

**New York State Transplant Council
Minutes of the November 10, 2021 Meeting**

Council Members in Attendance by Video Conference:

Council Members: Lewis Teperman, MD - Acting Chairperson; Barbara Breckenridge; Patricia Dahl; Nancy Gallo, RN; Aaron Glatt, MD; Milan Kinkhabwala, MD; Chris Kjolhede, MD; Naveed Masani, MD; Nancy Metzler; Ernesto Molmenti, MD; Ronnie Schwartz; Thomas Shanahan, Ph.D.; Michael Sosna

Persons Pending Appointment to the Council in Attendance by Video Conference: Jean Emond, MD; Andrew Flescher, Ph.D.

Council Members Not in Attendance: Patricia Dahl; Kevin Gramlich; Michael Kerr

Invited Guests and Speakers: Bruce Gelb, MD, NYKidney, Board Chairperson; Samantha Delair, Executive Director, NY Center for Liver Transplantation. Leway Chen, MD, UNOS Region 9 Representative

Staff: N. Agard; T. Irizarry; M. Kohn; J. Riegert; K. Salvio; S. Shulman, D. Symula; J. Treacy;

Meeting Summary

- **Call to Order, Report of the Chairperson and Review of Rules and Conduct of the Meeting**

Dr. Teperman, Acting Chair for the NYS Transplant Council, called the meeting to order, briefly reviewed the agenda.

Dr. Teperman introduced pending appointments to the Council including, Kevin Gramlich, Dr. Jean Emond and Dr. Andrew Flesher. Dr. Teperman announced Dr. Shanahan's and Ms. Irving's resignation from the Council, recognized them for their years of exemplary service and wished them well.

Ms. Agard walked through the Rules of the meeting and explained that the order of items on the agenda may shift as speakers and invited guests to become available. She reported the Dr. Zucker wanted to attend the meeting but was unsure if he was going to be available given his competing priorities. Review of the meeting rules included a brief review of Council Bylaws and Public Officers Law where applicable to Council meetings and member responsibilities.

- **Approval of Minutes**

Dr. Teperman asked Council members to review the minutes of the November 12, 2020 meeting and asked if there were any questions or concerns about the draft. There were no questions or concerns raised. A motion to approve was made by Dr. Molmenti; the motion was seconded by Mr. Sosna and Dr. Glatt. Twelve members voted to approve the minutes, zero opposed and zero abstained from the vote. The minutes were approved.

- **Update on Federal, State and Departmental Activities –**

Federal Updates:

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- President Trump Executive Order regarding Advancing American Kidney Health Dr. Bruce Gelb, Chairperson of NYKidney aka New York Center for Kidney Transplantation reported that after 20 years of advocacy, the Federal Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2020 bill that indefinitely extends Medicare coverage of immunosuppressive drugs for kidney transplant recipients for individuals who do not have other coverage has passed. Dr. Gelb updated Council members on what was happening with implementation of the Advancing Kidney Health Executive Order, that is reducing the number of Americans developing end-stage renal disease, having 80% of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant and doubling the number of kidneys available for transplant by 2030. Lastly, Dr. Gelb reported that NYKidney is advocating for passage of the Living Donor Protection Act at the Federal Level which would protect living donors against discrimination in obtaining life and disability insurance coverage. Questions and discussion followed.

- UNOS Update
This update was given by Dr. Leway Chen, Region 9 Representative of UNOS/OPTN.
Dr. Chen updated the group on UNOS donation and transplant data reporting that in 2020 the number of lives saved by deceased donor was the highest it has ever been, making it the 10th record year in a row for deceased donation. 2021 is on trend for an increase in deceased donor transplants as well.
Dr. Chen updated the group on COVID-related policy initiatives/changes made in response to the Covid pandemic and their status. In addition, he reported on:
 - a. UNOS equity efforts in access to transplants and continuous distribution;
 - b. One year report on results from change in liver allocation policy;
 - c. 3-month report of data following the removal of the DSA and region from kidney allocation;
 - d. OPTN efforts to improve system performance, including image sharing, recovery and usage maps, report of organ offers and improvement in DonorNet Mobile, improving the offer system and predictive analytics;
 - e. OPTN changes to the Transplant Program Performance Metrics; and the
 - f. Opportunity to get involved; where to review new proposals, attend regional meetings, etc.Questions and answers followed.

- 3. New CMS Conditions for Coverage and Performance Measures for OPO's
Council Member Gramlich was unable to attend the meeting at the last minute. His slides regarding the topic were distributed to members and the topic may be discussed at a later meeting.

State and Departmental Update

Ms. Agard updated the Council on the following State and Departmental items:

- New York Gift Act (NYGA): the goal is to schedule stakeholder meetings early in 2022. These meetings will be used to receive feedback on the statute change, answer questions, and give the opportunity to provide suggestions on the development of draft regulations and implementation. The Department is working on revisions to the Health Care Proxy Form in response to the NYGA changes

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and is in the process of Department approval with the end goal to publish these forms to our website.

