OPTN Membership and Professional Standards Committee
Performance Monitoring Enhancement Subcommittee
Meeting Summary
November 20, 2020
Conference Call

Richard Formica, M.D., Chair

Introduction

The Performance Monitoring Enhancement Subcommittee (the Subcommittee) of the Membership and Professionals Standards Committee (MPSC) met via Citrix GoToTraining on November 20, 2020, to discuss the following agenda items:

1. Meeting Goals
2. Scorecard Development Discussion
3. Next Steps: Review Process and Triggers

The following is a summary of the subcommittee's discussions.

1. Meeting Goals

The Performance Monitoring Enhancement Subcommittee Chair gave introductory remarks and expressed the goals of the meeting, which were to formulate and finalize the components of the scorecard, specifically

- Choose metrics for post-transplant & pre-transplant,
- consider a third dimension for patient experience; and
- discuss organ-specific differences

The subcommittee chair highlighted the importance of maintaining the focus of the meeting on formulating the metrics. The subcommittee will discuss how the metrics would be used to monitor programs at a future meeting.

2. Scorecard Development Discussion

A representative of the Scientific Registry of Transplant Recipients (SRTR) presented the Subcommittee with information on scorecard development. He presented a diagram to the subcommittee and explained the important domains of program performance. The diagram illustrated two important domains and associated functional areas that can be used to formulate metrics. The Subcommittee discussed these domains to determine appropriate metrics for pre- and post-transplant outcomes:

<u>Post-Transplant Outcomes Metrics</u>

SRTR staff discussed metrics that are currently available, which are one month, one year, and 3-year post-transplant outcomes. They also discussed the development of an additional metric, which will include a period prevalent cohort for 5-year outcomes. SRTR staff noted that the 5-year metric provides significant flexibility for the MPSC to develop both short-term and long-term metrics.

SRTR staff explained the difference between short-term and long-term outcomes and provided diagrams that illustrate the hazard function for adult graft failure from transplant through 3 years post-transplant

for kidney, liver, lung, and heart. They advised the committee that 90-day outcomes appear to capture most of the "high hazard" period immediately after transplant for short-term outcomes.

The Subcommittee was asked whether they supported the use of short-term and long-term outcomes and whether the long-term outcomes should be conditional on graft function at the short- term interval. Secondly, the Subcommittee was asked to address the appropriate period for short-term and long-term outcomes.

The chair initially noted that he thought the short-term outcomes captures list management, recipient selection and the way the multidisciplinary team works together during that initial period prior to the recipient being released for longer term care. So a short-term outcome could be a good measure of the internal functioning of the program.

Subcommittee members supported the use of short-term and conditional long-term outcomes agreeing that short-term captures a program's pre- and peri-operative phases. The long-term outcomes would measure different aspects if it was conditional on the short-term graft function. The Subcommittee supported the use of both short-term and long-term outcomes for the post-transplant phase. However, there was support for making long-term outcomes conditional on graft function at short-term outcomes. Using a conditional longer term metric in conjunction with a 90 day short term measure would help programs focus in on the areas for improvement.

An SRTR representative also noted that the MPSC may want to consider the use of surrogate bio-markers as a reproducible assessment of graft function. These biomarkers, such as estimated glomerular filtration rate (eGFR) for kidney, at one year would be predictive of longer-term outcomes without waiting 5 years for outcome data. This may be a measure that the Committee could consider for a future iteration of a scorecard.

Perioperative Care

The Subcommittee discussed the advantages of a short-term survival outcome of 90-days. Subcommittee members agreed that the 90-day outcome interval includes both the peri-operative and early post-transplant phases. Additionally, the 90-day outcome interval would be meaningful as a performance metric. One subcommittee member also observed that a 90-day interval could help programs focus on where the real area of need is in their programs and encourage them to take on higher risk patients. Another advantage noted by the subcommittee included being able to use a 90-day interval across all organ types.

The subcommittee members unanimously agreed on a short-term outcome of 90-days across all organ types.

