

**New York State Transplant Council
Minutes of September 18, 2024 Meeting**

Council Members in Attendance for the Purpose of Determining Quorum:

Council Members: Lewis Teperman, Barbara Breckenridge, Patricia Dahl, Andrew Flescher, Liise Kayler, Chris Kjolhede, Nancy Metzler, Michael Sosna, Nancy Gallo

Council Members in Attendance by Video Conference:

Kevin Gramlich, Milan Kinkhabwala, Ernesto Molmenti and Vincent Tilson

Council Members Not in Attendance:

Jean Emond, MD; Leonard Achan, Naveed Masani, MD; Aaron Glatt, MD

Invited Guests and Speakers:

Dr. James McDonald, Commissioner of NYS DOH, Macey Levan, JD, PhD, VP Patient & Donor Affairs, OPTN, Dr. Matthew Kohn, Wadsworth Laboratory

Staff: N. Agard; D. Busch; M. Glannon; M. Hennessey; T. Irizarry; L. Mosher; A. Nagy; L. Schillinger; S. Shulman; J. Treacy; Alia Wager; T. Wallace

Meeting Summary

1. Call to Order, Introductions and Report of the Chairperson

Dr. Teperman, Acting Chair for the NYS Transplant Council, called the meeting to order at 1:00 pm and reviewed the meeting agenda making note of inviting guests.

Council members identified themselves and Dr. Teperman reminded members that in order to establish a quorum a minimum of nine members must be physically present or present by video with special permission.

Dr. Teperman referenced the list of Council members included in meeting materials. He reported the information in the handout is posted to the Transplant Council webpage on the Department of Health (DOH) website and drew members attention to expired appointments encouraging members to speak to their appointing parties for reappointment.

Dr. Teperman announced Vincent Tilson has been appointed to fill the seat vacated by Michael Kerr's position as an advocate on the Council. Dr. Teperman also recognized the re-appointment of Kevin Gramlich.

2. Welcome and Remarks by Dr. James V. McDonald, MD, M.P.H., Commissioner, New York State Department of Health

Dr. McDonald introduced himself to Council members, thanked them for the assistance they provide to the Department in matters related to organ donation and transplantation and updated them on a number of topics. He reported that the Department of Health had updated its mission statement to include health equity as a foundational premise in its mission to protect and promote the health and well-being of New Yorker's.

Dr. McDonald acknowledged topics affecting organ donation and transplantation including concerns regarding increased federal scrutiny of the organ donation and transplant system and its funding, the Health Resources and Services Administration's (HRSA) oversight and modernization initiatives, advances in organ preservation, need to promote health equity for New Yorkers requiring transplant care and the need to increase the number of persons registering to become an organ, eye and tissue donor. Dr. McDonald noted the delay in the implementation of the Living Donor Support Program, identifying contributing factors and progress made to date, and introduced new staff members.

The floor was opened for questions. No questions were raised.

3. Approval of 05/23/2023 Minutes

Dr. Teperman asked Council members to review the minutes of the May 23, 2023 meeting and asked if there were any questions or concerns about the draft. A motion to approve was made by Dr. Sosna, seconded by Dr. Flescher. Patricia Dahl asked why remarks about LiveOnNY made by Ms. Gallo at the last meeting was not included in the meeting minutes. Dr. Teperman responded that the comments Ms. Dahl were referring to were of a political nature and not routinely included in Council minutes. Minutes were approved as written.

4. Review of Rules of the Meeting and Open Meetings Law Requirements

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 become available. Ms. Agard referenced Council Bylaws and Open Meetings Law requirements, reviewed the order of speaking and the process for voting on motions made during the meeting.

Ms. Agard highlighted a recent change which requires information on all boards and councils of state agencies including board/council membership, appointing body, dates of appointment and most recent re-appointment and dates terms expire be posted on agency websites. She reviewed a handout of the current information posted on the Transplant Council website that was included in the meeting materials. In addition, Ms. Agard reported that meeting announcements, agendas and minutes are required to be posted on the Council webpage.

5. Update on Federal, State and Departmental Activities –

Federal Update:

Macey Levan, JD, PhD, VP, OPTN Patient & Donor Affairs, spoke to the Council updating them on HRSA's modernization initiative affecting Organ Procurement and Transplant Network (OPTN) and United Network for Organ Donation (UNOS). Slides were provided.

