OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
December 9, 2021
Conference Call with GoToTraining

Ian Jamieson, Chair
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Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call in open and closed session via Citrix GoToTraining on December 9, 2021, and discussed the following agenda items in open session:

1. Performance Monitoring Enhancement Project Update
2. Two-Factor Authentication on UNet[sm]
3. Site Survey Revamp Report-out
4. Discussion of "on site" Physician & Surgeon Bylaw Requirements

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

1. Performance Monitoring Enhancement Project Update

Staff updated members of the Committee on the status of the Performance Monitoring Enhancement (PME) Project proposal. Specifically, the Board of Directors approved the proposal without any changes during its meeting on December 8, with some opposition but nothing unexpected and strong support overall for the proposal. The MPSC Chair thanked the subcommittee for its engagement, and the PME subcommittee chair for leading the project. The Chair also noted that the educational stage will be beneficial to the community. The PME subcommittee chair stated his appreciation and commented on the great job the regional representatives did educating their colleagues about the proposal during regional meetings, as reflected by the Board's vote of 35 in support and just 2 opposed to the proposal. A staff member stated that the implementation phase will begin soon and there will be more updates later.

2. Two-Factor Authentication on UNet[sm]

Staff provided the Committee with information about a new multi-factor authentication requirement for UNet[sm] users. He stated that UNOS has partnered with "Authy" to provide a second factor to authenticate all UNet[sm] users. He noted that the implementation will begin in early 2022, and utilizing Authy will be required for everyone logging into UNet[sm] going forward. The committee was given a link to download and setup an Authy account. He stated that committee members would receive additional instructions in early 2022.

3. Site Survey Revamp Report-out

Staff presented a report-on the Site Survey team's Revamp project. The goals of the project are to increase consistency across the survey types; strengthen collaboration, resources, and knowledge sharing; and reduce member burden while providing value-add monitoring services. To kick off the project, Site Surveyors conducted an analysis of currently monitored policies. The team conducted a Value Factor Analysis (VFA) and reviewed each individual policy's 3-year historical compliance rate, the

likelihood of each policy appearing in a sample, patient safety implications, and downstream data impacts. With the score information from the VFA, staff could analyze policies to determine if there was a better or different way of monitoring.

Staff are not retiring any policies in the living donor (LD) survey process; however, they are planning to expand some of the current monitoring. *Policies 13.4.A (Release of Protected Health Information)* and *13.4.C (Additional Requirements for KPD Donors)* focus on kidney paired donation (KPD) information and apply to all KPD programs, not just the OPTN program. KPD participants do not always fall into the sample timeframe, so staff will add in a process/template review in order to allow for discussion and education.

During OPO surveys, members have historically demonstrated a high rate of compliance with the following policies: *Policy 2.9 Required Deceased Donor Infectious Disease Testing* (#1. Blood and urine cultures); *2.11.C Required Information for Deceased Heart Donors* (#4. Echocardiogram); *2.11.D Required Information for Deceased Lung Donors* (#5. Sputum gram stain); and *2.13 Deceased Donor Management* (#5. Administering and monitoring fluid intake and output). Staff will retire our monitoring of these policies; however, they will continue to monitor the safety implications of results from some of these required tests through our monitoring of *Policy 15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions*. They will expand monitoring of *Policy 2.14.B Pre-Recovery Verification* to include a review of the verification process for when the intended recipient is known prior to organ recovery. They will also add a process review to the monitoring of *Policy 16.5 Verification and Recording of Information before Shipping* to allow an opportunity for further discussion and education as needed.

During transplant program surveys, members have historically demonstrated a high rate of compliance with the following policies: *3.2 Notifying Patients of Their Options, 3.5 Patient Notification, and 3.9 Removing Candidates from the Waiting List*. Staff will retire monitoring of these policies but for Policy 3.9 they will still have the transplant, death, and removal dates in the samples and will be able to educate if they see a potential noncompliance. They will retire the process review of *Policy 16.6.A Extra Vessels Use and Sharing* and *Policy 16.6.B Extra Vessels Storage* as they currently monitor compliance by using the Extra Vessels Report in TIEDI and are providing education and asking for corrective action plans (CAPs) when needed. They have seen a fairly low rate of compliance with *Policy 3.6.C Individual Waiting Time Transfers* so they will be expanding the monitoring of this policy to a process review for all organ groups. By shifting the focus away from self-reporting and having a process in place to discuss this with all members they believe they will be doing a greater service for our members. Related to the review of *Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%,* they want to expand to include a process/template review as they do not always have a sample and don't want to miss an opportunity to educate on the policy requirement.

