

SRC Meeting Minutes

SRTR Review Committee Meeting, HRSA Headquarters, Rockville, MD

July 18, 2023, 9:00 AM – 3:00 PM EDT

Voting Members Present:

Roslyn Mannon, MD (Co-Chair) ('23)
Sean Van Slyck (Co-Chair) ('25)
Ginny Bumgardner, MD, PhD ('24)
Deborah Maurer, RN, MBA ('25)
Emily Perito, MD, MAS ('25)
Ameen Tabatabai ('25)
David Vock, PhD ('24)
Chris Zinner ('23)

Voting Members Absent:

Kiran Khush, MD, MAS ('23)

Ex-Officio Members:

Laura Cartwright, PhD, MPH (OPTN/UNOS)
Shannon Dunne, JD (HRSA)
Sumit Mohan, MD, MPH (OPTN/DAC)
Jonah Odim, MD, PhD, MBA (NIAID/NIH)
Jennifer Prinz, RN, BSN, MPH-HPA
(OPTN/POC)

HRSA:

Adriana Martinez, MS
Frank Holloman
Chris McLaughlin
Suma Nair, PhD, MS

SRTR Staff:

Tonya Eberhard
Allyson Hart, MD, MS
Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Krista Lentine, MD, PhD
Amy Ketterer
Grace Lyden, PhD
Warren McKinney, PhD
Jon Miller, PhD
Cory Schaffhausen, PhD
Mona Shater, MA
Jon Snyder, PhD, MS
Nicholas Wood, PhD
David Zaun, MS

Welcome and opening remarks

Dr. Roslyn Mannon and Mr. Sean Van Slyck called the SRTR Review Committee (SRC) meeting to order. A new ex-officio member, Ms. Jennifer Prinz, representing the Organ Procurement and Transplantation Network (OPTN) Policy Oversight Committee (POC), introduced herself. Jennifer serves as the CEO of Donor Alliance, the organ procurement organization (OPO) serving Colorado and Wyoming.

Dr. Mannon reviewed the statement of conflict of interest management, then proceeded with the first agenda item.

Approval of the minutes

Dr. Mannon asked the committee to approve or suggest edits to the minutes from the SRC meeting held on April 19, 2023. There was a motion to approve and a second. The minutes were unanimously approved.

SRC nomination process

Dr. Mannon said that at the last meeting, the SRC discussed creating a nominating committee to provide transparency for selecting new members and widespread vetting for candidates. The committee, consisting of Dr. Mannon, Ms. Deborah Maurer, Dr. Kiran Khush, Dr. Emily Perito, Dr. Ryutaro Hirose, and Mr. Chris Zinner, created a nominating process and application materials that

were reviewed by SRTR and the Health Resources and Services Administration (HRSA). Dr. Mannon said nominating policies and procedures aimed to cultivate constituency and expertise needed for the SRC and subcommittees.

If approved, a call for nominations will go out to transplant centers, professional societies, patient advocacy groups, and other stakeholders. The application deadline is September 2023. The nominating committee will speak with applicants, review applications, and submit their choices to the SRC and subcommittees for review. Dr. Mannon said the application includes listing leadership roles, areas of expertise, and why the applicant would be a valued member of the SRC or one of its subcommittees. Applicants must also submit a curriculum vitae (CV) and personal statement. Dr. Jon Snyder added that while the nominating procedure does not prescribe the expertise needed to make up the committees, SRTR has historically strived to maintain a mix of OPO professionals, transplant physicians and surgeons with expertise in various organ types, and transplant administrators. The slate of members nominated by the committee will then be presented to HRSA leadership in the Division of Transplantation for comment prior to final invitations being extended.

Dr. Sumit Mohan asked if the nominating process needed to be as rigorous for patient representatives (such as providing a CV and personal statement). Dr. Mannon said there was flexibility in interpretation of these requirements for the subcommittees. She suggested that each subcommittee chair and co-chair review the application and edit it accordingly. Dr. Mannon called for a vote to approve the nominating process with the amendment to modify the application process for the subcommittees. All voting members agreed. Dr. Snyder noted that the final materials would be prepared following finalization by the subcommittee chairs and the posting of the call for nominations would proceed pending web programming.