Ms. Levan reviewed changes to the National Organ Transplant Act (NOTA) mandated OPTN responsibilities transition from a single contractor fulfilling all OPTN functions to a multi-vendor model. HRSA has divided the OPTN responsibilities into five

separate areas of work and is seeking multiple contractors to provide those responsibilities. HRSA plans to award the contracts by the end of fiscal year 2024. HRSA has designated the Independent Board of Volunteers to act as the OPTN board of directors. The designated board is entirely independent from UNOS. Overseen by HRSA, part of Independent Board of Volunteers request for proposals (RFP) tasks is to redesign the board structure. Regional counselors will automatically be removed. The plan is to hold a special election to replace all current board members. Concerns have been raised about this due to concerns about loss of institutional knowledge with a whole new board being seated.

Various actions of the OPTN were reviewed including implementation of a new offer filter system, new HRSA directives regarding pancreas and pancreas islet cell procurements requiring the addition of new disposition reason codes for pancreas' recovered from deceased donors sent for research, revisions (June 2024), to the kidney donor profile index (KDPI) to remove Donor's race and whether donor tested positive for HCV, work of the Expedient Task Force and the Transplant Growth Collaborative.

Ms. Levan reported that allocation of organs out of sequence is one of the biggest issues in transplantation today. In the past, organ allocation out of sequence was a rare occurrence but it has been increasing in the last few years and in 2023 alone, 12%-14% of all organs allocated were out of sequence. This pattern is more apparent with kidneys than other organs and OPTN has made this issue a priority to work on.

Lastly, Ms. Levan reported that there has been an increase in the number of members experiencing ransomware and security incidents putting members and the entire OPTN computer system at risk. June 2023, the OPTN board approved requiring all transplant hospitals, UNOS, and Histocompatibility labs a yearly test to ensure they are in compliance with the security system requirements in order to maintain access to the OPTN computer system. Members are now required to identify an organization point of contact with OPTN and ensure that members in the organization complete OPTN provided training. OPTN members are also now required to participate in an initial security readiness assessment followed by annual security attestations.

State and Department Updates:

Nancey Agard MS, RN, Director NYS Bureau Organ Donation and Transplant, provided an update on State, Department and Bureau matters.

Ms. Agard pointed Council members to meeting materials where a depiction of the Department's updated mission is included.

Recent Appointments:

- Johanne Morne, MS, has moved from acting to appointed DOH Executive Deputy Commissioner.
- Douglas Fish MD has been appointed to the Deputy Commissioner of the Office of Primary Care and Health System Management position filling the position previously held by John Morley.

Licensure, Survey and Surveillance Update:

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- Certificate of Need application for a new pediatric heart transplant program at Long Island Jewish Cohen's Children's Hospital was approved. Program will be working with the NYC office to prepare for and carry out a pre-opening survey.
- New York University Brooklyn has applied for a new adult kidney only program. If approved NYS will have 15 kidney transplant programs, not including the program at the Bronx Veteran's Administration Hospital with a second program in Brooklyn. Program will be involved in review of the application and bringing the Department's recommendation on the project to the Public Health and Health Planning Council.

Implementation of New Laws Establishing Additional Registry Enrollment Sources

- The implementation date of a law requiring the addition of the "Lauren's Law" question to the applications of health, disability and accident insurance plans was extended. The effect of this law will be to add more than 100 insurance plans as new Registry enrollment sources with the goal of providing one more way, one more place where people can join the Registry and become an organ, eye and tissue donor. An extender was necessary to address the concerns of the insurers regarding how to implement this new requirement, security of data, and other concerns.
- There is an electronic health record (EHR) bill that's pending signature by the governor at this time. This bill requires EHR's to have the ability to allow consumers to enroll directly in the registry through the electronic medical record's (EMR) portal.

Update on NYS Donate Life Registry

- Meeting materials include a one page update on the status of enrollments in the Registry. A recent milestone was met in that now 50% of New York's eligible population is enrolled in the Registry. We continue to lag behind other states, but steady progress is being made.
- NYS Donate Life Registry is in the process of adding the NYS Department of Environmental Conservation (DEC) and the NYS Health Insurance Plan as sources of enrollment into the Registry.

