

SRTR Visiting Committee Minutes

Teleconference

July 7, 2020, 9:00 AM- 12:00 PM CDT

<u>Voting Members Present:</u>	<u>Ex-Officio Members:</u>	<u>SRTR Staff:</u>
Jeffrey Orlowski, MS, CPTC (Co-Chair)	Shannon Dunne, JD (HRSA)	Tonya Eberhard
Jonathan Chen, MD	Alexandra Glazier, JD, MPH (OPTN-POC)	Ryutaro Hirose, MD
Richard Formica, MD	Jonah Odum, MD (NIH)	Larry Hunsicker, MD
Richard Knight, MBA	Darren Stewart, MS (OPTN/UNOS)	Ajay Israni, MD, MS
Brent Logan, PhD		Bertram Kasiske, MD, FACP
James Markmann, MD, PhD	<u>HRSA:</u>	Amy Ketterer
Sumit Mohan, MD, MPH	Chris McLaughlin	Jon Miller, PhD
James Pittman, RN, MSN		Donald Musgrove, PhD
		Caitlyn Nystedt, MPH, PMP
<u>Voting Member Absent:</u>		Nicholas Salkowski, PhD
Ken Newell, MD (Co-Chair)		Jon Snyder, PhD, MS
		Andrew Wey, PhD

Welcome and Opening Remarks

Co-Chair Jeffrey Orlowski and Dr. Jon Snyder called the SRTR Visiting Committee (SVC) meeting to order. Dr. Snyder emphasized that the meeting would focus on the effects of COVID-19 on the primary metrics of system performance published in the program and organ procurement organization reports. After Mr. Orlowski took roll call and reviewed the agenda, Dr. Snyder reminded members about conflict of interest management. Dr. Snyder commenced with the agenda.

Reporting Lag of Death Data

Dr. Andrew Wey introduced biostatistician Dr. Jon Miller, who presented an analysis of the lag in reporting of death data to OPTN/SRTR. Dr. Wey stressed the topic's relevance in evaluating the effects of COVID-19 on waitlist mortality and posttransplant outcomes.

Dr. Miller said that the data analysis began as an exercise to update and replicate some of the 2005 analyses of OPTN reporting of deaths (Levine et al. Analytical methods and database design: Implications for transplant researchers, 2005. Am J Transplant 2006;6(Part 2):1228-1242) in order to inform the current COVID-19 analyses. SRTR was interested in evaluating the current lag in death reporting to learn how quickly we could be relatively confident in evaluations of the impact of COVID-19 on waitlist mortality or mortality after transplant. The analysis considered differences between candidates and recipients, and differences across organ types. It also considered how reporting might differ by subgroups such as time on the waiting list, geographic location, and demographics.

The cohort included candidate and transplant recipient deaths from summer 2018. Identified deaths in each standard analytic file were counted from May 2018 to 22 months out. The analysis was performed with and without unverified deaths obtained from external sources of death data. Results showed that the lag in complete reporting was longest for kidney transplant candidates, with

reporting becoming 95% complete at approximately 6 months. Reporting for most of the other organs was 95% complete within 3 or 4 months for candidates on the waiting list. For transplant recipients, the reporting was relatively complete by 3 months after the deaths occurred when unverified deaths were included.

Dr. Larry Hunsicker asked how frequently an unverified death turned out to be not true, thereby affecting reporting accuracy. Dr. Snyder outlined UNOS's external death verification process, and concluded that an unverified death was rarely a mistaken death. Mr. Darren Stewart of UNOS concurred.

Dr. Miller addressed the possibility of different lags in death reporting based on different patient subgroups. For these analyses, the cohort included patients with a death date between May 2018 and August 2018. The analysis modeled the odds of true death reporting within 2 months of the date of death. Odds of death reporting by month 2 became lower as time elapsed from the time of listing or the time of transplant. Dr. Richard Formica said it was often difficult for transplant centers to gather death data for their waiting lists due to often incomplete reporting from dialysis units and having only the Limited Access Death Master File (LADMF) as an external source. Dr. Hunsicker asked if a linear relationship between time since listing/transplant and death reporting was appropriate, and how could it be less likely that recipients would not be accounted for in the first year when they are followed more closely than in later years. While there was currently no information on nonlinearities, Dr. Snyder noted that this analysis was designed to more generally assess the lag in death reporting, but a separate analysis could investigate lags within the first posttransplant year to assess implications for evaluations of first-year outcomes. Dr. Sumit Mohan was concerned about the implications of the analysis with respect to organ allocation, as candidates who have died often continue to receive organ offers. He noted that organ allocation could be improved if death data were available to centers through the ESRD network and Centers for Medicare & Medicaid Services' (CMS's) CROWNWeb system.

Dr. Hunsicker pointed out that while the data suggested a significant difference and impact of years since listing for kidney candidates/recipients, it would have little effect on the analyses since the odds ratio were so close to 1. Dr. Miller replied that it was important to remember that the odds ratios were scaled to a single year, so the effect across multiple years would be larger. He supported further investigation of nonlinearity in the effect of time since listing/transplant on death reporting.

