson Hart, MD, MS
Not in attendance:	**Not in attendance:**	David Zaun, MS
Roslyn Mannon, MD (Co-chair, '23)	Chris McLaughlin	**Not in attendance:**
	Shannon Tait	Bertram Kasiske, MD, FACP

Welcome and opening remarks

Mr. Jeffrey Orlowski called the SRTR Review Committee (SRC) meeting to order. He reviewed the agenda and conflict of interest management, then proceeded with the first item.

SRC membership updates

Dr. Jon Snyder noted certain voting members' terms were expiring at the end of the calendar year. Mr. Orlowski will be replaced by Mr. Sean Van Slyck, Executive Director of Sierra Donor Services. Mr. Richard Knight will be replaced by Mr. Ameen Tabatabai in his position as new Co-chair of the Patient and Family Affairs subcommittee. Dr. Sumit Mohan will be transferring to the Ex-officio Chair representing the Organ Procurement and Transplantation Network's (OPTN's) Data Advisory Committee, replacing Dr. Rachel Patzer. Dr. Mohan's replacement is still being finalized. Finally, Mr. James Pittman's term is expiring and his replacement is also currently being sought.

Approval of the minutes

Mr. Orlowski asked the committee to approve or suggest modifications to the minutes from August 17, 2022. There was a motion to approve followed by multiple seconds. The minutes were unanimously approved.

Task 5: Prioritization of recommendations

Dr. Snyder said that since the August meeting, SRTR finalized the *People Driven Transplant Metrics* consensus conference meeting report, which is under review at the *American Journal of Transplantation*. Stakeholder suggestions from the conference resulted in 160 recommendations. He reminded the committee of the 5-year project timeline and the phase beginning where SRTR works with SRC members and the Health Resources and Services Administration (HRSA) to prioritize these recommendations.

Dr. Snyder showed an updated version of the transplant system map (Figure 1), wherein each conference recommendation was tied to a lettered stop within the system. Recommendations were also categorized into three "ease of implementation" levels: 1) data available and relatively easy to implement, 2) data available but need significant development work to implement, and 3) data are not currently available and need development work and/or collection. Dr. Snyder proceeded to show the committee level-1 and -2 items that were indicated as priorities by conference participants. He noted that level-3 items and other items that were not necessarily prioritized by conference attendees would be addressed in the future.