The next phase of the revamp work was to ensure that our engagements with members are as similar as possible across the three survey types. Staff have historically shared data submission compliance rates in the living donor (LD) and OPO surveys; they will align this process on the transplant program side as well. Staff are excited about this new opportunity for education, and want to highlight the efforts members undertake to provide data to the OPTN. They will also align the LD reporting process with OPO-it will be based on survey sample timeframe rather than focusing just on the 5 donors in the sample and were their forms submitted on time-and this will give the member a better view of their overall compliance.

Regarding the review of accuracy of information reported on TIEDI forms, they will begin monitoring post-transplant infectious disease test results reported on the 6-month Transplant Follow-up Forms (TRF). This will provide an opportunity to continue the conversation with members about the recent PHS

policy changes that went into effect in March of this year that now affect every single transplant recipient. On the Living Donor side, they are adding a few fields to the list of what is monitored with a goal of increasing awareness and understanding of the data required in these fields. Lastly, on the OPO side, they are narrowing down the list of fields they will monitor on the Deceased Donor Registration (DDR) to those fields that require some type of interpretation prior to data entry and less focus on the fields that are directly pulling data from the OPO's record into TIEDI.

In the spirit of collaboration, they are building more time into the on-site visit so they can review resources on the OPTN website, including pending and recently implemented policy notices, will continue to demo OPTN offerings in the Data Services portal, and will assist members in developing corrective action plans in response to the survey findings. Staff mentioned process and protocol reviews earlier and will document those findings in the policy report. They also document in that report a summary of the conversations with members that detail their understanding of OPTN policy requirements. Staff will add a new section to this policy report where they will link and document the educational resources provided during the survey and deliver this to members.

The final theme in this project focused on collaboration while remaining cognizant of patient safety implications – how can staff provide value-add monitoring services more efficiently so that members see little to no disruption in their work. In the past, staff have separated out the organ-specific policy findings into what they have called clinical and administrative errors - did the patient's information entered into Waitlist meet the policy requirements, but didn't quite match what was in the medical record (administrative) or did the patient not meet the circumstances required by policy (clinical). Staff received a lot of feedback that in doing so they have unintentionally highlighted the administrative piece and were receiving multiple corrective action plans (CAP) for the same policy, which is often confusing and time intensive for the member. The big change here, with the goal of reducing burden and saving time for the members, is staff plan to report all organ-specific policy findings together and ask for just one corrective action plan geared towards an improved understanding of the policy requirements and what the system expects to be entered. On the back end, in the Survey Evaluation Tool (SET) they will still distinguish which non-compliance's would have changed the patient's status or score. They will be maintaining the thresholds for clinical scores of 90% or higher.

A second proposed change to reduce the burden on members is to implement thresholds of compliance rates that would not require a corrective action plan. This threshold will be implemented for policies that will not require a follow-up desk review per the SET. If the survey findings fall below this threshold, staff will request a CAP and help the member work through the development of that CAP. The threshold of 95% for these scenarios is set very high but they do expect (based on historical compliance data) that many members will benefit from this change.

Staff shared other Site Survey updates not directly related to the Revamp project. After more than a year of successful virtual site surveys since the start of the pandemic, site survey teams received overwhelmingly positive feedback about the virtual site survey experience but also heard that members miss the relationship-building opportunities offered by in-person visits. While COVID-19 presented a number of challenges in terms of connecting with members, it also offered new lessons. Staff is working to develop a hybrid model that will allow the highest-impact work to be conducted at the member facility while allowing chart review to remain virtual.