Dr. Miller presented the effect of a kidney candidate's state of residence on death reporting analysis results. Because the data included only deaths in summer 2018, extrapolating to the COVID-19 era would be difficult. Minnesota and Michigan were significantly more likely to correctly classify their deaths, and New York and New Jersey significantly less likely. Dr. Snyder noted that state was defined based on state of residence, not state of listing. Some differences were noted when analyzing the effect of state of residence on reporting lags for posttransplant deaths. North Carolina stood out for best reporting of posttransplant deaths.

Dr. Ryutaro Hirose raised several points to consider regarding death reporting for candidates and recipients. Because candidates may be followed more closely immediately post-listing as initial workups are completed, and again as they approach waiting times that would result in kidney offers, the effect of time may be bimodal instead of linear. Dr. Mohan concurred with these points.

Mr. Orlowski raised the possibility that allocation changes could change the lag time. Ms. Alexandra Glazier noted that death referrals were increasingly sent to OPOs electronically, making death reporting more timely, and could perhaps be cross-referenced with the waiting list. Dr. Hunsicker asked if numbers of people who die at home were somehow recorded, as only 50% of deaths occur in hospitals. Ms. Glazier said that while OPOs receive information from funeral homes and other places, data are incomplete. Dr. Snyder said that it was a topic worth pursuing.

Regarding kidney transplant candidate demographics, racial and ethnic minorities and candidates with lower educational levels were less likely than white candidates to be correctly classified as dead month 2 after death. Candidates living in rural areas had greater odds of being correctly classified.

Dr. Miller reiterated that the initial goal was replication of the 2005 analysis by Levine and colleagues using a more recent cohort. The replication compared differences in death and death reporting for recipients in 2016-2019. The analysis demonstrated a lag in reporting deaths after kidney transplant similar to the Levine et al findings, with OPTN-reported deaths clustering around the reporting anniversaries. Dr. Snyder noted that recent emergency OPTN policy changes that removed the follow-up reporting requirements for transplant programs during the COVID-19 pandemic may affect death reporting in the OPTN/SRTR data systems.

Dr. Miller concluded the presentation by noting a variation in reporting of death within 2 months based on different geographic and demographic subgroups, which could result in differential misclassification, and the COVID-19 analyses should be delayed a minimum of 3 months before assessing the effects of COVID-19 on waitlist and posttransplant mortality.

COVID-19 Evaluation

Dr. Wey presented the preliminary analyses assessing the impact of COVID-19 on the nation's transplant system. The focus of Dr. Wey's analysis was the effect on the performance metrics reported in the program-specific reports (PSRs) and OPO-specific reports (OSRs). Adjusted analyses focused on outcome differences pre/post COVID-19, differences across programs and Designated Service Areas (DSAs), trend analyses, and subgroup analyses. Evaluation goals included creating data that were publicly accessible and easily updatable as the pandemic evolves. Dr. Wey and his team compiled all analyses into an online application. He noted the following disclaimers: potential surveillance bias for waitlist mortality and posttransplant graft failure, use of data more recent than the 3-month lag recommended in the previous analysis, missing data for primary insurance status, and OPTN suspension of follow-up requirements.

Dr. Wey outlined the application's functionality and highlighted a few key results. The application is split into four major domains: waiting list, offer acceptance, posttransplant, and organ donation. Dr. Wey focused on kidney and adult categories, and showed the Descriptive, Adjusted Analyses, and Methods tabs for each organ. The vertical green line on the trend graphs marked when the pandemic was declared a national emergency on March 13, 2020.

Dr. Formica asked if the application could show how different centers compared with each other by transplant rate, so surgeons could get a better idea of how COVID-19 was affecting programs around them. Dr. Ajay Israni suggested formatting the data so they could be viewed by region or country overall, which Dr. Wey said was possible. Dr. Mohan said to be cautious in doing so to avoid

duplicating regional data available on the UNOS website. He also proposed changing the March 13 date since the effects of COVID-19 across the nation varied in timeframe by region. Dr. Snyder noted that March 13 was chosen simply as the firm date of the national emergency declaration, and future planned analyses will attempt to correlate findings with region-based differences in COVID-19 incidence.

The overall analyses, especially for kidney transplant, indicated that COVID-19 affected the transplant system, but determining whether it affected the system differentially by program, geographic area, demographic subgroups, or time was also important. On the Program Effects tab under Differences across DSAs, transplant rates dropped significantly in New York and New Jersey, with the New York DSA declining 54%, and New Jersey 75%. Massachusetts and Michigan also showed dramatic declines. The data suggested that the effect of COVID-19 was differential across the country, posing risk-adjustment problems. Regarding transplant rates, COVID-19 affected liver transplants less than kidney transplants.

Concerning offer acceptance, only kidney, liver, heart, and lung were reported with stratification by age group of interest. The number of offers decreased after COVID-19. The median offer number was included to gauge whether placing organs took longer. For kidneys, median offer number at acceptance increased from 5 to 9, suggesting that placing kidneys for transplant took longer after COVID-19. The unadjusted acceptance rate varied, but, surprisingly, increased. All acceptance rates included only match runs with an accepted offer.