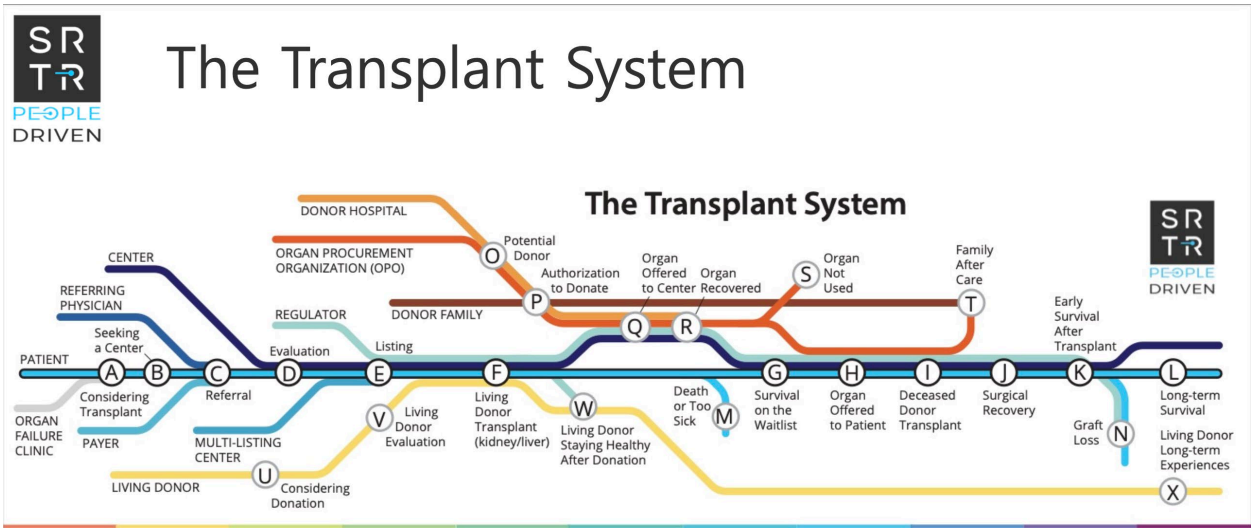

Figure 1. Updated Transplant System Map

Dr. Snyder first presented recommendations attributed to the patient line of the system map. The first stop there was Considering Transplant. Recommendations categorized as 1 or 2 (easy or medium-sized projects) consisted of A.1) personalized predicted waiting times, A.2) survival benefit of transplant versus alternate therapies (may be easier for kidney), and A.4) information on any absolute contraindications to transplant (eg, high body mass index).

Dr. Kiran Khush said that from a heart perspective, timing of analysis would be tricky for A.1, as waiting time prediction may be in flux based on allocation. She considered A.2 a 3 for ease level, due to the wide range of therapies to examine. Because contraindications vary by center, Dr. Khush suggested candidates contact centers directly for specific criteria. For A.2, Dr. Ginny Bumgardner suggested starting with comparing kidney to the alternate modality of dialysis. For A.4, she

suggested graphing data in terms of numbers of patients transplanted nationwide with their personalized parameters.

Dr. David Vock pointed out that a plethora of information can have the unintended consequence of exacerbating inequalities. While information can be an equalizer in society, oftentimes those with wealth and social capital have the ability to use such information. In the context of A.1 and A.4, people with the most resources could travel to centers with shortest waiting times or different listing criteria. Dr. Ajay Israni agreed that unintended consequences should always be considered, adding that using tools like the kidney decision aid tool with patients with predictive waiting times could address these inequality concerns. Mr. Knight said that patients in general are not able to do in-depth data analysis, so an artificial intelligence tool where patients can ask questions and be guided through data would be helpful. He added that the playing field cannot be completely leveled in terms of resource allocation for patients, but having information available and making patients aware of it would be a major success. How the information is communicated to patients via the SRTR website is an important factor to focus on.

Dr. Mohan suggested another framework in how to prioritize these recommendations with finite resources: ask what can be given to the patient that informs the decision-making process, or provides patients with a sense of control over the process. He thought spending a huge amount of resources on A.2 beyond what has already been done for showing survival benefits would be a mistake, as it would not change these decisions. Dr. Mohan added that A.1 was from the perspective of giving patients a sense of what to expect as opposed to being precise, and predictive waiting time depends on what a center is willing to accept, not what is available. Mr. Chris Zinner pointed out that patients wanted tools personalized to their situation, and suggested “what if?” tools, citing the iChoose Kidney tool from Emory University as an example.

Dr. Snyder moved on to recommendations for stop B, Seeking a Center, which suggested providing data on which centers are most likely to refer, evaluate, list, and perform transplant for a patient like me or my loved one. Dr. Khush said this would be difficult; from a heart standpoint, there were only data on people who were actually listed, not eligible patients who might have been referred or who were referred but not listed. Dr. Israni said while there was variation across centers in their criteria, SRTR could capture which centers actually perform transplant for patients with certain characteristics. Dr. Snyder added it was possible to allow patients to see which programs will accept them based on high body mass index, willingness to accept kidneys positive for hepatitis C, primary cause of death, and age.

Next, recommendations for stop E, Listing, included providing E.1) information about potential for and benefits of listing at multiple centers, E.6) data on timing of referral, listing, and transplant process, and E.8) data on outcomes after listing. Mr. Knight pointed out that getting waitlisted is where disparities really happen.

Next, recommendations for stop G, Survival on the Waitlist, proposed providing G.1) waitlist management tools to help programs understand their waiting list, including data that counter potential risk aversion to listing complex patients. Mr. Pittman said it was important for programs to have insight into the waiting list and types of patients undergoing transplant. Mr. Zinner added there was a widespread belief of transplant centers that risk associated with mortality on the waiting list

caused conservative patient selection behavior. He said it should be considered how to ensure transplant centers are given more tools to analyze their waiting lists while ensuring data do not lead to unintended consequences, like causing centers to be more conservative in selection.