Task 5 conference prioritization

Dr. Snyder said the consensus conference meeting report was published in the *American Journal of Transplantation* (AJT) on March 21, 2023. The subway imagery developed for the conference made the cover of the July 2023 issue.

Patient-friendly website update

Dr. Cory Schaffhausen gave updates on web development for the patient-friendly website. Design work started in 2022 with a subcontractor, and patient feedback on various web designs was collected. Thus far, a new web environment has been created to support the new website, website templates have been chosen and purchased, updated designs have been developed, including mobile-friendly versions of all pages, and Dr. Schaffhausen has completed patient, family, and living donor feedback sessions. SRTR is now focusing on finalizing design and functional requirements, migrating content into the new environment, building the new pages with the development team, and finalizing over 70 patient and living donor journey questions and answers.

Dr. Schaffhausen said there was a planned launch of the preview site of the new patient-friendly website in late 2023. Due to the different types of software underpinning the current website, integration of the new website will be done in stages. After the launch, the remaining content not in the preview will gradually be migrated over in the next 1 to 2 years until all content is in the new

environment. The existing website will then be retired. There will be two websites (existing site and preview site) for a period of time.

Dr. Schaffhausen highlighted a few website sections with screenshots. The first was the website preview banner on www.srtr.org, followed by the new website homepage in desktop and mobile format. Photographs feature a diverse range of people, with the homepage image potentially rotating each time the page is visited.

The next screenshot was a patient and living donor journey that is only focused on the patient or living donor line of the subway map. The pages give patient information on different portions of the transplant journey. The pages include organ-specific sections that expand to show text-based information, which serves an additional goal of search engine optimization (SEO). He reviewed the organ-specific versions of the interactive system map with user-selectable system lines, which include patient-focused questions and point to available information tailored to that part of the journey.

Ms. Maurer brought up the importance of having the transplant community help deploy this information to patients, and to not overlook those without internet access. She also commented that rural patients do not know subway maps. Dr. Jonah Odim also noted the need for embedded tutorials to allow for auto-training. Mr. Zinner agreed it was important to consider technology IQ being a spectrum for patients, and using SRTR as a patient engagement hub where professionals can use this information to collaborate with patients. He recommended 30-second to 1-minute video tutorials on the site. Dr. Schaffhausen added SRTR has webinars that will be updated with a new focus on educational videos for patients to navigate the data SRTR has for patients. Members agreed there are many unique opportunities for quality transplant education such as dissemination during the evaluation process or, as Dr. Mohan suggested, ways transplant centers could link to the information.

Dr. Perito pointed out the need to identify a scope and purpose of new information, and to acknowledge other data resources like HRSA and OPTN. Dr. Schaffhausen said SRTR is working on identifying information gaps and where patients can be sent to for that information. Dr. Hirose emphasized the need for SRTR to appear early on in web searches.

Dr. Schaffhausen next went over a screenshot of a Getting Started page, which was a summation of key reports and information across the SRTR website for patients and professionals. The next screenshot was the transplant center search, where users can do a side-by-side comparison.

Dr. Schaffhausen reviewed site and data navigation tools for patients. These included a landing page for kidney and liver decision aids. Next, he went over patient journey and interactive map questions that are organ specific and spread across the subway stops. He noted that some SRC members may be contacted for additional feedback on this section.

Mr. Ameen Tabatabai noted the need for more marketing. Dr. David Vock asked if SRTR would include information on how to afford transplants on the new website. Dr. Schaffhausen noted some information is available through insurance provider websites and SRTR will note that patients should contact their insurance provider for specifics. Members agreed it was important for certain

stakeholders to help address the insurance information gaps. Mr. Zinner noted the overlap of this initiative with the OPTN patient portal and the need for collaboration between the contractors.

Task 5 projects update

Prior to this update, Dr. Snyder recognized the passing of Ms. Amy Silverstein, a member of SRTR's Patient and Family Affairs Subcommittee (PFAS). Dr. Allyson Hart highlighted Ms. Silverstein's many contributions to SRTR and the broader field. The committee recognized Ms. Silverstein's passing with a moment of silence.