Post-operative Care

The Subcommittee discussed the appropriate measurement for longer-term outcomes. There is support for the 5-year period prevalent outcome, acknowledging that programs have less control over these longer-term outcomes. However, a subcommittee member noted that the community has achieved significant improvement of 1-year outcomes but has not demonstrated dramatic improvement on longer-term outcomes. Use of a 5-year period prevalent measure could incentivize programs to improve their efforts to maintain a relationship with recipients, and improve the transition of recipients to the community. The Subcommittee appears interested in evaluating and potentially using the 5 year period prevalent outcome once it is available and the community has some experience with it.

The subcommittee discussed what would be the appropriate time period for long term outcomes in a proposal that could be released in summer 2021 – 1 year or 3 year. Topics of discussion included:

- One significant limitation with the current 3-year outcome is it is not currently constructed in a period prevalent window. At the time, the Committee would receive these metrics, the outcomes could be far in the past.
- The 3-year outcome would change post-management resources for programs (i.e., transplant coordinators would have to follow the patient's longer and more intensively than currently). Programs would have less control over a patient's well-being after the patient has been referred back to community physicians.
- Some of the concerns with the current 1-year outcome measure raised by the community include that programs are highly concentrated in very high numbers so the variability between programs is small so is less useful metric to differentiate programs. In addition, there is concern that the risk adjustment is not sufficient to capture high risk so it disincentivizes higher risk transplants.
- 1-year conditional outcomes are going to be much better than the current 1-year outcomes so we would need to educate the community if the Committee adopts the 1-year conditional for long-term measurement. The concentration of programs under conditional 1-year outcomes at a high survival rate will be more extreme than current outcomes.
- Even though conditional 1-year outcomes may be more concentrated for majority of programs, those programs that are outliers will be better able to identify the areas of improvement since the outcomes would only include those after the first 90 days.
- Need to make sure that use of short- and long-term outcomes do not negatively affect program behavior resulting in decrease in higher risk transplants.
- One subcommittee member suggested that one-year survival is still deemed to be reasonable with more leniency in flagging. That subcommittee member supported 1-year survival conditional to 90-day survival outcomes.

A subcommittee member reference the use of a survival benefit metric. The SRTR staff opined that a survival benefit metric is really a composite metric because it takes into account the survival rate if a patient had not received a transplant at that program versus if they did receive a transplant at that program. One has to measure both of those things separately so it would be difficult to determine whether the areas for improvement exist in pre-transplant or post-transplant. So for MPSC purposes, it may be better to look at those components separately. The chair noted that a survival benefit metric might be a good metric to consider if the subcommittee supports a third domain of patient experience as part of the scorecard.

The Subcommittee supported including both 90-day survival and 1-year conditional on 90-day survival metrics in a proposed scorecard for public comment by a vote of 18 For, 1 Against, and 0 Abstentions.

The Subcommittee provided the following suggestions for topics to address in the public comment proposal document:

- Develop an explanation for the use of the term "conditional."
- Develop an explanation in terms of the anticipated flagging regime.
- Provide an opportunity for the community to provide feedback on whether a scorecard should include both short-term (90-day) and longer-term outcomes (1 year) or just 1 year outcomes.

<u>Pre-Transplant Outcomes Metrics</u>

The SRTR staff discussed the available risk-adjusted metrics for pre-transplant outcomes. The SRTR currently has three risk-adjusted metrics for waiting list outcomes, which include waitlist mortality rate ratios, overall and deceased donor transplant rate ratios, and offer acceptance rate ratios. The SRTR staff discussed the advantages and limitations of the waitlist mortality rate ratios, transplant rate ratios

and offer acceptance rate ratios. The waitlist mortality rate ratio measures a clear, clinically meaningful outcome for patients and does not clearly depend on donor supply demand. However, particularly for kidney, programs may not provide direct care to patients on the waiting list. The SRTR staff suggested that the overall and deceased donor transplant rate might not be an appropriate metric for the MPSC to measure since the metric does not directly measure the process that provides access to transplant and the metric depends on factors outside the control of the program including donor supply and demand. SRTR staff noted that the offer acceptance rate ratios directly measure a process of interest to the MPSC, there is variability between programs and it is clearly modifiable. On the other hand, programs may feel pressure to accept offers they normally would not consider, and there is a general discomfort in the community around being penalized multiple times for declining offers for multiple candidates from the same donor although the rate is adjusted based on sequence number. Finally, programs could aggressively use "weeder" fields thereby achieving good offer acceptance but providing poor access to transplant; however, appropriate use of filters to weed out offers the program would never have accepted could result in improvement in system efficiency. The SRTR suggested that the best pre-transplant metrics for use by the MPSC would be waitlist mortality rate and the offer acceptance rate.