Mr. Orlowski noted it was important to understand which centers are and are not transplanting, and the consequences of passing on certain organs. In addition, he noted the need to understand how to identify ways to help centers get those on the waiting list a suitable organ and to transplant. Dr. Bumgardner cautioned against assuming what data will or will not be used for, as centers are likely to use data differently based on local challenges. Providing the information is important.

Recommendations at stop H, Organ Offer to Patient, included providing H.1) predicted survival benefit to accept or decline an offer, H.2) data about the risks and benefits of willingness to accept marginal donor types, H.3) estimated waiting time to the next offer if declining the current offer, H.4) estimated time to a "better" offer if declining current offer, H.5) tools that facilitate shared decision-making between patients and providers in preparation for and at the time of organ offer, and H.6) a public-facing tool to predict donor-specific organ use.

Mr. Zinner said a tool associated with the OPTN's DonorNet platform was being released and addressed H.3 and H.4, while an app with the University of Chicago addressed H.2. Mr. Van Slyck commented that we should be mindful of using descriptive terms like "marginal" donors and consider other ways to describe "clinically complex" donors. Dr. Khush pointed out it is difficult to define donor organ quality, as there are so many "regional flavors" to the waiting list that are hard to quantify. Mr. Orlowski asked if H.6 should be redefined, as *public* is a broad term, and the general public may not have enough context to use such a tool. Mr. Van Slyck suggested creating a tool for H.3 that addressed current donation system activity in real time, overlaid by a generalized base of activity, eg, in region x, y offers could be expected in any given week.

For stop I, Deceased Donor Transplant, it was recommended to provide I.1) variation in transplant rates and I.2) utilization rates of clinically complex donor organs. Dr. Snyder went on to stop J, Surgical Recovery, for which it was suggested to show J.1) data on length of stay. For stop K, Early Survival After Transplant, it was recommended to provide K.1) predicted outcomes for a particular patient at a center if the patient undergoes transplant with a particular donor and K.2) metrics of tailored outcomes relevant to specific organ types beyond graft failure and death. Dr. Khush said it was important to be mindful of organ-specific considerations, as heart length of stay varies by etiology.

For stop L after transplant, Long-term Survival, it was recommended to provide L.1) posttransplant graft/patient survival metrics, adult versus pediatric, longer-term outcomes; and L.2) long-term outcomes for multiorgan recipients. Dr. Snyder noted that SRTR staff are currently working on a tool that shows outcomes for multiorgan candidates and recipients.

Next, Dr. Snyder reviewed the deceased donor system line, starting with stop O, Potential Donor, where the following was recommended: O.1) process timing data for potential deceased donor families. Mr. Orlowski and Mr. Van Slyck agreed it would be difficult to put actual values to this, but that there should be a general outline of the process that highlights key steps in the process.

For stop Q, Organ Offered to Center, it was recommended to show Q.1) data on acceptance and decline patterns by program, stratified by organ quality, organ type, and candidate characteristics, and specific information tailored for pediatric candidates. Dr. Mohan said current displays of organ offer acceptance were not helpful for patients and suggested creating new visualizations that are easier to understand. Mr. Orlowski added there was a need for data that tracked organ offers and late organ declines, as third parties becoming involved in the process created more complexities.

Dr. Snyder briefly reviewed stop S, Organ Not Used, where recommendations included S.1) providing organ nonuse rates stratified by organ and whether abdominal or thoracic. At stop T, (deceased) Donor Family After Care, which was added after the conference, recommendations included providing T.1) information to families on why donated organs were not used. Dr. Mohan said it seemed there was confusion around reasons an organ was declined for a patient versus why an organ was not used. He thought people were more interested in understanding why centers did not use an organ for their patients. Mr. Van Slyck said that the organ procurement organizations (OPOs) were the best entity to be interacting with donor families on these specifics. Dr. Khush did not find the recommendation useful because reasons for organ decline are vague and could be interpreted many ways.