Dr. Snyder reviewed nine prioritized Task 5 projects in addition to the patient-friendly website highlighted earlier, with the first four in development and referenced to stops on the system map, which he noted was on the cover of the July issue of AJT:

- A.1: Predicted waiting times
- B.1: Patient-specific search
- H.5: Offer decision aids
- L.1: Longer-term outcomes

A.1: Predicted waiting times

A working prototype of the heart calculator was previewed. Dr. Grace Lyden gave a brief overview of the tool. Dr. Perito suggested adding pediatrics to the decision tool.

B.1: Patient-specific search

Dr. Snyder noted that the patient-friendly website will include a patient-specific transplant program search functionality. Dr. Ajay Israni then gave an overview of work he has led with funding for the Agency for Healthcare Research and Quality (AHRQ) to develop patient-specific search functionality that could inform future SRTR site development. Dr. Warren McKinney reviewed results of a randomized controlled trial testing a tool that helps kidney patients find transplant centers that perform transplants for patients like them.

The study was a crossover trial designed to evaluate the TransplantCenterSearch.org search tool relative to the current SRTR website. Participants were randomly assigned to a website, and asked one of two questions to assess comprehension: 1) which center within a radius of a given zip code had the greatest experience performing transplants for recipients with age over 70 years? 2) which center had the greatest number of recipients with BMI greater than 40?

Results showed an eight-fold advantage in using the new search tool over the current SRTR website; however, the results varied significantly across the two questions, with one question about BMI being easier to answer correctly on both websites. Dr. Israni noted that this easier question was more likely to be answered correctly on the TransplantCenterSearch.org website. Dr. Israni noted the limitation that the study does not include the first five participants from the prespecified vanguard phase, since none successfully navigated to the results page without assistance. Dr. Israni said additional features being developed for the next 5-year AHRQ grant are chat agents, an enhanced help page, video tutorials including a survival-after-listing metric, a Spanish version of the tool, and randomized trials to see if the improved website performs better. Dr. Israni hoped to bring

the functionality from the trial to the SRTR patient-friendly website. Mr. Zinner said that the 5-tier rating was not patient-centric. Dr. Mohan agreed and added that how the 5-tier rating is presented, the volatility of the ratings, and use as a decision tool should be revisited. He noted that showing two metrics is challenging for patients. Dr. Israni responded that survival after listing incorporates the two metrics, namely waitlist mortality and posttransplant survival.

H.5: Patient decision aids

Dr. Snyder showed the kidney offer decision aid (liver is in progress). Dr. Schaffhausen noted that the tool was not meant to fill the same role as the decision analytics tool currently implemented in DonorNet. Rather, it is meant to educate patients about what organs a patient may want to consent to, by thinking about risks and benefits in a general sense. The tool has an upcoming pilot trial and will be integrated into the patient website in 2024. Dr. Snyder also noted the existence of the kidney transplant decision aid and waitlist outcomes calculator for shared decision-making between patients and providers, as well as the liver waitlist calculator, and noted that additional calculators for heart and multiorgan transplants are in progress.

L.1: Longer-term outcomes

Dr. Snyder noted that Dr. Lyden and Dr. Jon Miller are working on a tool to derive 10-year outcome estimates to support a tool to provide this information to patients. Dr. Miller added that the initial model has separate models for adults and pediatrics. Dr. Mohan asked how potential data incompleteness may affect estimates of 10-year outcomes. Dr. Miller said all data available to SRTR for internal purposes will be used. Dr. Miller also noted that the tool currently does not provide center-specific results.

Dr. Snyder noted that other prioritized projects will be started as effort allows:

- A.2: Survival benefit of kidney transplant
- E.1: Benefits of multilisting
- E.6: Timing of referral to transplant
- H.2: Risk/benefit of complex donors
- Q.1: Accept/decline patterns by program

HRSA address

Dr. Suma Nair, Associate Administrator for the Health Systems Bureau, welcomed the committee to HRSA and addressed the OPTN modernization efforts and HRSA's efforts to gather input from the community to guide future improvements to the system. The modernization efforts will focus on 1) governance with an independent board that represents the community and aims to improve and enhance organ policy based on evidence, 2) utilizing the best technology to support access to transplants, 3) harmonizing data and metrics, eg, with the Centers for Medicare & Medicaid Services (CMS), 4) in operations, realizing investment opportunities for support, 5) identifying intersecting priorities, and 6) developing transition and next-generation OPTN contracts.