Dr. Wey noted that geographic variability in the differences in kidney offer acceptance before and after COVID-19 indicate the need for adjustment. He noted that lower offer acceptance rates for older candidates coincided with lower transplant rates after COVID-19. Committee members commented on these findings, comparing the data with their own experiences in the field. Mr. Orlowski said that it was important to look at the data carefully, and not overreact to how programs and OPOS were viewed since the data show how the practice was quickly altered in a short period of time.

Living donor transplants decreased, as did transplants from deceased donors. Graph failure rates decreased 21% in an analysis that did not adjust for surveillance issues and/or lag in reporting.

Dr. Wey concluded that there were geographic differences in the effect of COVID-19 on posttransplant outcomes. Dr. Hirose asked if Dr. Wey could correlate the effects with the increase in COVID-19 by geography. Dr. Wey said these analyses would be added to the application.

The Donations tab included referral and donor yield analyses. The application allows users to stratify by donor characteristics and view unadjusted yield. Liver yield decreased throughout 2019 and in early 2020. The number of donors by DSA showed whether parts of the country were disproportionately affected pre/post COVID-19. Under Adjusted Analyses, kidney yield decreased, declining by 46% the first month after COVID-19 and later rebounding.

Dr. Wey noted that the team was finalizing the current analyses and planned to submit the web-based application to HRSA for approval in the coming weeks. The second round of analyses will include an investigation of the relationship between COVID-19 incidence by geography and outcomes.

Handling COVID-19 within the PSRs/OSRs

The third discussion topic was SRTR's recommendation to the committee for PSR/OSR evaluation in the immediate near term. Dr. Snyder led the discussion.

The fall/winter 2020 PSR cycle would be the first to include post-COVID-19 data. Because COVID-19 had a differential affect across DSAs and would confound the risk-adjusted evaluations, SRTR proposed excluding patient follow-up and donor conversion and yield after the emergency declaration on March 13, 2020. Follow-up for risk-adjusted evaluations would end on March 12, 2020, one day before the national emergency declaration. Unadjusted descriptive statistics unrelated to the risk-adjusted models would continue using normal cohorts, including information after March 12, 2020.

Applying these modifications to waitlist models, March 12, 2020, would be the stop date for transplant rate, waitlist mortality, patient mortality after listing, and offer acceptance. Posttransplant models would be administratively removed on March 12. For OPOs, SRTR proposed not to evaluate donors after March 12 for eligible death donation rate and organ yield models.

SRTR began a discussion with the Membership and Professional Standards Committee (MPSC) about implementing the changes, and would work with HRSA if it needed to communicate with CMS. If MPSC did not approve, SRTR could provide two different sets of metrics. SRTR would also be in touch with MPSC about changing the 2-year donor yield model cohort. Dr. Snyder turned the discussion to Mr. Orłowski to conduct a vote.

Ms. Glazier and Dr. Formica considered how the proposal would play out in the future. Dr. Snyder did not want to focus too much on the future plan, but rather on a short-term solution until SRTR and the committee devised a detailed plan for the long run. Mr. Orłowski agreed. Dr. Mohan thought of substituting an earlier date for March 12 to reflect that COVID-19 was spreading earlier; however, since the declaration of national emergency provided an objective date, the committee preferred continuing to use it. Mr. Orłowski conducted an acclamation vote that had unanimous approval.

Dr. Snyder said that SRTR would establish a plan with the communications team to announce the PSR/OSR modifications. Dr. Wey added that once PSR/OSR cohorts returned to normal, alternative approaches to handling the effect of COVID-19 should be investigated. Dr. Formica encouraged focusing the analyses on what was best for patients. Richard Knight agreed, saying that there was inconsistency across centers in procedures since COVID-19 emerged, leaving patients frustrated and fearful. Patients need accurate information.

Waitlist mortality: Relisting after removal for condition improved

Dr. Nicholas Salkowski presented on a recent, but rare problem regarding the calculation of waitlist mortality rates. In the waitlist mortality calculation, candidates are censored if they undergo transplant or transfer to another program, or 60 days after being removed from the waiting list due to recovery. Otherwise, follow-up is continued. In a recent situation, a lung candidate was removed due to refusing a transplant. Because this was not a censoring event, follow-up continued. That same candidate was later relisted at the same program. Because the new listing was separate from the original listing, the candidate was counted twice. If death occurred, it would be counted twice.

Dr. Salkowski proposed changing the censoring criteria. The censoring process would remain the same; however, a candidate would be censored for relisting at the same program, preventing overlap. If a candidate was removed and relisted, the follow-up for the first listing would be censored at the start of the second listing. The change would not be integrated into the upcoming PSR about to be released, given time needed to implement and validate programming. Mr. Orlowski took a vote for the proposal, which was supported unanimously.

Closing Business

With no brief updates or further business, the meeting concluded at 11:47 AM. The next meeting is scheduled via teleconference for September 2, 2020, from 9am to 3pm CDT.