- Legislation adding the “Lauren’s Law” question to Department of Environmental Conservation license applications. The goal is to meet with them in early 2022 and move towards implementation.
- Board of Elections progress toward online and automatic voter registration that include an opportunity to join the Registry.
- Bill that passed requiring “Lauren’s Law” to be added to electronic transactions carried out by the Office of Temporary Disability Assistance (OTDA), Higher Education Services Corp. (HESC) and Department of Tax documents. The bill has not yet been sent to the Governor’s office.
- DOH transplant center survey and surveillance activities: DOH resuming surveys of NYS transplant centers and will be using ePOC for submission of plans of corrections.
- Bone Marrow Registry law: Bill signed into law last year required the Department, in consultation with the Transplant Council to develop educational material regarding the Bone Marrow Registry. Dr. Kohn, from Wadsworth Center, presented the educational material draft, answered questions and asked Council members to review the information provided and provide feedback by November 26, 2021.

Report of Special and Standing Committees

Certificate of Need Regulatory Review Committee

Dr. Teperman explained that the committee met today and accomplished a lot of work. Reminded the group that the State had asked the committee to review the current CON regulations and identify opportunities for improvement. The Committee plans to develop a white paper that will describe our process and include our recommendations for regulatory change as well as concepts and measurable criteria for inclusion in the recommended revisions to the CON regulations.

Dr. Teperman walked through the factors the committee was taking into consideration. Initially 15 factors taking into consideration, but the committee has narrowed it down to their top four factors.

1. Access to Quality Transplant Services (Existing and Applicant)
2. Disease burden/Future prevalence of disease
3. Availability of required resources at applicant facility E.g., Medical & Surgical staff, UNOS requirements, etc. In response a question, Dr. Teperman indication that in their review of recent CON applications for new transplant programs that the Department asked for information that is included in the UNOS application and wanted to see that Key Personnel were already on staff at the applicant facility or minimally, have contract(s) with these practitioners committing to employment at the applicant facility.
4. Number of organs available for transplant (deceased & living). At the Committee meeting this morning it was discussed that since changes in allocation policy have been make the role/weight of this factor has changes. They recommended that the number of organs available for transplant now should not be considered when evaluating a program for approval.
5. The culture of donation is extremely important especially with regards to living donation. For approved programs, the Committee felt that outcomes should be looked at by UNOS and CMS, the facility should be responsible to inform the State of adverse action.

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Raised the role of Limited Review Applications during the morning meeting and it will be discussed more fully at the next meeting. The thought was that if a facility already has an established program, for example a kidney program adding a pancreas program or if the facility has a heart program adding a lung program, since you already have an established program, and the staff is already in place and has overlap, a limited review would be more appropriate instead of a full review CON.

Questions and answers followed.

- Dr. Emond asked if the criteria 6-15 would be removed. Dr. Teperman explained it will not be removed from the application. Ms. Agard explained that certain factors would not be an applicant responsibility instead they would be factors the Department will pay attention/looked at during the review and evaluation process.

COVID 19 and Transplantation in NYS

Samantha Delair, Executive Director of the NY Center for Liver Transplantation (NYCLT) briefly compared the overall status of COVID 19 in NYS by 10/30/20 and 10/13/21. She went on to discuss how COVID 19 data in transplant recipients has been collected from NYS transplant centers weekly since March 2020 and compared summaries of different components of the data including the total numbers of Covid positive cases, hospitalizations, ICU admissions, intubations, discharges and deaths among transplant recipients between 3/2020 and 12/31/20 compared those to those reported 1/1/21 through 10/31/21. This data included a break down by type of organ transplant received. Changes over time were evident. It is believed these numbers are higher in the transplant population versus the general population, however, this assumption has not been validated. Data regarding number of transplants performed and removals from the waitlist that occurred during this period was also presented. Discussion of transplant center policies regarding COVID 19 vaccination revealed that currently transplant centers are strongly recommending to patients that they are vaccinated however many are struggling with if they should mandate a patient vaccination before placing them on a waitlist and/or performing a transplant on them. Questions and discussion followed.

Ms. Agard provided the Council with an updated website where NYS is providing the public and health care providers with information and data related to the Covid 19 pandemic.

Additional Topics

Ms. Gallo raised the topic of a recent NY Time Article about organ donation and efforts to get the media on the side/in support of organ donation and transplant and asked if/what the roll of the Council or the Department could/should be. Dr. Teperman voiced his thought that this was not a topic to discuss/be approached by the State, but something individuals should address. No other discussion of this topic occurred.

Adjourned

- Motion to Adjourn the meeting was made by Ms. Metzler; the motion was seconded by Dr. Kjolhede
- The meeting adjourned at 3:08pm.