Dr. Mohan asked how duplicative data processes between SRTR and OPTN could be resolved. Dr. Nair emphasized the need for stronger data governance. Redundancy should be eliminated through restructuring data processes. Dr. Hirose pointed out the obstruction of data flow between agencies under Health and Human Services (HHS) and advocated for HRSA to work with HHS to resolve this issue. Dr. Nair said efforts were underway in working with CMS on data sharing. Dr. Mohan added that a good first step in having a more responsive OPTN data registry is being able to collect data relevant to today, without the archaic process of waiting to go through the Office of Management and Budget (OMB) process to make needed adjustments to the OPTN data collection system.

Mr. Zinner asked for clarification on the aims of the modernization effort and what the critical success factors are to achieve HRSA's goals. Dr. Nair said the goals included equitable access to transplant, and reductions in morbidity and mortality. She urged the community to determine the most important goals and said HRSA would make sure efforts align with HRSA's overall efforts. She said an important factor was to modernize infrastructure and have more transparency to increase public trust.

Dr. Perito emphasized the need for nationally aligned data. With hearing about contracts being split up, she said it was important to focus on keeping incentives aligned. Dr. Nair agreed with these concerns and said it was a focus of the division. Dr. Mannon asked how these efforts would be accomplished based on current and/or expected funding. Dr. Nair said there was strong support within the administration to increase funding and continuous efforts to retain the best possible resources.

Dr. Odim asked what HRSA envisioned for the national leadership structure of the transplant ecosystem and if changes needed to be made to accomplish alignment. Dr. Nair said a main focus is ensuring the current structure of the OPTN board is representative, independent, and free of conflicts. Mr. Van Slyck said it was crucial to remain focused on system goals and outcomes—in particular, reducing the nonuse of donated organs. Dr. Nair agreed, saying it was important to take a holistic view of system performance. Addressing infrastructure first for strong policy development and accurate data collection would help address Mr. Van Slyck's concerns.

OPO metrics

Dr. Snyder provided an update on the status of SRTR reporting of OPO metrics. The committee's prior recommendation to remove eligible death donation rates and eligible death data reporting from OPO reports was accomplished on July 6, 2023. It was previously approved by the committee to replace these metrics with SRTR's replication of the CMS OPO performance metrics. Per HRSA's request, SRTR did not include the CMS performance metrics in the reports released on July 6. Since the previous SRC meeting, CMS representatives gave a presentation to the OPTN's Membership and Professional Standards Committee (MPSC) on May 4, 2023, reviewing their metrics and plans for enforcing the metrics. CMS noted SRTR will also be reporting these metrics going forward and providing additional information beyond what CMS is reporting (eg, subgroup analyses and additional risk-adjusted analyses). SRTR is seeking further guidance on future inclusion of these metrics. Dr. Snyder noted the urgency, given CMS's performance evaluation period is in 2024 with performance standards being established based on 2023 performance.

Dr. Snyder said SRTR had a version of the metrics that replicated CMS metrics, and these were very close to CMS's calculations for most OPOs. Replication is almost exact, although this depends on getting data from the Centers for Disease Control and Prevention (CDC) and CMS (inpatient deaths for Medicare beneficiaries). Some differences are that SRTR reports for the current set of OPOs (56), while CMS is still reporting on 57. SRTR prepared a disclaimer noting that CMS's reports are those used for OPO certification. The SRC previously agreed to have SRTR replace the eligible death donation rates with the new metrics. Dr. Snyder reviewed previously-approved concept figures. He then opened the floor for discussion.