Living Donor Support Program

- Program has been working to implement the Living Donor Support Program by meeting with both internal and external stakeholders to gather information and has been working with the Living Donor Coordinator Group to provide feedback, opinion and guidance in the development of an eligibility application, policies, procedures, and regulations. A Living Donor Support Program website and educational materials will be created. It is the Department's intention to establish a Living Donor Support Program Advisory Committee from which to gain additional feedback and recommendations.

Wadsworth Update:

Matthew Kohn, PhD, Director Tissue Resources Program, Wadsworth Laboratories provided updated the Council on proposed revisions to Part 52 NYCRR Tissue Bank Regulations and asked for feedback. Slides were provided presenting current requirements and proposed changes. Dr. Kohn invited members and guests to provide feedback to him during the meeting or any time after the meeting.

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6. Report of Special and Standing Committees

a. Ethics Committee Update and Discussion:

The membership and charge of the Ethics Committee was reviewed. Dr. Andrew Flescher, Chair of the Ethics Committee reported on the work of the committee to date regarding Normothermic Regional Perfusion and presented a paper written by the Ethics Committee on the topic.

- The Ethics Committee reviewed the literature and existing positions on Normothermic Regional Perfusion (NRP) examining and assessing whether utilization of NRP after cardiac death is consistent with medical ethics and consistent with the Dead Donor Rule. Thoughts and opinions on this matter vary widely among medical professionals and ethicists. There are few published studies evaluating the effect of NRP on cerebral blood flow which contributes to the lack of consensus on the subject in the field. The Ethics Committee paper examines both sides of issue and concludes with the recommendation that the National Academy of Sciences, Engineering and Medicine should thoroughly examine this issue and make recommendations to the organ donation and transplant community.
- Much discussion ensued among Council members on the subject including the need for the paper to receive a broader review, including making the paper available for public review. It was recommended that a summary of the issue and questions being contemplated by prepared that is more oriented toward public consumption. It was noted that family education on the subject would be key when NRP was used.
- Motion made by Mr. Sosna to open the Ethics Committee paper to the NYS Transplant Council give the Transplant Council members additional time for review of the paper and provide comments within 30 days to Dr. Flescher. Motion seconded and approved.

Staff reviewed the work of the Ethics Committee in relation to evaluation of the Consensus Guidelines published by the American Academy of Neurology (ANN) and other groups regarding the determination of death (Journal of Neurology October/November 2023).

- Ms. Agard reported that the Committee reviewed the 2011 NYS Taskforce on Life and the Law Guidelines on the Determination of Death in relation to the current literature and the new AAN guidelines and determined that the 2011 Taskforce guidelines were out of date and needed to either be updated or replaced with recognition of a more current guideline. The 2011 guidelines are particularly lacking in the area of the determination of brain death in pediatric and neonate patients.
- The new AAN Consensus Guidelines are broken up into 7 sections, six more clinical categories of recommendation:
 - general principles of brain death/death by neurologic criteria (BD/DNC),