However, Dr. Mohan replied that a new set of decline codes that were more informative and granular were now in place. He thought this information was more useful for centers as opposed to donor families. Mr. Orlowski questioned if this should be provided, as broad generalizations about organ decline could be construed as misinformation that reinforced the myth of “no one would want my organs.” Dr. Allyson Hart presented another viewpoint: because this was information patients requested, the focus should be how such information was presented in light of potential negative consequences.

At stop W, Living Donor Recovery, recommendations included W.2) providing data on near-term complication rates. In the interest of time, the committee would return to level-3 items at the February meeting. Themes for these included recommendations on prelisting information and posttransplant quality of life.

The committee discussed the next steps of this process. Mr. Orlowski suggested members send feedback recommendations by next week to Dr. Snyder, who could compile them and send out for further discussion. Dr. Mohan proposed collecting comments in a Google document for more engagement. Dr. Snyder suggested sending a survey to rank recommendations, which Dr. Mohan thought might be easier. Dr. Snyder noted that SRTR would construct a survey to be distributed later in the week.

Supporting equity in transplantation: SRTR response to the NASEM report and Task 5 consensus conference

Dr. Warren McKinney’s presentation reviewed the National Academies of Sciences, Engineering, and Medicine (NASEM) report on equity and highlighted recommendations and congruency with some of the Task 5 consensus conference recommendations. He proposed that SRTR establish and maintain an equity-focused dashboard to improve transparency and support the transplantation system in local equity interventions.

In 2020, NASEM organized public meetings, webinars, etc, to guide the evaluation of the national transplantation system. Its goal was to examine gaps, barriers, and opportunities for improving costs, transparency, and clinical outcomes for deceased donor organ procurement, with a focus on reducing inequities. This entailed a review of policymaking processes, allocation modeling, quality improvement initiatives, and performance metrics. Having identified inefficiencies and inequities, NASEM made over a dozen recommendations in improvement to increase public and professional trust in donation and transplantation processes. Such actions included exploring policy alternatives and changing policymaking practices.

Dr. McKinney said these recommendations affect numerous outcomes and practices at different levels of the transplantation system. NASEM provided a framework that demonstrated value, transparency, and equity as foundations in the system, and conceptualized them as interconnected. These connected to crosscutting values of effectiveness, efficiency, timeliness, access, safety, and patient and family centeredness that were meant to be tracked across system levels. NASEM also identified stakeholders with recommendations mostly from professional groups.

NASEM's identified areas for improvement in the steps of the donation and transplantation pathway were condensed into seven steps. These spanned from organ procurement to posttransplant follow-up, with condensed steps in donation and the listing process. Dr. McKinney acknowledged the steps corresponded to stops on Dr. Cory Schaffhausen's transplant subway map, as well as identified outcomes by NASEM and requests from Task 5 participants.

He added it was important to consider how the targeted audience's access to the dashboard might affect content and framing of comparative data or determining what the appropriate denominator might be. For example, measures related to donation rates may convey difference valence when presented at a system, OPO, or geographic level. He noted NASEM prioritized processing patient outcomes, which largely fall outside of SRTR's scope, although SRTR could advocate for novel data collection to meet the recommendation. Dr. McKinney also noted that disparities created inequities for racial and ethnic minorities, women, patients older than 65 years, individuals with an intellectual disability, those of lower socioeconomic status, and undocumented immigrants.

Dr. McKinney introduced the NASEM recommendation categories, which were achieving equity; improving system performance to increase reliability, predictability, and trustworthiness; and resolving high rates of nonuse of procured organs. Achieving equity entailed setting the goal for achieving equity in 3 years, finalizing the continuous distribution framework for all organs, eliminating predialysis time points for the kidney allocation system, optimizing allocation algorithms and components, creating a dashboard with standardized metrics to track performance and evaluate results in the US transplantation system, and expanding oversight of transplantation system to include patients needing transplant but not on the waiting list (the last two were also recommended during SRTR's consensus conference).