Waitlist Mortality Rate

Subcommittee members agreed that the benefits of implementing a waitlist mortality rate included:

- Could encourage programs to examine how to improve the care of the patients on the waiting list, for example education and outreach to referring nephrologists.
- Some of the previous concerns with this metric may no longer be as relevant based on the changes to the allocation system with broader sharing that helps ensure that sicker patients on the waiting list get organs first. If programs avoid sicker patients, less likely to get offers and perform transplants so allocation system incentivizes listing sicker patients.
- It could be a useful metric to look at systems issues, and not just transplant system, that are barriers to getting patients transplanted before they die on the waiting list.

The Subcommittee also discussed some of the disadvantages of the waitlist mortality rate:

- Could deter programs from placing sicker patients on the waiting list. Programs control who they list and may decide not to list sicker patients who could benefit from transplant but also have higher risk of dying on the waiting list. Could result in unintended consequence of decreasing access to transplant.
- Can be affected by many factors out of the program's control (availability of specialists, late referrals, etc.) that may create an incentive to not list acutely ill patients.
- In liver, there are discrepancies in the availability of hepatologists across the country. In some areas, there are no hepatologists so have to rely on gastroenterologists to keep people alive. In that context, do not want to penalize programs for choosing less sick patients to list because the decision could be based on their ability to care for the patients. Could a comparison between programs that have significant differences in resource availability cause unintended consequences. This concern may reflect an issue of risk adjustment being able to capture characteristics of the service available in an area, for example, an underserved area.
- Not a helpful metric from a kidney perspective because kidney transplant programs do not provide direct care to patients on the waiting list. Two available options would be to not use for kidney programs but use for others or decrease weight of this metric for kidney programs.
- A waiting list metric, in context of kidney, should focus on ensuring that their waiting list population are healthy and encouraging programs to maintain contact with patients on the waiting list so that in the allocation phase, we are minimizing cold ischemia time. A metric

should focus on a program's effort to keep their waiting list population healthy and not just mortality.

- Can negatively affect programs that multi-list patients. The risk adjustment addresses listing for other organs.
- A useful metric can be tarnished by poor risk adjustment. The SRTR addressed a question on the ability to risk adjust to counteract the concerns about creating a disincentive to list sicker patients. The SRTR director noted that the Committee should separate the questions about what is a useful metric and whether the metric is accurately risk adjusted. The first question should be whether this metric measures an area of transplant program performance the Committee thinks is important. The MPSC can separately address whether there are gaps in the available data to better risk adjust for higher risk patients. If need better risk-adjusters, should identify the needed data and propose ways could capture better to the OPTN Data Advisory Committee and OPTN organ-specific committees.

Offer Acceptance Rate

The Subcommittee discussed the offer acceptance rate and provided the following feedback.

Subcommittee members agreed that the offer acceptance rate is an important metric to focus on patient needs. Programs must honestly evaluate what organs they are willing to accept and use the offer filters to remove offers that the program never accepts. Encouraging the use of offer filters is good and will contribute to efficiency of the system. Transplant programs may transplant more organs if they recognize that their acceptance rate will be affected. Another incentive that will be created by this metric is for programs to make sure that candidates are listed as active if ready for transplant and inactive if not ready for transplant. Programs clearly have control over this metric.