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- qualifications to perform BDD/DNC evaluations,
 - prerequisites for BD/DNC determinations,
 - components of a BD/DNC neurologic evaluation,
 - apnea testing as part of the BD/DNC evaluation,
 - ancillary testing as part of the BD/DNC evaluation, and
- a seventh category of special considerations for BD/DNC determination.
- The Ethics Committee wholeheartedly supports and recommends the Council support the AAN Consensus Guideline recommendations included in the first six categories and Special Considerations recommendations related to evaluation of BD/DNC in a patient who is pregnant, preservation of neuroendocrine function, and evaluation of BD/DNC in a patient with primary posterior fossa injury.
- There were two Special Consideration recommendations that garnered further discussion.
 1. Consent before evaluation for BD/DNC and
 2. Time of death and discontinuation of organ support.
- A AAN Consensus Guidelines Special Consideration recommended that clinicians do not need consent, unless otherwise stipulated by institutional policy or state law/regulations. In addition, AAN recommends that clinicians planning to evaluate a patient for BD/DNC make a reasonable attempt to inform the patients family of the plan to carry out this evaluation and provide family with an option to observe the clinical evaluation. *Ms. Agard reported that these consent related recommendations are consistent with the 2011 NYS Taskforce on Life and the Law guidelines as well as NYCRR 400.16 and thus not in conflict with existing policy.*
- The Ethics Committee spent considerable time discussing the Special Considerations recommendations related to discontinuation of organ support. *Committee members were in agreement with time of death recommendations.*
- The AAN Consensus Guidelines Special Consideration recommendations related discontinuation of organ support state “organ support may be continued after a period after BD/DNC, the length of which is based on the judgement of the attending clinician of record in accordance with institutional policy, to provide family with a reasonable but limited amount of time with the deceased patient before the discontinuation of support.” The rationale for this recommendation notes that some states legally require accommodation requests to continue organ support after BD/DNC determination under specific circumstances.
- NYCRR 400.16 recognizes determination of death by irreversible cessation of circulatory and respiratory criteria or irreversible cessation of all function of the entire brain, including the brainstem. These regulations also require hospitals to have policies that address their “procedure for the reasonable accommodation of the individuals religious or moral objection to the determination (of death) as expressed by the individual, or by the next of kin or other person closest to the individual.” The 2011 Taskforce on Life and the Law Guidelines on the Determination of Brain Death contain similar recommendations.
- The new AAN Guidelines and existing NYS policy are consistent with each other. *The Ethics Committee discussed whether NYS should allow*

for request to allow for continuation of life support after determination of death under special circumstances. There is no current NYS law or regulation that allows for continuation of life support after determination of death other than allowing families limited time to say their goodbyes, etc. Further discussion of the potential change to NYS policy will be needed.

b. NASEM Committee Update and Discussion:

Nancy Metzler reported to the council on the activities of the Council's National Academies of Science Engineering and Medicine (NASEM) Committee. She reported that after a review of the report, three major areas of work were identified, and workgroups were established to address each of them. These areas of work included: Determination of Performance Measures, Improve System Performance to Increase Access and Equity and Increase Use of Donated Organs.

The leaders of each workgroup reported on their work to date.

- The Improve System Performance Workgroup report was given by Carrie Lindower. She brought forward the groups primary recommendation at this time which was to seek change to current NYS policy prohibiting a patient from being listed in multiple NYS transplant centers. Much discussion followed including why the workgroup thought this was important and would improve system performance, if there were cost or Medicaid implications, etc. The Council asked the workgroup to pull together a document that supports their recommendation and includes both intended and unintended consequences of such a change to policy.
- Dr. Kaylor gave the report of the Increase Use of Donated Organs Workgroup. She reviewed the findings of the survey they carried out and that they were in the process of working on recommendations.
- The Performance Measures Workgroup has identified measure they think are important and potential data sources. More work on this is planned.

c. Organ Recovery Taskforce:

Nancy Agard reported to the Council on the history and status of the establishment of an Organ Recovery Taskforce.

The Transplant Council requested to form an Organ Recovery Taskforce to address questions and concerns being raised about the training and competencies of those procuring organs in NYS, the impact use of pump technologies may be having on organ procurement and a number of other issues. CMS rules charge the organ procurement organizations with identification of persons appropriate for this role.

Currently, staff is working with Council leadership to determine the membership of the Organ Recovery Taskforce. The New York Center for Liver Transplantation (NYCLT), New York Cardiothoracic Transplant Consortium (NYCTC) and New York Center for Kidney Transplantation (NYKidney) have recommended members. Outreach to other parties is underway.

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7. New and Other Business

- Colleen Flores, Northwell Health, reminded the Council that an announcement for public comment on the HOPE Act was released. The deadline is October 15, 2024. The Hope Act was signed into law November of 2013 allowing donors with Human Immunodeficiency Virus (HIV) to donate organs to recipients with HIV listed for kidney and liver transplant. Research protocols were designed to evaluate the feasibility, effectiveness and safety of such organ transplants and there is a proposal to widen that opportunity to other centers outside of the research trial and Institutional Review Board (IRB) requirement.

8. Adjourned

A motion to Adjourn the meeting was made and seconded. The meeting adjourned at 3:59 p.m.