Dr. Mannon asked if differences between SRTR's and CMS's versions of the metrics were sufficient to change the tiers. Dr. Snyder said even minor differences can result in changed tiers. HRSA has agreed SRTR can do additional risk adjustment to show how OPOs compare with each other after consideration of differences in the makeup of their potential donor populations. Dr. Mohan asked if available data lag renders these data uninformative to OPOs to support current quality improvement efforts. Dr. Snyder acknowledged that there is a 2-year lag in the availability of the metrics due to the release schedule of the death information from the CDC; however, SRTR is working on methods to project these numbers to estimate where the denominator may be in future eras where we already know donor counts. Dr. Mohan suggested thinking less about projecting the metrics and instead using the subgroup analyses to assess where quality improvement efforts should be targeted. Dr. Miller noted that CMS does not produce data within subgroups, so there would be no overlap there between SRTR and CMS reports. Mr. Van Slyck agreed.

Dr. Hirose suggested placing the data on the SRTR secure site instead if the reports cannot be made public until HRSA and CMS agree on an acceptable path forward. Members discussed if this information should be shared internally only or publicly. Mr. Zinner's initial reaction was to make it public. Dr. Mannon stated that the CMS data will be public, and thought this SRTR data could be kept internal. Dr. Odum brought up the possibility of providing the subgroup analysis as a consulting service offline for the OPOs. Dr. Snyder noted that SRTR has been approached by some OPOs for this information, but SRTR's goal is to provide useful information to all OPOs.

Members discussed the urgency of this decision. Dr. Hirose said if OPOs are decertified based on the data in the next 2 years, it could disrupt the entire system. Ms. Maurer suggested the data be placed on the secure site as an interim option, and Dr. Mannon made a motion to provide the overall, unadjusted data without tiers, subgroup analyses, and additional risk-adjusted analyses on the secure site. The motion was seconded. Mr. Zinner suggested another option where it was published on the public site within subgroups only, so as not to have direct conflict with CMS's reports. Dr. Miller said another option was to provide the numbers overall as CMS produced them with a footnote on the subgroups that the data are based on SRTR's best recreations of the metrics. Mr. Zinner agreed with this proposal, and advocated for public publication. Ms. Shannon Dunne noted that the footnote/disclaimer could be objected to and would need to be approved by HRSA.

The motion was then revised to displaying only subgroups on the secure site. No voting members were opposed to this. The next part of the motion called for providing adjusted data on the secure site. There were no disagreements. Lastly, there was a call for displaying overall data on the secure site. The voting members agreed to this. Mr. Zinner agreed to sharing data internally, since OPOs

needed the information quickly. However, he encouraged the committee to revisit this topic in the future in an effort to make the information public, once there is a decision between HRSA and CMS on what information can be shared publicly.

Dr. Mannon noted the OPO metrics being a controversial topic for the SRC. In the spirit of transparency, the committee wants to see the overall data published both publicly and internally. Lack of action is unacceptable and will have consequences for the transplant system. Dr. Hirose proposed the recommendation that CMS and HRSA discuss the data and make it all public, including the overall calculated by SRTR. There was a motion for this, and all members agreed.

System performance monitoring

Dr. Snyder recalled Task 5 recommendation 6.4 and National Academies of Sciences, Engineering, and Medicine (NASEM) recommendations 1 and 12 that called for creating system performance goals and dashboards to track progress on those goals. Dr. Snyder asked voting members to consider broad system goals, and asked voting and ex-officio members to consider the following questions:

1. If you had to pick one metric to answer the question “How is our nation’s transplant system performing,” what metric would it be?
2. Can this be “overall” (ie, for all organs at once) or should it only be presented separately for each organ type?

Committee answers were as follows: Dr. Mohan: life-years saved by transplant; Mr. Zinner: percentage of patients referred to transplant who are still alive x-years (eg, 15) after the referral; Ms. Maurer: percentage of end-stage organ failure that are referred to transplant; Mr. Van Slyck: increasing the number of donors and rate of transplant, dropping the rate of deaths; Dr. Bumgardner: how well is the system coordinated for efficiency (time of organ offer to time of organ arrival for transplant); Dr. Vock: having people live longer, happier lives, which is best approximated by total transplants; Dr. Perito: helping the most people live longer, better lives, and survival from entry into the system; Mr. Tabatabai: rate of transplant versus rate of listing, patients getting off the list faster; Ms. Prinz: utilization rate, numbers of donors and transplants, and decreasing deaths on the waiting list; Dr. Odum: demand and supply, with demand being listed patients and/or patients referred and supply being number of transplants, and lastly graft loss and patient death on the waiting list. All members but one expressed a preference for organ-specific metrics and goals rather than overall metrics and goals.