A Subcommittee member asked if the metric could control for OPO performance, geographical differences in donor population and waiting list size. The SRTR staff responded that these models are able to adjust for many donor factors, recipient factors and where the patient falls on the list. The SRTR evaluated donor supply and demand and in case of liver, median MELD at transplant and there was not a significant association between offer acceptance and these factors. The model adjusts for ratios of donor to recipient size, meaning height or weight, but heart model is the only model that adjusts for difference between donor and recipient age. The organ acceptance model does tend to favor programs with larger waiting lists but the offer acceptance model does not, which is one reason why the SRTR prefers the offer acceptance rather than the organ acceptance model. There are a number of small programs that have extremely good offer acceptance rate, even in kidney. The offer acceptance models are the most complex the SRTR builds because of the large amount of data available.

Some subcommittee members are skeptical about how the offer acceptance rate is measured and possible negative behavior changes that use of this metric may cause.

The subcommittee chair asked the Subcommittee to identify which components are appropriate to include in the public comment proposal. The Subcommittee had discussed having two metrics for pre-transplant and two metrics for post-transplant. Do we need two metrics to measure pre-transplant phase? Based on the discussion, is the waitlist mortality metric too flawed to include in a public comment proposal? Is the Subcommittee comfortable including offer acceptance rate as part of the public comment proposal? Feedback from the Subcommittee supported considering the two metrics discussed, waitlist mortality and offer acceptance rate, for inclusion in the public comment proposal to get feedback from the community. Waitlist mortality is very relevant for some organs but not as applicable to kidney so should include in the proposal. The Subcommittee participated in a poll to gauge

support for including two pre-transplant metrics as part of the monitoring scorecard, including waitlist mortality and offer acceptance rate.

The Subcommittee supported including waitlist mortality rate ratios and offer acceptance rate ratios for pre-transplant in the public comment proposal by a vote of 16 For, 2 Against, and 0 Abstentions.

Possible Third Dimension – Patient Experience

The Subcommittee discussed the patient experience as a possible dimension to be measured. The SRTR recently released patient mortality after listing as an intent-to-treat metric. The Subcommittee discussed the possibility of "patient mortality after listing" metric being used to measure patient experience and reviewed some of the known advantages and disadvantages. The Subcommittee brainstormed possible metrics including

- Patient-Reported Outcomes
- Survival Benefit Outcomes
- Stewardship metrics – late declines

Next Steps Review Process and Triggers:

The Subcommittee will continue its discussion of a possible third dimension for patient experience. In addition, the chair suggested that in preparation for a discussion of the review process and triggers at the next meeting, the Subcommittee consider the reviews they have participated in and think about which reviews they think the MPSC should be involved in and which reviews not. The Subcommittee may want to consider tiers for levels of response or other creative, innovative ways to design the review process and in which circumstances, the MPSC should intervene.

Upcoming meetings

- 12/15/2020 - MPSC Meeting, Conference Call 1:00 pm – 3:00 pm (EST)
- 12/18/2020 - MPSC Performance Monitoring Enhancement Subcommittee Meeting, 3:00-5:00pm, ET

Attendance

- **Subcommittee Members**
    - Richard N. Formica, Jr
    - Sanjeev K. Akkina
    - Nicole Berry
    - Errol L. Bush
    - Matthew Cooper
    - Adam M. Frank
    - Michael D. Gautreaux
    - Alice L. Gray
    - John R. Gutowski
    - Ian R. Jamieson
    - Christy M. Keahey
    - Mary T. Killackey
    - Jon A. Kobashigawa
    - Didier A. Mandelbrot
    - Virginia(Ginny) T. McBride
    - Willscott E. Naugler
    - Matthew J. O'Connor
    - Steven R. Potter
    - Jennifer K. Prinz
    - Lisa M. Stocks
- **HRSA Representatives**
    - Arjun U. Naik
- **SRTR Staff**
    - Nicholas Salkowski
    - Jon J. Snyder
    - Bryn Thompson
    - Andrew Wey
    - Ryo Hirose
- **UNOS Staff**
    - Sally Aungier
    - Tameka Bland
    - Robyn DiSalvo
    - Nadine Drumn
    - Amanda Gurin
    - Danielle Hawkins
    - Amy Minkler
    - Jacqui O'Keefe
    - Liz Robbins Callahan
    - Sharon Shepherd
    - Leah Slife
    - Gabe Vece
    - Betsy Warnick

- **Other Attendees**
    - None