Dr. McKinney said SRTR could respond to these recommendations by establishing a dashboard, speeding up the policy development process, or supporting existing efforts of a continuous distribution discussion. SRTR might also invest in exploring novel studies to evaluate the impact of socioeconomic status or provide linkages to supplemental data from other sources. For the dashboard, Dr. McKinney proposed that SRTR cover as many steps in organ donation and the

transplant pathway for current data as possible. The effort should involve multiple stakeholders and be patient focused. The dashboard should also report different outcomes disaggregated by race, with metrics risk adjusted for potential confounders when considering raw data. The tool would benefit from the expansion of the oversight to prelisting and beyond posttransplant. There would be opportunities to advocate for collecting more granular data on candidate, recipient, and donor residency, allowing an effective linkage with US Census data and geographic indexes of social risk and vulnerability.

Dr. McKinney highlighted outcomes from the NASEM report, and what information SRTR could include or develop for the equity dashboard. Starting with the donation step of organ procurement, the report highlighted inequities facing racial and ethnic minorities. The dashboard could display information on deceased donor rates, authorization rates, or raw data disaggregated by race tailored to fit OPO demographics or oriented to communities that face disparities. The next step of primary care/specialist assessment for suitability for transplant currently had no data but could be further explored.

The step of accessing the waiting list focused on disparity access, with a need for information on preemptive referral and listing rates. For time from waiting list to transplant, outcomes related to median waiting time, inactive time, and survival on waiting list were of interest. Regarding waitlist outcomes, information on tracking mortality measures could be developed, and transitions in waitlist removal due to death or deterioration. Living organ donation rates should also be included on the dashboard. Regarding deceased organ donation transplant, a wide variety of populations are affected by inequity in this stage. Key outcomes to consider include transplant rates, multilisting rates, and nonuse rates. For posttransplant outcomes, the primary focus would be rates of rejection and death, and long-term allograft survival.

Dr. McKinney pointed out additional equity dashboard considerations included whether it should be national, local, and/or program-specific focused, if it should report on just outcomes as rates and raw data or develop new metrics and measures to be risk adjusted. Another consideration was whether raw data and equity measures should be stratified by subpopulations, or instead whether the focus should be on groups known to experience disparities. Other considerations were if the dashboard should be a standalone tool and how much of it should be available to the public, providers, programs, etc.

SRC members agreed for the need to check on specific availabilities of some of the data points (eg, authorization rates), with organ-specific considerations having to be worked through. Mr. Knight considered what type of additional burden this project might put on the transplantation system. Dr. Vock pointed out breaking up transplant steps with conditional probability leads to difficulties in synthesizing the entire process. He emphasized the importance of viewing the entire process, and getting people through the “entire transplant subway” from an equity perspective. Dr. Snyder added that synthesizing what total outcomes look like for patients while discussing disparities and presenting a dissection of all the steps would be useful. Mr. Orlowski said that to achieve equity, there was a need to understand where the differences in equity occurred. Dr. Mohan agreed with Dr. Vock, and that while the focus up to this point was posttransplant outcomes, the process really began at referral. In order to provide a measure of how to get from “start to finish,” the starting

point cannot begin halfway down the journey, as a lot of attrition happens racially and socioeconomically up to that point in the course. Dr. McKinney thought while there are risks in breaking up the transplant pathway, there was value in having more than just the start-to-end view.

Dr. McKinney showed an example of the United Network for Organ Sharing (UNOS) Equity in Access to Transplant dashboard. It displayed overall variability, access to transplant, variability attributed to donation service areas (DSAs), calculated panel-reactive antibody, blood type, and so on and tracked variability over time. Dr. Ryutaro Hirose pointed out these steps were not just a sequential probability, but rather prerequisite to each other. Each step needed to be broken down because the bottleneck varied for each population. Once listed, the DSA in which a candidate is listed is the most important thing, not necessarily race or ethnicity. Drs. Mohan and Khush thought this effort was critical and SRTR should work with HRSA to prioritize the task.