Staff have conducted two rounds of collaborative calls this year with a focus on education of new policy requirements. In the first round, they reached every OPO and offered an opportunity to make members aware of the emergency policy that requires lower respiratory COVID testing on all lung donors. Site surveyors fielded many questions, facilitated some lab-specific conversations with Disease Transmission Advisory Committee (DTAC) (the sponsoring committee), and overall received many thanks for the time

spent providing this focused education in advance of the policy implementation. In the second round, they contacted all members with Vascular Composite Allograft (VCA) programs to ensure they were aware that living donor policy requirements now apply to all living VCA donors. Though this is still a rare scenario, they wanted to be sure these members were aware of the requirements in case they do pursue one of these cases in the future.

A final enhancement that staff are very proud of is real-time monitoring efforts. After the COVID emergency policy was implemented in May of this year, they began running a weekly report to assess compliance with the policy. This report shows any lung donors that did not have lower respiratory COVID results reported in DonorNet® prior to transplant. Staff are able to follow-up on these cases within a matter of days after the transplant event. Finally, staff receive a daily report of patients who are listed at programs that do not have an approved pediatric component. This report is shared with a departmental multidisciplinary group and that allows them to triage which team will need to start an investigation.

The Revamp project changes will require an update to the OPTN Evaluation Plan, which details for members what is reviewed on a site survey. Staff will coordinate informing the community of the pending changes to the process as well as to the evaluation plan, train the site survey team, and update internal documentation. They are targeting to implement these changes fully on site surveys conducted in the beginning of the second quarter of 2022.

Following the presentation, the Committee Chair asked, in reference to the collaboration theme, if surveyors point out the member Staffing Survey. Staff responded that they do not but can add that to the list of resources covered in the on-site experience. The Chair also expressed his interest in assessing staffing levels at programs and staff explained that until there are benchmarks or thresholds to compare that data to, the best they could do is collect data. No decision was made to start collecting this data.

A HRSA representative asked why staff did not provide a 3-year compliance rate for *Policies 16.6.A (Extra Vessels Use and Sharing*) and *16.6.B (Extra Vessels Sharing)* on the slide where they spoke about retiring the process review of these policies from the monitoring services. Staff explained that the process review does not entail a medical record review and therefore does not yield a compliance rate. The process review has provided an opportunity to gauge a member's understanding of the policy requirements but staff are able to tangibly assess their knowledge by use of data reported through the Extra Vessels Report in TIEDI and will continue to do so. Staff also explained that it would continue to conduct investigations when vessels from a donor who has tested positive for HIV, HBV or HCV are stored, which is prohibited by Policy 16.6.B.

4. Discussion of "On site" Physician & Surgeon Bylaw Requirements

Staff discussed the "On Site" Primary Physician and Surgeon Bylaw requirements with the Membership and Professional Standards Committee (MPSC). They explained that staff are currently performing routine updates to the membership application forms and asked for feedback on the level of detail the MPSC would like to see in the applications in order to assess a program's compliance with the bylaw requirement that programs have key personnel "on site". The MPSC was presented with two options: collect specific information about "on site" arrangement for a proposed primary physician and surgeon, or have the member attest and confirm that the proposed individual is "on site". The purpose of the discussion is not to define what acceptable "on-site" arrangements means, but rather considering what is asked for in the application.

Staff reviewed the Bylaw Requirements (*D.7: Membership Requirements for Transplant Hospitals and Transplant Programs,* and *D.7.A: Approval of Transplant Hospitals with Operating Rooms Beyond the Established Geographic Boundaries*) with the Committee. Specifically, the bylaws require programs have

certain key personnel on site, but the bylaws do not define "on site". The staff member provided example scenarios of different "on site" arrangements that the MPSC may be asked to consider. Staff also described the previous, and current, application questions on the membership applications, which over time have asked for different levels of detail regarding on-site arrangements

Staff shared previous MPSC discussions on the definition of "on site", many of which are reflected in the *MPSC's Request for Feedback* "*Update Transplant Program Key Personnel Training and Experience Requirements*", which was distributed for public feedback in early 2021. The MPSC has previously agreed that primary surgeons and physicians should physically be on site most of the time and agreed the bylaws should provide flexibility for the MPSC to approve appropriate arrangements, including the following: evaluation of distance between programs, programs' volumes, availability of additional physicians and surgeons, and other relevant factors, if a proposed primary was potentially "on site" at multiple programs.