Dr. Snyder showed the committee a few figures from an SRTR tool in development. The first showed reducing removals from the waiting list due to death or too sick for organs overall since 2016. Next was waitlist mortality counts for kidney, liver, heart, and lung. Dr. Snyder raised the question of whether it is more appropriate to trend a rate instead of raw counts.

Another option was to consider if we are doing more transplants relative to patients dying while waiting. The next figure showed trends in how many transplants were done relative to how many patients were removed due to death or being too sick. Dr. Snyder went over transplants-per-waitlist-death by each organ. Dr. Snyder hoped the discussion influenced members to think about the types of metrics and trends SRTR could present, and then we could work to create national system goals.

Notably, there are trends in lung transplant shown following continuous distribution identifying a “bolus effect,” which is being further explored.

NASEM findings regarding national system goals

Dr. Snyder said NASEM's conceptualization of goals were both trending a performance metric over time and reducing variation in system components (organ donation rate, donation after circulatory death [DCD] procurement, organ offer acceptance rates, nonuse rates). General goals included greater equity, higher rates of organ donation, and higher acceptance of offered organs.

Specific goals included reducing nonuse rates to 5% or less, increasing DCD procurement to at least 45% with no reduction in donation after brain death (DBD) donors, improving organ acceptance rates to those achieved by the 90th percentile program, and increasing transplants to 50,000 by 2026. In addition, NASEM listed targets to reduce variation in key metrics for equity including sex, place of residence, race and ethnicity, socioeconomic status, presence of stressors caused by racism, transplant program-level variance, and OPO-level variance.

Other organizations' system goals

NASEM and the Association of Organ Procurement Organizations (AOPO) put forward the goal of increasing transplants to 50,000 by 2026. Dr. Snyder projected the number would be 41,069 by the end of 2023. Over the past 5 years, transplants increased 4.8% on average. Continuing at that pace would lead to 46,972 transplants by the end of 2023. To reach the goal, there would need to be an annual increase of 6.5%. Neither organization called out organ-specific metrics for this.

The ESRD Treatment Choices Learning Collaborative (ETCLC), a CMS project to increase kidney transplants, has the following goals: 1) increase the number of deceased donor kidneys transplanted by 28%, 2) decrease the current national discard rate of all procured kidney kidneys with a kidney donor profile index (KDPI) ≥ 60 by 20% / KDPI < 60 by 4%, and 3) increase the utilization of high-KDPI kidneys recovered (KDPI ≥ 60) by 28%. For the first goal, the target number is 26,170. Dr. Snyder projected that if the 5% annual increase continues, the total will reach 26,095 by 2027.

SRC recommendation for system performance metrics/goals

The committee discussed whether SRTR should be engaged in this discussion about system performance metrics and goals. Mr. Zinner said if the transplant system was going to be disrupted, it should be done to drive a set of metrics that represent the performance of the system. He thought SRTR was well-equipped to handle this task. There was general support by the committee for this. Dr. Snyder said a year from now, he would like for SRTR to have identified key drivers that should be monitored for system performance, and describe variation across the United States. A dashboard could be created to contain these metrics. Ms. Dunne consulted the contract language for Task 5 and confirmed the NASEM findings fit into the Task 5 goal of defining recommendations for performance metrics. She reminded the committee of the OPTN and HRSA dashboards and to avoid duplication. Mr. Frank Holloman supported SRTR in this initiative. HRSA could take the recommendations from this work and decide what happens with each recommendation.

Living Donor Collective update

Dr. Krista Lentine presented on the Living Donor Collective (LDC), an effort to establish a lifelong donor candidate registry. LDC is working to address the lack of systematic data collection on donor candidates, including a lack of a comparator group to assess the attributable risk of donation, and data on long-term follow-up. Dr. Lentine said solutions included registering and following donor candidates to understand donation barriers and create comparator groups to support future outcomes assessments. Also, the 2022 Task 5 metrics consensus conference called for the moral and ethical obligation to increase living donation and collect long-term data.