Mr. Knight said he was less concerned about the concept of equity, and more interested in the right thing being done for everyone. The unpleasant reality was data suggest the transplantation system was not doing an equitable job. Mr. Knight said that when things are looked at in terms of additional burdens, it suggests affirmative action. He preferred the perspective of diversity management, and integrating things into overall strategy as an entity operates and functions. When additional funding needs to be sought out to get something done, it should be included in the system already. Mr. Knight was not concerned with which administrations were involved in the process—an organization should be striving to provide service to people regardless. He emphasized the capacity for improvement, and how it can be difficult when organizations continue to operate in "healthcare silos."

With the committee giving support for this project, Dr. Snyder said SRTR would work with Ms. Shannon Dunne of HRSA on the next step, and learn more about the dashboards that Ms. Dunne mentioned HRSA already has underway.

"Discarding the term 'discard'" viewpoint

Dr. Hart said one prominent piece of feedback from the patients, donors, and family members (particularly of deceased donors) at the Task 5 consensus conference was that the term "discard" was offensive and should not be used. Dr. Hart led an effort to author a viewpoint on this topic, which was submitted to the *American Journal of Transplantation* and accepted on first review. Dr. Snyder noted that SRTR will be changing this vernacular in its reports. Mr. Orlowski said the OPO community was also focused on identifying ways to work with transplant centers to increase utilization rates of available organs.

Dr. Mohan had mixed feelings about the language change. He thought the term discard should allow people to feel uncomfortable, as it pertains to not using a viable organ. He thought using a negative "non-utilization" was not a good substitute, and they should instead opt for a term not hyphenated and complex. He also suggested partnering with the Centers for Medicare & Medicaid Services (CMS) learning collaborative, which focused on improving non-utilization rates. Mr. Orlowski said it was important to shift the focus to the goal of increasing utilization rather than decreasing non-utilization. Dr. Hart reiterated that the term had a strong negative reaction from families and it was important to also keep families and patients in focus.

SRTR's flagging reports: Should SRTR continue the CMS report?

Dr. Snyder stated that SRTR creates flagging reports that are provided to transplant programs on the SRTR Secure Site. Historically, these reports presented to programs the review criteria that the Membership and Professional Standards Committee (MPSC) uses to determine which programs it will review and CMS criteria used for its evaluations. SRTR always provided both. Two years ago, SRTR split the report into MPSC criteria (posttransplant adult and pediatric graft survival review criteria, pretransplant review criteria) and CMS review criteria (graft and patient survival at 1-year for adult and pediatric).

CMS dropped the review criteria for its ongoing review of transplant programs a few years ago, while still using the criteria according to regulations for initial certification of transplant programs. Because of the use for initial certification, SRTR decided to keep producing and providing the report. However, SRTR recently received feedback that the report was confusing to programs, because CMS does not perform ongoing review.

SRTR proposed to continue to create the report and provide the CMS flagging report upon request, but not supply it on the Secure Site to avoid concern and confusion. Members agreed with the proposal.

Report from subcommittees

The next Patient and Family Affairs Subcommittee meeting is scheduled for December 6, 2022. Dr. Hart said the subcommittee will be prioritizing Task 5 recommendations. At the last Human Centered Design Subcommittee (HCDS) meeting in September, Dr. Schaffhausen said the Task 5 consensus conference was recapped. He also presented project results for redesigning the SRTR website, a special project that ended in September 2022. He was currently working on the agenda for the January 2023 meeting, which may include looking at next steps for the website. Mr. Zinner added that the new website content aimed to be more patient centric. For the Analytical Methods Subcommittee (AMS), Dr. Snyder said the last meeting was postponed until early March 2023, due to delays in developing the new model-building process. Three additional members (Erika Helgeson, William [Bill] Irish, and Megan Neely) recently joined the subcommittee to add additional biostatical support.

Closing business

With no other business being heard, the meeting concluded. The next meeting is scheduled for February 3, 2023, 10:00 AM-1:00 PM CST.