The Committee discussed whether to request specific information on the membership applications regarding "on site" arrangements, and the implications of collecting and evaluating such information. The Committee's comments and staff responses are summarized below

- Is there a way to tell if an organ is turned down due to lack of personnel, noting the potential patient safety impact of insufficient coverage? It would not be wise to have one physician or surgeon responsible for two sites.

  A staff member explained that staff has historically looked into this and deemed that a program's staffing availability is hard to assess and could be different for each program depending on each programs unique circumstances. A program's coverage plan requirement should indicate 24/7, 365 days a year of coverage, and programs must notify patients should there be no staff available. Currently the Bylaws do not prohibit someone from being a primary at two different programs at the same time.

- Is an on-call schedule requested from programs and would this cover the on-site issue.

  Staff responded that a program coverage plan is required per the Bylaws and it is requested as a part of the membership application, most notably for single surgeon or physician programs. However, the coverage plan alone may not indicate the extent to which a proposed primary is on-site. Staff clarified that call schedules are not specifically mentioned in the bylaws.

- A primary could have a conflict of interest being affiliated with two programs. Each program's situation is different.

  Staff explained that the Bylaws do not prohibit an individual from serving as a primary at two programs or hospitals.

- The MPSC Chair requested data on the number of primary physicians and surgeons across different hospitals that are serving as primary for more than one program or hospital (adult and pediatric programs and others). He also requested data on programs that have previously inactivated due to primary surgeon or physician unavailability.

At the conclusion of its discussion, Committee members supported collecting detailed information in the application about the amount of time that the proposed primary surgeon and physician will be on site

and will use the requested information to assess whether a proposed individual meets the "on site" requirement, and to promote consistency in MPSC decision.

Upcoming Meetings

- o January 20, 2022, 1-3pm, ET, Conference Call
- o February 22-24, 2022, Chicago (tentative)
- o March 25, 2022, 1-3pm, ET, Conference Call
- o April 22, 2022, 1-3pm, ET, Conference Call
- o May 31, 2022, 3-5pm, ET, Conference Call
- o June 29, 2022, 1-3pm, ET, Conference Call
- o July 12-14, 2022, Chicago

Attendance

- **Committee Members**
  - Nicole Berry
  - Christina Bishop
  - Emily Blumberg
  - Timothy Bunchman
  - Todd Dardas
  - Richard N. Formica Jr
  - Reginald Gohh
  - Barbara Gordon
  - John Gutowski
  - Nicole Hayde
  - Ian R. Jamieson
  - Christopher Jones
  - Andrew Kao
  - Christy Keahey
  - Mary Killackey
  - Anne M. Krueger
  - Gabriel Maine
  - Virginia (Ginny) T. McBride
  - Jerry McCauley
  - Kenneth McCurry
  - Dan Meyer
  - Bhargav Mistry
  - Willscott Naugler
  - Michael Pham
  - Steve Potter
  - Elizabeth Rand
  - Pooja Singh
  - Jason Smith
  - Laura Stillion
  - Parsia Vagefi
  - Sean Van Slyck
  - Gebhard Wagener
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun Naik
  - Raelene Skerda
- **SRTR Staff**
  - Ryo Hirose
  - Jon Miller
  - Jon Snyder
  - Bryn Thompson
  - David Zaun

- **UNOS Staff**

  - Sally Aungier

- o Dawn Beasley
- o Matt Belton
- o Tameka Bland
- o Tory Boffo
- o Shawn Brown
- o Tommie Dawson
- o Robyn DiSalvo
- o Nadine Drumn
- o Demi Emmanouil
- o Katie Favaro
- o Michael Ferguson
- o Liz Friddell
- o Lauren Guerra
- o Asia Harris
- o Danielle Hawkins
- o Kay Lagana
- o Ann-Marie Leary
- o Ellen Litkenhaus
- o Jason Livingston
- o Sandy Miller
- o Amy Minkler
- o Steven Moore
- o Alan Nicholas
- o Jacqui O'Keefe
- o Rob Patterson
- o Dina Phelps
- o Michelle Rabold
- o Liz Robbins Callahan
- o Louise Shaia
- o Olivia Taylor
- o Stephon Thelwell
- o Roger Vacovsky
- o Marta Waris
- o Betsy Warnick
- o Trevi Wilson
- o Claudia Woisard
- o Emily Womble
- o Karen Wooten
- **Other Attendees**
  - o None