Dr. Lentine went over the history of the LDC, which began as a pilot project in 2016 upon HRSA's request for SRTR to establish a national living donor candidate registry. While OPTN also collects data, it does so on only those who donate. OPTN donor follow-up is mandatory but limited to 6 months, 1 year, and 2 years. The LDC registers donor candidates (individual seen at a program for evaluation), and registration is currently voluntary. The LDC framework allows for examination of patterns and disparities in candidate conversion to donation.

The pilot found the reasons for not donating included medical risk, psychosocial reasons, anatomical reasons, candidate opt-out, and economic barriers. Dr. Lentine discussed collaboration efforts with OPTN to look holistically at data collection and address the needs of the transplant community, leading to a concept paper entering OPTN Public Comment in August 2023. The crux of the proposal is to mandate collection of candidate registration data by the OPTN. Mandated center follow-up could be limited to assessing near-term donor safety and then long-term follow-up shifted to SRTR. Whether follow-up consists of data linkages, targeted surveys, combinations thereof, etc, remains to be discussed.

Dr. Lentine said two committees are being formed to support and inform the LDC. One is the living donor steering committee, led by Dr. Hart and Dr. Amy Waterman, to give feedback on postdonation and follow-up; the first meeting is July 24, 2023. The other is a transplant steering committee, in which participating program representatives share best practices and provide recommendations to SRTR in operating the LDC.

Dr. Perito asked if follow-up would be patient reported or through the center. Dr. Lentine said that LDC follow-up does not involve any reporting through the center. Since the LDC is operated under HRSA's public health authority, there is no institutional review board (IRB) needed for data collection. She also informed the committee of batch upload options for submission of donor candidate registration data by transplant centers; for example, the LDC is partnering with MedSleuth's BREEZE donor intake screening system to create a data export to ease the burden of entering data into the LDC system. Dr. Mohan thought this project was a better fit for OPTN and that reporting data separately to SRTR and OPTN creates a larger workload. He also thought going to a company (MedSleuth) that belongs to a large dialysis organization (DaVita) was potentially problematic. He encouraged SRTR to consider electronic medical record (EMR)-based data collection systems and common data models such as the Observational Medical Outcomes Partnership (OMOP) and Epic's Cosmos system. Dr. Mohan thought that the LDC should probably be a part of discussions with HRSA and CMS about collection of referral and evaluation data.

Dr. Mohan said for programs to enroll in the LDC, participation needed to be easy and accessible. Dr. Hart and Dr. Lentine clarified that there is a concept paper out to discuss moving the initial candidate registration data to OPTN, and continuing short-term data collection by OPTN but moving the long-term follow-up to the LDC, which seeks to avoid a substantial increase in data collection burden on programs. Dr. Hart also agreed this was part of a bigger conversation, as how to transfer data electronically should not be limited to the LDC, but to improve all OPTN data collection.

Reports from the subcommittees

Mr. Tabatabai said PFAS is looking forward to reviewing new material that has not received patient opinion yet, and making more use of PFAS such as surveys, additional feedback, etc. Other focus areas are having more synergy with the subcommittees and the LDC, and focusing on marketing SRTR materials to patients.

Dr. Schaffhausen said the next Human Centered Design Subcommittee (HCDS) meeting is scheduled for September 2023. The agenda will be planned in the coming weeks. Some time will be dedicated to the patient-friendly website and Task 5 projects. Mr. Zinner added there will be focus on filling the empty subcommittee seats, as three members leave at the end of the year.

Dr. Snyder said the next Analytical Methods Subcommittee (AMS) meeting is scheduled for August 2023. There are a few analytic projects being worked on, the long-term outcomes project in particular. There is ongoing work for the program-specific report risk model updates, which will be implemented for the January 2024 release.

Closing business

With no other business being brought forward, the meeting concluded at 3:00 PM. The next meeting will be virtual, with the date to be determined. Winter and summer meetings will be virtual. Spring and fall meetings are being planned for in-person in Washington, DC.